การศึกษาขนาดของข้อเท้า เพื่อออกแบบพัฒนาข้อเท้าเทียมสำหรับประชากรไทย

นายยุทธนา คณาสุข

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต
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ANKLE MORPHOMETRY

FOR DEVELOPMENT OF TOTAL ANKLE PROSTHESIS

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ยุทธนา คณาสุข : การศึกษาขนาดของข้อเท้า เพื่อการออกแบบพัฒนาข้อเท้าเทียมสำหรับประชากรไทย. (ANKLE MORPHOMETRY FOR DEVELOPMENT OF TOTAL ANKLE PROSTHESIS) อ.ที่ปรึกษาวิทยานิพนธ์หลัก : ศ.นพ.พิบูลย์ อิทธิระวิวงศ์, อ.ที่ปรึกษาวิทยานิพนธ์ร่วม : อ.ดร. ไพรัช ตั้งพรประเสริฐ, อ.ดร. ชัญญาพันธ์ วิรุฬห์ศรี, 51 หน้า

โรคข้อเท้าเสื่อมเป็นโรคที่พบได้บ่อย สาเหตุส่วนใหญ่เกิดหลังจากได้รับอุบัติเหตุซึ่งต่างจากข้อสะโพกและข้อเข่าเสื่อม ที่เกิดจากความเสื่อมตามอายุ ในปัจจุบัน การรักษาที่ได้รับการยอมรับมากที่สุด คือการผ่าตัดเชื่อมข้อเท้า แต่มีข้อเสีย คือการขยับข้อเท้าจะเสียไป จึงมีการพัฒนาข้อเท้าเทียมขึ้นเพื่อให้ข้อเท้าสามารถขยับได้ใกล้เคียงกับปกติ แต่ในปัจจุบันยังไม่มีข้อเท้าเทียมแบบใดที่ได้รับการยอมรับอย่างสากล การพัฒนาออกแบบยังคงเป็นไปอย่างต่อเนื่อง ทั้งนี้ ข้อมูลสำคัญในการออกแบบพัฒนาคือการศึกษาขนาดข้อเท้า ซึ่งยังไม่มีข้อมูลเหล่านี้ในประชากรไทย

การศึกษาขนาดข้อเท้าในประชากรตัวอย่างจำนวน 32 ราย โดยอาศัยภาพสะท้อนคลื่นแม่เหล็กซึ่งเป็นการตรวจแบบสามมิติ นำภาพที่ได้จากหน้าตัดที่เหมาะสม วัดตัวแปรที่สำคัญในการออกแบบพัฒนาข้อเท้าเทียม ได้แก่ ความยาวทางด้านหน้าและด้านข้างของกระดูกทาลัส และทิเบียส่วนปลาย, รัศมีสมมติของกระดูกทาลัส, ความกว้างของขนาดข้อเท้า รวมถึงมุมบิดของข้อเท้า ทั้งนี้ตัวแปรบางตัวไม่ใช่ความยาวที่แท้จริง เนื่องจากการบิดของข้อเท้า จึงมีการปรับความยาวนั้นด้วยสมการทางตรีโกณมิติ แล้วเปรียบเทียบกับค่าจริง พบว่า ไม่ต่างกันอย่างมีนัยสำคัญทางคลินิก จากวิธีการนี้ ได้นำมาประยุกต์ใช้กับตัวแปรอื่นที่ไม่สามารถวัดค่าได้จริง

ผลที่ได้พบว่า ขนาดข้อเท้าผู้ชายมีขนาดใหญ่กว่าผู้หญิงอย่างมีนัยสำคัญทางสถิติทุกตัวแปร ยกเว้นมุมบิดของข้อเท้า เมื่อเปรียบเทียบกับข้อมูลที่มีอยู่เดิม พบว่า ขนาดของตัวอย่างคนไทย มีขนาดเล็กกว่ารายงานจากยุโรปและประเทศจีนอย่างมีนัยสำคัญ ซึ่งสามารถอธิบายจากความต่างกันทางเชื้อชาติ การวัดโดยเครื่องมือที่ต่างกัน รวมถึงการวัดความยาวที่มีการบิดเอียงของข้อเท้าในรายงานเดิม ทำให้ค่าที่ได้คลาดเคลื่อนจากความเป็นจริง

การเปรียบเทียบข้อมูลที่ได้กับขนาดของข้อเท้าเทียมที่มีอยู่ในปัจจุบัน พบว่าขนาดของข้อเท้าเทียมที่มีขนาดค่อนข้างใหญ่กว่าข้อเท้าของประชากรตัวอย่าง ทั้งนี้ข้อเท้าเทียมรุ่น TNKที่ผลิตโดยบริษัทในประเทศญี่ปุ่นมีขนาดใกล้เคียงกับขนาดของข้อเท้าของประชากรตัวอย่างมากที่สุด

สาขาวิชา วิศวกรรมชีวเวช ลายมือนิสิต......................................

ปีการศึกษา 2552 ลายมือชื่ออ.ที่ปรึกษาวิทยานิพนธ์หลัก......................

ลายมือชื่ออ.ที่ปรึกษาวิทยานิพนธ์ร่วม......................

ลายมือชื่ออ.ที่ปรึกษาวิทยานิพนธ์ร่วม......................

###5187246020 : BIOMEDICAL ENGINEERING
KEYWORDS: ANKLE MORPHOLOGY, TOTAL ANKLE ARTHROPLASTY

YUTTHANA KHANASUK : ANKLE MORPHOMETRY FOR DEVELOPMENT OF TOTAL ANKLE PROSTHESIS. THESIS ADVISOR: PROF.PIBUL ITITRAVIVONG, THESIS CO-ADVISOR: PAIRAT TANGPORNPRASERT, CHANYAPHAN VIRULSRI, 51 pp.

The goal standard treatment of ankle osteoarthritis is arthrodesis. Alternatively, total ankle arthroplasty can improve function. No ideal design for this operation. The novel systerms are developing. The fundamental data to achieve that is ankle morphology.

This study measure of 32 ankle by MRI which is 3D modality. The appropriate section was selected and measure the parameters the important to creat the ankle prosthesis. The parameters include the anteroposterior, mediolateral diameter of talus and distal tibia, sagitl radius of talus, malleolar width and malleolar axis. Some parameters can not measure directly. Because external rotation of normal ankle distort the true length, the adjust method by trigonometrical equation modify the parameters closed to reality. The comparison of the true talar AP length and the adjusted sagital talar length demonstrate no statistical and clinical significant. This modification method will applied to some parameters.

The results shows the detail of 10 ankle parameters. Female group has smaller size than male group significantly except malleolar axis that is not different. The non adjusted parameters compare with the current data from Europe show sample population have smaller parameters except tibial width. If compare with data from China, the sample have no statistical significant except sagital radius of talus. But if compare both Europe and China with adjusted parameters, all parameters except tibial width, sample population are smaller significantly. The reasons of this phenomenon are different in race, the different measurement tool (2D or 3D) and the effect of external rotation of ankle.

Ankle parameters play an important role to design and size the novel total ankle prosthesis. No system design for Thai people available now. This study shows that TNK (from Japan) is the most compatible one for Thai population.

Field of Study: Biomedical Engineering
Academic Year: 2552

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

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CHAPTER I
INTRODUCTION

Ankle osteoarthritis (OA ankle) is a progressive cartilage degenerative disease and characterized by pain, a reduced range of motion, loss of quality of life, generalize disability and other invaliding symptoms. In over 70 percent of OA ankle, the eitiology is post traumatic origin (eg: ankle fracture, maleolus fracture, ligamentous injury). The rest are distributed in secondary (ankle arthritis; as rheumatoid arthritis, inflammatory arthritis, etc.) and primary arthritis.[(1)]

The goal of end-stage OA ankle treatment is to relieve symptoms, such as pain and stiffness and improve function. Ankle arthrodesis (ankle fusion) has been the typically chosen orthopaedic treatment for OA ankle. However, the complication in ankle arthodesis, such as degeneration of adjacent joints, non-union and malunion led to the introduction of total ankle replacement (TAR).

The first ankle prosthesis is report in early 1970 by Frankin G.Alvine, but Becacause of the high complication rate of this implant (10 year survival rate is 42%) and the good results obtained with ankle fusions markedly delayed the development and advancement in ankle arthroplasty.

In last 15 year, however, new design have been implanted with encouraging mid and long term results.[(2)] S.L. Haddad present a systematic review of 49 studies, using AOFAS (American Orthopaedic Foot and Ankle Society): the ankle-hindfoot scale score was 78.2 for TAR and 75.6 for ankle arthrodesis, 10 year survival rate was 77%, revision rate was 7%, primary reason for the revisions being loosening and/or subsidence 28%.

There are several designs in total ankle replacement that are different in concepts and mechanincs of the current implants but the ideal ankle implant has yet to be developed. However, current expectations for TAR are reproducible technique, minimal bone resection, rapid and adequate bone ingrowth, minimal constraint, replication of physiologic ankle motion, minimal complications and need for early revision, long-term survivorship and predictable pain relief.[3]

The fundamental data to manufacture the implants is morphologic data. There are a little of ankle morphologic data and no data for Asian or Thai population. This project is making to study the ankle morphology of Thai population in order to develop the novel ankle implant and to compare which current design is the most suitable for Thai people.

CHAPTER II
LITERATURES REVIEW

There are several designs of total ankle prosthesis available now, at least 20 systems are in use worldwide. The total ankle replacement (TAR) systems are different in principle of mechanic to replace the natural ankle joint. They are classified to two generation.

The first generation characterized by cemented,constrained, 2compartment designs; for example Agility (Depuy, U.S.), TNK (Kyocera, Japan). The second generation designs are 3-component implant with minimal constrained; eg. STAR (Scandinavian Total Ankle Replacement, Waldmar Link, Germany), Buechel-Pappas (Endotec,U.K.), Salto (Tornier, France), Hintegra (New Deal SA, France), Mobility (Depuy, U.S.), Bologna Oxford ankle (BOX, Finsbury, U.K.). The other 3 component TAR also have been developed including the ESKA implant (GmbH and co), Ankle Evolution system (AES , Biomet , Netherlands), OSG ankle (Corin, England), Albratross (Group Lepine, France), Ramses (Fournitures, France), Inbone (Inbone technologies, formerly Topez orthopaedics), Eclipse (Integra life science holdings).[(3)] Of these devices only the Agility was approved by the U.S. Food and Drug Administration (FDA) for use in the United States before 2006. The STAR, which was approved in Jan 2008.

The Agility prosthesis, the most implanted prosthesis in the United States, has found almost no interest in Europe. There are 2 reason that can explain this difference between Europe and the U.S.. First, FDA (Federal Drug Administration) approved only Agility prosthesis which manufactured in U.S. the other designs are still under FDA investigation and can be implanted only in restricted numbers by a select pool of surgeons for the moment. This reason cause by most U.S. surgeons do not have an unrestricted access to the prosthesis currently used in Europe. Second, European surgeons, who have access to the different designs in use today including Agility prosthesis, made their choice for the more anatomic and less invasive model.[4]

For Agility, the original principle was 2 components semi-constrained, the articulating surface of tibia was 20º externally rotation in order to mimic normal ankle. The talus was also semi-constrained, allowed mediolateral translation and rotation underneath the polyethylene. The anterior aspect was wider than posterior to provide more stability in stance phase. The talus component was made of titanium that has poor wear qualities against polyethylene. The most complication found are tibial base fracture, posterior tibial subsidence, limit size available.[5]

The company develop the next generation TAR to solve these problems. First, to correct tibial base fracture, the tibial component was thickened; this increase the strength about 400% and also convert the talar component form titanium to cobalt-chrome which are stronger and less reactive to polyethylene. Second, in terms of posterior tibial subsidence, the prosthesis was augmented the posterior aspect of tibial component to increase talar surface and the stress to distal tibia was decreased. Finally, the limitation of sizes available was adjusted. The system increased from 3 to 6 sizes and provide the revision talar component.[6,7]

The new Agility are broad-based talus component to reduce subsidence. This implant has front-loading polyethylene locking system which easy to change the polyethylene in revision procedure. This new system is also able to mismatch component. The clinical results of new Agility have been reported. The longest mean follow up (9-years) 11% conversion to arthrodesis was observed. The other investigator reported 306 ankles found that with revision as the end point, 5-year survival rate was 54%; with implant survival as the end point, 5-year survival rate was 80%. If the patient is limit to older than 54 years old, the 5-year survival rate increased to 89%.[6-9]

The STAR (Scandinavian total ankle replacement) and the Buechel- Pappas (BP) designs are the best mechanic feature at the moment. They are unconstrained system which are mobile bearing and 3 components, cementless and on-growth design. For the STAR, tibial component is symmetrically trapezoidal tibial shape which wider in the front and has two cylinders that provide an interference fit with the prepared tibial surface. The talar component is symmetrical convex that fail to respect the relatively smaller medial curvature and larger lateral radius of curvature of the natural talus, which may occasionally lead relatively loose lateral ligaments and relatively tigh medial ligaments. The BP system has a central stem that requires a window cut into the anterior tibial cortex. The talar component also has a single radius.[3]

P.L.R. Wood corrected 200 STAR ankle surgery, mean follow up at 88 months found that 5-year and 10-year survival rate was 93.5 and 80.3% respectively.[10] The study of 12-year survival rate of BP implant was 92%, but this reported by the inventors of this prosthesis.[11]

The Salto design has more anatomic shape of the tibial plateau to enhance the contact with anterior and posterior corticalis and to avoid contact with lateral malleolus or the medial soft tissue. This prosthesis has asymmetrical talar components with slightly smaller radius on the medial side to avoid painful stress on the deltoid ligament and to mimic as closely as possible the physiologic motion of the talus. The Salto has limit report for mid and long term result.[3]

Pascal F. Rippstein classified the severity of ankle to 3 type, and each type is suitable for different designs.[4]

1. The nice arthrosis, in this group the arthrosis is located between the top of the talar dome and the corresponding tibial surface. The joint space between malleoli is mainly preserved. The BP prosthesis resurfaces only the arthritic part of the joint and leaves intact the malloelar joint is appropriated for this type.

2. The acceptable arthrosis, in this group the arthrosis is not limited to the talar dome but extends to the malleolar joints. The overall geometry of the ankle is still well preserved. The STAR design resurfaces the arthritic surfaces by covering the dome and both sides of the talus is suitable.

3. The ugly arthrosis, the anatomy and the biomechanic of these mostly post traumatic ankles are severely altered. A simple resurfacing is less likely to work. The ankle joint is radically excised and best replaced by the Agility prosthesis.

Current systematic reviews of 49 studies[2] show the better result of TAR from new designs, but no one is the best option for all patient. Because of improving of the ankle biomechanic knowledge and modern technology, the novel TAR designs are developing. The basic data to produce the implant is morphology.

Alberto Leardini, studied the geometry and mechanics of the human ankle complex and and ankle prosthesis. It was demonstrated that in intact ankle joint, the geometry of the articular surfaces is strickly related to that of the ligaments and that current prosthesis designs do not restore physiologic pattern of ligament tensioning. A novel design based on ligament and shape compatibility may improve TAR results.[13]

Only few studies have reported on ankle joint geometrical measurement[14-18] (Kempson et.al., 1975, Mariani and Patella 1977, Fessy et.al., 1997, Rita Stagni 2004, Andrea Hayes et.al.2006, Chien et.al.2008). Although large samples have been analysed by these authors. (41, 100, 50, 36, 21 and 10 subjects respectively)

The methods used to perform morphological measurement are vary. Kempson, Mariani and Patella, Fessy used standard radiograph and measured joint morphometry directly by using protractors or goniomters. Whereas Rita proposed a new semi-automatic method based on standard radiograms that can assessed accurately, repeatable and little dependent on operator's skill. This method used software designed for the purpose and developed in MATLAB (The Mathworks, Inc.). Only studies of Andrea Hayes et.al. and Chien et.al. revealed ankle morphology on 3D-CT images. Andrea measured only the talar dimension (anterior, middle and posterior of superior talar dome) and the arc radius of talar dome from Europe patient. Chien studied from 10 chinese cadavers followed by Stagni's study.[15]

The result of reports are comparable in some dimensions because of various technique and parameters.In overall, there are a lillte difference. Stagni also presented that the TAR designs now available (STAR, BP, ALBRATROSS, TNK, BOX) seems to cover a very limited range and to be in general underestimations of real ankle dimensions.[15] This may be critical to the full coverage of the cortical bone at the bone cuts by the relevant prosthetic components, necessary to limit the risk of component sinking. Recently, Chien et.al. founded that Chinese population have smaller size distal tibia and suggest that current tibial components might not be suitable for this bone in Chinese population. That stress fractures at the medial and lateral malleoli may occur more frequently.[18]

Now, no data available of Thai population. This project is making to reveal the ankle morphology of thai population that is the fundamental data for developing the ankle prosthesis. The study also compare the current prosthesis with in coming data. The ankle parameters and the important of kinetic and biomechanic of ankle joint are included in this project.

CHAPTER III

MATERIALS AND METHODS

3.1 Research methodology

Objectives

To study morphology of ankle joint Thai population with MRI base and measure the parameters that necessary for the mechanics of the ankle joint.

Research questions

<u>Primary</u>

What is the ankle morphology of Thai population?

<u>Secondary</u>

1. Are the ankle parameters of Thai population similar to the current data? (European population)
2. Are the current TAR designs suitable for Thai population?

Design descriptive study

Population and sample

<u>Target population</u> : Thai population

<u>Sample</u> : all patient who did the MRI of ankle in Chulalongkorn Memorial Hospital or Prachacheun imaging center in 6 months period of time. (June 2009 to March 2010)

3.2 Patients Selection

From June 2009 to March 2010, consecutive ankle magnetic resonance imaging (MRI) studies were performed in Thai subjects.The selection criteria of each subject included 20 to 60 years of age, no clinical symptom and sign of ankle arthritis. The exclusion criteria are patient who have any bony fracture and dislocation, any inflammatory joint disease eg: rheumatoid arthritis, gouty arthritis, osteoarthritic change or bony deformity.

Because MRI ankle is less common study, collect the data in Chulalongkorn Memorial Hospital alone may consume a long period of time. So collect the imaging from 2 instituted may shorter time, we using the data from subject whom did elective MRI ankle in Prachacheun Imaging Center too.

The sample size determination

Using

$$n = \frac{Z^2\,\text{б}^2}{d^2}$$

n = number of sample

$Z = Z\alpha/2$, α=0.05 ; Z = 1.96

Б = variance of data (2.1mm – 2.9 mm)

d = acceptable error (1 mm)

Calculate sample size 32.3.

There are 39 cases available in this study : 27 from Chulalongkorn memorial hospital, 12 from Prachacheun Imaging center. 7 were excluded because of 3 had osteoarthritic change, 3 had fracture of ankle presented.

The basic information of the subjects in this study are shown in table1.

Table1

The basic information of the subjects

Sex	Subjects	Age (year)	SD
Total	32	42.53	9.22
Male	11	43.55	9.37
Female	21	42.00	9.33

3.3 MRI Measurements

In Chulalongkorn Memorial Hospital, MRI was performed by Signa 1.5 Tesla Exite HD, General Electric (G.E.) and for Prachacheun Imaging Center, MRI was performed using a 1.5 Tesla whole body MR imaging system (Siemens 1.5 Tesla, Avanto, Germany) with an extremity coil. Pulse sequences were T1-weighted images. The direction of axial slice imaging placed the slice perpendicular to the ankle joint in the coronal plane and perpendicular to the long axis of tibia in the saggital plane. All images were reconstructed at 3-mm intervals.

The protocol of the scanning parameters was shown in table 2

Table 2

Scanning parameters

Scan Direction				Axial or Sagittal			
Matrix *(preferred)*				512 x 512			
Slice thickness				1.0 or 2.0 mm			
Scanning Technique Options:							
	Flip Angle	TR(ms)	Echo Train	TE(ms)	Slice (mm)	FOV (cm)	Voxel (mm^3)
*3D-FEMR*** *(preferred)*	20	6.7	1	2	1.5	~14	~0.75
3D T2– SPGR	40	50	1	5	1.5	~14	~0.75
2D T2 - SPGR	90	2800	6	31	2	~14	~0.75

** This protocol is only available in MRI machines equipped with Cardiovascular CV/i gradients.

All measurements were recorded in millimeters using DICOM images program.

These dimensions are summarized as the mean and standard deviation (SD).

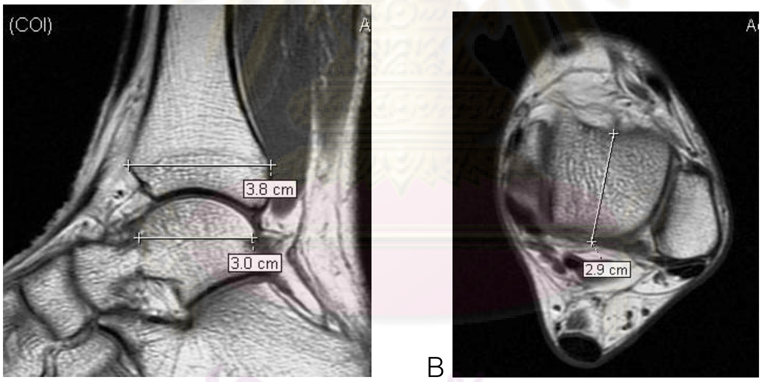
3.4 parameters

The images from MRI were collected in DICOM file. The parameters of ankle Were measure in millimeter. Both of talus and distal tibia were measure in 2 dimensions; anteroposterior (AP) and mediolateral (ML). The detail of parameters and method of measurement are described below.

Plane of determination

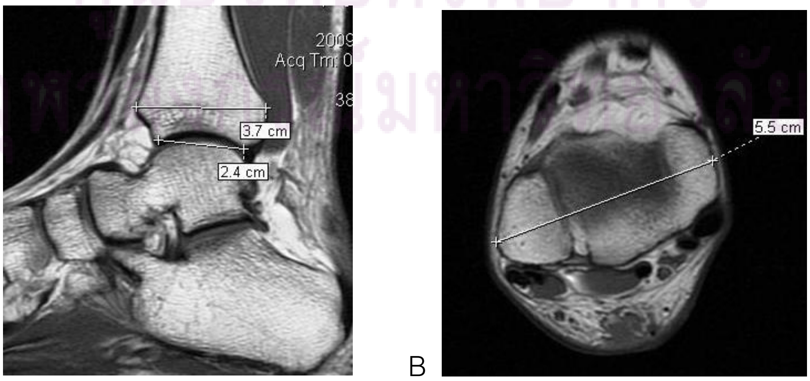
Anteroposterior (AP)

The consideration of AP dimension can be perform on axial plane and sagital plane. The sagital cut is mush easy to measure than axial cut but the minimal axial rotation of ankle deteriorate the length. The true AP diameter must perform by axial cut or calculate the degree of rotation by mathematical formula.



A B

Figure 1 talus, axial cut (B) is more accurate measurement than sagital cut (A)

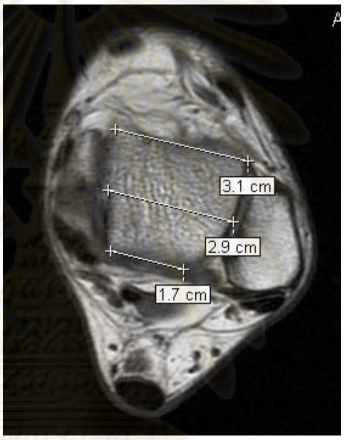


A B

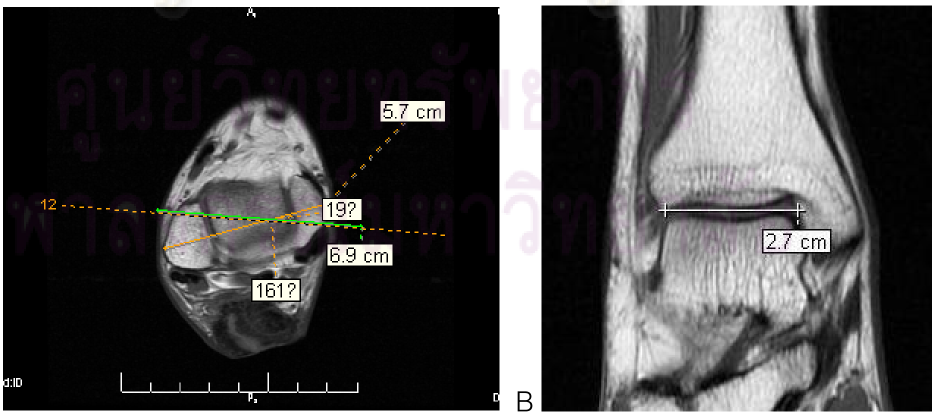
Figure 2 distal tibia, sagital view (A) easy to measure but not true length due to ankle rotation (B)

<u>Mediolateral (ML)</u>

Mediolateral diameters of both bones can be measure by two planes; axial and coronal. For talus, the anterior diameter is longer than posterior so measure the ML diameter by coronal cut is not accurate. The width of the talus can be identified by axial cut and the talus was measure at anterior, posterior and middle part. For distal tibia, the axial cut is impossible to measure because flaring of distal tibia is not linear. Alternatively we can measure ML diameter by coronal plane.



<u>Figure 3</u> axial cut of talus shows anterior border is wider than posterior

A


<u>Figure 4</u> mediolateral diameter of distal tibia from coronal plane (B) does not represent true length because external rotation of ankle anatomy (A).

<u>Important parameters</u>

Refer to study of stagni[(15)], they described the 12 ankle parameters,

<u>Tibia</u>

1. TiAL tibial arc length

Length of the chord connecting the most posterior and the most anterior points of the tibial mortise.

2. SRTi sagital radius of the tibial mortise

The radius of the circumference by least-square fitting the points of the tibial mortise profile.

3. APG anteroposterior gap

The distance along the tibial longtitudinal axis between A and B

4. APA anteroposterior inclination angle of the tibial mortise

The angle between the segment AB and the tibial anteroposterior axis

5. MTiTh tibial thickness at the maximal anterior border

Distance between the most anterior point of the tibial anterior profile and the corresponding point along the tibial anteropostereior axis on the posterior tibial profile.

6. MDA distance of level of MTiTh form the anterior limit of the mortise

Distance along the tibial longitudinal axis between A and C

7.MDV distance of the level of MTiTh from the vertex of the mortise

Distance along the tibial longitudinal axis between the vertex of the tibial mortise

<u>Talus</u>

1. TaAL trochlea tali length

Length of the segment connecting the most posterior and the most anterior point of the trochlea tali sagital arc.

2. SRTa sagital radius of the trochlea tali arc

Radius of the circumference by least-square fitting the points of the trochlea tali arc profile.

3. TiW tibial width

Distance of the two intersection of the two lines by least-square fitting the internal profiles of the two malleoli and the line fitting the top of the tibial mortise.

4. TaW talar width

Distance of the two intersection of the two lines by least square-fitting the medial and lateral talar articular profile and the line fitting the top of the talar articular profile.

5. MalW malleolar width

Distance along the mediolateral axis between the most medial point of the medial profile of the tibial and the most lateral point of the fibular

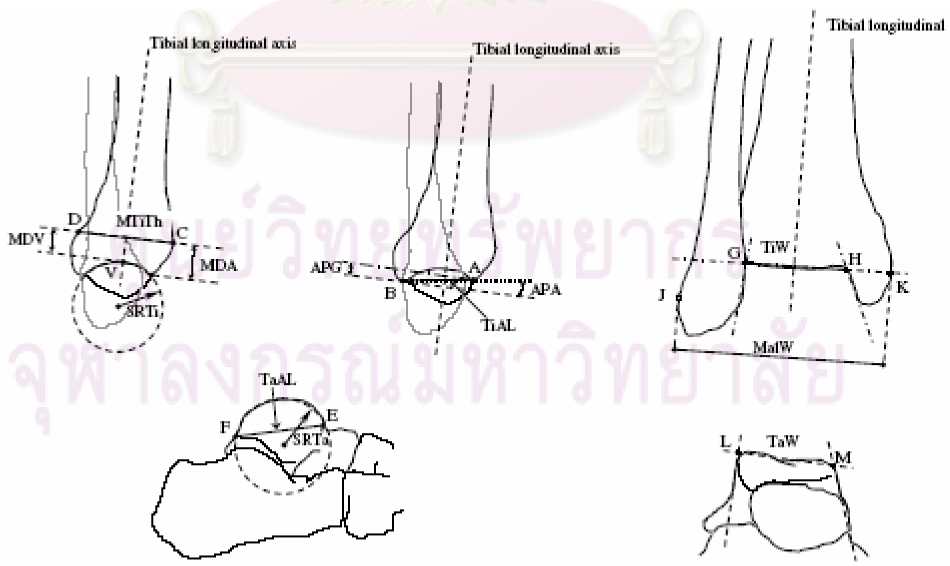


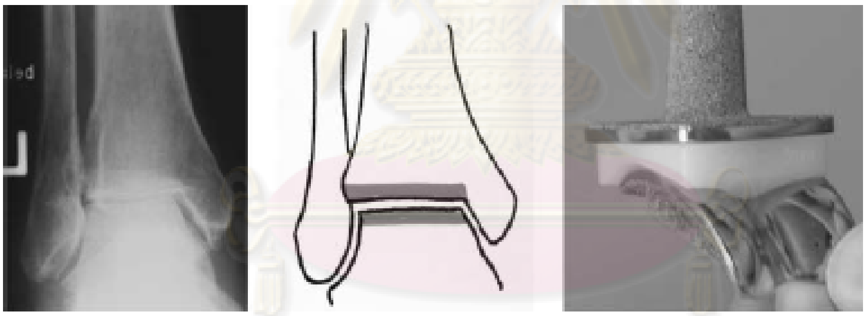
Figure 5 The ankle parameters by Stagni

This study using plane film and computer program to enhance edge of the bone so this technique is two dimension measurement. Some parameter can not measure from 2D eg: ML diameter of the talus. (anterior part is wider than posterior, 2D show interpose of picture so this parameter is incorrect)

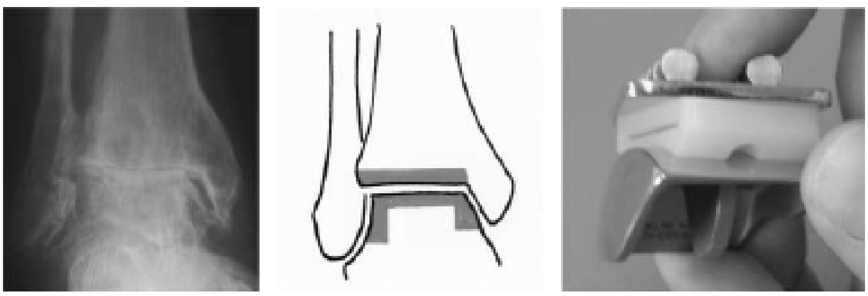
Chien study ankle parameter in Chinese cadaver with MRI. This 3D imaging were measured by 2D technique follow Stagni protocol. Some parameter do not represent real data.

Pascal F. Rippstein classified the severity of ankle to 3 type, and each type is suitable for different designs.

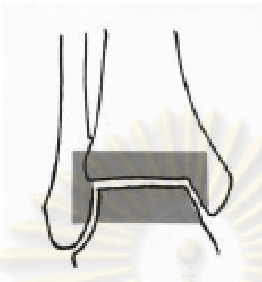
1. The nice arthrosis, in this group the arthrosis is located between the top of the talar dome and the corresponding tibial surface. The joint space between malleoli is mainly preserved. The BP prosthesis resurfaces only the arthritic part of the joint and leaves intact the malloelar joint is appropriated for this type.



2. The acceptable arthrosis, in this group the arthrosis is not limited to the talar dome but extends to the malleolar joints. The overall geometry of the ankle is still well preserved. The STAR design resurfaces the arthritic surfaces by covering the dome and both sides of the talus is suitable.



3. The ugly arthrosis, the anatomy and the biomechanic of these mostly post traumatic ankles are severely altered. A simple resurfacing is less likely to work. The ankle joint is radically excised and best replaced by the Agility prosthesis.



Not all parameter that propose before is important to the new total ankle implant design. The essential parameter include.

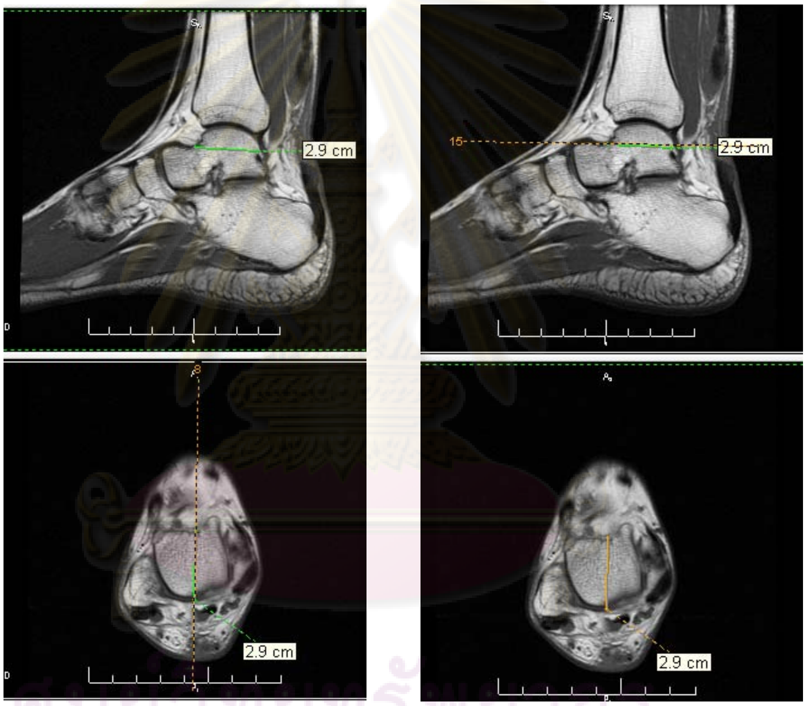
parameters	Talus	tibia
AP	TaAL SRTa	MTiTh TiAL
ML	TaW	TiW MalW axis

Paramerter of talus

<u>AP dimesion</u>

1. TaAP talar anteroposterior diameter

Talus is a special tarsal bone. Upper border which articulate to tibial mortise is elliptical shape like a part of cylinder. Thus AP diameter depends on the cut of the image. We identify this by axial view. The selected cut is the base of talar trochlea which is the highest diameter.



<u>Figure 6</u> talar arc length measured by axial cut is more accurate than sagital view because of ankle external rotation.

2. SRTa sagital radius of talar trochlea

Ankle acts as a pivot joint, the dome of talus looks like a sphere. From biomechanics study; the instantaneous axis of rotation (IAR) of the motion is not consist on one point, but the different of the IAR is very samall and not significant. We assume that talar dome is sphere in order to estimate the rage of motion of the ankle. The measure was done by select a circle that is the compatible of the talar trochlea on the sagital view.

The sagital view on the MRI is not true sagital because of the ankle rotation We can modified by mathematical calculation

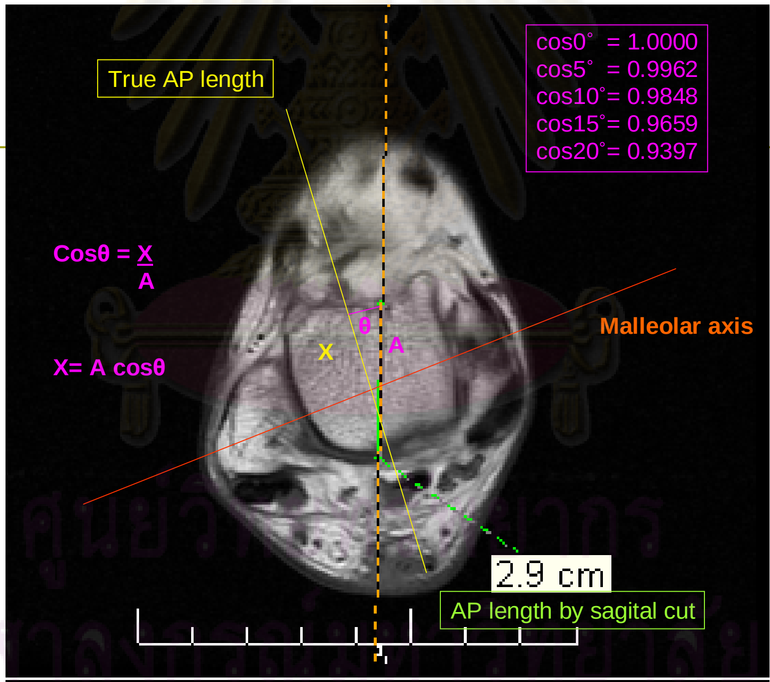


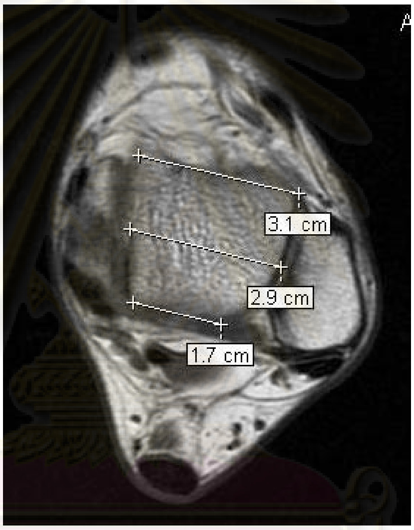
Figure 7 trigonometric calculation so adjust true length of ankle parameter.

In normal population, ankle has external rotation about 15-20 degree, the adjusted length is about 3-6% smaller than measure on sagital cut, this is no clinical significant. In order to easy to measure we use sagital cut and accept the small error of the measurement.

<u>ML dimension</u>

3. TaW talar width

The trochlea of talus is widen at anterior part, that is confirm by study of Andrea Hayes. The measurement of the variable of ML diameter of this bone must be done on the axial view. We will measure the cut that talus appears trapezoidal shape. If the cut is too proximal, the estimation is lower that actual size and if the cut is too distal, the flaring of the talar neck will disturb the measurement or the diameter will be larger.



<u>Figure 8</u>   mediolateral diameter of talus described in 3 part, anterior, posterior and middle legth on axial cut.

Parameter of distal tibia

AP dimesion

1. MTiTh maximal tibial thickness

Distal tibia is flaring and called metaphysic, the most anterior cortex appear vertex. This convexity acts as a buttress mechanism when ankle dorsiflexion. The posterior part of distal tibia called posterior malleolus appear convex too. This convexity prevents the ankle subluxatin when ankle plantarflexion

The metaphyseal flare of distal tibia can be measure on sagital cut from the point of most convexity of anterior cortex to the most convexity of the posterior cortex . the metaphyseal flare assume of the bony stock when cutting bone before prosthesis insertion.

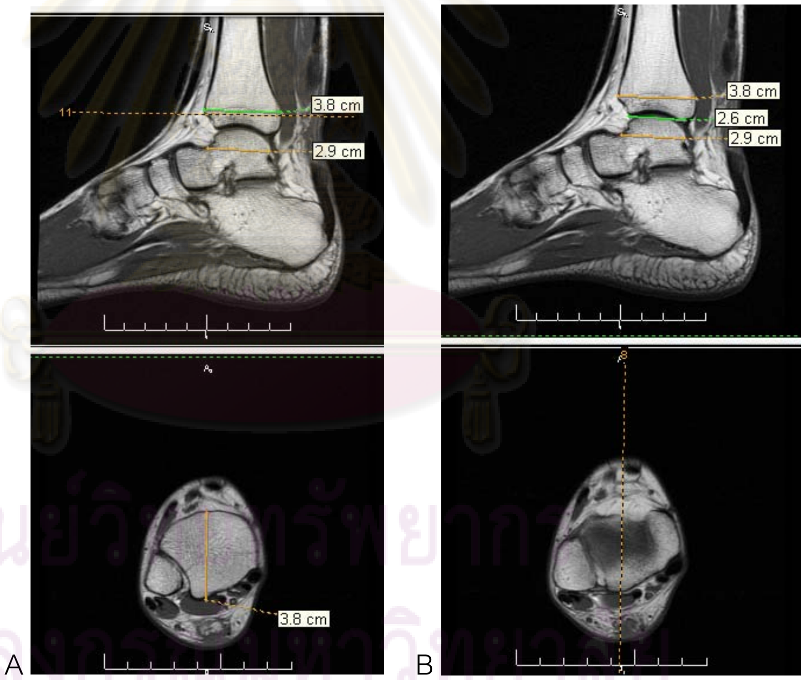


Figure 9 (A) maximal thickness of distal tibia
(B) tibial arc length

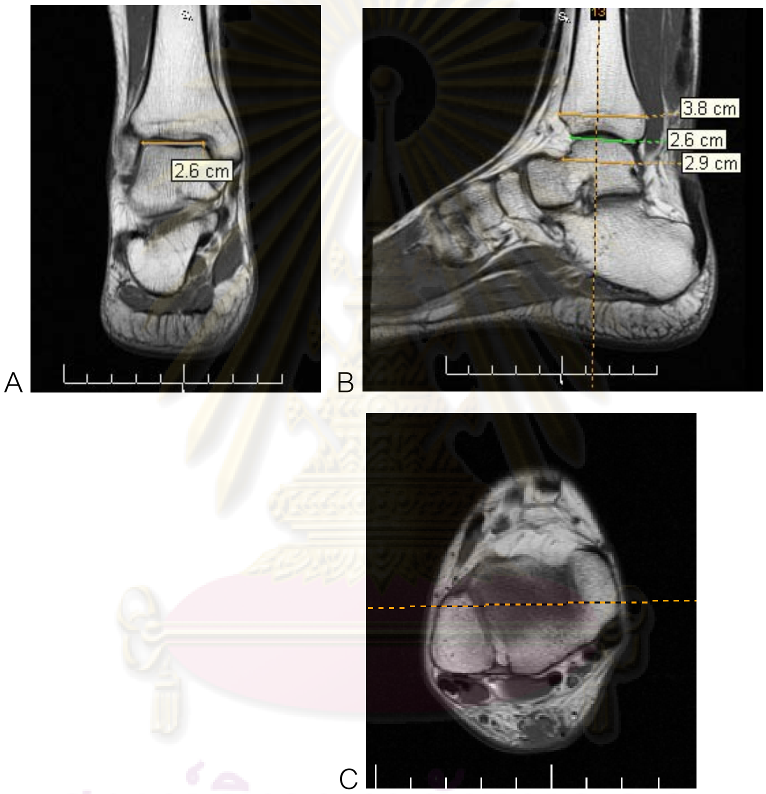
2. TiAL tibial arc length

We can measure the length of arc length or tibia by the anterior point of tibial mortise to the posterior one . These AP diameters are measure on sagital view, this view is not true sagital on anatomical position. We can adjusted by calculation.

<u>ML dimension</u>

1. TiW tibial width

Actual tibial width from coronal view is not true length by the external rotation of the ankle. This can be modified by trigonometric calculation. We select the cut that can clearly seen the distal tibia.



<u>Figure 10</u> (A)tibial width will measure on coronal cut and adjusted by calculation (B,C) the sagital cut and axial cut on the coronal plane

2. MalW malleolar width

From study of Stagni, they use the most convex of malleoli to described malleolar width. That is not really true because ankle has minimal external rotation. It can be demonstrated by axial cut.

In the surgical technique recommendation of TAR procedure, the implant placed on the anatomical position that mean minimal external rotation. So we will measure the malleolar width by the anatomy. The measurement must be done on axial view.

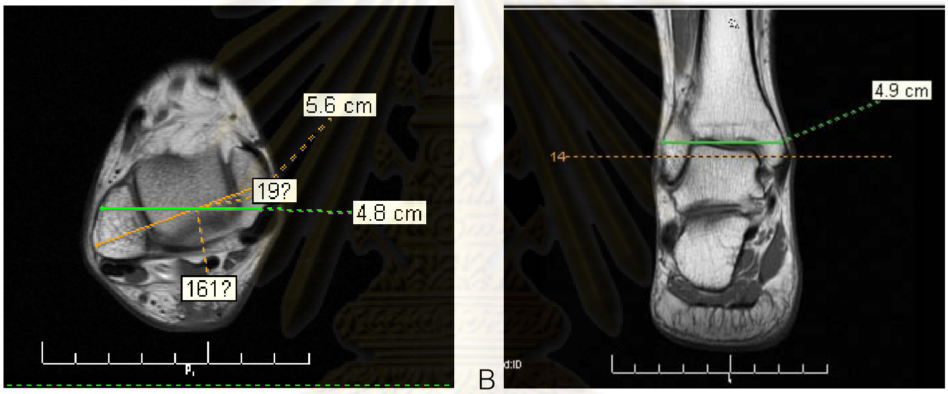
A B


Figure 11   (A) malleolar width

(B) coronal cut show the level determination of malleolar width

The rest of the parameters such as APG, APA, MDA, MDV, SRTi are not clinical significant to the ankle implant design. We will measure and analyse of the important parameter only.

3.5 Total ankle prostheses

Ankle prosthesis devided into 2 generation.

1. First generation

characterized by cemented, constrained, 2-compartment designs; for example Agility (Depuy, U.S.), TNK (Kyocera, Japan).

2. Second generation designs

are 3-component implant with minimal constrained; eg:

STAR (Scandinavian Total Ankle Replacement, Waldmar Link, Germany),

Buechel-Pappas (Endotec,U.K.),

Salto (Tornier, France),

Hintegra (New Deal SA, France),

Mobility (Depuy, U.S.),

Bologna Oxford ankle (BOX, Finsbury, U.K.).

The other 3-component TAR also have been developed including the ESKA implant (GmbH and co),

Ankle Evolution system (AES, Biomet, Netherlands),

OSG ankle (Corin, England),

Albratross (Group Lepine, France),

Ramses (Fournitures, France),

Inbone (Inbone technologies, formerly Topez orthopaedics),

Eclipse (Integra life science holdings).[3]

The parameter of the implants is available only one company

STAR: Scandinavian total ankle replacement

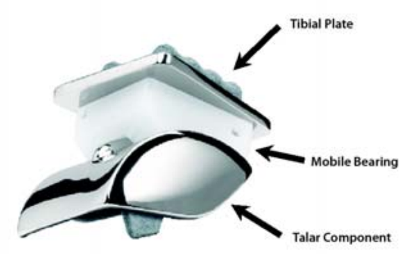
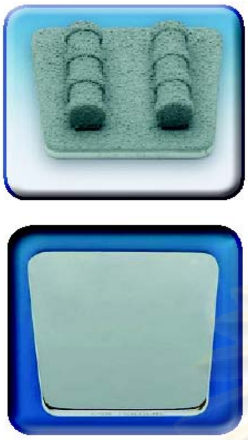
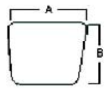


Figure 12 STAR prosthesis

Tibial Components
Material: CoCrMo Alloy
Titanium Plasma Spray

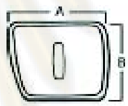




Item No. Cementless	Size	A mm	B mm
400-260	X-Small	30	30
400-261	Small	32	30
400-262	Medium	32.5	35
400-263	Large	33	40
400-264	X-Large	33.5	45

A

Talar Components
Material: CoCrMo Alloy
Titanium Plasma Spray



Item No. Cementless	Size	Side	A mm	B mm
400-250	XX-Small	Right	28	29
400-252	X-Small	Right	30	31
400-254	Small	Right	34	35
400-256	Medium	Right	36	35
400-258	Large	Right	38	35

B

Table 3 size of STAR prosthesis (A) tibial compartment, (B) talar compartment

We cannot access the parameter from the other company but the parameter that we use to compare to Thai population are from Stagni's study[15].

3.6 Statistical analysis

The results were represented as mean, standard deviation (SD), 95% confidence interval are also present to compare various parameters of ankle joint between the genders. Statistical analysis of the results was done using t-test by two-tailed p values option. A p value of < 0.05 indicated a significant effect. The program using to calculated is Microsoft Excel XP and SPSS version 11.5 for Windows.

CHAPTER IV
RESULTS

Morphologic data of the talus and distal tibia follow the protocol in chapter III listed

<u>Talus</u>

1. TaAP = talus AP length
2. TaAL = talar arc length
3. TaW = talar width

   (aTaW = anterior, mTaW = middle, pTaW = posterior)
4. SRTa = sagital radius of talus

<u>Distal tibia</u>

5. TiAL = tibial arc length
6. MTiTh = maximum tibial thickness
7. TiW = tibial width
8. MalW = malleolar width
9. axis = malleolar axis

These parameters are not all true length; eg: TaAL, SRTa, TiAL, MTiTh, TiW. They are effected by external rotation of ankle. We try to modified the length by calculation instead of measure true length because of inability to measure some parameters.

The model to test the hypothesis that calculation can be estimated the parameter is comparison of adjusted TaAL (the sagital length) and TaAP (the true length)

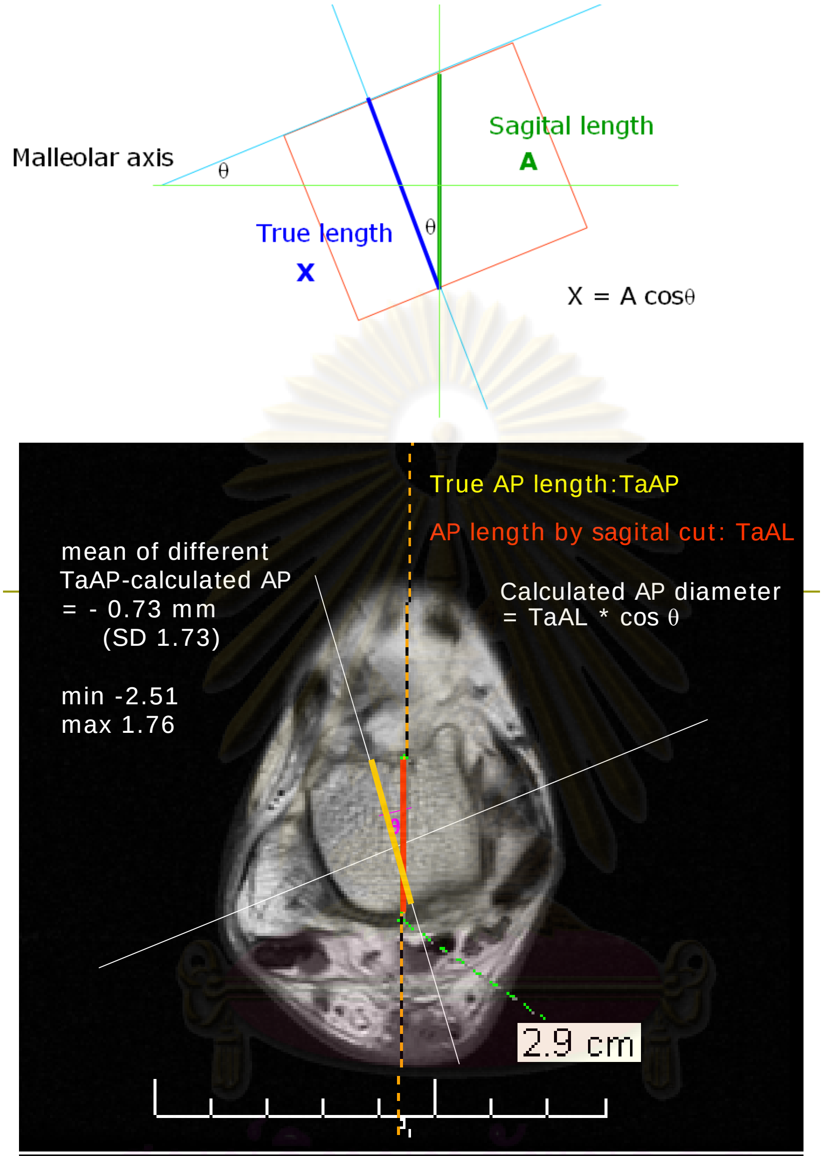


Figure 13 the modification method by trigonometric calculation

The mean of different of TaAP and adjusted TaAL is -0.73, SD 1.73. the minimum is -2.51 and the maximum is 1.76. 95% confidence interval is -1.21 to -0.25. The mean of different and 95% confidence interval are in the clinical acceptable. We assumption this method can be modified to the other parameter.

In the AP length, the modification can be done by this equation but in the ML width, the modification can be done as below.

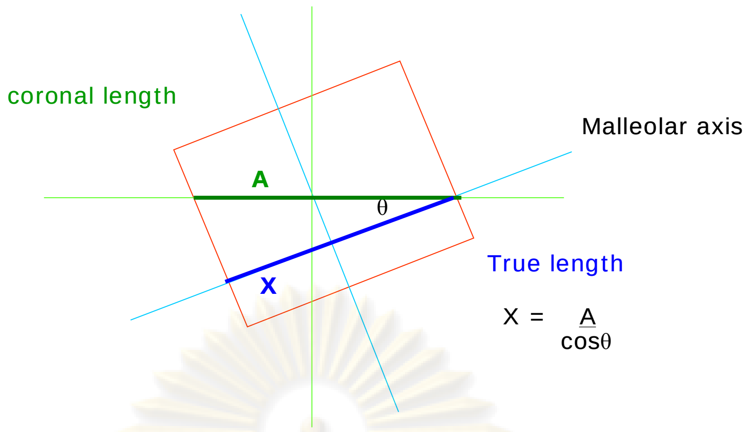


Figure 14 the modification method applied with ML diameter

The AP parameters that need to modified are SRTa, TiAL, MTiTH so we marked a to aSRTa, aTiAL, aMTiTH to described adjusted.

The ML parameter that need to modified is TiW so call aTiW instead.

The parameters had collected in millimeters and analysed by SPSS. The result of the parameters are show in the table 4.

Table 4 mean and standard deviation of the ankle parameters

	N	Mean	Std. Deviation	Std. Error Mean
TAAP	32	28.5000	2.35550	.41640
ATAW	32	28.0313	3.53311	.62457
MTAW	32	26.9063	2.85521	.50473
PTAW	32	19.5938	2.16809	.38327
ATIAL	32	24.0809	2.78446	.49223
AMTITH	32	33.3544	2.83107	.50047
ATIW	32	31.8672	4.52654	.80019
MALW	32	58.5000	4.77899	.84481
AXIS	32	21.6563	6.55798	1.15930
ASRTA	32	16.7191	1.76761	.31247

Table 5 95% confidence interval of the ankle parameter

	Test Value = 0					
					95% Confidence Interval of the Difference	
	t	df	Sig. (2-tailed)	Mean Difference	Lower	Upper
TAAP	68.444	31	.000	28.5000	27.6508	29.3492
ATAW	44.881	31	.000	28.0313	26.7574	29.3051
MTAW	53.308	31	.000	26.9063	25.8768	27.9357
PTAW	51.123	31	.000	19.5938	18.8121	20.3754
ATIAL	48.922	31	.000	24.0809	23.0770	25.0848
AMTITH	66.647	31	.000	33.3544	32.3337	34.3751
ATIW	39.825	31	.000	31.8672	30.2352	33.4992
MALW	69.246	31	.000	58.5000	56.7770	60.2230
AXIS	18.680	31	.000	21.6563	19.2918	24.0207
ASRTA	53.506	31	.000	16.7191	16.0818	17.3563

The result of compare the male and female group are in table 6

Table 6 mean and standard deviation of male and female group

Group Statistics

	SEX	N	Mean	Std. Deviation	Std. Error Mean
TAAP	1.00	11	30.1818	1.25045	.37703
	2.00	21	27.6190	2.33401	.50932
ATAW	1.00	11	30.2727	4.24478	1.27985
	2.00	21	26.8571	2.47560	.54022
MTAW	1.00	11	29.0000	2.36643	.71351
	2.00	21	25.8095	2.48232	.54169
PTAW	1.00	11	21.4545	1.75292	.52853
	2.00	21	18.6190	1.68749	.36824
ASRTA	1.00	11	18.0541	1.52584	.46006
	2.00	21	16.0197	1.47816	.32256
ATIAL	1.00	11	25.9409	2.28797	.68985
	2.00	21	23.1067	2.54964	.55638
AMTITH	1.00	11	35.4318	2.69027	.81115
	2.00	21	32.2662	2.27758	.49701
ATIW	1.00	11	35.2709	4.26970	1.28736
	2.00	21	30.0843	3.59640	.78480
MALW	1.00	11	62.8182	3.31114	.99835
	2.00	21	56.2381	3.78027	.82492
AXIS	1.00	11	22.4545	5.20315	1.56881
	2.00	21	21.2381	7.25193	1.58250

The 95% confidence interval compare male and female group and also p-value of the different of 2 group are presented in table 7.

Table 7 95% confidence interval of male and female parameters

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
TAAP	Equal variances assumed	7.025	.013	3.379	30	.002	2.5628	.75849	1.01373	4.11181
	Equal variances not assumed			4.044	29.942	.000	2.5628	.63369	1.26850	3.85704
ATAW	Equal variances assumed	5.414	.027	2.889	30	.007	3.4156	1.18237	1.00087	5.83030
	Equal variances not assumed			2.459	13.664	.028	3.4156	1.38919	.42917	6.40200
MTAW	Equal variances assumed	.000	.988	3.507	30	.001	3.1905	.90975	1.33251	5.04844
	Equal variances not assumed			3.561	21.310	.002	3.1905	.89583	1.32914	5.05181
PTAW	Equal variances assumed	.397	.533	4.456	30	.000	2.8355	.63629	1.53601	4.13498
	Equal variances not assumed			4.402	19.739	.000	2.8355	.64416	1.49067	4.18033
ASRTA	Equal variances assumed	.211	.649	3.658	30	.001	2.0344	.55614	.89860	3.17018
	Equal variances not assumed			3.621	19.850	.002	2.0344	.56187	.86178	3.20700
ATIAL	Equal variances assumed	.076	.785	3.089	30	.004	2.8342	.91765	.96016	4.70832
	Equal variances not assumed			3.198	22.484	.004	2.8342	.88625	.99855	4.66993
AMTITH	Equal variances assumed	.029	.866	3.510	30	.001	3.1656	.90181	1.32388	5.00737
	Equal variances not assumed			3.328	17.673	.004	3.1656	.95130	1.16436	5.16690
ATIW	Equal variances assumed	.804	.377	3.635	30	.001	5.1866	1.42699	2.27232	8.10092
	Equal variances not assumed			3.440	17.599	.003	5.1866	1.50772	2.01384	8.35941
MALW	Equal variances assumed	.001	.975	4.869	30	.000	6.5801	1.35130	3.82036	9.33981
	Equal variances not assumed			5.081	22.964	.000	6.5801	1.29506	3.90081	9.25936
AXIS	Equal variances assumed	1.341	.256	.492	30	.626	1.2165	2.47122	-3.83046	6.26336
	Equal variances not assumed			.546	26.820	.590	1.2165	2.22833	-3.35715	5.79005

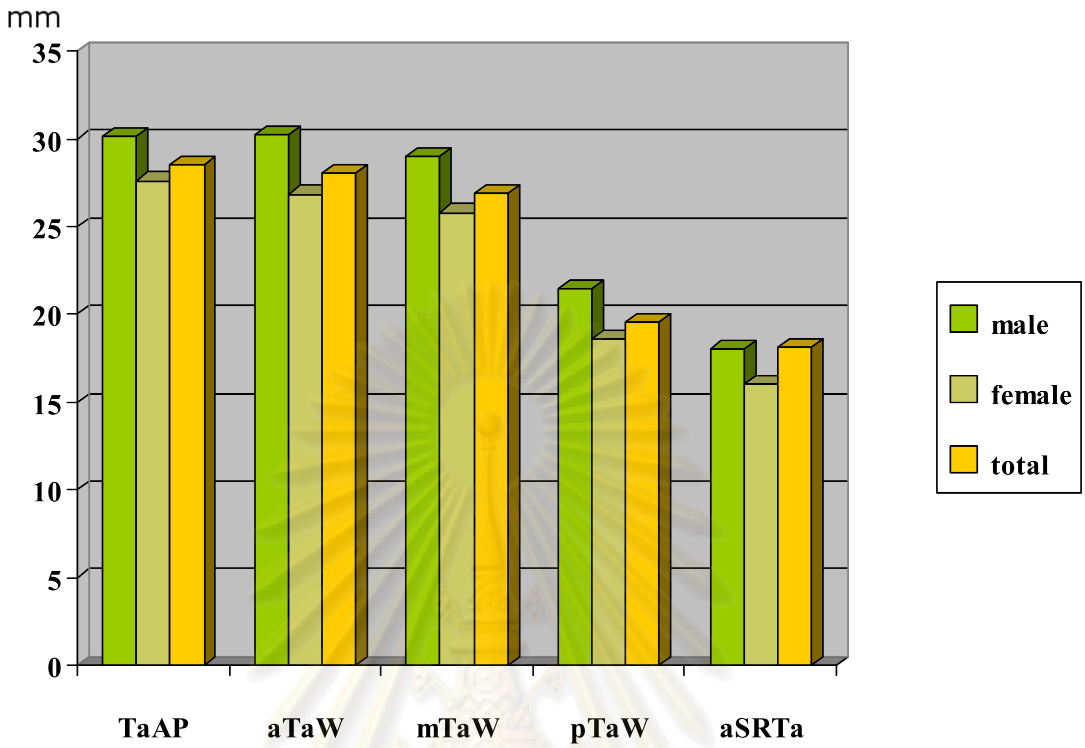


Figure 15 chart present mean of talar parameters compare with male, female and total group

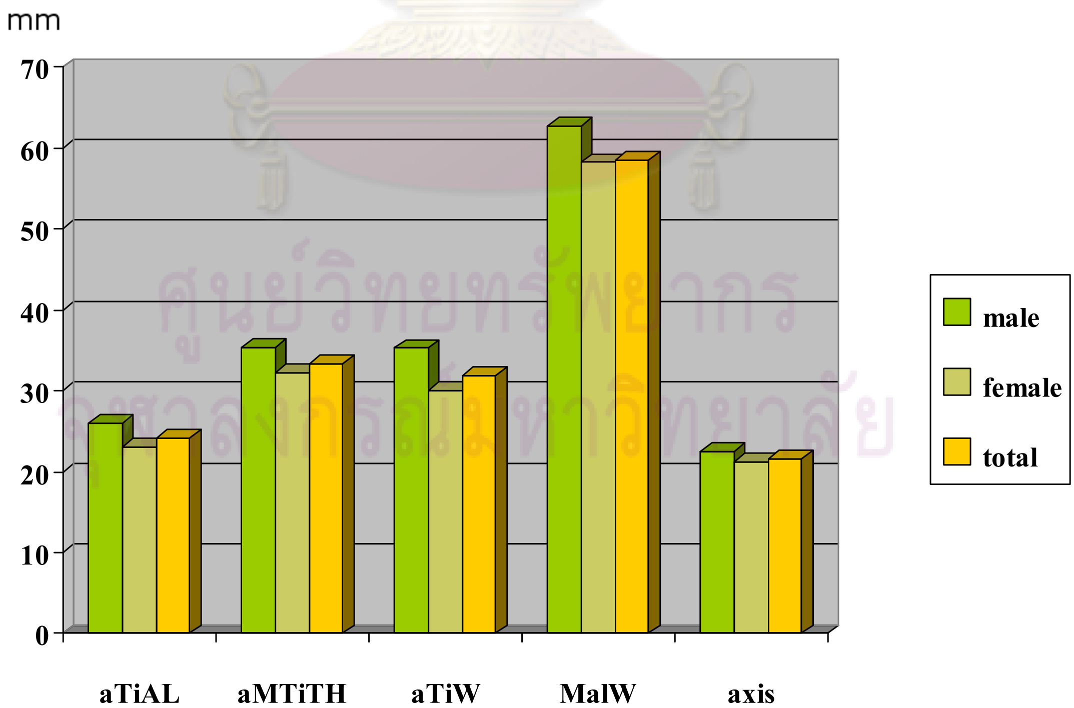


Figure 16 chart present mean of distal tibia parameters compare with male, female and total group

The comparison of the current data from Stagni (west) , Chien (east) and Andrea are present in table 8.

Table 8 comparison of the Stagni (west) , Chien (east) and this study (Thai)

Parameters	Stagni (n=36)	Chien (n=10)	This study (n=32)	Adjusted data
SRTa*	23.4 ± 3.1	22.1 ± 2.7	21.6 ± 6.5	18.1 ±1.9
Taw	30.4 ± 3.3	29.9 ± 2.1	28.0 ± 3.5	NA
TaAL*	41.7 ± 4.4	32.3 ± 2.9	31.7 ± 2.8	28.5 ± 2.4
TiAL*	31.4 ± 3.5	NA	26.1 ± 2.9	24.1 ± 2.8
MTiTh*	46.4 ± 3.9	NA	36.2 ± 3.1	33.3 ± 2.8
SRTi	27.8 ± 4.4	29.8 ± 7.9	NA	NA
MalW	69.0 ± 7.6	61.5 ± 2.8	58.5 ± 4.8	NA
TiW*	31.9 ± 3.5	31.9 ± 2.4	29.3 ± 3.5	31.8 ± 4.5

Table 9 comparision of the talar parameter

parameters	Hayes (n=21)	This study (n=32)
Talar radius (mid sagital)	20.7 ± 2.6	21.6 ± 6.5
Talar dome		
Anterior	29.9 ± 2.6	28.03 ± 3.53
Middle	27.9 ± 3.0	26.91 ± 2.86
posterior	25.2 ± 3.7	19.59 ± 2.17

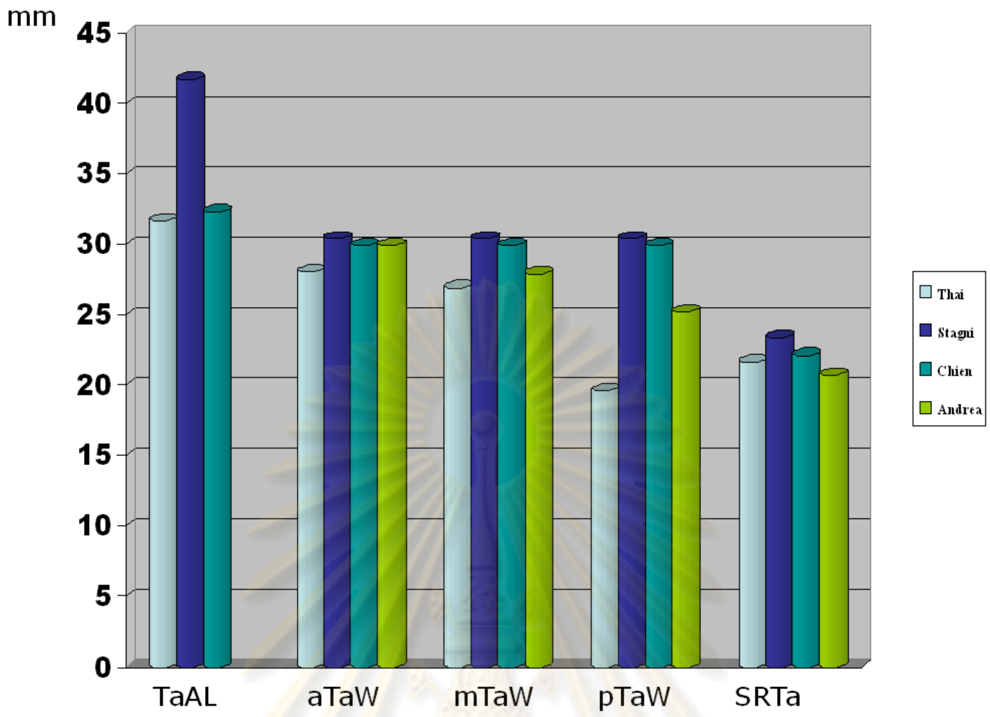


Figure 17 comparision of current data of talus by mean

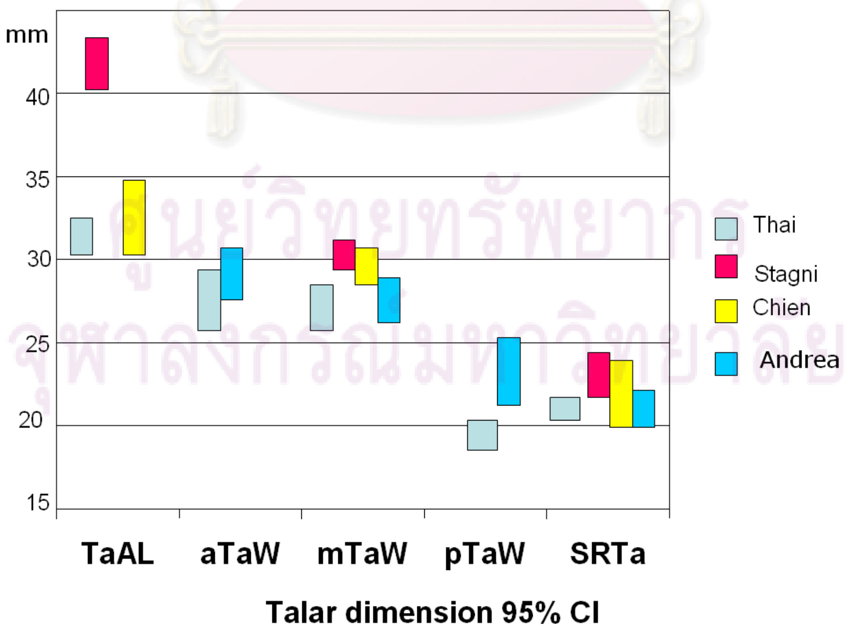


Figure 18 comparison of current data of talus by 95% confidence Interval

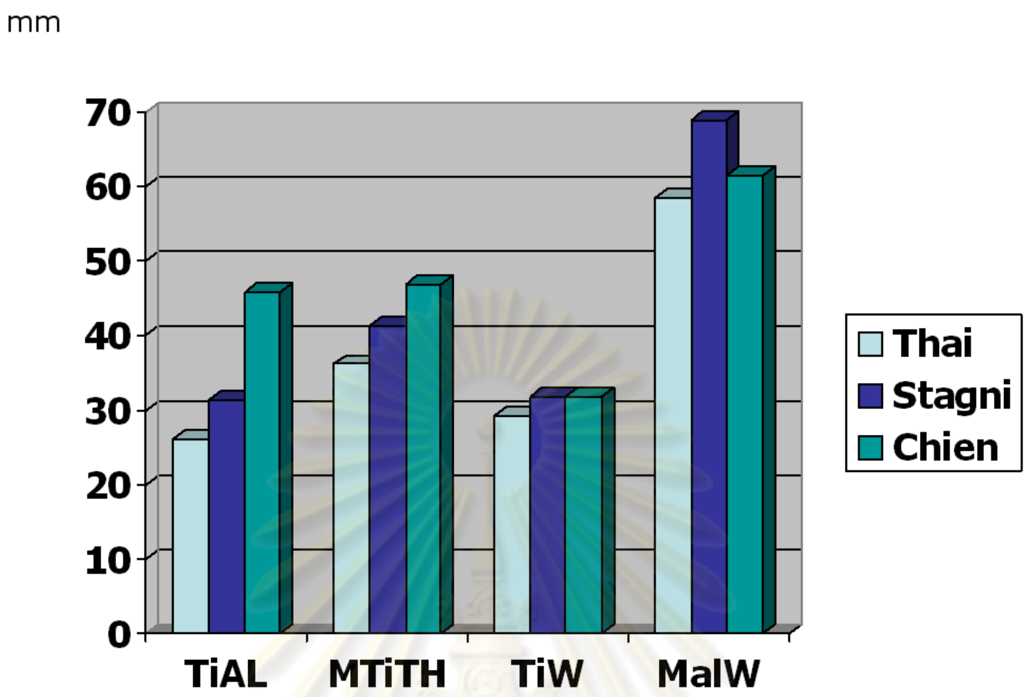


Figure 19 comparision of current data of distal tibia by mean

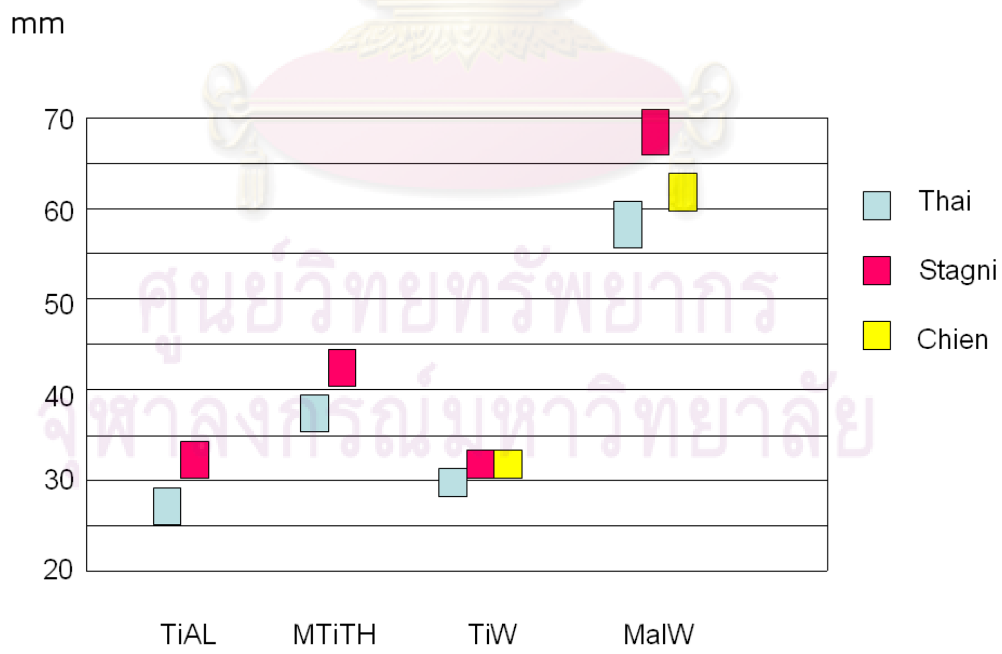


Figure 20 comparison of current data of distal tibia by 95% confidence interval

CHAPTER V

DISCUSSION

Ankle morphologic studies are available in a few amount. Most comes from the west. The technique to measure are vary: 2 dimension by plain x-ray, 3 dimension by CT scan, MRI. The error of measurement may caused by interposition of 2 D technique and ankle external rotation. The rotation of ankle make the anteroposterior diameter larger and mediolateral diameter smaller. This effect can be modified by calculation. The degree of external rotation (malleolar axis) influence of the overestimation of the AP length, so trigonometric formula will adjust that parameter close to the reality. The different of true length and adjust legth shows no clinical significant. We implied that modification technique can applied to the other parameters.

Thai data present male parameters are statistical significant than female. The only one parameter that has no significant is malleolar axis. This fact is the same of the current data which come from European and Chinese.

The current data compare with this study demonstrate Thai ankle have smaller diameter than European and Chinese. This phenomenon can be explained by 3 reasons.

1. The bony structure of Thai population is smaller. The parameter also show that smaller than Chinese. We compared of the true length from adjusted parameter and the length that are not adjusted. The result are the same. Most of parameter are smaller except tibial width TiW.

2. The overestimation of the technique that come form technique of semi-automated measurement. This technique measure dimensions base on the plain x-ray. We believe that there is an effect of interposition of the view.

3. The ankle external rotation. Chien measure the parameter from MRI but the parameter and technique of measurement follow Stagni technique. They did not recognize the effect of ankle external rotation that can mask the true length. This study modified the effect by calculation and proved the calculated method had smaller different length compared to true length.

4. Tibial width (tibial width) is the only one parameter that Thai parameter had no statistical significant compare with European or Chinese. The explaination is adjusted tibial width has larger width compare to the original width.

The other current data is Andrea which measure the ankle parameter only talus by CT scan. This report is the only one that present the anterior, middle and posterior talar width. When compare to this study, Thai parameter has no statistical significant by 95% confidence interval in anterior and middle talar width but Thai tend to be smaller. The posterior talar width demonstrate Thai has less width significantly. It may be from the different cut of determination. Posterior talus tend to has more curve than anterior so the different cut effect the width easily.

This parameters from the study compare with the total ankle prostheis available now are show in the figure 21.1 and 21.2

Talar compartment

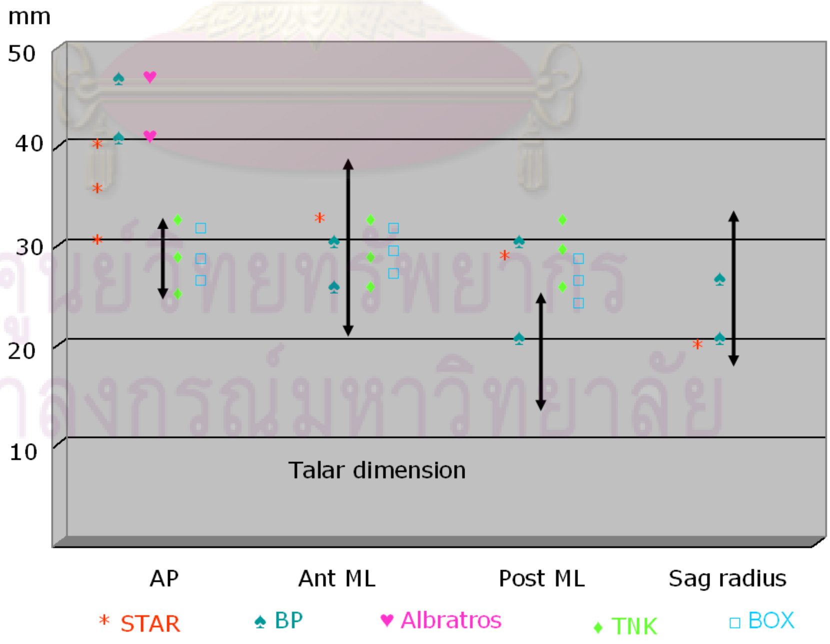


Figure 21.1 the comparison of the current designs. The two head arrow demonstrate the rage of parameter. The symbols present the various systems of total ankle arthroplasty

Distal tibia

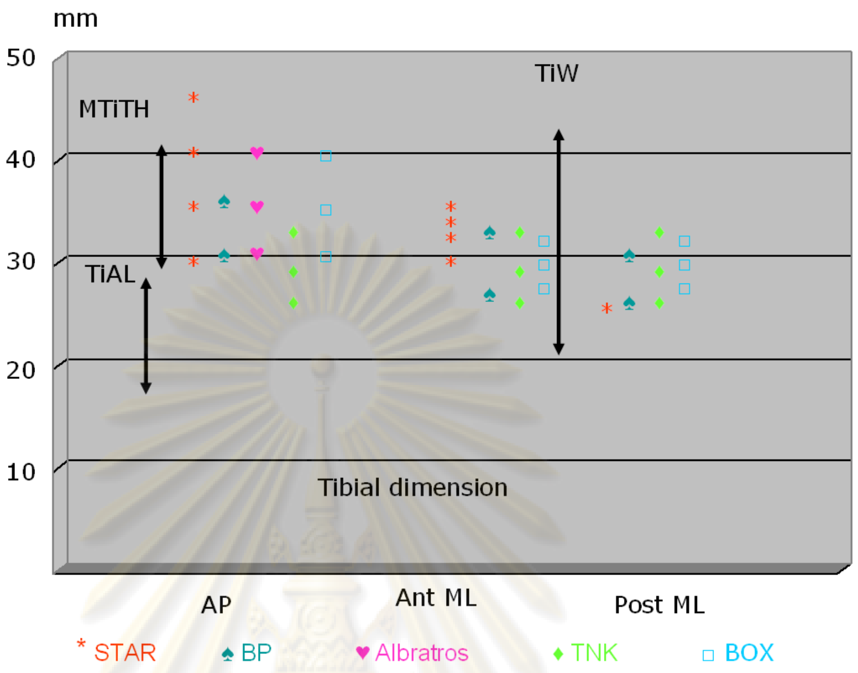


Figure 21.2 the comparison of the current designs. The two head arrow demonstrate the rage of parameter. The symbols present the various systems of total ankle arthroplasty.

The figure shows that talar component from 3 company have overestimation in anteroposterior aspect. In mediolateral aspect, anterior part diameters are in length but some company have overestimation to the posterior part. The tibial component in most design are in the range.

The malleolar axis is the parameter that no one recognize before. The average external rotation of ankle is about 15-20 degree. This study measure the axis demonstrated mean 21.6 degree, SD 6.56. 95% confidence interval is 19.29-24.02.

Now no one design for Thai population. TNK system from Japan is the most compatible with Thai ankle

The limitation and error of this study may by

1. Small population, simple sampling technique, not vary in the other part of Thailand so this study can not represent of Thai ankle completely but the information from this study can clue the design and developing of the novel total ankle arthoplasty for Thai people.

2. It is better if we do a reconstruction of the ankle MRI to real 3D and use the program creat the plane of interest then measure of the parameters. This recommend technique has high validity.

CHAPTER VI
CONCLUSION

Ankle osteoarthritis has different natural history from hip or knee. The main cause is post traumatic. The major age group is younger. The goal standard treatment of the disease is ankle arthrodesis that has limit range of motion in activity. The new operation to promote ankle function is total ankle arthroplasty.

Total ankle arthroplasty in the past had low survival rate. Better knowledge of material and biomechanic help the total ankle arthroplasty had longer survival rate. But until now there is no design which is the best. The new design are still developing. The fundamental data to design and sizing is morphology of ankle.

This study presents the ankle dimensions in anteroposterior and mediolateral that seems different from the current data. Thai population are smaller in size than those European and Chinese people. This phenomenon can be explained by race, different technique used to measure (plain x-ray 2D and MRI 3D) and the effect of ankle external rotation . The study described the important parameter to design the ankle prosthesis for Thai.

Ankle parameter play an important role to design and size the novel total ankle prosthesis. No system design for Thai people available now. This study shows that TNK (from Japan) is the most compatible one for Thai population.

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