# VALIDITY AND RELIABILITY OF GIRTH MEASUREMENT (CIRCUMFERENCE MEASUREMENT) FOR CALCULATING RESIDUAL LIMB VOLUME IN BELOW KNEE AMPUTEES

Mrs. Jariya Boonhong

A Thesis Submitted in Partial Fulfillment of the Requirements
for the Degree of Master of Science in Health Development
Faculty of Medicine
Chulalongkorn University
Academic Year 2004

ISBN 974-17-6951-2

Copyright of Chulalongkorn University

# ความถูกต้องและความแม่นยำของ girth measurement (circumference measurement) ในการคำนวณหาปริมาตรตอขาของผู้ที่ถูกตัดขาระดับใต้หัวเข่า

นาง จริยา บุญหงษ์

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต สาขาวิชาการพัฒนาสุขภาพ คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย ปีการศึกษา 2547 ISBN 974-17-6951-2

ลิบสิทธิ์ของจุฬาลงกรณ์มหาวิทยาลัย

|                 |                | (Circumference Measurement) for Calculating Residual             |
|-----------------|----------------|--|
|                 |                | Limb Volume in Below Knee Amputees                               |
| Ву              |                | : Jariya Boonhong, M.D.  |
| Field o         | of Study       | : Health Development   |
| Thesis          | Advisor        | : Associate Professor Manathip Osiri, M.D.,                      |
| Thesis          | Co-advisor     | : Associate Professor Thewarug Werawatganon, M.D., M.Sc.         |
| Accepted by the | e Faculty of l | Medicine, Chulalongkorn University in Partial Fulfillment of the |
| Requirements f  | or the Master  | r's Degree   |
|                 |                |  |
| ( Profe         | ssor Pirom K   | Kamol-ratanakul, M.D., M.Sc.)                                    |
| THESIS COM      | MITTEE         |  |
|                 |                |  |
|                 |                |  |
| ( Profe         | ssor Kamma     | nt Phanthumchinda, M.D., M.Sc.)                                  |
|                 |                |  |
|                 |                | Thesis Advisor   |
| ( Asso          | ciate Profess  | or Manathip Osiri, M.D.)   |
|                 |                |  |
| ( Assoc         | ciate Professo | or Thewarug Werawatganon, M.D., M.Sc.)                           |
| จุฬ             | าดง            | Member   |
| (Assoc          | ciate Professo | or Kingkaew Pajareya, M.D., M.Sc.)                               |
|                 |                | Member   |
| (Assist         | ant Professor  | Somrat Lertmaharit, M.Med. Stat.)                                |

: Validity and Reliability of Girth Measurement

Title

จริยา บุญหงษ์: ความถูกต้องและความแม่นยำของ girth measurement (circumference measurement)ในการคำนวณหาปริมาตรตอขาของผู้ที่ถูกตัดขาระดับใต้หัวเข่า (Validity and Reliability of Girth Measurement (Circumference Measurement for Calculating Residual Limb Volume in Below Knee Amputees) อ.ที่ปรึกษา: รศ.พญ.มนาธิป โอศิริ, อ. ที่ปรึกษาร่วม: รศ.นพ.เทวารักษ์ วีระวัฒกานนท์

วัตถุประสงค์: เพื่อศึกษาความถูกต้องและความแม่นยำของ girth measurement ในการคำนวณ ปริมาตรตอขาของผู้ที่ตัดขาระดับใต้หัวเข่า

รูปแบบการวิจัย: การเปรียบเทียบปริมาตรที่คำนวณได้จาก girth measurement กับวิธีการมาตรฐาน สถานที่ทำการวิจัย: ภาควิชาเวชศาสตร์ฟื้นฟู รพ. จุฬาลงกรณ์ และหน่วยกายอุปกรณ์ ศูนย์สิรินธร เพื่อการฟื้นฟูแห่งชาติ

กลุ่มตัวอย่าง: ผู้ป่วยที่ได้รับการตัดขาระดับใต้หัวเข่าจำนวน 51 ราย

วิธีดำเนินการวิจัย: ผู้ป่วยได้รับการวัดปริมาตรตองาโดยวิธีแทนที่น้ำโดยใช้เครื่องมือวัดปริมาตร และวิธีวัดเส้นรอบวงของตองาทุกระยะห่าง 4 เซนติเมตร โดยทั้งสองวิธีทำซ้ำสองครั้ง คำนวณ ปริมาตรโดยสูตรทางคณิตศาสตร์ของ girth measurement สองสูตรคือ สูตร frustum และสูตร cylinder ผู้ป่วยที่ได้รับการตัดขามาไม่เกิน 6.5 เดือน จะได้รับการนัดมาวัดซ้ำเพื่อหาปริมาตรที่ เปลี่ยนแปลงของตองา ข้อมูลที่ได้นำมาวิเคราะห์หาปริมาตรที่แตกต่างกันและ 95% confidence interval (CI) ของปริมาตรตองาที่หาได้จากวิธีทั้งสอง หาปริมาตรที่แตกต่างกันของการวัดซ้ำครั้งที่ หนึ่งและสองของ วิธี girth measurement และหาปริมาตรที่แตกต่างกันและ 95% confidence interval ของการวัดปริมาตรที่เปลี่ยนแปลงจากวิธีทั้งสอง

ผลการวิจัย : ปริมาตรแตกต่างเฉลี่ย (95%CI) ของวิธีแทนที่น้ำและการคำนวณจาก girth measurement ทั้งสูตร frustum และสูตรcylinder เท่ากับ -14.03 ซม³ (-27.23,-0.84) และ -13.52 ซม³ (-26.70,-0.35) ปริมาตรที่วัดได้ครั้งที่หนึ่งและสองของ girth measurement ทั้งสูตร frustum และ สูตร cylinder แตกต่างกันเฉลี่ย (95% CI) เท่ากับ -4.23 ซม³ (-8.09,-0.37) และ

-4.25 ซม $^3$  (-8.11,-0.40) ปริมาตรตองาที่เปลี่ยนแปลงวัดโดยคำนวณจากสูตร frustum และสูตร cylinder แตกต่างจากวิธีแทนที่น้ำเฉลี่ย (95% CI) เท่ากับ 3.81 ซม $^3$  (-8.02,15.64) และ 3.88 ซม $^3$  (-7.99,15.74)

สรุป: girth measurement ทั้งสูตร frustum และสูตร cylinder มีความถูกต้องและแม่นยำเพียง พอที่จะนำมาคำนวณหาปริมาตรตองาในผู้ป่วยตัดงาระดับใต้หัวเง่า แต่อาจจะมีความถูกต้องไม่ เพียงพอในการวัดปริมาตรที่เปลี่ยนแปลงเพียงเล็กน้อยงองตองา

| สาขาวิชา การพัฒนาสุขภาพ | ลายมือชื่อนิสิต                |
|-------------------------|--------------------------------|
| ปีการศึกษา 2547         | ลายมือชื่ออาจารย์ที่ปรึกษา     |
|                         | ลายมือชื่ออาจารย์ที่ปรึกษาร่วม |

##4675002330 : MAJOR HEALTH DEVELOPMENT

KEY WORD : RESIDUAL LIMB VOLUME/ BELOW KNEE AMPUTEES/ GIRTH MEASUREMENT

JARIYA BOONHONG: VALIDITY AND RELIABILITY OF GIRTH MEASUREMENT

(CIRCUMFERENCE MEASUREMENT) FOR CALCULATING RESIDUAL LIMB VOLUME IN BELOW KNEE AMPUTEES

THESIS ADVISOR: ASSOC.PROF. MANATHIP OSIRI, M.D.,

THESIS COADVISOR: ASSOC.PROF. THEWARUG WERAWATGANON, M.D., M.Sc.

**Objective :** To assess the validity and reliability of girth measurement for calculating the residual limb volume.

**Design :** Comparison of girth measurement with gold standard in calculating residual limb's volume.

**Setting :** King Chulalongkorn Memorial Hospital and Sirindhorn National Medical Rehabilitation Center.

**Subjects**: 51 below-knee amputees

**Methods**: Residual limb volumes of each subject were measured by water displacement method with volumeter and girth measurement method by measured segmental circumferences with a tape measure twice for each method. Each segment volume was calculated by frustum and cylinder formulas of girth measurement method and summed them up to be the calculated residual limb volume. The stump volumes were measured again 4 weeks later in subjects who had their limbs amputated less than 6.5 months. Mean difference and

95% confidence interval (CI) between volume of water displacement and girth measurement, 1<sup>st</sup> and 2<sup>nd</sup> calculated volume of girth measurement, and changing volume of water displacement and girth measurement were calculated by simple calculation.

**Results :** The difference of mean volume (95% CI) of water displacement and girth measurement, frustum and cylinder formulas were -14.03 cm<sup>3</sup> (-27.23,-0.84) and -13.52 cm<sup>3</sup> (-26.70, -0.35), respectively. The mean difference of calculated volume (95% CI) of the 1<sup>st</sup> and 2<sup>nd</sup> measurement of frustum and cylinder formulas were -4.23 cm<sup>3</sup> (-8.09, -0.37) and -4.2 cm<sup>3</sup> (-8.11,-0.40). The mean difference of changing volume (95% CI) of water displacement and frustum formula, and water displacement and cylinder formula were 3.81 cm<sup>3</sup> (-8.02,15.64) and 3.88 cm<sup>3</sup> (-7.99,15.74).

**Conclusion:** The girth measurement, both frustum and cylinder methods were valid and reliable for calculating the residual limb volume in below knee amputees. But both of them might not valid enough to calculate the small changing volume.

| Department     | Health Development | Student's signature    |
|----------------|--------------------|------------------------|
| Field of study | Health Development | Advisor's signature    |
| Academic year  | 2004               | Co-advisor's signature |

#### **ACKNOWLEDGEMENTS**

I would like to express my gratitude to Department of Rehabilitation Medicine and Faculty of Medicine, Chulalongkorn University for giving me the great opportunity to study in this course.

I am very appreciate and deeply grateful to my advisor, Associate Prof. Manathip Osiri, my co-advisor, Associate Prof. Thewarug Werawatganon, and all teachers of Thai CERTC for their kind help and advice in clinical epidemiology and improving my thesis.

I am also grateful to Dr. Prapan Pongkanittanol, the director of Sirindhorn National Medical Rehabilitation Center in allowing this research to be studied and reported.

Finally, I would like to give special thanks to my parents, my husband and my lovely kids for their loves, understanding and supports.

This study was financially supported by the Ratchadapiseksompotch Fund of the Faculty of Medicine, Chulalongkorn University.



# **CONTENTS**

| ]                               | Page |
|---------------------------------|------|
| ABSTRACT (THAI)                 | iv   |
| ABSTRACT (ENGLISH)              | v    |
| ACKNOWLEDGEMENTS.               | vi   |
| CONTENTS.                       | vii  |
| LIST OF TABLES.                 | ix   |
| LIST OF FIGURES.                | X    |
| CHAPTER I                       |      |
| RATIONALE AND BACKGROUND        | 1    |
| CHAPTER II                      |      |
| LITERATURE REVIEW               | 3    |
| CHAPTER III                     |      |
| RESEARCH DESIGN AND METHODOLOGY | 5    |
| 3.1 Research Questions          | 5    |
| 3.2 Research Objectives         | 5    |
| 3.3 Research Hypothesis         | 6    |
| 3.4 Conceptual Framework        | 6    |
| 3.5 Study Diagram               | 7    |
| 3.6 Key Words                   | 8    |
| 3.7 Operation Definition        | 8    |
| 3.8 Research Design.            | 8    |
| 3.9 Target Population.          | 8    |

|   | Page |
|---|------|
| 3.10 Sample Population                  | 8    |
| 3.11 Inclusion Criteria                 | 8    |
| 3.12 Exclusion Criteria.                | 9    |
| 3.13 Sample Size Estimation             | 9    |
| 3.14 Procedure                          | 9    |
| 3.15 Data Collection and Management     | . 12 |
| 3.16 Data Analysis                      | 13   |
| 3.17 Ethical Consideration              | 13   |
| CHAPTER IV                              |      |
| RESULTS                                 | .14  |
| CHAPTER V                               |      |
| DISCUSSION                              | 20   |
| CHAPTER VI                              |      |
| CONCLUSION.                             | 24   |
| REFERENCES                              | 25   |
| APPENDICES                              | . 27 |
| 1. Patient Information and Consent Form | 28   |
| 2. Case Record Form.                    | 31   |
| VITAE                                   | 36   |

# LIST OF TABLES

| TABLE          |  | Page  |
|----------------|--|-------|
| 1. Patient bas | seline characteristics   | 14    |
| ŕ              | mean difference, and 95% CI of mean difference of residual line at measured by water displacement and girth measurement met          |       |
| measureme      | mean difference, and 95% CI of mean difference of first and seent of residual limb volume by water displacement and girth ent method |       |
| ·              | mean difference, and 95% CI of mean difference of changing at measured by water displacement and girth measurement methods.          | od 18 |
| volume th      | on correlation coefficients of residual limb volume and changing at measured by water displacement and calculated by girth method    |       |
|                |  |       |

# LIST OF FIGURES

| FIGURE  | Page |
|---|------|
| 1. Volumeter and collecting container with scale                                      | 10   |
| 2. The circumferential measurement  | 11   |
| 3. The different volume of water displacement and cylinder formula method against the | e    |
| measured volume from water displacement method  | 16   |
| 4. The different volume of water displacement and cylinder formula method against the | e    |
| measured volume from water displacement method  | 16   |
|   |      |
|   |      |
|   |      |
|   |      |
|   |      |
|   |      |
|   |      |
|   |      |
|   |      |

#### CHAPTER I

#### RATIONALE AND BACKGROUND

After limb amputation, all of the residual limbs will be swelling. In this immature period, the stump is not proper to fit with permanent prosthesis. Thus, during the first two months of the posthealing period, while the residual limb is still swelling, one of the aims of treatment is to control the edema and reduce the residual limb volume. When the residual limb's volume changes decrease to a relatively stable point, a first permanent prosthesis should be considered. So the residual limb's volume is mostly concerned during the preprosthetic training program.

There are many techniques that may be used to assess the volume of the limbs. Among these, two methods are most commonly used. They are the followings:

- 1) Water displacement volumetric measurement. This method is used for measuring limb volume and based on the Archimedes' Principle. According to this principle, the water volume displaced is equal to the volume of the object immersed in the water. This method is considered the "gold standard" for measuring the limb volume.(1,2) Despite the documented reliability of volumetric measurements, there are disadvantages in the use of water displacement measurements in the practice setting. These disadvantages are related to the set-up and use of the volumeter(3), transport, design and certain patient conditions.(3,4) Volumeters that are big enough for limbs have the capacity to hold several liters of water, take several minutes to fill and empty and are difficult to move once filled with water. Due to the size of the volumeter, the collection container and the graduated cylinder, it is difficult to transport the equipment to other places. Additionally, the use of water displacement volumetric measures is unsuitable for patients with skin ulcer(4) and patients in the immediate postoperative period.(1)
- 2) Girth measurements (circumference measurements). This method is simple, efficient and clinically useful.(4) The measurement is done at fixed points on the limb (every 4cm.) and calculated the limb volume from the girth measurements using of mathematical formula. There are two basic formulas for calculating the limb volume. The first is cylinder formula(5,6) and the other, truncated cone (frustum) formula.(7,8) The limb is divided into segments, with each segment represents a cylinder or cone. The total volume is determined by adding the volume of all segments together.

From literature review, there has been no study directly comparing the girth measurement volume and the water displacement volume of residual limbs.(1,4,6-8,10-11,13,15) Available studies were for the whole leg or thigh and leg or leg and foot. Since the water displacement method for measuring the residual limb volume is not convenient for clinical use, the use of girth measurement may be used instead. However, there is a need to assess the validity of girth measurement for calculating the residual limb volume. From the existing data, most of the studies used correlation coefficients to determine validity of girth measurement. According to Altman and Bland(9), the use of correlation is misleading. A high correlation does not mean that the two methods agree with each other. The correlation coefficient measures the strength of a relation between two variables, not the agreement between them. In this present study, we sought to determine the validity of girth measurement for calculating residual limb volume in below knee amputees by exploring the agreement between the girth measurement (circumference measurement) and the water displacement method using simple calculations suggested by Altman and Bland.



#### **CHAPTER II**

#### LITERATURE REVIEW

Katch and Katch(7) compared the frustum formula of girth measurement and water displacement technique in calculating volume of the normal leg in 70 subjects. The correlation between the two methods was high (r = 0.95) with the standard error of estimates equal to 0.48 liter. And the intertrial reliability for each girth measurement was above r = 0.95 with a standard error for a single measure not exceeded 0.75 cm(3).

Lenniham and Mackereth(8) published a case-series report on the value of calculation the leg volume from frustum formula in three cases with the iliac vein occlusion and hypovolemic shock. They could estimate the deficit volume by calculation a leg volume difference and replace the appropriate fluid volume to all of the patients until recovery from the shock.

Bunce et al(5) use the cylinder formula of girth measurement for calculating the upper limb volume in patients with post-mastectomy lymphedema to compare the treatment efficacy (massage, pneumatic compression, bandaging and education). The results of the study were multimodal therapy could reduce lymphoedematous limb volume by at least half in 18 of 25 patients.

Perrin and Guex(10) compared the frustum formula and optoelectronic systems (Perometer) with water displacement method for calculating the lower limb volume in both normal limb and diseased limbs. The study showed that the limb volumes measured by the Perometer are virtually identical to those obtained by water displacement method. In contrast, the frustum formula methods tend to overestimate the limb volume in normal subjects. In diseased limbs, there are no significant differences between the Perometer and frustum method.

Sitzia(11) compared the cylinder with frustum formulas and stated that the frustum formula was intrinsically most accurate. This is easy to visualize because most extremities are shaped like a cone rather than a cylinder. The results of this study indicated that the cylinder formula consistently underestimated the percentage of excess volume by an average of 1.5 % compared with the frustum formula.

Whitney et al(12) examined the reliability of lower-extremity girth measurements within and between raters. Intraclass correlation coefficients (ICCs) ranged from 0.91 to 1.00. The ICCs of the first measurements of each day ranged from 0.81 to 0.98, suggesting this method is highly reliable. Thus, in clinical practice, single measurement is adequate and reliable.

Pani et al(4) compared the water displacement volume of a leg with the calculated volume in 100 patients with unilateral lower limb lymphedema from filariasis. The measurement included the volume of the leg at 30 cm above the ground and the whole foot. The results of this study showed that the 2 methods of measurement was correlated, with r = 0.61 for nonedematous limbs and r = 0.80 for edematous limbs.

Stranden(13) compared the calculated volume of the leg using truncated cone formula with the water displacement volume in patients with leg edema following femoropopliteal bypass grafting. His calculated volume of the leg did not include the foot. The results showed a correlation coefficient of 0.98. There was slight overestimation of edema using the calculated volume method, with an increase in leg volume of greater than 11 %. Standen stated, however, that the calculated volume method was satisfactory for clinical use.

Kaulesar Sukul et al(1) compared the water displacement volume with the calculated volume from the cylinder method and the truncated cone method for the measurement of leg without foot volume. The measurement point started at 3 cm below the medial gap of the knee joint and ended at just above the medial malleolus. Their "leg volume" from water displacement was the volume of the leg minus the volume of the ankle and foot. The results showed that Pearson correlation coefficient was 0.99 for the cylinder method. Results from the truncated cone method indicated a Pearson correlation coefficient for the truncated cone method of 0.93. Kaulesar Sukul et al reported that only the cylinder method could be used interchangeably with the water displacement model.

Mueller(14) used the frustum formula from Katch and Katch(7) to calculate the residual limb volume for comparing the decreased volume from removable rigid dressing with elastic bandages in preprosthetic management of patients with below-knee amputations. However the results from this study were questionable because the validity and reliability of the primary outcome measurement have never been assessed in the residual limb of below knee amputees.

#### **CHAPTER III**

#### RESEARCH DESIGN AND METHODOLOGY

#### 3.1 Research Questions

- 3.1.1 Primary research question
- Are girth measurements (both frustum and cylinder formula) valid for calculating the residual limb volume in below knee amputees?
  - 3.1.2 Secondary research questions
- 1) Are girth measurements (both frustum and cylinder formula) reliable for measuring the residual limb volume of below knee amputees?
- 2) Are girth measurements (both frustum and cylinder formula) valid for measuring the *changing volume* of residual limb in below knee amputees?

# 3.2 Research Objectives

- 3.2.1 Primary Objective
- To assess the validity of girth measurement for calculating the residual limb volume in below knee amputees by determining the mean difference of volume and 95% CI (cm³) that girth measurement (both frustum and cylinder formula) are likely to differ from the water displacement method.

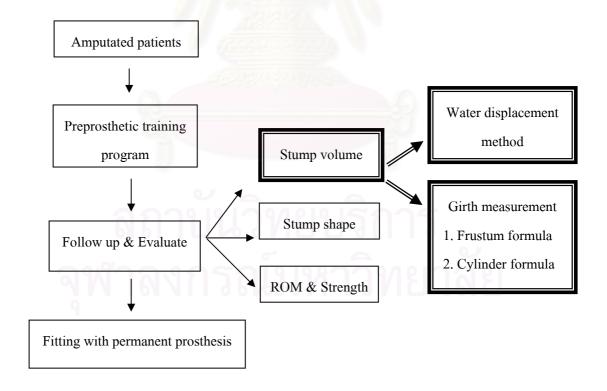
#### 3.2.2 Secondary Objectives

- 1) To assess the reliability of girth measurement by determining the mean difference of volume and 95% CI (cm<sup>3</sup>) of the first and second measurement by girth measurement method.
- 2) To assess the validity of girth measurement for measuring the *changing volume* by determining the mean difference of volume and 95% CI (cm<sup>3</sup>) that girth measurement (both frustum and cylinder formula) are likely to differ from the water displacement method in measuring the *changing volume*.
- 3) To compare the validity between frustum and cylinder formula by comparing the mean difference of volume and 95% CI (cm³) that are likely to differ from the water displacement method.

#### 3.3 Research hypothesis

- 1) The girth measurements (both frustum and cylinder formula) are valid for calculating the volume of residual limb in below knee amputees (if 95% CI of mean difference of volume is in the range of  $\pm 10\%$  of mean residual limb volume that measured by water displacement method).
- 2) The girth measurements (both frustum and cylinder formula) are reliable for calculating the volume of residual limb in below knee amputee (if 95% CI of mean different volume of the first and second measurement is in the range of  $\pm$  5% of the mean residual limb volume that calculated by the first measuring of the girth method).
- 3) The girth measurement (both frustum and cylinder formula) are valid for calculating the *changing volume* of residual limb in below knee amputees (if 95% CI of mean difference of *changing volume* is in the range of  $\pm 10\%$  of mean *changing volume* that measured by water displacement method).

# 3.4 Conceptual Framework



# 3.5 Study Diagram

Below knee amputated subjects



Measure residual limb volume by

Assess the validity and reliability of

girth measurement

1. Water displacement method

2. Girth measurement method

- - 1) Frustum formula
  - 2) Cylinder formula



Subjects who have been amputated < 6.5 months

# Follow up 1 month

Measure residual limb volume again by

- 1. Water displacement method
- 2. Girth measurement method
  - 1) Frustum formula
  - 2) Cylinder formula



Calculate the changing volume





Assess the validity of girth measurement in calculating the changing volume

#### 3.6 Key words

Residual limb volume

Below knee amputee

Girth measurement.

#### 3.7 Operational Definition

#### 3.7.1 Water displacement method:

This method for measuring the limb volume is considered the gold standard.(7,8) Using Archimedes' principle, the water volume displaced is equal to the volume of the object immersed into the water. This technique measures the limb volume by immerse the limb into the volumeter that filled with the water and measure the displacing water volume.

#### 3.7.2 Girth measurement:

Girth measurement or circumference measurement is one of the primary methods for calculating the limb volumes by measuring the limb's circumference and using the mathematic formula to calculate the volume. There are two formulas that are accepted for calculating the limb volume, the frustum or cone formula(2,10) and the cylinder formula.(15,16)

# 3.8 Research design

Comparison of the girth measurement with gold standard in calculating the residual limb volume.

# 3.9 Target population

Below knee amputated patients.

#### 3.10 Sample population

All of the below knee amputated patients who are consulted for rehabilitation and prescription of the prostheses at King Chulalongkorn Memorial Hospital and Sirindhorn National Medical Rehabilitation Center.

#### 3.11 Inclusion criteria

- 1) Conscious and cooperation.
- 2) Good healing wound and no ulceration on the residual limb.
- 3) Fair to good sitting balance.
- 4) Agree to participate in the study and sign a consent form.

#### 3.12 Exclusion criteria

- 1) Complicated stump (non-healing, infected or ulcerative stumps)
- 2) Refuse to participate in the study.

#### 3.13 Sample size estimation

To estimate the mean differences of volume that are measured by the two methods, the sample size is calculated by the following formula.

$$n = Z_{\infty/2}^2 SD^2 / d^2$$

Set the confidence of data conclusion at 95%

$$Z_{\infty/2} = Z_{0.05/2} = 1.96$$
 (two tail)  
SD = Standard deviation of data = 312  
d = Acceptable error = 99

$$n = (1.96)^{2} (312)^{2} / (99)^{2}$$
$$= 38$$

There is no study comparing the water displacement volume and the girth measurement volume in residual limb. The value of standard deviation was from the article that studied volume changes in postoperative below knee residual limbs by water displacement method.(17) The mean volume and standard deviation of residual limbs measured by water displacement method was  $997 \pm 312$  ml.(17) We used the value of standard deviation from this study with the idea that the standard deviation of mean volume measured by water displacement method should be wider than that of the mean difference of volume (difference measured by the two methods). The accepted error (d) is 10% of mean residual limb volume (997 ml).

#### 3.14 Procedure

After preparing all the equipments and materials (volumeter, collecting container with scale, measuring tape, and permanent marker), circumferential measurements and volumetric measurements are performed on the subjects who are recruited in the study. The subjects are marked the upper level of measurement at the level of tibial tubercle on the residual limbs. The circumference measurements are performed, the most proximal measurement point is marked and

the following points are 4-cm increments down to the distal end of the residual limb as shown in Figure 2. For assessing the reliability, the measurement will be repeated again at 5 min. after the first measuring. After that, the subjects are instructed the appropriate placement of their residual limbs in the volumeter. The volumeter is placed on the floor with the collecting container. The volumeter is filled with water until the water overflow out of the spout. When the water stop dripping from the spout, the "topping off" procedure is completed. The initial "topping off" fluid was discarded from the collecting container. The empty container was then put back under the spout of the volumeter to collect the water from the volumetric measurement. The patients are seated and slowly lowered their residual limbs into the volumeter until the level of the water meets the marked level on the residual limbs. The participants are instructed to keep their residual limbs vertical and stationary. Contact between the residual limbs and the side of the volumeter is avoided. When the water stops dripping from the spout, the participants then remove their residual limb from the volumeter. The amount of water is recorded as the below knee water displacement volume of the residual limb in cm<sup>3</sup>. The measurement by this method will be repeated again at 5 minutes, after the first measurement, to assess the reliability.

Before performing the circumferential measurements, the subject's stumps have to be wrapped with the elastic bandages for not less than two hours (to make the stumps in good shape and easy to measure).

The volumeter (figure 1) was validated by the water 500 ml and 1,000 ml water ten times for each volume. The mean measured volume and standard deviation were 499.6  $\pm$  1.43 ml and 999.1  $\pm$  1.10 ml, respectively.



Figure 1 Volumeter and collecting container with scale

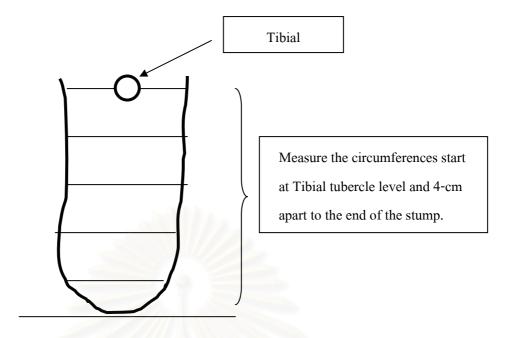


Figure 2 The circumferential measurement



#### 3.15 Data Collection and Management

Case record form was generated for each individual subjects to record the data (Appendices), which included:

- 1) Demographic data and baseline characteristics
  - -Age (years)
  - -Gender
  - -Date of amputation
- 2) Date of being measured residual limb volume
- 3) Collecting hospital
- 4) The volume of residual limb that measured by water displacement method (cm<sup>3</sup>) both the first and second time at the first and follow up visit.
- 5) Circumference of the residual limbs in each point, 4-cm interval (cm) both the first and second times in the first and the follow up visit.
- 6) Length of the each section of the residual limbs (cm) both the first and second time in the first and the follow up visit.
- 7) The volume of residual limb that calculated from frustum (cone) formula (7,18) both the first and second time at the first and follow up visit, as the following:

$$V = (h) (C^2 + Cc + c^2) / 12(\pi)$$

C = the proximal circumference of each section

c = the distal circumference of each section

h = length of each section

8) The volume of residual limb that calculated from cylinder formula (5) both the first and second time at the first and follow up visit, as following:

$$V = \pi \left( \text{circumference} / 2\pi \right)^2 h$$

Circumference = the mean of adjacent circumferences

h = length of each section

- 9) The changing volume of residual limb that measured by water displacement method
- 10) The changing volume of residual limb that calculated from frustum (cone) formula
  - 11) The changing volume of residual limb that calculated from cylinder formula

#### 3.16 Data Analysis

Using SPSS statistical program version 11.0 to analyze the data.

- 1) Calculate the mean difference of volume and 95% CI of girth (both frustum and cylinder formula) and water displacement method at the first visit
  - \* use the first time measurement of each method to calculate the difference
- 2) Calculate the mean difference of volume and 95% CI of the first and second time measurement that measured by water displacement method at the first visit
- 3) Calculate the mean difference of volume and 95% CI of the first and second time measurement that measured by girth method at the first visit
- 4) Calculate the mean difference of changing volume and 95% CI of girth (both frustum and cylinder formula) and water displacement method

#### 3.17 Ethical Consideration

- 1) All participants will receive rationale and detailed information of the study.
- 2) All participants will be encouraged to participate in the study and sign informed consents.
- 3) This study uses only easy, simple and external measurement.
- 4) The author recruits only the proper participants so there should not be serious adverse effects happen in this study. But if there is unexpected event that make subjects have any risk, the researcher will be responsible for the care of the patients.

# **CHAPTER IV**

# **RESULTS**

A total of 51 below-knee amputees were recruited in the study, 27 persons from King Chulalongkorn Memorial Hispital and 24 persons from Sirinthorn Rehabilitation Center. The amputees' demographic data and baseline characteristics are shown in Table 1.

Table 1 Patient baseline characteristics

| Characteristics                  |                        |  |
|----------------------------------|------------------------|--|
| Number of amputees               | 51                     |  |
| Age in years (mean± SD)          | $55 \pm 18$            |  |
|                                  | Min = 19, Max = 91     |  |
| Sex Male [number (%)]            | 35 (68.6)              |  |
| Female [number (%)]              | 16 (31.4)              |  |
| Duration of amputation in months | 5.47 (3.60,16.30)      |  |
| [median (IQR)]                   | Min = 0.6, Max = 31.13 |  |

IQR = interquartile range

The median time of having the amputated limb was 5.5 months, range from 0.6 to 31.1 months. There were 31 subjects (60.8%) who have been amputated limb less than 6.5 months and were followed up the residual limb volume. The mean ( $\pm$  SD) duration of being followed up was 29.0  $\pm$  4.99 days.

All of 51 subjects were measured for their residual limb volumes by the water displacement method and calculated the volume by girth measurement method (both frustum and cylinder formulas). The comparison of measured volume of both methods was shown in Table 2.

Table 2 The mean, mean difference, and 95% CI of mean difference of residual limb volume that measured by water displacement and girth measurement methods.

| Method   | First                | Difference from      | 95% CI of mean                |
|----------|----------------------|----------------------|-------------------------------|
|          | measurement          | WD method            | difference (cm <sup>3</sup> ) |
|          | $Mean \pm SD (cm^3)$ | $Mean \pm SD (cm^3)$ |                               |
| WD       | 686.71± 286          |                      |                               |
|          |                      | 1112-                |                               |
| GM       |                      |                      |                               |
| Frustum  | $700.74 \pm 289$     | $-14.03 \pm 46.91$   | -27.23, -0.84                 |
|          |                      |                      |                               |
| Cylinder | $700.23 \pm 289$     | $-13.52 \pm 46.83$   | -26.70, -0.35                 |
|          |                      |                      |                               |

WD = water displacement method, GM = girth measurement method

The mean, mean difference and 95% CI of mean difference of water displacement and girth measurement method (frustum and cylinder formula) were shown in Table 2. The difference in mean volume measured by water displacement and frustum formula method was -14.03 cm<sup>3</sup>. The difference in volume measured by the water displacement and cylinder formula method was -13.52 cm<sup>3</sup>. The negative values mean that both of calculated volumes were higher than the measured volume from water displacement method. The  $\pm 10\%$  mean of residual limb volume that measured by water displacement method was  $\pm 68.67$  cm<sup>3</sup>. The 95% CI of difference in mean volume measured by the water displacement and calculated by the girth measurement method (both frustum and cylinder formulas) were within the  $\pm 10\%$  of measured volume of water displacement method. However, the mean different volume and 95% CI of mean different volume of cylinder formula was less than the volume calculated from frustum formula.

The relation between the different volume (between the water displacement and cylinder formula and between the water displacement and frustum formula methods) and measured volume from the water displacement method were investigated by scatter plot in Figure 3 and 4. From the scatter plot, there was no obvious relation between the different volume and measured volume from the water displacement method. It showed that the difference or the measurement error was not varied to the size of the residual limb.

Diff. vol. of WD & cylinder formula

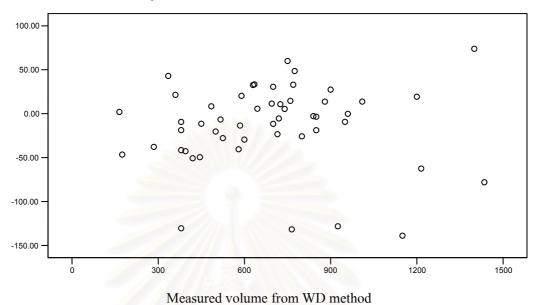


Figure 3 The different volume of water displacement and cylinder formula method against the measured volume from water displacement method

Diff. vol. of WD & frustum formula

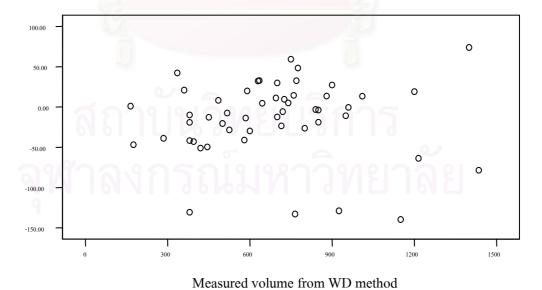


Figure 4 The different volume of water displacement and frustum formula method against the measured volume from water displacement method

All methods were repeated to evaluate the reliability of the measurements. The mean volumes of the first and second measurement in each method are shown in Table 3. The difference in mean volume (and 95% CI of mean difference) of the first and second measurement by the water displacement and calculating from frustum and cylinder formula methods were 2.20 cm<sup>3</sup> (-5.48, 9.87), -4.23 cm<sup>3</sup> (-8.09,-0.37), and -4.25 cm<sup>3</sup> (-8.11,-0.40), respectively. The  $\pm$  5% of first measured volume of water displacement and first calculated volume by frustum and cylinder formula methods were  $\pm$  34.34 cm<sup>3</sup>,  $\pm$  35.04 cm<sup>3</sup>, and  $\pm$  35.01 cm<sup>3</sup>, respectively. From the Table 3, the 95% CI of mean different volume of first and second measured or calculated volumes of all methods were within the  $\pm$ 5% mean of the first measured or calculated volume.

Table 3 The mean, mean difference, and 95% CI of mean difference of the first and second measurement of residual limb volume by water displacement and girth measurement methods

| Method   | Fi <mark>rs</mark> t | Second             | Difference                        | 95% CI of          |
|----------|----------------------|--------------------|-----------------------------------|--------------------|
|          | measurement          | measurement        | Between                           | mean               |
|          | $Mean \pm SD$        | $Mean \pm SD$      | 1 <sup>st</sup> & 2 <sup>nd</sup> | difference         |
|          | (cm <sup>3</sup> )   | (cm <sup>3</sup> ) | measurement                       | (cm <sup>3</sup> ) |
|          |                      |                    | Mean $\pm$ SD                     |                    |
|          |                      |                    | (cm <sup>3</sup> )                |                    |
| WD       | 686.71± 286          | $684.51 \pm 291$   | $2.20 \pm 27.28$                  | -5.48,9.87         |
| GM       | 00011                | <u></u>            | 2005                              |                    |
| Frustum  | $700.74 \pm 289$     | $704.97 \pm 290$   | $-4.23 \pm 13.72$                 | -8.09,-0.37        |
| 2010     | 00000                | 70101000           |                                   | ט ו                |
| Cylinder | 700.23± 289          | $704.48 \pm 290$   | -4.25 ± 13.71                     | -8.11,-0.40        |

WD = Water displacement method, GM = Girth measurement method

Table 4 The mean, mean difference, and 95% CI of mean difference of changing volume that measured by water displacement and girth measurement methods. (in 31 subjects)

| Method   | Changing volume                  | Difference                       | 95% CI of mean               |
|----------|----------------------------------|----------------------------------|------------------------------|
|          | Mean $\pm$ SD (cm <sup>3</sup> ) | From WD method                   | difference(cm <sup>3</sup> ) |
|          |                                  | Mean $\pm$ SD (cm <sup>3</sup> ) |                              |
| WD       | $40.06 \pm 65.25$                |                                  |                              |
| GM       |                                  | 11/22                            |                              |
| Frustum  | $36.25 \pm 80.07$                | $3.81 \pm 32.25$                 | -8.02, 15.64                 |
| Cylinder | $36.18 \pm 80.02$                | $3.88 \pm 32.34$                 | -7.99, 15.74                 |

WD = Water displacement method, GM = Girth measurement method

The 31 subjects, who have been amputated limb for less than 6.5 months, were followed up for the residual limb volume. The mean, mean difference and 95% CI of mean difference of changing volume measured by the water displacement and calculated by the girth measurement methods (frustum formula and cylinder formula) are shown in Table 4. The  $\pm 10\%$  means of changing volume that measured by water displacement method was  $\pm 4$  cm<sup>3</sup>. The mean different of changing volume of frustum formula and water displacement method was 3.81cm<sup>3</sup> and of cylinder formula and water displacement method was 3.88 cm<sup>3</sup>. The 95% CI of mean difference of changing volume of girth measurement method (frustum and cylinder formulas) were more than  $\pm 10\%$  of mean changing volume that measured by water displacement method.

Table 5 The Pearson correlation coefficients of residual limb volume and changing volume that measured by water displacement and calculated by girth measurement method.

| Measurement                       | Correlation coefficients | p value |
|-----------------------------------|--------------------------|---------|
| WD and frustum formula            | 0.987                    | 0.01    |
| for residual limb volume          |                          |         |
| WD and cylinder formula           | 0.987                    | 0.01    |
| for residual limb volume          | 11/1/2-2-                |         |
| WD and frustum formula            | 0.922                    | 0.01    |
| for changing residual limb volume |                          |         |
| WD and cylinder formula           | 0.921                    | 0.01    |
| for changing residual limb volume |                          |         |

WD = Water displacement method

The Pearson correlation coefficients of the water displacement and girth measurement method (frustum and cylinder formula) for measuring the residual limb volume and the changing residual limb volume are shown in Table 5. Although the correlation coefficients of the changing residual limb volume were less than the residual limb volume, they were still very high.



#### **CHAPTER V**

#### DISCUSSION

In this study we determined the validity of girth measurement (both frustum and cylinder formulas) for calculating the residual limb's volume by exploring the agreement between them and water displacement method, which was accepted the gold standard for measuring the limb volume. The agreement was explored by calculating the 95% CI of difference in mean volume of both methods. The range of both frustum and cylinder formulas were within the acceptable limit. Thus, the girth measurement methods, both frustum and cylinder formulas, were valid to calculate the residual limb volume compared with the water displacement method.

For comparing to the previous studies, Pearson correlation coefficients of both measurement methods were analyzed. The correlation coefficients of frustum or cylinder formula and water displacement for measuring the residual limb's volume were high (r = 0.987). These high correlation coefficients supported the results of previous studies that evaluated the agreement of them in measuring the leg's volume.(1,7,13)

The negative value of means and 95% CI of mean differences (Table 2) showed that the calculated volumes from frustum and cylinder formulas were overestimated. Similar to the study by Stranden in 1981(13), which compared the calculated volume of the leg using frustum formula with water displacement volume in patients with leg edema following femoropopliteal bypass grafting. This study concluded that there was a slight overestimation of limb volume from the frustum formula method due to limb edema.

When the mean difference from water displacement of both formulas were compared, the cylinder formula was different from the gold standard less than the frustum formula. However, the range of 95% CI of difference in mean of cylinder formula was within the frustum formula's range. From these findings, we could not confidently conclude that the cylinder formula was more valid than the frustum formula for calculating the residual limb volume. Still, the cylinder formula might be more valid than the frustum formula. The residual limbs during postamputated and preprosthetic period may be in cylindrical shape rather than cone shape. Kaulesar Sukul et al(1) reported in 1993, the comparison between these two calculated formulas in measuring the leg without foot volume using the correlation coefficients, which were 0.99 versus 0.93. They concluded that only the cylinder method could be used interchangeably with the water displacement model.

From the scatter plots of the different volume of water displacement and cylinder formula (figure 3) and water displacement and frustum formula (figure 4) against the measured volume from water displacement method, we have found similar results. There were no relation between the different volumes and the volume of residual limbs. So the errors of measurement did not vary with the size of residual limbs.

The 95% CI of mean difference of the first and second measurement by girth measurement, frustum and cylinder formulas, were within the acceptable range ( $\pm$  5% of mean volume of first time measurement by each method). The frustum and cylinder formula were reliable to calculate the residual limb volume. Our findings agreed with the studies by Katch VL et al(7) and Whitney SL et al(12). Katch et al(7) compared the frustum formula of girth measurement and water displacement technique in calculating volume of normal legs and reported that the intertrial reliability was above 0.95. Whitney et al(12) examined the reliability of lower extremities within and between raters, reported intraclass correlation coefficients (ICCs) range from 0.91 to 1.00 and concluded that it was reliable.

For measuring the changing volume of the residual limbs, the mean different volume from water displacement of the frustum and cylinder formulas were within the limits (± 10% of mean changing volume of water displacement) but 95% CI of them were out of the limit range. The girth measurement, both frustum and cylinder formulas may not be valid enough to measure the small changing volume. The mean changing volume was 40.06 cm<sup>3</sup>, which was only 5.83% reduction of volume when compared to the first measurement (Table 2). The small changes of residual limb volumes could be explained by all of the subjects recruited into this study had to have good wound healing to prevent the complication from the water displacement method. Thus after the wound heals, the swollen residual limbs will be much decreased in size and made the volume changes in the next 4 weeks negligible.

The 95% CI of mean difference of the first and second measurement of water displacement, frustum formula and cylinder formula were -5.48, 9.87; -8.09, -0.37; and -8.11, -0.40, respectively. The difference of the first and second measurement of all methods was about 20-25% of the mean changing volume (8-10 cm<sup>3</sup> from 40 cm<sup>3</sup>). The water displacement method and girth measurement may not be reliable to detect the small changing volume of these patients' stumps.

The water displacement method was difficult to set up and operate the volumeter. The measurement was appropriate for the persons who have a good sitting balance and cooperation.

While the amputees lowered their stumps into the volumeter until the level of the water met the mark level, at this time they should not move their stumps for a few minutes. The moving stump, even a little, can produce erroneous measurement because the water would easily drip from the spout. From the studied field, it was hard to hold the amputees' stumps in a fix position. This was an important error that may make this method not reliable enough to measure the small change of the stump's volume. Even though the water displacement method is accepted to be the gold standard for measuring the limb's volume, the accuracy of measuring the small changing volume is still questionable in this study. To eliminate the error and improve the reliability of the test, the new design of volumeter or supporting equipment is needed. The residual limb should be slowly lowered downward into the volumeter by the supporting machine to prevent moving or tilting of the residual limb during measuring process.

For the girth measurement, each stump was measured 3-6 circumferences separately and then used the mathematic formulas to calculate the residual limb's volume. The repeated measurements may cause more incorrect calculation of volume and poor reliability. To reduce this error, the length of the measured segment may have to increase to reduce the times of circumferential measurement. A further study is recommended to prove this idea. The plane of each circumference measurement also affected the accuracy of measurement. The horizontal plane or the plane that was at the right angle with the stump's vertical axis was correct to measure each circumference. If we can have the method to make the correct circumferential measurement, the reliability of this method will be increased.

Thirty-one subjects were measured for the changing volume of their residual limb volumes. This small sample size could affect the precision of 95% CI. Thus, we could not confidently conclude that both mathematic formulas were not valid to measure the changing volume of the residual limbs.

The correlation coefficients of frustum formula and water displacement method for calculating the changing volume was 0.922 and of cylinder formula and water displacement method was 0.921. Both correlation coefficients were very high. If we take only correlation coefficients into account, both of the mathematic formulas may be mistakenly concluded to be valid for measuring the changing volume. This confirmed the suggestion by Altman and Bland(9) that the use of correlation coefficients to evaluate the agreement between the two methods for measuring the same thing was misleading. A high correlation does not mean that the two methods agree with each other. The correlation coefficient measures the strength of a relation

between two variables, not the agreement between them. Alman stated that if one would like to replace the old method with the new method, what one should know is how much the new method is likely to differ from the old method. If the difference is not large enough to cause problems in clinical interpretation we can replace the old by the new method. He suggested using simple calculation to explore the difference.

From our study, we concluded that the girth measurement method was simpler and easier to handle than the water displacement method. This method agreed significantly with the water displacement method but was not reliable enough to measure small changes of the limb volumes. The water displacement method needed more cooperation from the subjects to slowly immerse the stump into the volumeter. And the volumeter required time and space to set the equipments.



#### **CHAPTER VI**

#### **CONCLUSION**

The girth measurement methods, both the frustum and cylinder formulas, were valid and reliable for calculating the residual limb volume in below knee amputees compared with the water displacement method. The cylinder formula may be more valid than frustum formula for calculating the residual limb volume. The validity and reliability of the girth measurement, both frustum and cylinder formulas,

for calculating the small changing volume was questionable. The clinical use in this point should be carefully considered.

Further studies should be conducted to prove the validity and reliability of the girth measurement, both frustum and cylinder formulas, for measuring the changing volume of the residual limbs. The following points should be concerned:

- 1. The prevention of residual limbs moving or shaking during the measuring period by using the equipment or machine for suspension and stabilization.
- 2. Every circumference measurement should be done at a fix point and in a horizontal plane.
- 3. The number of subjects should be large enough to determine the reliability of the measuring methods to detect small changes of residual limb volumes.

The correlation coefficient is not a proper indicator for determining the agreement between the two measuring methods that measure the same thing. A better way to establish in agreement between the two measuring methods is to explore the likelihood of difference of both methods. A clinically insignificant difference allows us to replace the older method with the new one.

#### REFERENCES

- Kaulesar Sukul DMKS, den Hoed PT, Johannes EJ, van Dolder R, Benda E. Direct and indirect methods for quantification of leg volume: Comparison between water displacement volumetry, the disk model method and the frustum sign model method, using the correlation coefficient and limits of agreement. J Biomed Eng 1993 Nov;15(6):477-480.
- 2. Megens A, Harris SR, Physical therapist management of lymph-edema following treatment for breast cancer: a critical review of its effectiveness. Phys Ther 1998 Dec;78(12):1302-1311.
- 3. Mortimer PS. Investigation and management of lymphoedema. Vasc Med Rev 1990 Dec;1(1):1-20.
- 4. Pani SP, Vonamail P, Yuvaraj J. Limb circumference measurement for recording edema volume in patients with filarial lymphedema. Lymphology 1995 Jun;28(2):57-63.
- 5. Bunce IH, Mirolo BR, Hennessy JM, Ward LC, Jones LC. Post-mastectomy lymphoedema treatment and measurement. Med J Aust 1994 Jul;161(2):125-12.
- 6. Charge H. Treatment of lymphoedema. Nurs Times 1995 Jul; 91(30):53-58.
- 7. Katch VL, Katch FI. A simple anthropometrics method for calculating segmental leg limb volume. Res Q 1978 May; 45(2):211-214.
- 8. Lennihan R, Mackereth M. Calculating volume changes in a swollen extremity from surface measurements. Am J Surg 1973 Nov;126(5):649-652.
- 9. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet 1986 Feb;1(8476):307-310.
- Perrin M, Guex JJ. Edema and leg volume: Methods of assessment. Angiology 2000 Jan;51(1):9-12.
- 11. Sitzia J. Volume measurement in lymphoedema treatment:examination of formulae. Eur J Cancer Care 1995 Mar;4(1):11-16.
- 12. Whitney SL, Mattocks L, Irrgang JJ. Reliability of lower extremity girth measurements and right- and left-side differences. J Sport Rehabil 1995 Jan;4(1):108-115.
- 13. Stranden E. A comparison between surface measurements and water displacement volumetry for the quantification of leg edema. J Oslo City Hosp 1981 Dec;31(12): 153-155.
- 14. Mueller MJ. Comparison of removable rigid dressing and elastic bandages in preprosthetic management of patients with below-knee amputations. Phys Ther 1982 Oct;62(10):1438-41.

- 15. Commean PK, Smith KE, Cheverud JM, Vannier MW. Precision of surface measurements for below-knee residual. Arch Phys Med Rehabil 1996 May;77(5):477-486.
- 16. Ward LC, Bunce IH, Cornish BH, et al. Multi-frequency bioelectrical impedance augments the diagnosis and management of lymphoedema in post-mastectomy patients. Eur J Clin Invest 1992 Nov;22(11):751-754.
- 17. Golbranson FL, Wirta RW, Kuncir EJ, Lieber RL, Oishi C. Volume changes occurring in postoperative below-knee residual limbs. J Rehabil Res Dev. 1988 spring; 25(2): 11-18.
- 18. Casley-Smith JR. Measuring and representing peripheral oedema and its alterations. Lymphology 1994 Jun; 27(2): 56-70.





#### APPENDIX 1

#### PATIENT INFORMATION AND CONSENT FORM

# ข้อมูลสำหรับผู้ป่วยและใบยินยอมอนุญาต

การศึกษาทางคลินิก: ความถูกต้องและความแม่นยำของ Girth measurement
(Circumference measurement) ในการคำนวณหาปริมาตรตอขาของผู้ที่ถูกตัดขาระดับใต้หัวเข่า

# เรียน ผู้ป่วยทุกท่าน

ท่านเป็นผู้ที่ได้รับเชิญจากแพทย์ให้เข้าร่วมการศึกษาทางคลินิคเพื่อทดสอบความถูกต้อง ของวิธีการคำนวณปริมาตรตอขาด้วยวิธีวัดเส้นรอบวงในผู้ป่วยตัดขาระดับใต้หัวเข่า ก่อนที่ท่านจะ ตกลงเข้าร่วมการศึกษาครั้งนี้ ขอเรียนชี้แจงเหตุผลและรายละเอียดในการวิจัยดังนี้

### บทนำ

ภายหลังการตัดขาถึงแม้แผลผ่าตัดจะสมานคีแล้ว แต่ตอขาของผู้ป่วยจะยังมีลักษณะบวม ใม่ได้รูป ซึ่งยังไม่เหมาะที่จะหล่อเบ้าและตัดขาเทียม ผู้ป่วยจะได้รับโปรแกรมฟื้นฟูและติดตาม ผลการรักษาโดยแพทย์จนกว่าตอขาจะยุบตัวลงถึงจุดที่ปริมาตรของตอขาเปลี่ยนแปลงน้อยมาก หรือไม่เปลี่ยนแปลงอีก จึงจะเป็นช่วงเวลาที่เหมาะสมในการตัดขาเทียม

วิธีที่เป็นมาตรฐานในการวัดปริมาตรตองาในปัจจุบันคือวิธีการแทนที่น้ำซึ่งค่อนข้าง ยุ่งยากและ ไม่เหมาะสมสำหรับผู้ป่วยบางกลุ่มและตองาบางลักษณะ แต่ยังมีวิธีการคำนวณปริมาตร ตองาจากสูตรทางคณิตศาสตร์ โดยใช้เส้นรอบวงของตองาซึ่งวิธีนี้ง่าย สะควกและสามารถใช้ได้กับ ผู้ป่วยทุกกลุ่ม

เนื่องจากการคำนวณปริมาตรตอขาด้วยสูตรคณิตศาสตร์โดยใช้เส้นรอบวงนี้ยังไม่ได้รับการ ทดสอบความถูกต้องมาก่อน การศึกษาครั้งนี้จึงต้องการวัดความถูกต้องของการคำนวณด้วยวิธี ดังกล่าว

### วิธีการ

ในการศึกษาวิจัยนี้ผู้ป่วยที่เข้าเกณฑ์และยินยอมเข้าร่วมการศึกษาวิจัยจะ ได้รับการวัด ปริมาตรตอขาทั้งสองวิธีคือวิธีการแทนที่น้ำและการวัดเส้นรอบวงแล้วจึงคำนวณปริมาตรจากสูตร ทางคณิตศาสตร์ โดยทำการวัดสองครั้งคือครั้งแรกที่มาพบแพทย์และอีกหนึ่งเดือนหลังจากนั้น

#### การประเมินผล

ผู้วิจัยจะคำนวณปริมาตรที่เปลี่ยนแปลงในช่วงระยะเวลาหนึ่งเคือนจากทั้งสองวิธีแล้วจึงนำ ผลที่ได้มาเปรียบเทียบกัน

# ประโยชน์ที่จะได้รับ

ผู้ป่วยทุกท่านที่เข้าร่วมในการวิจัยนี้จะได้รับการคูแลอย่างใกล้ชิดตั้งแต่ภายหลังการตัดขา การให้การฟื้นฟู จนถึงภายหลังการใส่ขาเทียมแล้ว และข้อมูลที่ได้จะเป็นประโยชน์อย่างยิ่งในการ ให้การคูแลรักษาผู้ป่วยต่อไป

# จำนวนผู้เข้าร่วมโครงการ

มีผู้ป่วยเข้าร่วมโครงการทั้งสิ้น 42 ราย

# คุณสมบัติของผู้เข้าร่วมโครงการวิจัย

เป็นผู้ป่วยที่ได้รับการตัดขาระดับใต้หัวเข่าไม่เกินระยะเวลา 6 เดือน แผลผ่าตัดสมานตัวดี และไม่มีแผลบนตอขา ผู้ป่วยมีการทรงตัวระดับปานกลางถึงดีในท่านั่งและให้ความร่วมมือดี

### การรักษาความถับ

ผลของการศึกษานี้จะใช้สำหรับวัตถุประสงค์ทางวิชาการเท่านั้น ข้อมูลต่างๆเกี่ยวกับตัว ท่านจะถูกเก็บเป็นความลับ การตีพิมพ์เผยแพร่ผลงานทางวิชาการจะไม่มีการระบุชื่อของผู้เข้าร่วม โครงการ คณะกรรมการจริยธรรมของการศึกษานี้และหน่วยงานที่มีหน้าที่รับผิดชอบอาจทบทวน บันทึกข้อมูลของท่าน โดยมีวัตถุประสงค์เพื่อตรวจดูความถูกต้องของข้อมูลและวิธีการต่างๆของ การศึกษาวิจัยและข้อมูลทางการแพทย์ของท่านอาจถูกนำไปจัดเก็บไว้ในคอมพิวเตอร์ จากการลงนามในเอกสารยินยอมเข้าร่วมโครงการวิจัย ท่านอนุญาตให้ดูแลบันทึก เก็บข้อมูลและ โอนย้ายข้อมูลดังกล่าวข้างต้น

# สิทธิผู้ป่วย

การเข้าร่วมการศึกษานี้เป็นไปโดยสมัครใจ ท่านอาจปฏิเสธที่จะเข้าร่วมโครงการหรือถอน ตัวจากการศึกษาได้ตลอดเวลาโดยไม่กระทบต่อการดูแลรักษาที่จะได้รับจากแพทย์

#### การลงนาม

เพื่อเข้าร่วมโครงการศึกษาวิจัย ท่านหรือผู้แทนโดยชอบด้วยกฎหมายต้องลงนามพร้อม วันที่ในใบยินยอมเข้าร่วมโครงการวิจัยที่แนบด้วยกันนี้

หากท่านมีปัญหาหรือข้อสงสัยประการใด กรุณาติดต่อ พญ. จริยา บุญหงษ์ ภาควิชาเวชศาสตร์ ฟื้นฟู คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย ตึกเจริญ-สมศรี ชั้น 1 โรงพยาบาลจุฬาลงกรณ์ โทร. 256-4433

# ใบยินยอมเข้าร่วมการศึกษาวิจัย (Consent form)

| เลขที่คนไข้  | นามสกุล                        |                                  |
|--|--------------------------------|----------------------------------|
| ข้าพเจ้าได้รับทราบจาก พญ.<br>วัตถุประสงค์ วิธีการศึกษา รวมทั้งทรา<br>ซักถาม ทำความเข้าใจเกี่ยวกับการศึกษาค่            | าบถึงผลดีที่จะได้รับ ความ      | เสี่ยงที่อาจเกิดขึ้น ข้าพเจ้าได้ |
| ข้าพเจ้ายินคีเข้าร่วมการศึกษาวิจั<br>นี้เมื่อใดก็ได้ โดยไม่จำเป็นต้องแจ้งเหตุผ<br>ว่าจะให้ดูแลรักษาผู้ป่วยอย่างใกล้ชิด |                                | - 01                             |
| ผู้วิจัยรับรองว่าจะเก็บข้อมูลเฉพ<br>ในรูปที่เป็นสรุปผลการวิจัย การเปิดเผยจำ<br>กระทำได้เฉพาะกรณีจำเป็น ด้วยเหตุผลท     | ข้อมูลเกี่ยวกับตัวข้าพเจ้าต่อห |                                  |
| ข้าพเจ้ายินคีให้ข้อมูลของข้าพเจ้<br>นี้  | าแก่คณะแพทย์ผู้รักษา เพื่อ1    | ไระ โยชน์ในการศึกษาวิจัยครั้ง    |
| ข้าพเจ้าได้อ่านข้อความข้างต้นแ   | ล้วและมีความเข้าใจดีทุกปร      | ะการ และได้ลงนามในใบ             |
| ยินยอมนี้ด้วยความเต็มใจ  |                                |                                  |
| (ชื่อผู้ป่วย)  | (ลายเซ็น)                      | (วันที่)                         |
| (ชื่อพยาน)   | (ลายเซ็น)                      | (วันที่)                         |
| (ผู้วิจัย)   | (ลายเซ็น)                      | (วันที่)                         |

## **APPENDIX 2**

## CASE RECORD FORM

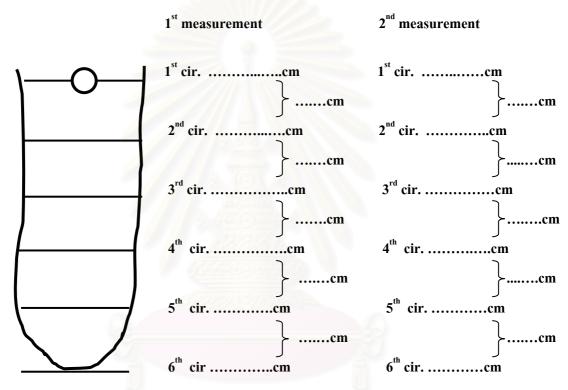
**Title :** Validity and reliability of Girth measurement (Circumference measurement) for calculating residual limb volume in below knee amputees.

Investigator: Jariya Boonhong MD.

| Data Entry No  |
|--|
| 1. Date//  |
| Patient's name   |
| AddressTel   |
| Collecting Hospital  |
| Demographic Data   |
| 2. Ageyears  |
| 3. Gender  |
| 4. Date of amputation/   |
| <u>Outcome</u>   |
| I. Residual limb volume that measured by Water Displacement method |
| First Visit  5. 1 <sup>st</sup> measurement                        |
| 6. 2 <sup>nd</sup> measurement                                     |
| 7. Different 1 <sup>st</sup> & 2 <sup>nd</sup> measurement (5-6)   |
| Follow up Visit  |
| 8. 1 <sup>st</sup> measurementcm <sup>3</sup>                      |

### II. Residual limb volume that measured by Girth Measurement method





• Calculated from **Frustum formula** 

$$V = (h) (C^2 + Cc + c^2) / 12(\pi)$$

C = the proximal circumference of each section

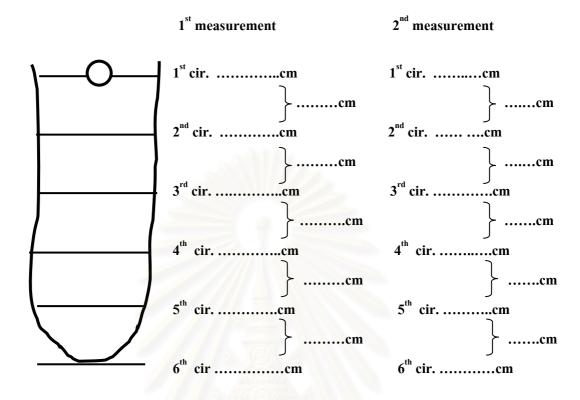
c = the distal circumference of each section

h = length of each section

|                              | 1 <sup>st</sup> measurement | 2 <sup>nd</sup> measurement |
|------------------------------|-----------------------------|-----------------------------|
| 1 <sup>st</sup> segment vol. | cm <sup>3</sup>             | cm <sup>3</sup>             |
| 2 <sup>nd</sup> segment vol  | cm <sup>3</sup>             | cm <sup>3</sup>             |

| 3 <sup>rd</sup> segment vol.   | cm <sup>3</sup>   | cm <sup>3</sup>   |
|--|---|---|
| 4 <sup>th</sup> segment vol.   | cm <sup>3</sup>   | cm <sup>3</sup>   |
| 5 <sup>th</sup> segment vol.   | cm <sup>3</sup>   | cm <sup>3</sup>   |
| 12. Total residual limb vol.   | in 1 <sup>st</sup> measurement                                  | cm <sup>3</sup>   |
| 13. Total residual limb vol.   | In 2 <sup>nd</sup> measurement                                  | cm <sup>3</sup>   |
| 14. Different 1 <sup>st</sup> & 2 <sup>nd</sup> meas   | sured volume (12-13)  | cm <sup>3</sup>   |
| • Calculated from C  | ylinder formula   |   |
|  | $V = \pi$ (circumference  | / 2π) <sup>2</sup> h  |
| Circumfe   | rence = the mean of adjacen                                     | nt circumferences   |
|  | h = length of each secti  | on  |
|  |   |   |
|  |   |   |
|  | 1 <sup>st</sup> measurement                                     | 2 <sup>nd</sup> measurement   |
| 1 <sup>st</sup> segment vol.   | 1 <sup>st</sup> measurement                                     | 2 <sup>nd</sup> measurement   |
| 1 <sup>st</sup> segment vol.  2 <sup>nd</sup> segment vol.   |   |   |
| 9  | cm <sup>3</sup>   | cm <sup>3</sup>   |
| 2 <sup>nd</sup> segment vol.   | cm <sup>3</sup>   | cm <sup>3</sup>   |
| 2 <sup>nd</sup> segment vol.  3 <sup>rd</sup> segment vol.   | cm <sup>3</sup>   | cm <sup>3</sup>   |
| 2 <sup>nd</sup> segment vol.  3 <sup>rd</sup> segment vol.   | cm <sup>3</sup>   | cm <sup>3</sup>   |
| 2 <sup>nd</sup> segment vol.  3 <sup>rd</sup> segment vol.  4 <sup>th</sup> segment vol.  5 <sup>th</sup> segment vol.                               | cm <sup>3</sup> cm <sup>3</sup> cm <sup>3</sup>                 | cm <sup>3</sup> cm <sup>3</sup> cm <sup>3</sup> cm <sup>3</sup> cm <sup>3</sup> |
| 2 <sup>nd</sup> segment vol.  3 <sup>rd</sup> segment vol.  4 <sup>th</sup> segment vol.  5 <sup>th</sup> segment vol.  15. Total residual limb vol. | cm <sup>3</sup> cm <sup>3</sup> cm <sup>3</sup> cm <sup>3</sup> | cm <sup>3</sup> cm <sup>3</sup> cm <sup>3</sup> cm <sup>3</sup> cm <sup>3</sup> |

## Follow up Visit



### Calculated from Frustum formula

$$V = (h) (C^2 + Cc + c^2) / 12(\pi)$$

C = the proximal circumference of each section

c = the distal circumference of each section

h = length of each section

|   | 1 <sup>st</sup> measurement | 2 <sup>nd</sup> measurement |
|---|-----------------------------|-----------------------------|
| 1 <sup>st</sup> segment vol.                                | cm <sup>3</sup>             | cm <sup>3</sup>             |
| 2 <sup>nd</sup> segment vol.                                | cm <sup>3</sup>             | cm <sup>3</sup>             |
| 3 <sup>rd</sup> segment vol.                                | cm <sup>3</sup>             | cm <sup>3</sup>             |
| 4 <sup>th</sup> segment vol.                                | cm <sup>3</sup>             | cm <sup>3</sup>             |
| 5 <sup>th</sup> segment vol.                                | cm <sup>3</sup>             | cm <sup>3</sup>             |
| 18. Total residual limb vol. in 1 <sup>st</sup> measurement |                             |                             |

| 19. Total residual limb                         | o vol. In 2 <sup>nd</sup> measurement  | cm <sup>3</sup>             |  |
|---|--|-----------------------------|--|
| 20. Different 1 <sup>st</sup> & 2 <sup>nd</sup> | measured volume (18-19)  | cm <sup>3</sup>             |  |
| 21. Changing volume                             | that measured by Frustum formula (12-  | (8) cm <sup>3</sup>         |  |
| Calculated from Cylin                           | nder formula   |                             |  |
|   | $V = \pi \text{ (circumference } / 2\pi)^2 \text{ h}$ Circumference = the mean of adjacent circumferences h = length of each section |                             |  |
|   | 1 <sup>st</sup> measurement  | 2 <sup>nd</sup> measurement |  |
| 1 <sup>st</sup> segment vol.                    | cm <sup>3</sup>  | cm <sup>3</sup>             |  |
| 2 <sup>nd</sup> segment vol.                    | cm <sup>3</sup>  | cm <sup>3</sup>             |  |
| 3 <sup>rd</sup> segment vol.                    | cm <sup>3</sup>  | cm <sup>3</sup>             |  |
| 4 <sup>th</sup> segment vol.                    | cm <sup>3</sup>  | cm <sup>3</sup>             |  |
| 5 <sup>th</sup> segment vol.                    | cm <sup>3</sup>  | cm <sup>3</sup>             |  |
| 22. Total residual limb                         | o vol. in 1 <sup>st</sup> measurement  | cm <sup>3</sup>             |  |
| 23. Total residual limb                         | o vol. In 2 <sup>nd</sup> measurement  | cm <sup>3</sup>             |  |
| 24. Different 1 <sup>st</sup> & 2 <sup>nd</sup> | measured volume (22-23)  | cm <sup>3</sup>             |  |
| 25 Changing volume                              | that measured by Cylinder formula (15-   | 22)cm <sup>3</sup>          |  |

### VITAE

Mrs. Jariya Boonhong was born on June,1971 in Bangkok Province, Thailand.

She graduated as Medical Doctor from the Faculty of Medicine, Chulalongkorn University in 1995.

During 1996-1997, she attended internship program at Hadjai Hospital, Songkhla Province.

In 1998, she attended Residency program of Physical Medicine and Rehabilitation at Department of Rehabilitation Medicine, Faculty of Medicine, Chulalongkorn University and was certificated in 2000.

In 2000, she worked as instructor in Department of Rehabilitation Medicine, Faculty of Medicine, Chulalongkorn University.

From 2004 to present, she was Assistant Professor, Department of Rehabilitation Medicine, Faculty of Medicine, Chulalongkorn University.







