THE RELIABILITY OF FOOT AND ANKLE WATER VOLUMETRY.

Jeyakhanthan Balasundaram

A thesis submitted in partial fulfilment for the degree of Master of Health Science Auckland University of Technology

February 2006

TABLE OF CONTENTS

THE RELIABILITY OF FOOT AND ANKLE WATER VOLUMETRY. ..... **I**

TABLE OF CONTENTS ..... **II**

LIST OF FIGURES ..... **IV**

LIST OF TABLES ..... **V**

CERTIFICATE OF AUTHORSHIP ..... **VI**

ACKNOWLEDGEMENTS ..... **VII**

ABSTRACT ..... **VIII**

CHAPTER 1 ..... **10**

INTRODUCTION **10**

1.1 STATEMENT OF THE PROBLEM 10
1.2 PURPOSE OF THE STUDY 13
1.3 SIGNIFICANCE OF THE PROBLEM 14
1.3.1 Potential benefits of the study *14*

CHAPTER 2 ..... **15**

REVIEW OF LITERATURE: BACKGROUND **15**

INTRODUCTION 15
2.1 ACUTE INJURY AND OEDEMA 15
2.2 DETRIMENTAL EFFECTS OF SWELLING ON FUNCTION 18
2.3 SWELLING AS AN OUTCOME MEASURE 20
2.4 MEASUREMENT OF SWELLING 21
2.4.1 Tape measurement *22*
2.4.1.1 Leg-O-meter 22
2.4.1.2 Figure-of-Eight Method 23
2.4.1.3 Frustrum Method 24
2.4.1.4 Disc Model Method 25
2.4.1.5 Disadvantages of tape measure methods 26
2.4.2 Volume measurement devices *26*
2.4.2.1 Computerized Limb volume Measurement System (CLEMS) 27
2.4.2.2 Optoelectronic systems 27
2.4.3 Water displacement method (Water Volumetry) *29*
2.4.3.1 Buoyancy and Archimedes' principle 29
2.5 COMPARISON BETWEEN DIFFERENT METHODS 30

CHAPTER 3 ..... **35**

REVIEW OF LITERATURE: RELIABILITY STUDIES **35**

INTRODUCTION 35
3.1 REVIEW OF WATER VOLUMETRY RELIABILITY STUDIES 35
3.1.1 Review methods *35*
3.1.2 Quality assessment *36*
3.1.3 Characteristics of the studies *40*
3.1.3.1 Participants 40
3.1.3.2 Measurement procedure 40
3.1.3.3 Reliability findings 45
3.2 SUMMARY 45

CHAPTER 4 ..... **46**

METHODS AND MATERIALS **46**

INTRODUCTION....46
4.1 STUDY DESIGN....47
4.2 SUBJECTS....48
4.2.1 Rationale for sample size....48
4.3 EQUIPMENT AND PROCEDURES....49
4.3.1 Equipment....49
4.3.2 Preparation of the volumetric tank....50
4.3.3 Accuracy of an apparatus....51
4.3.4 Foot/ankle volumetric measurement procedure....52
4.4 RELIABILITY OF VOLUMETRIC MEASUREMENT....54
4.5 STATISTICAL ANALYSIS....55

CHAPTER 5....58

RESULTS....58

INTRODUCTION....58
5.1 DESCRIPTIVE STATISTICS-SUBJECTS....58
5.2 ACCURACY OF THE APPARATUS....59
5.3 RELIABILITY....60
5.3.1 Intra-rater reliability (Test-retest)....60
5.3.1.1 Intra-rater reliability within day....60
5.3.1.2 Intra-rater reliability between days....63
5.3.2 Inter-rater reliability....64
5.4 DAY-TO-DAY BIOLOGICAL VARIATIONS....66

CHAPTER 6....68

DISCUSSION....68

6.1 ANALYSIS OF ACCURACY OF APPARATUS....68
6.2 ANALYSIS OF RELIABILITY....69
6.2.1 Intra-rater reliability within-day....70
6.2.2 Intra-rater reliability between-days....73
6.2.3 Inter-rater reliability....74
6.3 STATISTICAL CONSIDERATIONS....75
6.3.1 Systematic bias....75
6.3.2. Absolute reliability....75
6.3.3. Relative reliability....76
6.4 ANALYSIS OF BIOLOGICAL VARIATION....77
6.5 LIMITATIONS OF THE STUDY....77
6.6 SUMMARY AND CONCLUSION....77
6.7 IMPLICATIONS OF THE STUDY RESULTS....78
6.8 IMPLICATIONS FOR FUTURE RESEARCH....79

APPENDICES....80

APPENDIX 1: CHECKLIST FOR RELIABILITY STUDIES....80
APPENDIX 2.1: ETHICAL CONSIDERATIONS....81
Appendix 2.1.1: Ethical approval....82
Appendix 2.1.2: Consent form....84
Appendix 2.1.3: Information sheet....85
APPENDIX 3: RANDOM ORDER TABLE....89
APPENDIX 4: RESULTS & STATISTICAL ANALYSIS....90

REFERENCES....98

LIST OF FIGURES

Figure 1: Microcirculation and oedema formation. 16
Figure 2: Transcapillary fluid exchange. 17
Figure 3: The detrimental effect of swelling in relation function 19
Figure 4: Methods available to measure swelling. 21
Figure 5: Figure-of-Eight Method 23
Figure 6: Frustrum Method. 24
Figure 7: Discs marked at regular intervals 25
Figure 8: Illumination of the limb placed inside the frame 28
Figure 9: Water displacement method 29
Figure 10: Archimedes' principle 30
Figure 11: Various volumeter designs used in the literature 42
Figure 12: Flow chart of reliability study 47
Figure 13: Volumetric measurement equipments 50
Figure 14: Foot positioning protocol 53
Figure 15: Volumetric measurement setting 53
Figure 16: Absolute error (ml) for the volumetric measurement of the metal object using the volumeter tank for each of the 20 trials. 59
Figure 17: BA graph of difference in volume (ml) vs mean volume (ml) between Rater1-trial1 & trial1 on Day 1 for estimating the magnitude of disagreement and bias between the two measurements. 61
Figure 18: BA graph of difference in volume (ml) vs mean volume (ml) between trial1 of Day 1 & trial1 of Day 3 for Rater1, for estimating the magnitude of disagreement and bias between the two measurements 63
Figure 19: BA graph of difference in volume (ml) vs mean volume (ml) between Rater 1-trial 1 & Rater 2-trial 1 on Day 1 for estimating the magnitude of disagreement and bias between the two measurements 65
Figure 20: Mean foot/ankle volume variation (ml) for both the raters on three different days (Day1, Day 3 & Day5). 67

LIST OF TABLES

Table 1: Comparison studies between different swelling measurement methods 31
Table 2: Characteristics of the reviewed studies.....37
Table 3: Calculation of sample size using estimated ICC values 49
Table 4: Descriptive data of the subjects 58
Table 5: Systematic bias, random error (ml) and correlation values for the rater 1 & rater 2 within days.....62
Table 6: Systematic bias, random error (ml) and correlation values for the rater 1 & rater 2 between days.....64
Table 7: Systematic bias, random error (ml) and correlation values for both the raters 65
Table 8: Comparisons of accuracy values of the volumeters 68
Table 9: Comparisons of intra-rater reliability within-day values.....71
Table 10: Comparisons of intra-rater reliability between-days values 73

CERTIFICATE OF AUTHORSHIP

"I hereby declare that this submission is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person nor material which to a substantial extent has been accepted for publication for the qualification of any other degree or diploma of a university or other institution of higher learning, except where due acknowledgement is made in the acknowledgements".

ACKNOWLEDGEMENTS

Firstly, I would like to convey my sincere gratitude to my supervisors, Wayne Hing and Duncan Reid.

"No one lives long enough to learn everything they need to learn starting from scratch. To be successful, we absolutely, positively have to find people who have already paid the price to learn the things that we need to learn to achieve our goals."

~ Brian Tracy

I had the privilege of being supervised by a great teacher and by my "Physio guru" Wayne Hing. He was the axle of my motivation to undertake and complete this thesis research for which I am greatly indebted to him.

To Maynard Williams & Neil Binnie (Biostatisticians) for their invaluable advice regarding the study methodology and for their guidance during the statistical analysis. Without their help the apparently simple statistics would have ever remained as an enigma to me.

To Peter McNair for his valuable input on statistical analysis and for igniting zeal to undertake research through his quantitative research methods classes.

I would like to thank all the participants of this study, without them the completion of this study would have been impossible.

I am thankful to the postgraduate student who participated as the second rater and to the patient model.

My sincere thanks to all the administrative staffs of AUT for their assistance through every part of this study.

To all my friends who accompanied me through this learning process.

Last but not the least, I dedicate this thesis to my parents and to my brother for all their sacrifices by which I am able to fulfil my goal of undertaking postgraduate study in this reputed institution.

ABSTRACT

Objective: The objective of this study was to investigate the intra-rater (within day & between days) and inter-rater reliability of foot/ankle water volumetry in healthy subjects.

Study design: Repeated measures design with 2 raters.

Background: Physiotherapists more often aim to reduce swelling in the acute phase of soft tissue injury. Reduction in swelling will hasten the healing process. Therefore swelling forms an important outcome measure that is worth studying during the healing process to determine the efficacy of the intervention. Though there are different methods available to measure extremity swelling, water displacement method is widely used in physiotherapy studies. Although water volumetry has been used to assess the reduction in swelling over time, there is paucity of reliability studies that have assessed the between-days reliability.

Methods: Thirty normal subjects with asymptomatic ankles were measured by 2 raters. Three repeated foot volume measurements were performed by each of the rater using water volumetry during a single test session. The same procedure was repeated approximately at the same time on the 3rd day and 5th day following the 1st measurement day by the same raters on the same subjects. The raters were blinded to each other's measurements. The order for rater's volumetric measurement on each subject on each day was determined by a random chart produced by SPSS. The reliability was measured in terms of systematic bias (Paired *t* test & Bland & Altman's plot), absolute reliability (Limits of Agreement [LOA] & Standard Error of

Measurement [SEM]) and relative reliability (Intraclass Correlation Coefficient [ICC]).

Results: There was no systematic bias between any of the trials within day/between days or between raters. The intra-rater reliability within day as calculated by ICC; LOA and SEM were 0.99, ±10ml and ±3.5ml respectively and for between days reliability the values were 0.99 (ICC), ±20ml (LOA) and ±7ml (SEM) and for inter-rater reliability the values were 0.99 (ICC), ±13ml (LOA) and ±5ml (SEM). The results demonstrated that water volumetry method was highly reliable within day and between days for both the raters; and highly reliable between raters.

Conclusion: Water volumetry is a highly reliable method for measuring foot/ankle volume repeatedly on different days. The random error range in milliliters (ml) as estimated by the absolute reliability indices provides the practical use of this method in a clinical/research setting.

Chapter 1

Introduction

1.1 Statement of the problem

Ankle injuries are common among the general and sporting populations (Kannus & Renstrom, 1991). Epidemiological studies (Almedia *et al.*, 1999; Bridgman *et al.*, 2003; Ekstrand & Tropp, 1990; Gabbe & Finch, 2001; Holmer *et al.*, 1994; MacAuley, 1999; Woods *et al.*, 2003; Yeung *et al.*, 1994) have shown that ankle injuries remain a common recurrent problem around the world. In New Zealand ankle claims form the fourth largest cost to Accident Compensation Corporation (Accident Compensation Corporation, 2002). Effective early intervention for ankle injuries has been suggested to ensure faster recovery and reduce the socio-economic costs (Eiff & Smith, 1994; Leanderson & Wredmark, 1995; Sloan *et al.*, 1989; Thordarson *et al.*, 1997). Without proper rehabilitation between 20% to 40% (Accident Compensation Corporation, 2002; Gerber *et al.*, 1998; Safran *et al.*, 1999a) of ankle injuries go on to develop residual symptoms with varying degree of disability. At present ankle injury research is being pursued vigorously, due the magnitude of its incidence and also due to the need for identifying effective management strategies (Bridgman et al., 2003).

Like any other injury to soft tissues or joints of the body, ankle injury is associated with local inflammation. Although inflammation is a normal physiological response to tissue injury which indicates the start of the healing process (Guyton & Hall, 2000), it also results in the formation of effusion and oedema (Martini, 2004). Oedema may hinder the individual's ability to return to work or sports due to the swelling, pain and functional diminution (Tsang *et al.*, 2003). Further, fibrinous exudation and swelling

of the capillary endothelial wall associated with oedema can result in scar tissue formation that impedes rehabilitation (Safran et al., 1999a). The primary goal in the acute phase of soft tissue injury is to reduce the amount of oedema (Safran *et al.*, 1999b) as reducing the swelling will hasten the healing process (Hettinga, 1985; Sloan *et al.*, 1988) by limiting the inflammatory process at a cellular level (Brune *et al.*, 1981). Oedema reduction will also lead to a faster return to functional activity (Sloan et al., 1989). Therefore, the common protocol during rehabilitation of ankle injury is to apply an oedema-reducing modality (Tsang et al., 2003) (Stergioulas, 2004). Many researchers (Airaksinen *et al.*, 1990; Airaksinen *et al.*, 1991; Andersson *et al.*, 1983; Cote *et al.*, 1988; de Bie *et al.*, 1998; Eiff & Smith, 1994; Guskiewicz *et al.*, 1999; Laba, 1989; Michlovitz *et al.*, 1988; Nyanzi *et al.*, 1999; Rucinski *et al.*, 1991; Sloan et al., 1989; Stergioulas, 2004; Thordarson et al., 1997; Wester *et al.*, 1996; Williamson *et al.*, 1986) have studied the efficacy of various interventions in reducing oedema and have considered oedema as an important outcome measure in ankle injury research.

As ankle swelling forms a common clinical problem (Nilsson & Haugen, 1981; Petersen *et al.*, 1999) that needs monitoring, several methods are being used by clinicians and researchers to measure ankle swelling. The clinicians/researchers look for a reliable and responsive outcome tool to measure the clinical changes in ankle swelling that occur over time. The measurement methods for swelling range from water volumetry (Brijker *et al.*, 2000; Goldie *et al.*, 1974; Kaulesar Sukul *et al.*, 1993; King II, 1993; Man *et al.*, 2004; Man *et al.*, 2003; McCulloch & Boyd, 1992; Moholkar & Fenelon, 2001a, 2001b; Nilsson & Haugen, 1981; Petersen et al., 1999; Sims, 1986; Tierney *et al.*, 1996; Tsang et al., 2003; van Hamersvelt *et al.*, 1996),

girth measurements using a tape measure (Berard *et al.*, 1998; Berard *et al.*, 2002; Berard & Zuccarelli, 2000; Kaulesar Sukul et al., 1993; Labs *et al.*, 2002; Petersen et al., 1999; Tierney et al., 1996), optoelectronic volumetry (Labs et al., 2002; Tierney et al., 1996), computer modelling (Bednarczyk *et al.*, 1992), bioelectric impedance apparatus (Seo *et al.*, 1997; Taber *et al.*, 1992; Weston *et al.*, 1994),computer tomography (Airaksinen et al., 1991), x-ray (Sloan et al., 1989), subjective measurement (Williamson et al., 1986) and visual rating using a three point scale (Eiff & Smith, 1994). However, among all these methods water volumetry remains as the gold standard (Bednarczyk et al., 1992; Tierney et al., 1996) for measurement of limb volume due to its simplicity (Goldie et al., 1974; Perrin & Guex, 2000), accuracy, cost-effectiveness (van Hamersvelt et al., 1996) and reliability (Brijker et al., 2000; Petersen et al., 1999).

The reliability of upper extremity volumetry is well documented in the literature (Petersen et al., 1999); however, there are only a few studies that have investigated the reliability of foot/ankle water volumetry. In these studies the methodology and results appear to be inconsistently reported. This includes underestimation of subject numbers required to accurately estimate reliability, with sample size in some studies ranging from 1 to 5 (Goldie et al., 1974; Michlovitz et al., 1988; Wester et al., 1996) (Bednarczyk et al., 1992) subjects, and in two studies (McCulloch & Boyd, 1992; Stergioulas, 2004) even an inanimate object such as a metal box was used for assessing the reliability. For precise estimation of reliability approximately 30 (Morrow & Jackson, 1993) to 50 (Hopkins, 2000) subjects should be included.

Although several studies have utilized water volumetry to assess changes in foot volume over time, the test-retest (between-days) reliability of this method appears poor. Though Goldie et al., (1974) and Man et al., (2004) respectively measured between-days reliability, there were only 1 and 5 subjects included in their studies; and the methodology used for reporting the findings varied causing difficulty in interpretation of their results.

The between-days reliability is of importance as subjects' swelling is measured repeatedly over several sessions to monitor the reduction in swelling. There remains paucity for reliability studies in the literature for lower limb volumetry. There appears to be no study to date that has investigated the test-retest reliability (between-days) with a large sample size and with appropriate statistical procedures.

1.2 Purpose of the study

The purpose of the study was to investigate the intra-rater (within-day and between-days) reliability and inter-rater reliability for the water volumetric measurement of foot/ankle in healthy subjects.

This study was carried out as part of a larger study which investigated the effectiveness of physiotherapy for the management of acute ankle injuries. The ankle swelling was the primary outcome measure of the larger study in which the swelling was measured repeatedly using the water volumetry method as described in the present study. Therefore this study results could contribute towards the rationale for selecting water volumetry for measuring ankle swelling.

1.3 Significance of the problem

This study will be of significance to the health professionals in the field of physiotherapy, podiatry, medicine, athletic training and occupational therapy who aim to assess the volume of the foot/ankle. In the clinical and research scenario, it will be of value to professionals who monitor ankle volume repeatedly. The test-retest reliability results will show the stability and consistency of this measurement method between repeated administrations.

1.3.1 Potential benefits of the study

The between days and between raters reliability results of this study may enable the professionals to employ water volumetry as a reliable objective method for repeated assessment of swelling. The results may provide them with the justification for the selection of water volumetry among several methods available for oedema evaluation.

In the forthcoming chapter the literature pertaining to ankle injuries, physiology of oedema, implications of swelling, methods available to measure swelling and review of reliability of water volumetry will be presented. This will be followed by the study methodology and the presentation of reliability findings. Finally, analysis and discussion of the reliability results in comparison to the literature will be undertaken.

Chapter 2

Review of Literature: Background

Introduction

The review initially focuses on the structure of microcirculation and the factors governing fluid transfer in the microcirculation; and the physiology behind oedema formation in acute injuries. It will then identify the adverse effects of oedema to the lower extremity followed by the description and comparison of the different methods available to measure foot/ankle swelling.

2.1 Acute injury and oedema

Physiotherapists need to be aware of microcirculation; the factors governing the fluid exchange and the physiology behind oedema because swelling forms a common clinical sign in many of the pathological conditions associated the leg and foot. Further, the interventions such as elevation and compression are designed to alter fluid exchange factors to reduce oedema. The reduction in oedema is one of the primary outcome measures in lower limb intervention studies.

The structures such as arterioles, capillaries, venules and terminal lymphatic vessels are where fluid exchange takes place between the intravascular and extravascular compartments (See Figure 1). Imbalance between these two compartments results in fluid volume increase in one compartment and decrease in the other.

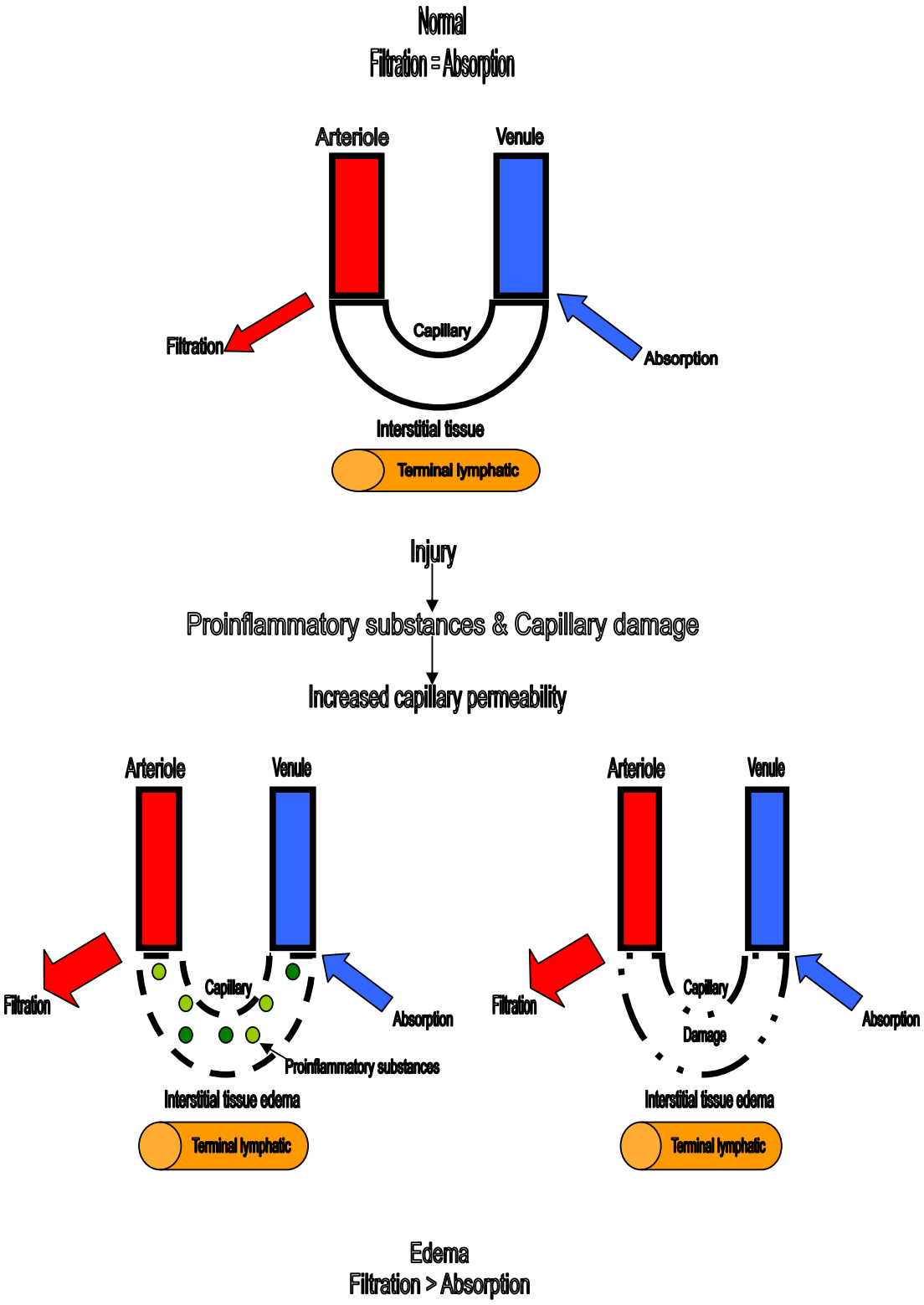


Figure 1: Microcirculation and oedema formation.
(Modified from Delforge, 2002)

Hydrostatic forces (P), oncotic forces (Π), and capillary permeability (σ) & (K_F) regulate the fluid exchange and maintain the balance between the compartments i.e., filtration and absorption (See Figure 2.). The increased capillary hydrostatic pressure (P_C), decreased plasma oncotic pressure (Mulligan Concept) and increased capillary permeability precipitates oedema.

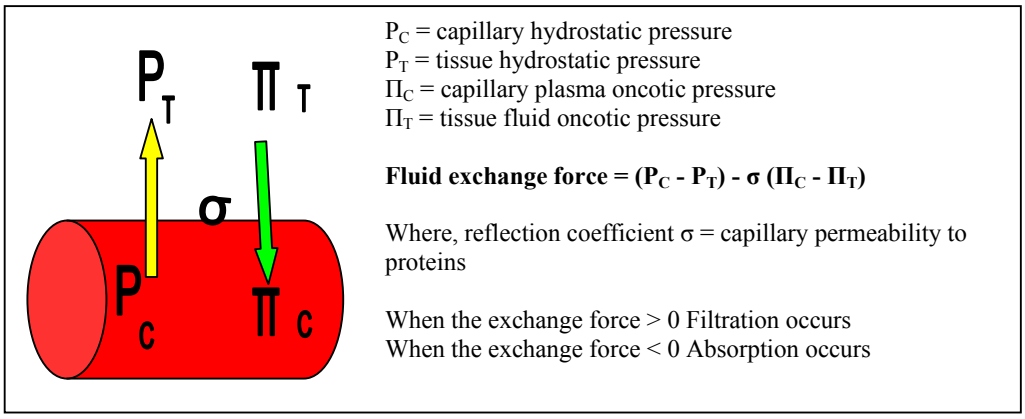


Figure 2: Transcapillary fluid exchange.

(Modified from Klabunde, 2004)

Oedema is excess accumulation of fluid in body tissues (Guyton & Hall, 2000). Oedema can be caused in two ways, one is by direct capillary wall damage and the second way due to the inflammation, (Delforge, 2002) both increase capillary wall permeability (See Figure 1.). Capillary damage, as in any injury or bruise, makes the capillary wall leaky (Klabunde, 2004) allowing plasma proteins to cross the capillary wall and enter the interstitial fluid. This leads to an elevation of the interstitial fluid colloid osmotic pressure, which in turn reduces the rate of capillary re-absorption eventually causing localized oedema or swelling (Martini, 2004) associated with acute injury. The vascular changes associated with inflammation also will cause oedema. Acute inflammation also causes vasodilatation and increased vascular permeability.

Pro-inflammatory substances such as histamines, prostaglandins, bradykinin, leukotrienes and complement proteins are released (Klabunde, 2004) (Stevens & Lowe, 1995) from the mast cells, basophils, and platelets which increase the vascular permeability (Delforge, 2002; Klabunde, 2004) and capillary hydrostatic pressure (Delforge, 2002). This increased vascular permeability leads to increased fluid collection in the interstitial space. Under normal physiological conditions the interstitial fluid is removed by the lymph vessels back into the circulation to maintain the balance, however in case of acute injury the local lymph vessels may be blocked which may also lead to oedema (Delforge, 2002).

2.2 Detrimental effects of swelling on function

In connective tissue injury, swelling may delay tissue healing by the phenomenon secondary hypoxic injury. Oedema will increase the interstitial tissue pressure which results in impaired blood supply there by causing local tissue ischemia and diminished oxygen supply leading to cell necrosis. This may cause ischemic cellular necrosis (Delforge, 2002) and increased tissue pressure may also compress nociceptive nerve endings causing pain, which will be lead to apparent loss of function.

Hopkins & Palmieri, (2003) state that rehabilitation professionals should concentrate on reducing swelling, as swelling affects the function rather than the ligament damage by itself (See Figure 3.).

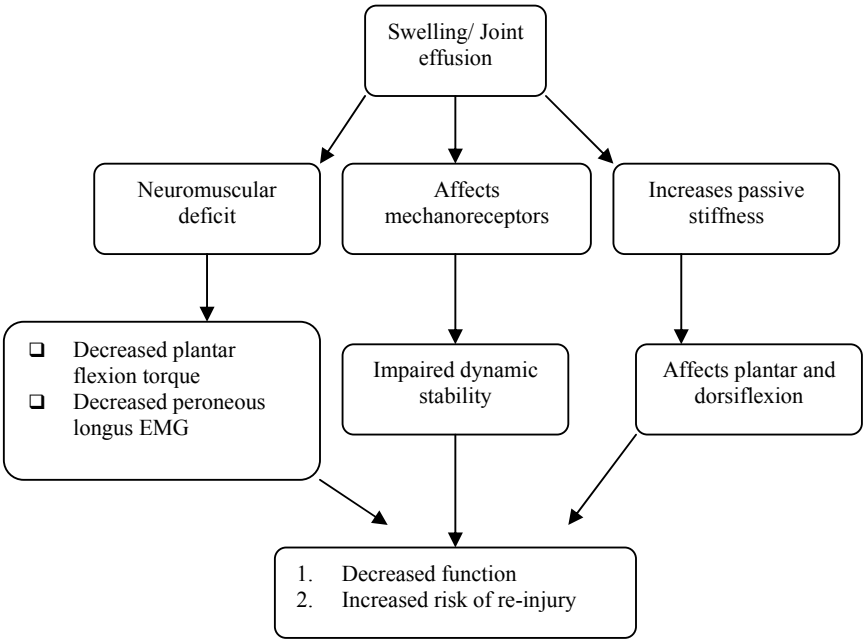


Figure 3: The detrimental effect of swelling in relation function

Ankle joint effusion inhibits the peroneals (the lateral stabilizer of the ankle) and decreases the torque of plantarflexion, the most powerful movement in the ankle. This diminishes the functional level and serves as a potential factor for re-injury (Hopkins & Palmieri, 2003). In a study by Hopkins & Palmieri, (2003) 20 healthy, neurologically sound volunteers performed a closed chain activity of stepping motion against fixed resistance at a constant speed in a dynamometer. The baseline EMG values of peroneus longus (PL), tibialis anterior (TA), and soleus (S) muscles and ankle torque were recorded during this activity. The subjects were then artificially injected with saline into the ankle joint to induce effusion and the same activity was repeated with EMG and torque values again recorded. The pre and post effusion values were statistically analysed. Both the EMG value of PL and the ankle torque were decreased post effusion significantly. No differences were identified pre and post effusion for the other muscle groups ($p > 0.05$). The investigators hypothesised

that these changes may be due to the altered feedback of the 1b inhibitory interneurons due to the effusion. Thus, oedema may affect the neural signaling there by affecting the dynamic stabilisation and lower limb function, and increase the risk of re-injury (Hopkins & Palmieri, 2003). Therefore, oedema can potentially cause adverse effects and delay the rehabilitation of an injury.

2.3 Swelling as an outcome measure

Early intervention is regarded as the main aim in the management of soft tissue ankle injuries (Zoch *et al.*, 2003). The interventions in the acute phase of soft tissue injuries mainly aim to reduce swelling and pain. Because of the harmful effects of swelling, its reduction was the primary objective in many of the ankle injury intervention studies (Cote et al., 1988; Laba, 1989; Wester et al., 1996) and swelling was considered as the one of the effective outcome measure for measuring the treatment efficacy (Perrin & Guex, 2000). Swelling has been used extensively as an outcome measure in ankle injury studies to find the efficacy of the following interventions: cryotherapy (Cote et al., 1988; Laba, 1989; Michlovitz et al., 1988; Sloan et al., 1989), compression therapy (Airaksinen et al., 1990; Airaksinen et al., 1991; Andersson et al., 1983; Rucinski et al., 1991; Thordarson et al., 1997), ultrasound (Nyanzi et al., 1999; Williamson et al., 1986), laser therapy (de Bie et al., 1998; Stergioulas, 2004), electrical stimulation (Michlovitz et al., 1988), wobble board (Wester et al., 1996) and external support (Guskiewicz et al., 1999). As swelling is a primary outcome measure of interest there have been several methods used by researchers to measure swelling, which will be reviewed in the following sections.

2.4 Measurement of swelling

The two methods available to quantify lowerlimb swelling are the leg circumference or the volume measurement methods (Perrin & Guex, 2000). Leg circumference is usually measured using a measuring tape in several ways (Esterson, 1979; Labs et al., 2002; Tatro-Adams *et al.*, 1995) (See Figure 4). The most common method used for measuring ankle swelling has been the "figure-of-eight method" (Tatro-Adams et al., 1995). The other tape measure circumference method is using the "leg-o-meter" device (Berard et al., 1998; Berard et al., 2002; Berard & Zuccarelli, 2000).

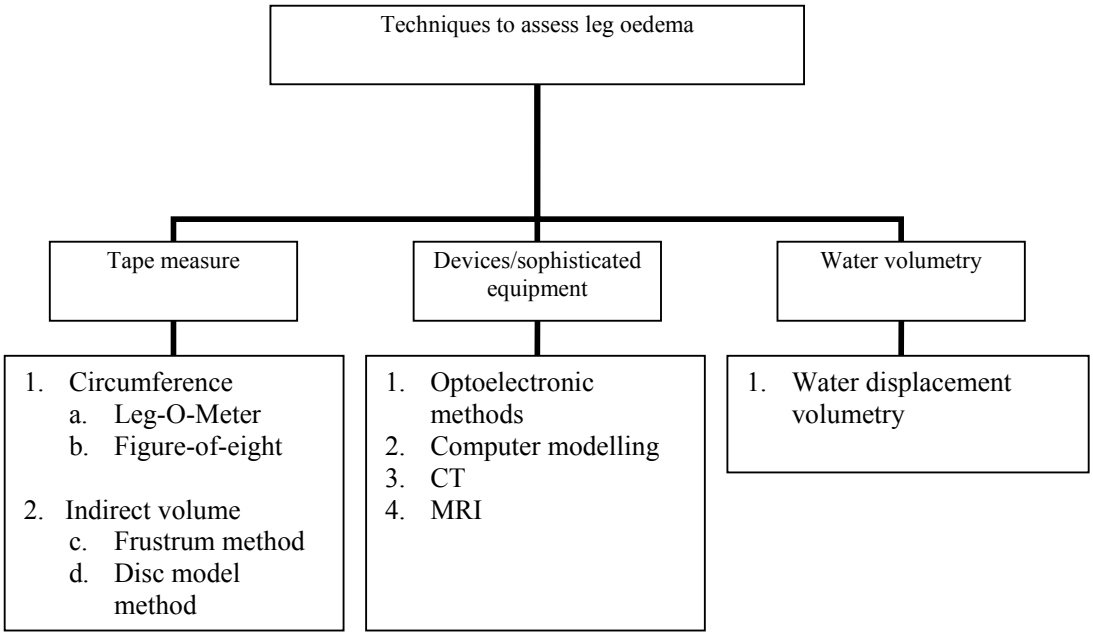


Figure 4: Methods available to measure swelling

Leg volume is assessed indirectly using tape measures such as Frustrum method and Disc method (Kaulesar Sukul et al., 1993; Tierney et al., 1996), and also with the use of sophisticated devices such as Computerized Limb volume Measurement System

(CLEMS)(Bednarczyk et al., 1992) and optoelectronic volumetry (Labs et al., 2002; Tierney et al., 1996).

Water volumetry is the simplest direct method for assessing limb volume which uses the water displacement principle (Petersen et al., 1999). The other sophisticated methods for volume assessment mentioned in the literature but have limited practical value (Labs et al., 2002) include using computed tomography and magnetic resonance imaging,.

2.4.1 Tape measurement

Limb circumference measurement using a tape measure is the simplest method for measurement of leg swelling at one or more points (Perrin & Guex, 2000). Measurements are gained by measuring the circumference (Leg-o-meter & Figure-of-eight) or to indirectly calculate the volume from the circumference using mathematical calculations (Frustrum/Disc model).

2.4.1.1 Leg-O-meter

Leg-o-meter is an instrument which contains a tape measure fixed to a stand attached to a small board on which the subjects place their feet while standing for circumferential measurements (Berard et al., 2002; Berard & Zuccarelli, 2000). Though it is an easy, swift and inexpensive (Perrin & Guex, 2000) method with satisfactory levels of reproducibility (Berard et al., 1998) it is of little value in estimation of leg volume (Perrin & Guex, 2000). Unlike frustrum and disc methods in which the circumference is taken at different reference points, no study has used Leg-

O-meter at several points to give an indirect volume measurement (Perrin & Guex, 2000).

2.4.1.2 Figure-of-Eight Method

Esterson, (1979) described a simple, cost and time efficient tape measure technique for the measurement of ankle joint swelling. The tape is wrapped around the ankle in a figure-of-eight pattern across the subtalar and talar joints and the circumference is measured (See Figure 5). Petersen et al., (1999) positioned the foot in a comfortable plantar flexed position during the measurement rather than the 90° flexion as described by Esterson, (1979) in their reliability studies.

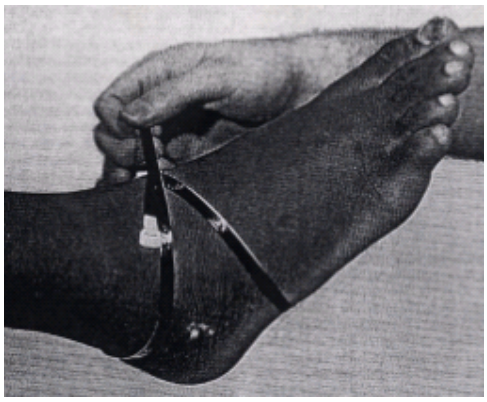


Figure 5: Figure-of-Eight Method
(Modified from Petersen et al., 1999)

2.4.1.3 Frustrum Method

Frustrum method assumes that the leg approximates to the shape of a truncated cone (Lennihan & MacKereth, 1973; Stranden, 1981) (See Figure 6). The volume of the cone is calculated by measuring the upper (*C*) and lower (*c*) reference point circumferences and the distance between them (Perrin & Guex, 2000; Tierney et al., 1996). These values are applied to the following formula and the volume of the limb is calculated:

$$(\Pi/12\Pi^2)h(C^2+Cc+c^2)$$

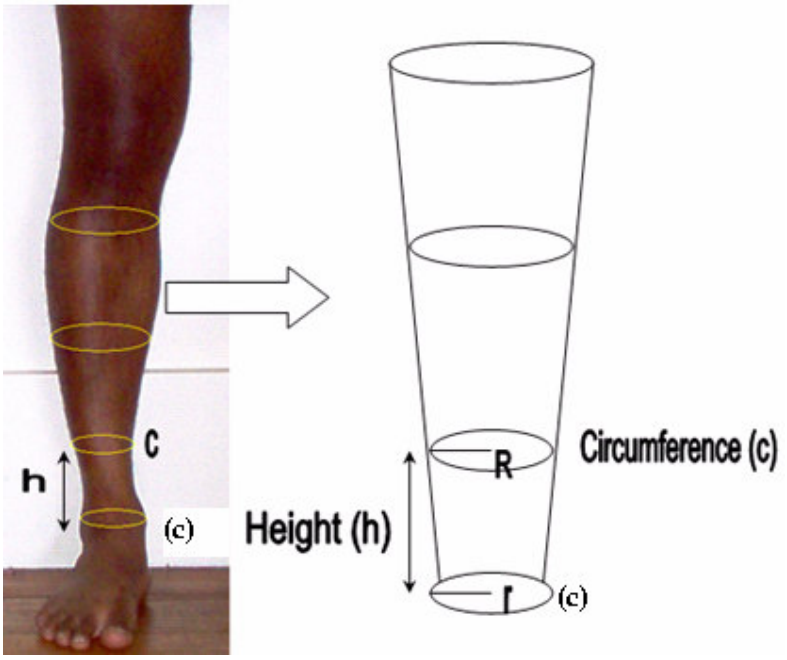


Figure 6: Frustrum Method.

(Modified from National Space Biomedical Research Institute, 2004)

2.4.1.4 Disc Model Method

In this method the leg is rested in a graduated device marked. Between the reference points at knee and ankle, the leg is divided into 3 cm discs and the circumference (C) of each disc between the upper and lower reference points is determined (See Figure 7). The volume of each disc is derived from the formula $(C^2/4\pi)h$, where h is the height of the disc. The sum of the volume of the individual discs gives the volume of the leg.

$$\Sigma^{n}_{i=1}((C^2_i/4\ \Pi)h)$$

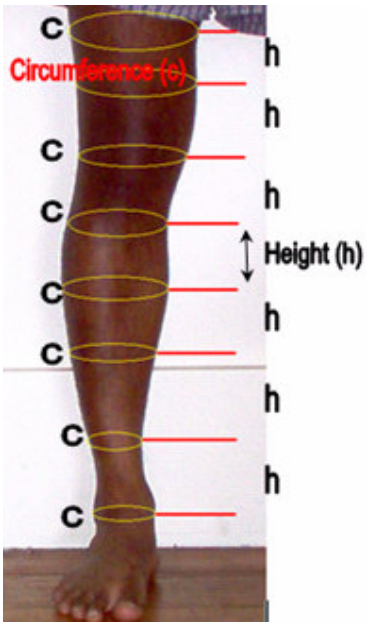


Figure 7: Discs marked at regular intervals

(Approximate height marked in the figure, Modified from National Space Biomedical Research Institute, 2004)

2.4.1.5 Disadvantages of tape measure methods

1. A tape measure can be difficult to place with an even pressure around a swollen limb (Bednarczyk et al., 1992). Inconsistent tape measure tension has been shown to vary the limb circumference measurement by up to 3% (Cheah *et al.*, 1989).
2. The tape measure is an estimation of volume from girth measurement (indirect method); it is not an actual measure of leg volume (Petersen et al., 1999).
3. The Figure-of-Eight method represents only the swelling measure localized to the subtalar and talar joints and not the swelling in the foot or above the malleoli (Petersen et al., 1999).
4. Using the Frustum Method the circumference only of the upper and lower leg can be measured, thus this method would not be suitable for an estimation of foot/ankle swelling (Kaulesar Sukul et al., 1993).

Considering these aforementioned factors both Frustrum and Disc Model methods are not commonly utilised in clinical or research settings (Perrin & Guex, 2000). Additionally the tape measure appears not to measure diffuse swelling, because this measure does not represents lowerlimb volume beyond the ankle joint (Petersen et al., 1999).

2.4.2 Volume measurement devices

Though volume measurement using devices such as a bioelectric impedance apparatus, (Seo *et al.*, 1995; Seo et al., 1997), CT and MRI are reported in the literature, they have limited practical use and are hardly used in clinical trials (Labs et al., 2002). CLEMS and Optoelectronic Volumetry have been used interchangeably to

measure volume in two studies against the gold standard water volumetry method (Bednarczyk et al., 1992; Tierney et al., 1996).

2.4.2.1 Computerized Limb volume Measurement System (CLEMS)

CLEMS was developed by a team of clinicians and engineers in Canada (Bednarczyk et al., 1992). This system can measure both upper and lowerlimb volume and the limb can be measured in any position suitable for the patient. CLEMS consists of a mechanical arm, a digitizer, and a personal computer. The mechanical arm has five linkages with optical encoders, which serve as a hand held stylus for tracing the portion of the limb measured. Longitudinal traces of the leg are made and twelve data streams are recorded and then are converted into transverse cross sections. This information is then processed using a computer software package. The volume of each cross-sectional slice is determined and the summation of the volume of all the slices provides the total volume of the limb. This method is yet to be used in any clinical trial so the practical use of this method is not known.

2.4.2.2 Optoelectronic systems

Optoelectronic systems use infrared rays to measure limb reference points from which the volume is calculated electronically (Tierney et al., 1996). These systems consist of chassis with a sliding metal frame mounted on runners. The frame is fitted with two rows of 240 to 200 infra red light emitting diodes (LEDs) at right angles to each other. Opposite to these are two rows of infrared detecting diodes (Pero-System, 2004; Perrin & Guex, 2000; Tierney et al., 1996). The LEDs in the frames illuminate the limb and the sensors move over the limb (See Figure 8). The limb is placed inside the frame and markers are directed to the upper and lower reference points. As the frame

is moved the limb interrupts the beam and the dimensions (*x*-axes and *y*-axes) is measured and the position of the limb (*z*-axes) determined by the sensors. The data is processed using a computer and a three dimensional image of the limb is created from which the volume between the reference point can be analysed quantitatively. The disadvantage of this equipment is that it is highly expensive and the volume must be measured at right angles so the slightest variation in the angle of the foot will produce errors (Perrin & Guex, 2000).

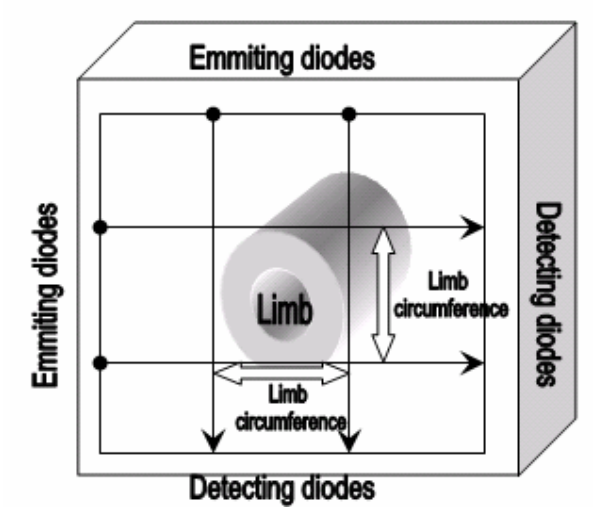


Figure 8: Illumination of the limb placed inside the frame
Figure modified from Pero-system, (2004)

2.4.3 Water displacement method (Water Volumetry)

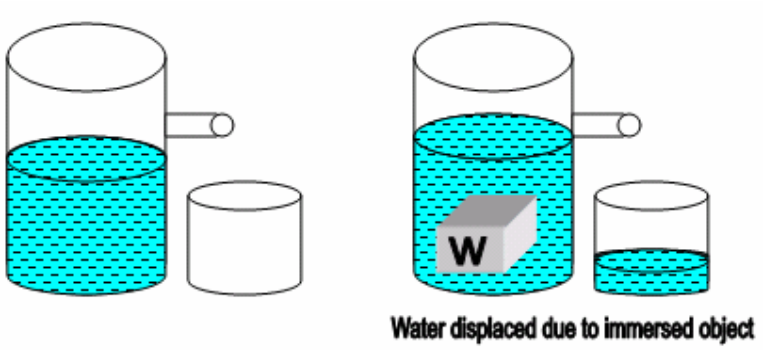


Figure 9: Water displacement method

The water displacement method is one of the oldest methods devised by Archimedes (287-212 BC) for measuring the volume of irregular objects (See Figure 9). It is used in the medical literature for volumetric analysis of the upper limb (Busse *et al.*) and lower limb (foot/ankle) volume to evaluate the efficacy of intervention. Goldie et al., (1974) was the first to use foot volumetry as an objective measure for studying the effect of antiphlogistic drugs in ankle sprains. Though there are many other indirect methods used to measure leg volume, as mentioned in the previous sections water volumetry still remains the cheap, accurate, reliable and direct method that is used in the clinical/ research settings (Brijker et al., 2000; Moholkar & Fenelon, 2001b; Nilsson & Haugen, 1981; Petersen et al., 1999).

2.4.3.1 Buoyancy and Archimedes' principle

Water volumetry is based on the physical principles devised by Archimedes. Archimedes (287-212 BC) was the first to propose the use of the water displacement method to calculate the mass of irregular objects (Alexandrou, 2001; Massey, 1998). The Archimedes' principle states that "the buoyant force exerted by a fluid on a object

is equal to the weight of the fluid displaced by the object" (Cromer, 1997; Nave & Nave, 1985) (See Figure 10). When an object is partially or fully submerged in a fluid an upward force is exerted on that object. This upward force is known as the buoyant force and it is equal to the volume of the object immersed (Cromer, 1997; Nave & Nave, 1985). Applying this principle to volumetry when the foot is immersed into a volumetric tank the buoyancy force exerted by the water in the tank displaces water which is equal to the volume of the foot immersed.

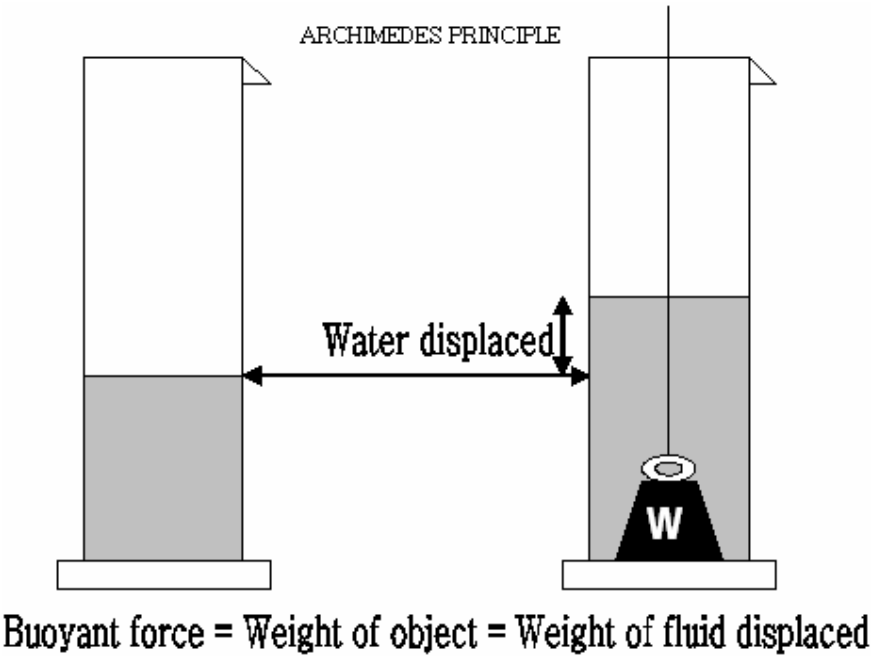


Figure 10: Archimedes' principle

2.5 Comparison between different methods

Water volumetry has been compared with most other measurements methods. These include CLEMS (Bednarczyk et al., 1992), Optoelectronic volumetry (Tierney et al., 1996) and tape measures (Bednarczyk et al., 1992; Kaulesar Sukul et al., 1993; Petersen et al., 1999), while Optoelectronic volumetry was compared with tape measurement in another study (Labs et al., 2002) (See Table 1.).

Table 1: Comparison studies between different swelling measurement methods

Study	*Methods*	*Subjects*	*Sample size*	*Results*	*Conclusion*
Labs et al., (2000)	Optoelectronic volumetry Vs tape	Healthy volunteers	30	Reliability coefficient <.05 Significant difference between methods	Both are reliable Both are not interchangeable
Bednarczyk et al., (1992)	Water volumetry Vs CLEMS	2 spinal cord injury, 2 multiple sclerosis, 1 cerebral palsy	5	Correlation between: CLEMS & volumetry= 0.992 CLEMS & volumetry with tape= 0.318 & 0.341	CLEMS and volumetry are significantly related whereas both CLEMS and volumetry were not related with tape
Tierney et al., (1996)	Water volumetry Vs optoelectronic volumetry Vs Disc Vs Frustrum method	10 healthy volunteers 17 venous/lymph disease patients	27	Indirect methods were significantly different from volumetry p<.005	Volumetry methods were accurate than indirect methods & optoelectronic method was quicker
Sukul et al., (1993)	Water volumetry Vs Disc Vs Frustrum method	Healthy volunteers	20	Correlation coefficient: Volumetry & disc 0.99; Volumetry & frustrum 0.93	Volumetry is interchangeable with disc but not with frustrum
Petersen et al., (1999)	Water volumetry & tape (Figure of 8)	Ankle swelling	29	ICC volumetry & tape: Inter 0.99, 0.98; Intra 0.98, 0.99	Both are reliable

Labs et al., (2000) compared the reliability of tape measurement and Optoelectronic volumetry. The limb circumference at two levels; ankle level and mid-calf were measured three times using both methods in 30 healthy volunteers. Results showed high reliability (Reliability coefficient < 0.95) for both these methods. On comparison between both the methods, it was found that they cannot be used interchangeably because of the constant bias associated with the volumetry. Volumetry measurements

showed significantly ($p < 0.05$) larger circumferences of the limbs when compared to the tape methods. In conclusion the authors suggested that Optoelectronic volumetry and tape measurements could not be used interchangeably for limb assessment.

CLEMS, Water volumetry and tape measurement methods were also compared in a study by Bednarczyk et al., (1992) where 5 neurological patients with pitting oedema were assessed. CLEMS and Water volumetry showed high correlation, where as both these methods showed poor correlation when compared with the tape measure method (See Table 1). The authors suggested that CLEMS could be used in place of Water volumetry since it has the same accuracy and reliability and it was quicker than water volumetry. The tape model was not suitable as it did not include foot/ankle volume and therefore it has low volume readings when compared with the other methods (Mean leg volume CLEMS 3163.86cc, Volumetry 3176.99cc, tape 2538.49cc).

In a study by Tierney et al., (1996) volume measurements using Water and Optoelectronic volumetry, Frustrum and Disc methods were performed on 10 healthy volunteers and 17 oedematous patients. An average of three measurements for each method was considered as the limb volume. Data analysis showed that both the water and Optoelectronic volumetry methods agreed closely (a difference of less than 3%). Whereas the indirect methods overestimated the limb volume; with the Frustrum method differed from the Water volumetry by as much as 12% and by 8% with disc method.

In a study by Sukul et al., (1993) Water volumetry method was compared with the Disc and Frustrum method in 20 normal subjects. The limits of agreement and

correlation coefficient were calculated from the data. High correlation was found between the Volumetry and Disc method, but not between the Volumetry and Frustrum method. The mean volume obtained by Volumetry, Disc and Frustrum were 2771ml, 2822ml and 2187ml respectively. The mean difference between the Volumetry and Disc methods was -45ml whereas the difference for the Volumetry and Frustrum was 521ml. These results demonstrated that Volumetry and Disc methods are interchangeable, but the Volumetry cannot be replaced with Frustrum method.

Petersen et al., (1999) compared the reliability of Water volumetry and Figure-of-eight tape method for measuring the ankle swelling in 29 ankle injured subjects. Two raters performed three trials of both the methods. The studies findings demonstrated that both the methods had a high intra-rater and inter-rater reliability (See Table 1). The authors concluded that the tape measure method was ideal for measuring localized swelling, whereas for measuring accurately the diffuse swelling associated with lowerlimb injuries, Water volumetry is more suitable than the Figure-of-eight tape measure method.

The findings of the above studies suggest that Water volumetry can be used interchangeably with CLEMS (Bednarczyk et al., 1992) and Optoelectronic volumetry methods (Tierney et al., 1996) for measuring volume. Though, Water volumetry and Optoelectronic volumetry can be used interchangeably, the major disadvantage of optoelectronic system is they are expensive (15,000 euros). Except for Sukul et al., (1993), previous studies (Labs et al., 2002; Petersen et al., 1999; Tierney et al., 1996) agree that the tape methods cannot be used to replace the other measurement methods.

Among the three methods described the Water volumetry remains the simplest test and the gold standard of reference (Perrin & Guex, 2000).

Chapter 3

Review of Literature: Reliability studies

Introduction

In this section, the methodology for reviewing the water volumetry studies, the quality assessment of the included studies and the characteristics of studies will be presented. Finally, the findings from this review will be summarized

3.1 Review of water volumetry reliability studies

There are wide variations in the methodology and reporting of water volumetry reliability analysis. This review aimed to identify the reliability studies conducted on water volumetry and review their methodology and findings.

3.1.1 Review methods

Published studies up to August 2004 were retrieved from the following literature databases: MEDLINE, Physiotherapy evidence database (PEDro), Cochrane Library (Cochrane central register of controlled trials), Cumulative Index to Nursing & Allied Literature (CINHAL) and Sport discus. Relevant abstracts were reviewed and the most relevant studies were retrieved and reviewed in full. Additional papers were identified and reviewed from their bibliographies. The following search terms were used alone and in combinations: water volumetry, foot volumetry/volume, water displacement method, volumetric measurement, ankle swelling/oedema/effusion, ankle outcome measures, and reliability/repeatability. In total 13 studies focusing on the reliability of foot/ankle water volumetry were included for analysis. The upper limb studies were not included.

3.1.2 Quality assessment

Quality assessment of a published study is of importance while evaluating the results of a study as differences in the quality of study methods may bias the results (Moher *et al.*, 1996). Tools such the PEDro Scale and the Cochrane Musculoskeletal Injuries Group (CMSIG) scale (Gillespie *et al.*, 2004) are available for assessing the quality of randomized controlled trials; however there was no tool in the literature for evaluation of reliability studies. Therefore a checklist (See Appendix: 1) was prepared after analysing the reliability review articles (Atkinson & Nevill, 1998; Bruton *et al.*, 2000; Eliasziw *et al.*, 1994; Keating & Matyas, 1998; Ludbrook, 2002; Morrow & Jackson, 1993). The checklist contained 8 major criteria dealing with the study aim, study design, participants, procedures, reliability measures, hypothesis testing, relative reliability, absolute reliability and reporting of results. It also contained other sub-criteria under the major criteria. However a score was not allocated to each criterion unlike the other evaluation tools. The studies were assessed using the checklist and their details have been listed in the Table 2.

Table 2: Characteristics of the reviewed studies

Keys: NP= Not Performed, Intraclass Correlation Coefficient= ICC, SEM=Standard Error of Measurement, LSD= Least Significance Difference, CV= Coefficient of Variation & NA= Not Available

Study	*Aim*	*Design*	*Participants*		*Procedure*			*Reliability measures*					*Results*
			Sample size	Population	No: of trials	Apparatus	Foot positioning Protocol	Combination of reliability indices	Systematic bias	Relative reliability		Absolute reliability	
										ICC/Pearson	ICC type		
Petersen et al., (1999)	Reliability of water volumetry and tape	Repeated measures, Intra & inter-rater	29	Ankle swelling. Men=12, women=17 Age: Range 18-48, Mean(±SD) = 25(± 6.9)	2 raters each 3	Commercial plexiglass tank. Specifications: 33cmx14cmx23cm	Ankle plantar flexed: toe touched front wall & calf in contact with posterior wall	3 (2 Relative & 1 Absolute)	NP	ICC & Pearson's for comparing between tape & volumetry	Inter-rater (2,3) Intra-rater (3,1)	SEM	Inter-rater ICC =0.99 Intra-rater =0.98 SEM: rater 1 & 2= 17ml
Man et al., (2004)	Effect of body position on foot& ankle volume	Repeated measures, (test-retest) 24 to 48 hrs time elapsed between first & second test session	5, bilateral foot & ankle measurements	Healthy, uninjured Age=NA, Men=NA, women=NA	4 raters each 3	Commercial plexiglass tank (Similar to Petersen et al., 1999)	Neutral dorsiflexion: lower leg in contact with back wall & sole flat on the bottom	2 (Relative & Absolute)	NP	ICC	Intra-rater (3,k)		Intra-rater ICC=0.99 for each rater LSD=15 to 47 ml
Man et al., (2002)	Effect of electrical stimulation on foot& ankle volume	Repeated measures, (test-retest)	5, bilateral foot & ankle measurements	Healthy, uninjured Age=NA, Men=NA, women=NA	2 raters each 3	Commercial plexiglass tank (Similar to Petersen et al., 1999)	Neutral dorsiflexion: lower leg in contact with back wall & sole flat on the bottom	2 (Relative & Absolute)	NP	ICC	Intra-rater (3,k)		Intra-rater ICC=0.998 & .999 LSD=15 to 25 ml
Moholkar & Fenelon, (2001b)	To identify any right to left foot & ankle	Repeated measures	20	Healthy, uninjured Age: range 19	3	Commercial plexiglass tank (Similar to Petersen et al.,	Neutral dorsiflexion: similar to Man et al., 2004	2 (Hypothesis testing & Absolute)	Paired sample t-test	NP	-	SEM	Alpha value: Right=0.998,

	volume variations			to 27, Men=18, women=2		1999)							left=0.9997, SEM for Right & left= 30.1229ml
Moholkar & Fenelon, (2001a)	To investigate diurnal variations of foot & ankle volume	Repeated measures	20	Healthy, uninjured Age: range 19 to 27, Men=18 women=2	3	Commercial plexiglass tank (Similar to Petersen et al., 1999)	Neutral dorsiflexion: similar to Man et al., 2004	Hypothesis testing	Paired sample t-test	NP	-	NP	Alpha value: Right=0.9998, left=0.9997
van Hamersvelt et al., (1996)	To study the mechanism of oedema formation due to vasodilators	Repeated measures, two groups: healthy volunteers & patients	49	27 Healthy, uninjured, 22 patients Age=NA, Men=NA women=NA	NA	Custom made tank: 20 litre tank with a foot rest is placed on electronic balance	Foot rests in the foot support & heel against the back wall	Absolute	NP	NP	-	CV%	CV%: volunteers 0.32%, patients 0.28%
Brijker et al., (1999)	To measure the reproducibility of water volumetry	Repeated measures design	10	Healthy, uninjured	3	Custom made tank: 42cmx42cmx42cm, tap 18cm from bottom of one wall	Knees are bent at 90° over the edge of bed & both feet are immersed	Absolute	NP	NP	-	CV%	CV%= 0.47%
Wester et al., (1996)	Effect of wobble board training after ankle sprain	Repeated measures design	1	Healthy, uninjured	20	Custom made tank: 41cmx20cmx20cm	Neutral dorsiflexion: similar to Man et al., 2004	NA	NP	NP	-	NP	±15ml
Michlovitz et al., (1988)	Effect of ice & electrical stimulation in ankle sprain	Repeated measures design	1	Healthy, uninjured	10	Commercial plexiglass tank. Specifications: NA	Neutral dorsiflexion: similar to Man et al., 2004	NA	NP	NP	-	NP	±25ml
Goldie et	To study the	Measured	1	Healthy,	NA	Custom made	Heel and calf	Absolute	NP	NP	-	CV%	CV%=

al., (1974)	effect of antiphlogistic drugs in ankle sprain	diffbbberent times during a 6 weeks period		uninjured		tank. Specifications: 30cmx26cmx15cm. Plastic pipe 7cm from the top of tank connected with a rubber tube served as outlet	close to the wall						Same session 0.4% Same time of day 0.3% Different times of day 2.4%
Laba & Roestenburg, (1989)	Evaluation of ice therapy for acute ankle sprain	NA	10	Healthy, uninjured	NA	Custom made tank. Specifications: Two tank chambers with tap fixed at 25cm height	Heel placed against the back wall	NA	NA	NA	-	NA	NA
McCulloch & Boyd, (1992)	To investigate volume variations in dependent position & whirlpool bath	Successive trials	Metal weight	No human subjects	10	Commercial tank. Specifications: 46cmx23cmx34cm	-	NA	NA	NA	-	NA	No greater than 2mm variation between measurements
Stergioulas, (2004)	Efficacy of laser therapy in ankle sprain	Successive trials	Metal weight	No human subjects	10	Commercial tank. Specifications: NA	-	NA	NA	NA	-	NA	No greater than 2mm variation between measurements

Keys: NP= Not Performed, ICC= Intraclass Correlation Coefficient, SEM=Standard Error of Measurement, LSD= Least Significance Difference, CV= Coefficient of Variation & NA= Not Available

3.1.3 Characteristics of the studies

3.1.3.1 Participants

All the studies except Petersen et al., (1999) and van Hamersvelt et al., (1996) have included uninjured healthy subjects. Petersen et al., (1999) have included subjects with soft tissue ankle injury, fracture and swelling as a result of pregnancy. van Hamersvelt et al., (1996) included healthy individuals and patients, however the details of the patients were not available. The sample size of the included studies ranged from 1 to 49 (See Table 2).

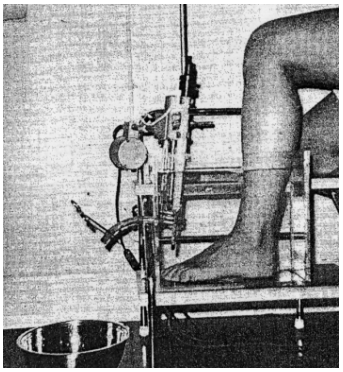
3.1.3.2 Measurement procedure

The volumetry procedure involves selection of a suitable apparatus, preparation of the apparatus by filling it with water and maintaining the tank in equilibrium for the foot measurement, then ensuring proper foot placement into the tank that is reproducible each time on repeated measurements and finally measuring the water displaced. The studies are varied between them by means of number of trials, apparatus used, positioning of the foot during repeated measurements and the cut-off point for stopping the water flow. The variation between the studies regarding the number of trials performed ranged form 3 trials to 20 trials (See Table 2).

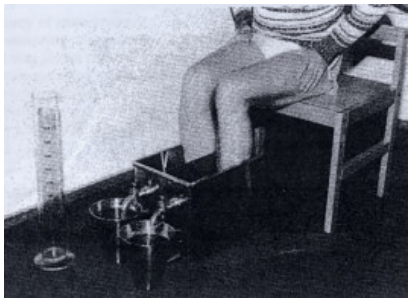
Regarding the measuring tank, five studies (Man et al., 2004; Man et al., 2003; Moholkar & Fenelon, 2001a, 2001b; Petersen et al., 1999) have used the same commercially available plexiglass tank (33cmx14cmx23cm), while McCulloch & Boyd, (1992) used a similar commercial tank with a slightly larger specification (46cmx23cmx34cm), and 2 studies (Michlovitz et al., 1988; Stergioulas, 2004) have

not provided the details of the commercial tank used for measurement. All the commercial plexiglass tanks were similar in construction with an outflow snout for water displacement.

Custom made tanks were used in 5 other studies (Brijker et al., 2000; Goldie et al., 1974; Laba, 1989; van Hamersvelt et al., 1996; Wester et al., 1996). Laba & Roestenburg, (1989) used a tank with 2 separate compartments with separate outflow channels to measure both the lower legs at the same time (See Figure 11c). Brijker et al., (1999) measured both the lower legs using a large single chamber tank (42cmx42cmx42cm). The outflow channel in the custom made tanks had external taps (Laba, 1989; Wester et al., 1996) unlike the commercial tanks, Goldie et al., (1974) had a rubber tube outflow and the water flow was stopped by clamping with an artery forceps. In van Hamersvelt et al., (1996) study the customized tank did not have any outflow channel, and their construction was different from the routine though the tank worked on the water displacement principle. Their tank had a steel foot platform suspended in the water tank, which was placed over a balance. When the foot was placed in the platform the increase in weight was measured from the scale and the foot volume was calculated.

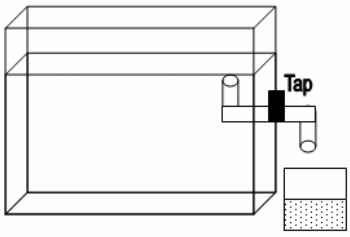


a. Goldie et al., (1974)

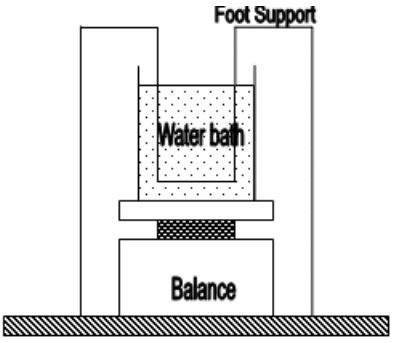


b. Nilsson & Haugen (1981)

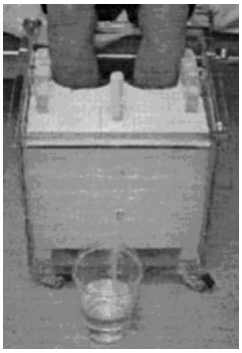
c. Laba & Roestenburg, (1989)



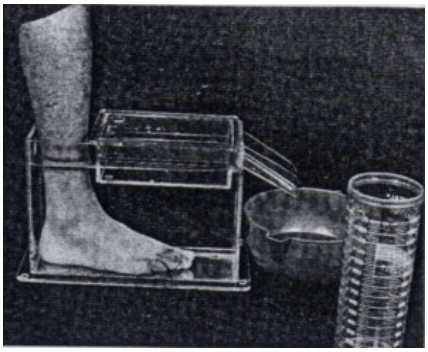
d. Wester et al., (1996)



e. van Hamersvelt et al., (1996)



f. Brijker et al., (2000)



g. Moholkar & Fenelon, (2001)

Figure 11: Various volumeter designs used in the literature

(Modified from a. Goldie et al., 1974, b. Nilsson & Haugen 1981, c. Laba & Roestenburg, 1989, d. Wester et al., 1996, e. van Hamersvelt et al., 1996, f. Brijker et al., 2000 & g. Moholkar & Fenelon, 2001)

The other variation seen in the studies were in the methods used to reduce surface tension to achieve accuracy. Obturator is a plastic device included with most of the commercially available volumeters (See Figure 11g). Once the subject's leg is positioned into the volumeter the obturator is placed on the top of the volumeter, along the front wall of the apparatus above the outflow spout. The purpose of the obturator is to reduce the wave formation in the water surface of the tank to improve the accuracy of measurement (Cloughley & Mawdsley, 1995) by decreasing the surface tension of water (Moholkar & Fenelon, 2001a, 2001b). However Petersen et al., (1999) disapproves with this notion, the authors claim that the use of obturator is of minimal importance and best reliable results were achieved both in their pilot and research study without the use of the obturator. Three studies (Michlovitz et al., 1988; Moholkar & Fenelon, 2001a, 2001b) have used obturator and one (Wester et al., 1996) filled soapy water in the tank to reduce the surface tension of the water to decrease the time taken for measurements. Brijker et al., (1999) positioned a block of foam in the tank to diminish the water waves and to increase accuracy.

Regarding the foot positioning during measurement, all the studies have adopted the neural ankle position (Chalk *et al.*, 1995; Goldie et al., 1974; McCulloch & Boyd, 1992; Moholkar & Fenelon, 2001a, 2001b; Sims, 1986; van Hamersvelt et al., 1996) with the calf/heel against the posterior wall of the tank while measuring the foot and ankle volume measurement for reproducibility. Peterson et al., (1999) in his study for establishing the reliability of volumetry measurement in ankle sprain subjects has used modified protocol with the forefoot in contact with the anterior wall and the calf in contact with the posterior wall of the tank, which would place the ankle in plantar flexion. The investigators suggest that this position may be adapted easily by ankle

sprain patients with initial swelling and initial lack of range of motion (Petersen et al., 1999).

.

All the studies took measures to maintain the temperature within this range (22-35°C) during the measurements. The water temperature should be monitored between 20-35°C for accurate readings (King II, 1993). However, 3 studies (Michlovitz et al., 1988; Stergioulas, 2004; Wester et al., 1996) have not provide any information regarding the water temperature.

The cut-off point where the receptacle is removed from the tank for measurement is important as this may influence the volume readings and reliability of measurements. Most of the studies (Brijker et al., 2000; Moholkar & Fenelon, 2001a, 2001b; Stergioulas, 2004; Wester et al., 1996) have considered the cut-off point to be when the water has completely stopped running from the outflow snout. In some studies the recipient container was removed when the dribbling frequency was 10 or less/minute (Laba, 1989) or 1 or less drip/second (Man et al., 2004; Man et al., 2003; Petersen et al., 1999) and even 20 seconds from the moment of dripping commenced was considered as a cut-off point by Brijker et al., (1999). The last procedure is measuring the displaced water in the receptacle; graduated cylinder (McCulloch & Boyd, 1992; Michlovitz et al., 1988; Moholkar & Fenelon, 2001a, 2001b; Petersen et al., 1999; Stergioulas, 2004) and electronic weighing scale (Brijker et al., 2000; Goldie et al., 1974; Man et al., 2004; Man et al., 2003; van Hamersvelt et al., 1996; Wester et al., 1996) were used for this purpose. In Laba & Roestenburg, (1989) the graduated cylinders served as the receptacle and the volume was measured directly from the cylinder.

3.1.3.3 Reliability findings

All the studies have varied in their methods used to analyse and report the reliability findings. The reliability was analysed using ICC, SEM and CV (See Table 2). All these studies have demonstrated high reliability even though there were variations in their measurement procedures. There were only two studies that had investigated the between-days reliability (Goldie et al., 1974; Man et al., 2004). But the inconsistency in analysing and reporting the results have made comparison between these studies difficult. In their study Goldie et al., (1974) have reported reliability using CV, whereas ICC was used by Man et al., (2004)

3.2 Summary

The review of the reliability studies has highlighted the following key issues. Except, for a few studies (Petersen et al., 1999; van Hamersvelt et al., 1996) all the other studies have underestimated the sample size required to accurately estimate reliability (Hopkins, 2000; Morrow & Jackson, 1993). No studies were identified that have examined between days reliability with large sample size and have analysed all the three indices of reliability (systematic bias, relative reliability & absolute reliability).

Chapter 4

Methods and Materials

Introduction

This study was performed in 3 stages. The population sample included in this study was normal healthy individuals without any foot and ankle injuries or cardiovascular pathology. Right foot/ankle volume was measured and the data the intra-rater and inter-rater reliability for foot volumetry was estimated.

4.1 Study design

A "repeated-measures design" was undertaken for this reliability study. Three repeated measurements were made by each of two raters on a random sample of 30 subjects on three different days (Refer Figure 12).

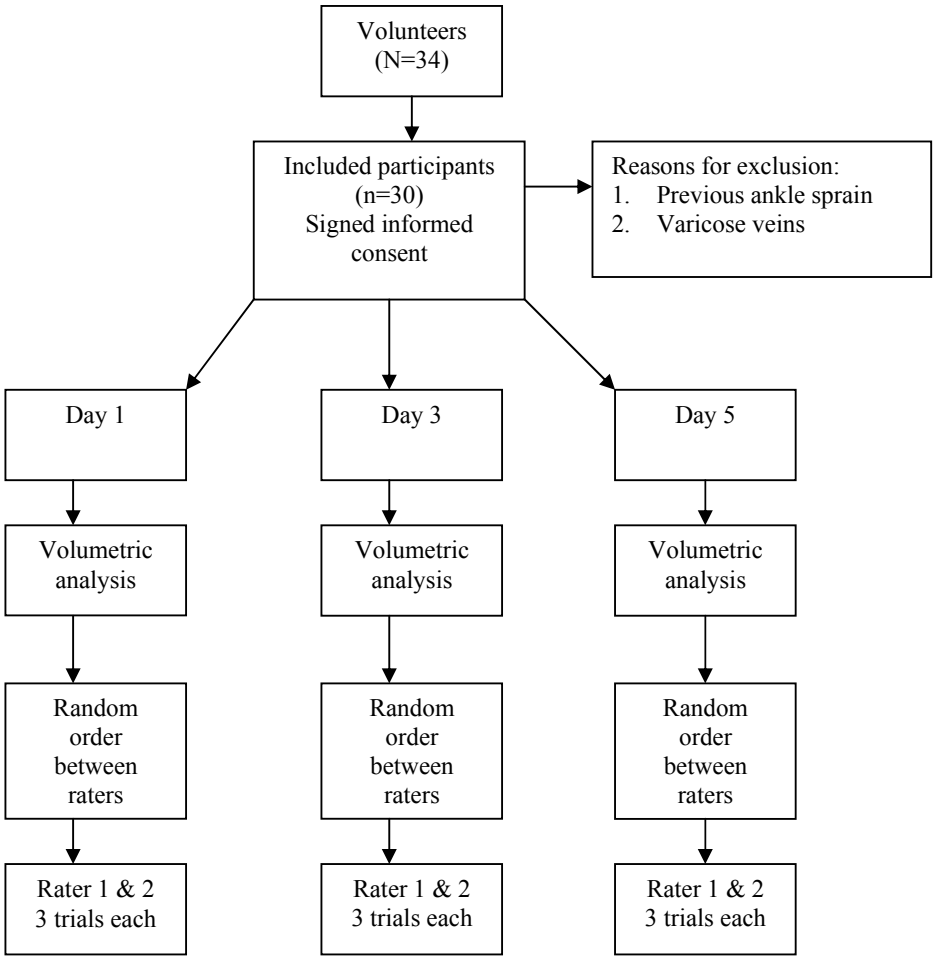


Figure 12: Flow chart of reliability study

4.2 Subjects

The Auckland Ethics Committees granted approval to the study (See Appendix: 2.1.1). The approval was then reported to the institutional ethics committee where the study was conducted. Each subject read and signed the approved consent form prior to participation (See Appendix: 2.1.2). The study methods were explained clearly to the subjects.

A total of 34 volunteers were recruited through advertisement in the University notice board. Four subjects were excluded during participant screening as 3 had a previous ankle injury and 1 had varicose veins. Thirty healthy, uninjured subjects (Age 29.03 years SD: 4.4, Height 169.7 cm SD: 6.40, Weight 79.93 kg SD: 12.75) who met the inclusion criteria were included in the study. The subjects were excluded if there were any history of previous foot/ankle injury or surgery, history of cardiovascular disease or local peripheral circulatory (venous/lymphatic) disorders as these may be associated with persistent peripheral edema and volume fluctuations. They were also excluded if they were diabetic or taking diuretics or had any skin infections, open wounds in the lower leg or if any female subject was pregnant.

4.2.1 Rationale for sample size

The sample size for this study was estimated using the expected intraclass correlation (ICC) for the intra-rater and inter-rater reliability coefficient of this study. Walter et al., (1998) have developed a formula which uses the expected ICC reliability coefficient (ρ) to calculate the required sample size for reliability study. The authors (Walter *et al.*, 1998) have provided the required number of participants (*k)* for various repetitions of trials (*n)*, and for different estimated null and alternate reliability values

(ρ_0 & ρ_1) with a fixed significance level (α =0.05) and power (β =0.20) in their study. This study hoped for a reliability of at least 0.8 or higher, for 3 observations under fixed significance level and power. From the sample size estimation table (Walter et al., 1998), the required sample size of 30 (approximating 32.5) was arrived for this study (See Table 3). This number agrees with Morrow & Jackson, (1993) suggestion that a minimum of 30 subjects are required for assessing the reliability of a measurement.

Table 3: Calculation of sample size using estimated ICC values

Significance level (α)	*Power (β)*	*Reliability values*		*Trials (n)*	*Participants required (k)*
		Null ($H_0 : \rho_0$)	Alternate ($H_0 : \rho_1$)		
0.05	0.20	0.8	0.9	3	32.5

4.3 Equipment and procedures

The accuracy study of the volumetric apparatus was carried out by the principal investigator (Rater 1). The second rater for the inter-rater reliability study was a postgraduate physiotherapy student (Rater 2). Both the raters conducted practice trials of the volumetric procedures with 5 volunteers to familiarize with the research setting.

4.3.1 Equipment

- A custom made volumetric tank was designed using Plexiglass of 6mm thickness (Modern signs (NZ) Ltd, Auckland, New Zealand) with inside measurements of 30cm length x 20cm wide x 30 cm deep (See Figure 13). A water tap at 20 cm height from the bottom of tank was fixed in one of the walls.

- Electronic scale (accuracy 0.01g, VIBRA-CG, Wedderburn scales Ltd, Auckland, New Zealand) was used to weigh the amount of water displaced.
- A clinical thermometer was used to measure the water temperature.
- A recipient container was used to collect the displaced water from the tank.
- A measuring jug was used to fill and to collect the overflowing water while preparing the tank for the measurement.

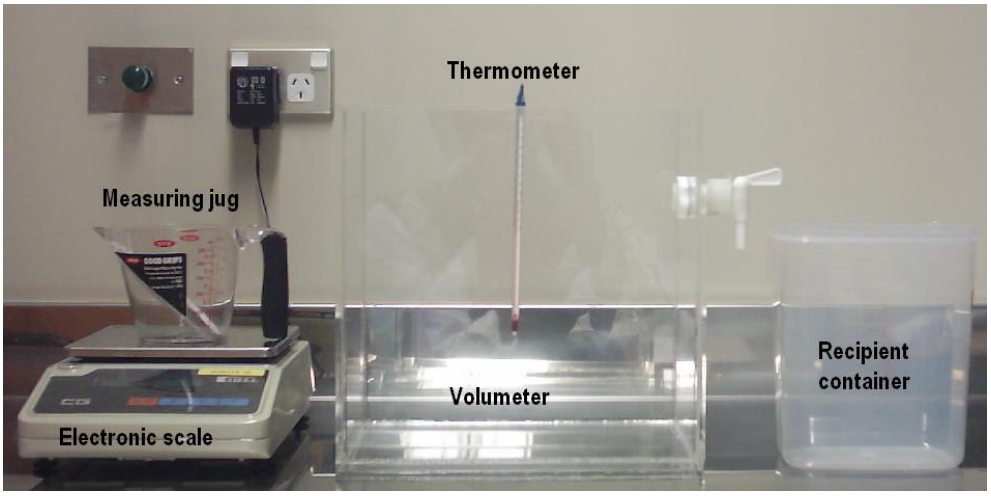


Figure 13: Volumetric measurement equipments

4.3.2 Preparation of the volumetric tank

The volumeter was placed on a flat surface in proximity to the water tap. Using the measuring jug the volumeter was filled with water just above the level of the closed tap. A skin thermometer was used to measure the water temperature inside the volumeter, the temperature was measured before each measurement and it was maintained within 25-35° C range by adding fresh water from the tap. The recipient container was placed beneath the tap in the volumeter and the tap was opened and the displaced water was collected in the recipient container. When the dribbling of the water stopped completely the tap was closed (cut off point). Then the recipient

container was removed and the displaced water was emptied and the recipient container was dried thoroughly with a towel to remove any water in it. The dry recipient container was placed again beneath the tap and the volumeter is now ready for measurement.

Before the data collection the electronic scale was prepared by placing it on a leveled surface and the weight of the empty recipient container was measured. The scale was set to display the weight of the displaced water minus the weight of the empty container whenever the container with the displaced water was weighed.

4.3.3 Accuracy of an apparatus

The apparatus was prepared as mentioned above and a solid object of known volume was dispensed into the prepared tank. It was surmised that theoretically the amount of water displaced should be equal to the volume of the solid object placed into the tank for the tank to be accurate. The tap was opened and the water displaced into the recipient container was collected and weighed. The weight of the water displaced was measured in grams (g) and it was directly converted into milliliters (ml). This direct conversion of grams into milligrams is possible because at the room temperature the relative volume of water reaches unity (van Hamersvelt et al., 1996). The tank was prepared as mentioned above before the next trial. The temperature was monitored and maintained to 30° C while refilling the apparatus by adding water. The same procedure was repeated for another 19 consecutive trials and the displaced water was weighed.

4.3.4 Foot/ankle volumetric measurement procedure

The foot positioning as suggested by Peterson et al., (1999) was demonstrated to the subjects by the raters (See Figure 14). The subjects were allowed to practice the foot positioning in an empty tank before the data collection. The subjects' lower leg was washed and then wiped with a towel before measurements. The subjects were seated behind the volumeter (See Figure 15). The subjects lowered their foot into the tank as if the foot rests in the bottom of the tank, with the forefoot (toes) in contact with the anterior wall of the tank (wall with the tap) and the posterior of the leg (calf muscle bulk) in contact with the posterior wall of the tank (wall opposite the tap). Once they lowered the leg the foot was shaken gently to eliminate any air bubbles. The subjects were asked to maintain this position throughout the measurement period and for the next consecutive trials. Once the waves in the surface were settled the tap was opened and the displaced water was collected in the recipient container. The subjects were allowed to take their leg out of the volumeter. The recipient container with the displaced water was weighed in the scale and the displaced volume was noted. This displaced volume represents the volume of the foot and ankle.

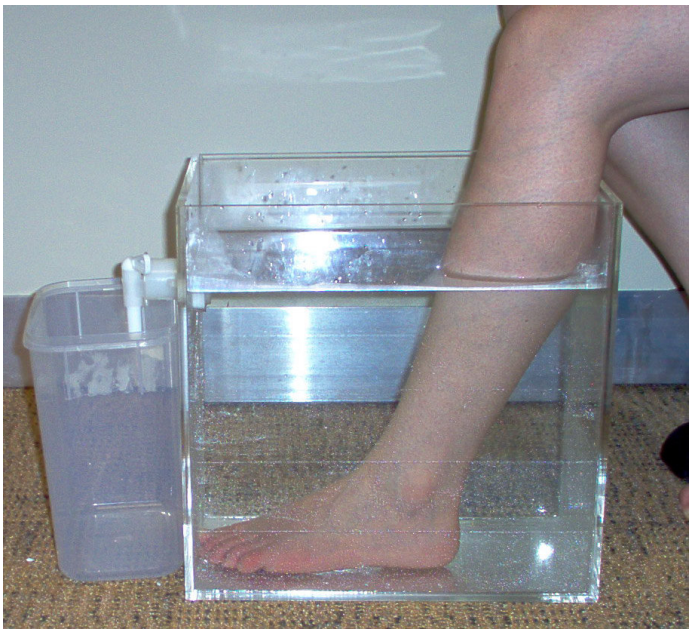


Figure 14: Foot positioning protocol

Figure 15: Volumetric measurement setting

4.4 Reliability of volumetric measurement

For retest reliability a measurement is taken on a subject on one occasion and the same measurement is repeated on the subject again on another occasion. The measurements on the two occasions over a period of time are compared for consistency.

The measurements were made on three different days in a week (day 1, day 3 and day 5) for all subjects. All subjects were measured at the same time on which they were measured on the previous day. On each day 3 volumetric measurements were done by both the raters totaling 6 measurements for every subject on a day. The apparatus was prepared as mentioned above and three consecutive trials were conducted for each subject. The subjects' leg was wiped and dried with a towel again before the next measurement. Each measurement was completed within 5 minutes and the whole procedure was completed on an average within 15-20 minutes for each subject by one rater.

A random order of assessment for both the raters was determined using a random table (See Appendix: 3) created by SPSS© 11.0 for Windows® (SPSS Inc., Illinois, U.S.A.). The random table was prepared by permuted block randomization (Altman & Bland, 1999) for a block size of two. Each rater performed three volumetric measurements as per the order determined by the random table. Both the raters were blinded to each others measurements. At the time of data collection the subject, a volunteer for data recording and one of the raters was present in the data collection room, where as the second rater was outside or away (Nave & Nave, 1985) from the room during the period or data collection. A third person (volunteer) other than the

raters was always present in the data collection room who recorded the electronic scale readings. On each day the raters recorded in a separate data collection sheet so that they were not aware of the previous day's volumetric measurements. The data collected during the reliability studies were used for analyzing the foot/ankle volume variations between days in normal subjects.

4.5 Statistical analysis

Statistical analyses were performed using SPSS© 13.0 for Windows®; and Microsoft® Excel 2002 software was used for data entry and for calculating descriptive statistics. The significant differences were accepted at the alpha level of 0.05.

1. Accuracuy of apparatus: For assessing the accuracy of the apparatus the percentage error (PE) was estimated. The PE was calculated by using the known volume of the solid object ($True_{volume}$) and the volume of the water displaced ($Found_{volume}$) by the solid object for each of the 20 successive trials. The values were substituted in the formula below:

$$PE = \frac{(True_{volume} - Found_{volume})}{True_{volume}} \times 100\%$$

2. Reliability: The 3 volumetric set of scores from both the raters were used for reliability analysis. All the 3 reliability measures; (a) detection of systematic bias, (b) absolute reliability (random error) and (c) relative reliability were calculated from the data to estimate the intra-rater reliability (within day & between days) for both the raters and the inter-rater reliability. Since analysis of variance (ANOVA) assumes the

data to be normally distributed, tests of normality were undertaken on the volumetric data.

(a) Systematic bias: Paired *t*-test, Bland & Altman's (BA) plots and 95% confidence interval (CI) of the mean difference ($\bar{d}$) were used for detecting systematic bias between trials (Atkinson & Nevill, 1998) on the same day, between days and between testers. BA plot was arrived plotting the absolute difference between trials against the individual mean of both trials {Bland, 1986 #293}. BA plot provided a rough indication of systematic bias and random error. It also helped to assess for the presence of heteroscedastic errors. The 95% CI was calculated using the formula (Rankin & Stokes, 1998) below:

$$CI = \bar{d} \pm t_{n-1} SE$$

Where t is the student's t-test statistic, n is the number of subjects and $SE = SD_{diff} / \sqrt{n}$, and SD_{diff} is the standard deviation.

(b) Absolute reliability: Random error was calculated in terms of Bland and Altman's 95% limits of agreement (LOA) and by standard error of measurement (SEM). Using $\bar{d}$ and SD_{diff} LOA (Rankin & Stokes, 1998) was calculated as following:

$$LOA = \bar{d} \pm 1.96 SD_{diff}$$

The SEM was calculated as the square root of mean square error (MS_E) from the ANOVA table (Eliasziw et al., 1994; Hopkins, 2000; Stratford & Goldsmith, 1997).

$$SEM = \sqrt{MS_E}$$

(c) Relative reliability: The intra-rater and inter-rater reliability was calculated using the Intraclass Correlation Coefficient (ICC). Within day and between days intra-rater reliabilities for both the raters were determined using the ICC model (1, 1). This type is used when the subjects are from a random sample from a population and repeated measurements are made by the same rater, and the repeated measurements are a random selection from many possible measurements (Shrout & Fleiss, 1979). Inter-rater reliability coefficient was determined using the ICC model (2, 1). This model is utilized when each subject was assessed by each rater, and this rater was sampled from the population of possible raters (Shrout & Fleiss, 1979). The rater is considered as random effect. Among the two available types in SPSS (Absolute agreement and Consistency types) for two-way model "absolute agreement" type was calculated for inter-rater reliability in this study. Absolute agreement type includes bias in its calculation whereas consistency type is independent of systemic bias (McGraw & Wong, 1996). However, if the change in mean between the raters is relatively small (no systematic bias) there will not be any difference between both these types of ICC (Weir, 2005). For one-way ICCs only absolute agreement is measurable (McGraw & Wong, 1996).

3. Repeated measurement ANOVA was performed to assess the effect of the days (time interval) on the foot and ankle volume from the data collected by both the raters.

Chapter 5

Results

Introduction

This chapter will be presented in 4 parts. The first part deals with the descriptive details of the subjects. The second part will furnish the accuracy of the volumetric apparatus. The third part details the intra-rater reliability (within days & between days) and inter-rater reliability of water volumetry method. In the fourth part the day-to-day variability results in the foot/ankle volume will be presented.

5.1 Descriptive statistics-Subjects

All the 30 subjects foot/ankle volume data recorded from the 3 trials on each day by both the raters (R1 & R2) were included for analysis (See Appendix 4: Table 4.1 & Table 4.2). All the subjects completed the test and retest phases of the study. The demographic details of the subjects are presented in the Table 4.

Table 4: Descriptive data of the subjects

	Criteria	N	Mean ± SD	Range
All subjects		30		
	Age (Years)		29.03 ± 4.4	22 to 39
	Weight (kg)		79.93 ± 12.75	50 to 103
	Height (cm)		169.7 ± 6.40	150 to 181
	Volume (ml)		1431.7 ± 152.71	1197 to 1723
Male				
	Age (Years)		28.58 ± 4.07	23 to 39
	Weight (kg)		78 ± 10.60	57 to 103
	Height (cm)		171.42 ± 6.40	160 to 180
	Volume (ml)		1461.1 ± 161.89	1212 to 1723
Female				
	Age (Years)		30.18 ± 4.98	22 to 38
	Weight (kg)		66.09 ± 12.75	50 to 92
	Height (cm)		168.45 ± 6.40	158 to 181
	Volume (ml)		1381 ± 126.41	1197 to 1536

5.2 Accuracy of the apparatus

The volume of the metal object measured 20 times using the volumetric tank was 1109.56 ± 1.13 ml, with a range of 1107.90 to 1111.72 ml. The true volume of the immersed metal object was 1110ml. The greatest difference between measurements was 2.10 ml. The mean difference for all the trials was 0.44 ml. The absolute error (volume difference) for the volumetric measurement of the metal object using the volumeter tank is presented in the Figure 16.The absolute and the percentage errors for each trial are given in the Table 4.3 in the Appendix 4. The mean percentage of error was 0.04%.

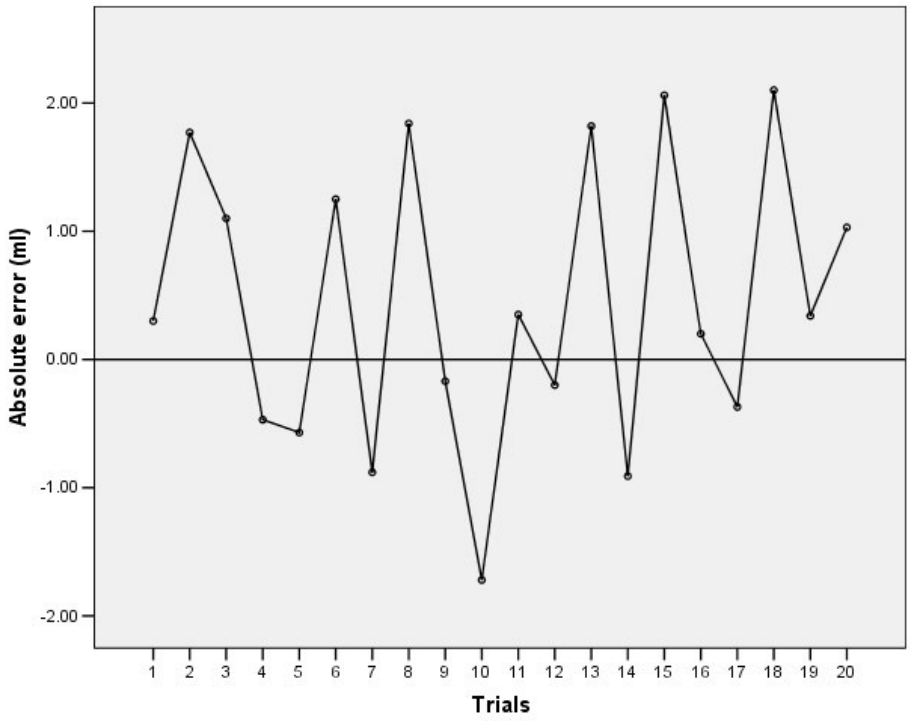


Figure 16: Absolute error (ml) for the volumetric measurement of the metal object using the volumeter tank for each of the 20 trials.

5.3 Reliability

The intra-rater reliability (within day & between days) for both the raters and inter-rater reliability will be presented in this part.

5.3.1 Intra-rater reliability (Test-retest)

The systematic error, random error and retest correlation were calculated for both the raters separately to assess the intra-rater reliability. The trials performed on each day were used to estimate the within day reliability and the measurement made on different days (Day 1, 3 & 5) were used for calculating between days reliability.

5.3.1.1 Intra-rater reliability within day

Systematic bias was assessed by means of paired *t*-test, 95% Confidence interval (CI) for the mean difference ($\bar{d}$) and by the Bland & Altman (BA) plots. The paired *t*-test between all the trials for both the raters showed that p values were greater than 0.05 in all the occasions suggesting that there was no systematic bias between the trials (See Appendix 4: Table 4.4). The 95% CI of $\bar{d}$ also showed that there was no bias between any of the trials for both the raters, as the value '0' was within the range of difference (See Table 5).

The BA plots were used to examine whether the magnitude of difference is independent of the mean. The BA plots were also used to assess the magnitude of disagreement. The BA plot for the rater1 (R1), between trial 1 and trial 2 on day 1 is presented in the Figure 17. The plot shows that the mean difference does not increase with the size of the mean, and also the magnitude of difference is in the range of –

10ml to +9ml between the trials. The plots between the remaining trials within each days showed that the magnitude of difference was in the same range (-10, 9ml) between all the trials and the range was same for both the raters (See Appendix 4: Figure 4.1 for Day 1-rater 1 graphs).

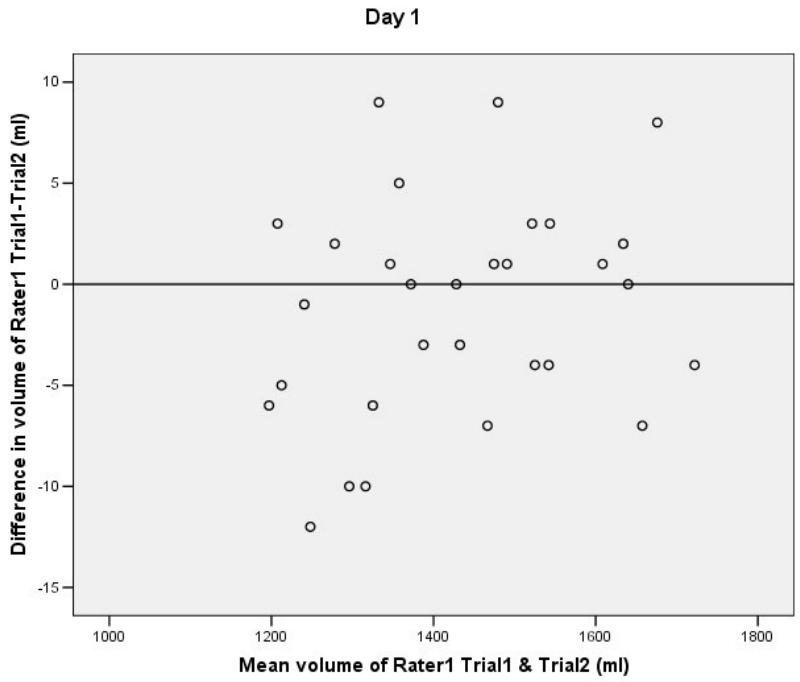


Figure 17: BA graph of difference in volume (ml) vs mean volume (ml) between Rater1-trial1 & trial1 on Day 1 for estimating the magnitude of disagreement and bias between the two measurements.

The random error was assessed using 95% Limits of agreement (LOA) and by Standard error of measurement (SEM). The LOA for R1 on day 1 between trial 1 and 2 was –11.6ml to + 9.2ml, the LOA for the other trials on the same day was in the range of ±10ml. All the other trials in the two remaining days (Day 3 & 5) were also in the same ±10ml range (See Table 5). The R2 also had an average range of ±10 ml for all the trials on the different days. The SEM was found to be on an average of

±3.5ml for both the raters. In summary the LOA was in the range of ±10ml and SEM was ±3.5ml for both the raters within the days.

The Intraclass correlation coefficient (ICC) was identical (ICC= 0.999) for both the raters between each trial on all the three different days, indicating high reliability (See Table 5).

Table 5: Systematic bias, random error (ml) and correlation values for the rater 1 & rater 2 within days

Raters	Days	Trials	95% CI of $\bar{d}$		95% LOA (ml)		SEM (ml)	ICC
		(Between trials)	Lower	Upper				
Rater 1								
	1							
		1-2	-3.16	0.78	-11.6	9.2	3.7	.999
		2-3	-1.41	1.54	-7.7	7.8	2.5	.999
		1-3	-3.28	1.04	-12.5	10.2	3.8	.999
	3							
		1-2	-2.79	1.39	-11.7	10.3	3.8	.999
		2-3	-2.33	1.50	-10.5	9.6	3.6	.999
		1-3	-2.95	0.72	-10.7	8.5	3.4	.999
	5							
		1-2	-0.90	2.48	-8.1	9.7	3.1	.999
		2-3	-2.05	0.78	-8.1	6.8	2.7	.999
		1-3	-1.71	2.01	-9.6	9.9	3.5	.999
Rater 2								
	1							
		1-2	-2.45	1.61	-11.1	10.2	3.8	.999
		2-3	-2.02	1.58	-9.7	9.2	3.4	.999
		1-3	-3.35	2.07	-14.9	13.6	5.0	.999
	3							
		1-2	-1.59	1.98	-9.2	9.6	3.3	.999
		2-3	-2.50	0.37	-8.6	6.5	2.7	.999
		1-3	-2.29	0.56	-8.3	6.6	2.7	.999
	5							
		1-2	-1.59	2.03	-9.3	9.7	3.4	.999
		2-3	-2.34	2.70	-13.0	13.4	4.7	.999
		1-3	-1.25	2.05	-8.3	9.1	3.1	.999

5.3.1.2 Intra-rater reliability between days

There was no evidence of systematic bias between all the trials (See Figure 18 & Table 6). The BA plots showed that the range of difference between the measurements was in the range of ±20ml for both the raters (See Appendix 4: Figure 4.2 for Day1-3 graphs for rater 1). The LOA and SEM were in the range of ±20ml and ±7ml respectively for both the raters (See Table 6). This shows that the error has increased two-fold during repeated measurements on different days. The average ICC values for both the raters were 0.998. ICC values were of little use in estimating the change in reliability during the repeated measurements on different days, as they remained in the 0.99 ranges.

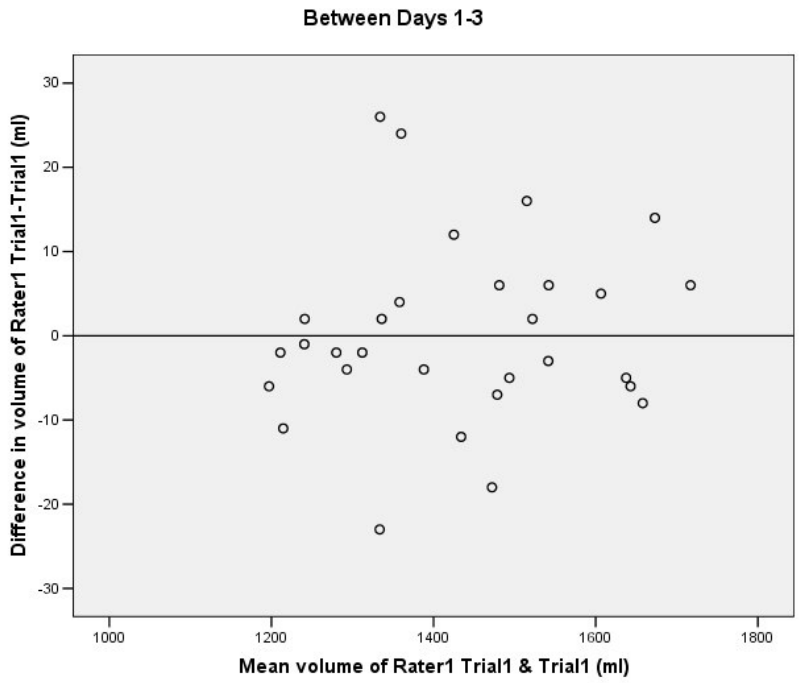


Figure 18: BA graph of difference in volume (ml) vs mean volume (ml) between trial1 of Day 1 & trial1 of Day 3 for Rater1, for estimating the magnitude of disagreement and bias between the two measurements

Table 6: Systematic bias, random error (ml) and correlation values for the rater 1 & rater 2 between days

Raters	Days	Trials	95% CI of $\bar{d}$		95% LOA (ml)		SEM (ml)	ICC
	(Between days)	(Between trials)	Lower	Upper				
Rater 1								
	1-3							
		1-1	-3.85	4.27	-21.1	21.5	7.6	.997
		2-2	-3.12	4.52	-19.4	20.8	7.2	.997
		3-3	-3.12	3.55	-17.3	17.7	6.2	.998
	3-5							
		1-1	-4.75	2.37	-19.9	17.5	6.7	.998
		2-2	-3.60	4.19	-20.2	20.7	7.4	.997
		3-3	-2.62	2.78	-14.1	14.3	5.1	.998
	1-5							
		1-1	-5.24	3.27	-23.3	21.4	8.1	.997
		2-2	-2.22	4.22	-15.9	17.9	6.1	.998
		3-3	-3.14	3.73	-17.7	18.3	6.1	.998
Rater 2								
	1-3							
		1-1	-4.42	3.34	-20.9	19.8	7.4	.997
		2-2	-3.72	3.87	-19.8	20.0	7.2	.997
		3-3	-4.52	2.99	-20.5	18.9	7.2	.997
	3-5							
		1-1	-4.09	1.70	-16.4	14.0	5.5	.998
		2-2	-4.87	2.53	-20.6	18.2	7.0	.998
		3-3	-2.90	3.05	-15.5	15.7	5.5	.999
	1-5							
		1-1	-6.09	2.62	-24.6	21.1	8.3	.997
		2-2	-5.04	2.85	-21.8	19.6	7.5	.997
		3-3	-4.32	2.93	-19.7	18.3	6.8	.998

5.3.2 Inter-rater reliability

There was no evidence of systematic bias between all the trials as shown by the paired *t*-test, 95% CI of $\bar{d}$ and BA plots (See Figure 19 & Table 7). The ranges of difference between the measurements were in the range of ±13ml for both the raters (See Appendix 4: Figure 4.3 for BA plots between raters on day 1). The LOA and SEM were in the range of ±13ml and ±5ml (See Table 4.4). When compared to the within day intra-rater reliability, inter-rater reliability had a slightly higher range of error, but better than the between day reliability. The average ICC value was 0.999 (See Table

7), again they were less informative in showing the changes in the reliability values between the intra and inter-rater reliability.

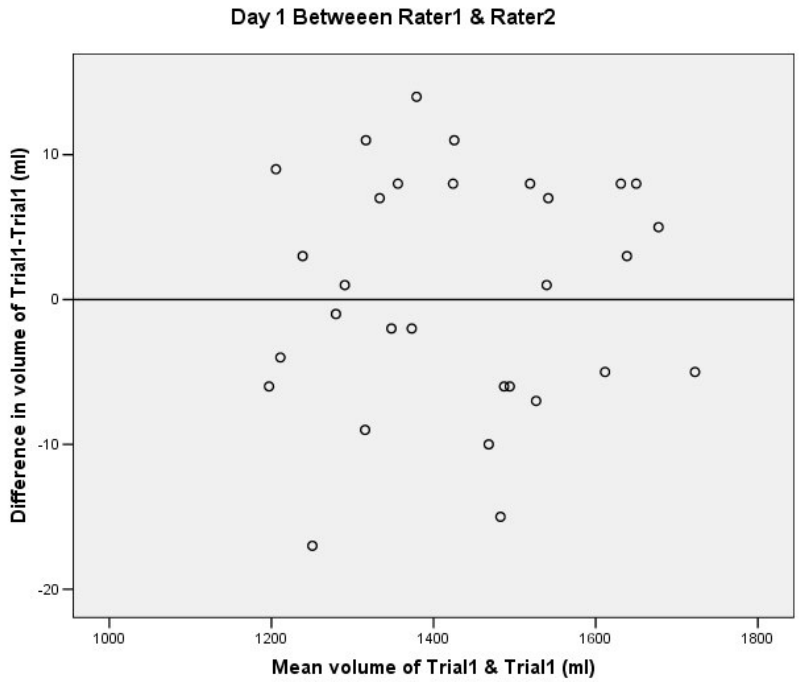


Figure 19: BA graph of difference in volume (ml) vs mean volume (ml) between Rater 1-trial 1 & Rater 2-trial 1 on Day 1 for estimating the magnitude of disagreement and bias between the two measurements

Table 7: Systematic bias, random error (ml) and correlation values for both the raters

Days	Trials	95% CI of $\bar{d}$		95% LOA (ml)		SEM (m1)	ICC
	(Between R1& R2)	Lower	Upper				
1							
	1-1	-2.40	3.57	-15.1	16.3	5.6	.998
	2-2	-0.88	3.59	-10.4	13.1	4.3	.999
	3-3	-1.06	3.19	-10.8	14.7	4.0	.999
3							
	1-1	-2.80	2.47	-14.0	13.7	4.9	.999
	2-2	-2.09	3.54	-14.0	15.5	5.3	.998
	3-3	-2.09	2.25	-11.3	11.5	4.1	.999
5							
	1-1	-3.32	2.98	-16.7	16.4	5.9	.998
	2-2	-3.29	1.81	-14.1	12.7	4.8	.999
	3-3	-2.83	2.99	-15.2	15.4	5.5	.998

R1=Rater 1, R2=Rater 2, $\bar{d}$ = mean difference

5.4 Day-to-day biological variations

There was no statistically significant day-to-day variation in the normal foot/ankle volume as estimated from both the raters measurements. Independent ANOVA calculations showed no significant difference between the 3 days for foot/ankle volume changes for both the raters ($p>0.05$). Figure 20, allows comparison of the mean change in volume between the 3 days for both the raters.

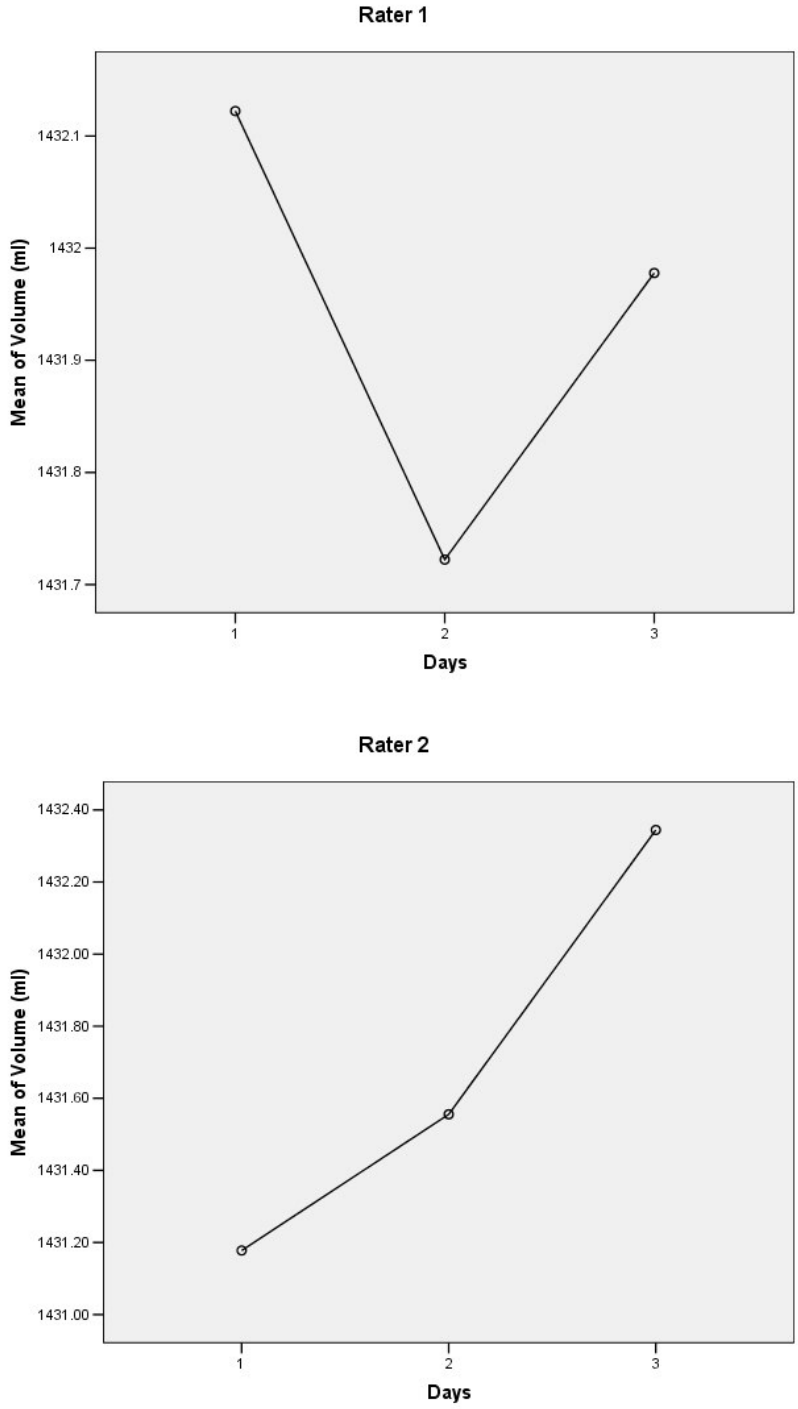


Figure 20: Mean foot/ankle volume variation (ml) for both the raters on three different days (Day1, Day 3 & Day5).

Chapter 6

Discussion

The aim of this study was to investigate the within-day, between-days and between-raters reliability of the foot/ankle water volumetry. The within-day reliability was high (ICC 0.99), as was the between-days reliability (ICC 0.99) and between-raters reliability (ICC 0.99) demonstrating that the volumetric measurement of the foot/ankle using the water volumetry method is highly reliable.

6.1 Analysis of accuracy of apparatus

The Table 8 provides the comparisons of the volumeter accuracy of the current study (Balasundaram *et al.*, 2005) with the other study findings. The accuracy testing conducted in this study demonstrated that the volumeter used in the present study was highly accurate (See Table 8).

Table 8: Comparisons of accuracy values of the volumeters

Studies	*Accuracy values*		
	Percentage error (PE) %	Coefficient of variation (CV) %	Greatest difference between measurements (ml)
Balasundaram, (2005)	0.44	0.10	2.10
Nilsson & Haugen, (1981)	0.80	-	10
Sukul et al., (1993)	-	0.38	10
Van Hamersvelt et al., (1996)	-	0.16	
Brinjer et al., (2000)	-	0.09	

The variables that could affect the accuracy are the volumeter design and the methodology used (Waylett-Rendall & Seibly, 1991). The volumeter designs of different studies have been compared earlier. Although volumeter design was variable between studies, there was little variation in the findings.

The next factor that could affect the accuracy is the testing methodology. The findings of two studies (Brijker et al., 2000; van Hamersvelt et al., 1996) are similar to the current study, the CV values were within the similar range (CV 0.16, 0.9). However, respectively the PE and CV values of two studies (Kaulesar Sukul et al., 1993; Nilsson & Haugen, 1981) were higher indicating lower accuracy when compared to the current study. This is because the displaced water was measured in a graduated cylinder divided into 5ml increments in these two studies (Kaulesar Sukul et al., 1993; Nilsson & Haugen, 1981), thereby making it necessary to round to the nearest 5ml. Whereas, in the other studies the displaced water was weighed accurately on a weighing scale. The approximation of the volume of the displaced water could have caused the variation in these two studies (Kaulesar Sukul et al., 1993; Nilsson & Haugen, 1981).

6.2 Analysis of reliability

In the current study the intra-rater reliability (within-day & between-days) for both the raters and inter-rater reliability between the 2 raters were calculated on three different days. The values of the current study presented along with the findings of the other studies for comparison in the Tables 9 & 10.

6.2.1 Intra-rater reliability within-day

Comparisons of the within-day reliability values with the current study are presented in the Table 9. The ICC values for both the raters (0.99) of the present study agree with those reported by two other studies (Man et al., 2003; Petersen et al., 1999). Further, in the current study findings demonstrated that there were no significant difference ($p > 0.0.5$) between all the trials was similar to the findings of Moholkar & Fenelon, (2001a &b). The absence of significance difference between trials proves that there was no bias between repeated measurements and therefore indicating high reliability.

Table 9: Comparisons of intra-rater reliability within-day values

Study	*Method*	*Reliability values*				
		Systematic bias	Absolute reliability			Relative reliability
			LOA ± (ml)	SEM ± (ml)	CV %	ICC
Balasundaram, (2005)	2 raters Day 1, 3, 5	No bias p>0.05	10	3.5	-	0.99
Petersen et al., (1999)	2 raters	-		17	-	0.98
Man et al., (2004)	2 raters	-	-	-	-	0.99
Moholkar & Fenelon, (2001b)		No bias p>0.05	-	-	-	-
Moholkar & Fenelon, (2001a)		No bias p>0.05	-	-	-	-
Van Hamersvelt et al., (1996)	Volunteer subjects	-	-	-	0.32	-
	Patients	-	-	-	0.28	-
Brijker et al., (1999)		-	-	-	0.47	-
Goldie et al., (1974)		-	-	-	0.30	-

Keys: LOA= 95% Limits of Agreement, SEM=Standard Error of Measurement, CV= Coefficient of Variation ICC=Intraclass Correlation Coefficient

The current study was similar in methodology to the studies of Man et al., (2003) and Moholkar & Fenelon, (2001a, 2001b). However, the key differences were the sample population and the foot positioning. The plantar flexed foot positioning protocol as suggested by Petersen et al., (1999) was used in the current study. The other studies utilized the neutral dorsiflexed positioning (Man et al., 2003; Moholkar & Fenelon, 2001a, 2001b). The sample population in Petersen et al., (1999) was ankle-injured

patients; however, in other studies the foot/ankle volume of healthy volunteers was measured (Man et al., 2003; Moholkar & Fenelon, 2001a, 2001b), as was the case in the current study.

These differences in foot positioning and sample population have not affected the ICC values of these studies (See Table 9). Interpretation of ICC alone could be often misleading, as they remain high even if there was a large absolute error (Atkinson & Nevill, 1998; Hopkins & Palmieri, 2003). For this purpose the present study calculated ICC along with SEM and LOA.

The SEM of the current study was small (±3.5ml) indicating high reliability for this study when compared to Petersen et al., (1999) (SEM = ±17ml). This change in error range is expected because the SEM varies from sample to sample (Morrow & Jackson, 1993). The healthy volunteers in this study could have maintained their foot stable inside the tank during repeated measurements when compared to the ankle injured patients in Petersen et al., (1999). This could be the reason for low SEM during measurements in the current study.

A comparison of this study finding with other studies (Brijker et al., 2000; Goldie et al., 1974; van Hamersvelt et al., 1996) was not possible because they have reported reliability using CV.

6.2.2 Intra-rater reliability between-days

The main objective of this study was to determine the between-days reliability for water volumetry. The between-days reliability values of the current study compared with the other studies are presented in the Table 10.

Table 10: Comparisons of intra-rater reliability between-days values

Study	*Type*	*Reliability values*				
		Systematic bias	Absolute reliability			Relative reliability
			LOA ± (ml)	SEM ± (ml)	CV %	ICC
Balasundaram, (2005)	Days 1, 3, 5 approximately same time 2 raters	No bias p>0.05	20	7	-	0.99
Man et al., (2004)	24 to 48 hrs 4 raters	-	-	-	-	0.99
Goldie et al., (1974)	Same time over 6 weeks 1 rater	-	-	-	0.40	-

Keys: LOA= 95% Limits of Agreement, SEM=Standard Error of Measurement, CV= Coefficient of Variation ICC=Intraclass Correlation Coefficient

Two studies (Goldie et al., 1974; Man et al., 2004) have reported the between-day reliability for the volumetry method (Man et al., 2004 & Goldie et al., 1974). However, comparison with one study (Goldie et al., 1974) is not possible as the finding was reported using CV.

In the study by Man et al., (2004) 4 raters performed bilateral foot volume measurements on 5 healthy subjects. The methodologies of the both studies were similar except for the foot positioning, number of raters and number of subjects measured. Both the studies demonstrated similar ICC results (See Table 10)

In the present study the ICC values were same for both the within-day and between-days reliability measurements (See Table 9 & 10). However the absolute reliability values demonstrated a two-fold increase in the error range for between-day measurements (LOA ±20ml, SEM ±7ml) when compared to the within-day variations (LOA ±10ml, SEM ±3.5ml). This is because the factors contributing to the error may change over the amount of time (Trochim, 2004).The closer the time difference, the smaller the error (within-day), the larger the time gap between repeated measurements the procedure becomes less reliable (Trochim, 2004). This explains the variations in the within-day and between-days reliability measurement.

In comparison to these studies (Goldie et al., 1974; Man et al., 2004) the current study is stronger in the study methodology with a large sample size (n=30) and in reporting of the reliability. To date none of the studies have reported the between-days reliability in absolute reliability indices (LOA & SEM). The LOA and SEM are useful for practical purposes in judging the usefulness of the measurement method or apparatus (Weir, 2005).

6.2.3 Inter-rater reliability

The results of the current study demonstrated an inter-rater reliability of LOA ±13ml, SEM ±5ml and ICC 0.99. This result is in agreement with those reported by Petersen et al., (1999) on injured subjects (ICC=0.99). As mentioned earlier the current study utilised the similar methodology as in Petersen et al., (1999) study. The raters in Petersen et al., (1999) were physiotherapy students with limited experience with performing volumetric measurements similar to this study.

6.3 Statistical considerations

The analysis and reporting of the reliability of volumetry has varied considerably in the previous studies. Earlier studies have analysed either one (Brijker et al., 2000; Goldie et al., 1974; Moholkar & Fenelon, 2001a, 2001b; van Hamersvelt et al., 1996) or two (Petersen et al., 1999) forms of reliability. Weir et al., (2005) have recommended a three-layered approach for a comprehensive analysis of reliability. In recent reliability publications three important components of reliability are measured: systematic bias, absolute reliability, and relative reliability (Hunter *et al.*, 2004). This is the first study that has reported reliability of foot/ankle volumetry in all the three forms of reliability for better perception of the results and for comparison with the other studies.

6.3.1 Systematic bias

Systematic bias provides information about the differences in measurements between repeated tests (Atkinson & Nevill, 1998). However hypothesis testing alone is not accepted as a standard reliability testing procedure, therefore they should be used with additional statistical measures (Bruton et al., 2000). Systematic bias is measured using paired *t*-test or by repeated measures ANOVA. The usefulness of this test measure is that it shows whether there was any learning effect or fatigue between the trials (Atkinson & Nevill, 1998).

6.3.2. Absolute reliability

Absolute reliability is practically useful as it is expressed in actual units of measurement; SEM, CV% and LOA are calculated for absolute reliability. However, Chinn (1991) suggests that CV% should no longer be used as the error percentage

may be misleading during larger observations. The advantage of absolute reliability is that it is not affected by the range of measurements unlike ICC (Atkinson & Nevill, 1998). A smaller SEM means greater reliability (Bruton et al., 2000). The SEM results obtained for this study were 3.5ml (between sessions), 7ml (between-days) for both the raters and 5ml (inter-rater). LOA represents the error or tolerance interval (Chatburn, 1996). However comparison LOA results with other studies is not possible, as no other study has utilized LOA to calculate reliability of foot/ankle volumetry.

6.3.3. Relative reliability

Relative reliability is measured by ICC, which reflects the degree of consistency and agreement among the measurements (Bruton et al., 2000). An ICC value close to 1 indicates excellent reliability (Atkinson & Nevill, 1998). The ICC values for this study were 0.99 for both intra-rater (between measurements & between-days) and inter-rater reliability in all the three days indicating a high reliability. The current study results are in agreement with the ICC values found in three similar studies (Man et al., 2004; Man et al., 2003; Petersen et al., 1999) in the literature.

The main disadvantage of ICC is that it is sensitive to heterogeneity of the sample of participants (Atkinson & Nevill, 1998; Hopkins, 2000); ICC is higher for heterogeneous sample and lower for homogeneous data (Atkinson & Nevill, 1998). This could be possibly misleading because ICC value will be higher even if there is a large absolute error or systematic bias between measurements (Hopkins, 2000; Weir, 2005).

The researchers (Man et al., 2004; Man et al., 2003) often provide the ICC value (0.99) and report that their results are highly reliable, without providing the magnitude of error (error in ml), which forms an useful value for the clinicians/researchers.

6.4 Analysis of biological variation

Biological variations in the subjects may alter the reliability of the procedure by causing random error during repeated measurements (Atkinson & Nevill, 1998). The findings of this study indicated that there was no statistically significant variation in the foot/ankle volume on different days. These results are in agreement with Nilsson & Haugen, (1981) and Brijker et al., (2000) results on uninjured subjects. All possible measures where taken to control the biological variations in this study, the subjects were measured at the same time on different days.

6.5 Limitations of the study

The subjects in the current study were healthy volunteers. The findings of this study may not be directly applicable to ankle injured subjects, as the between-day reliability in ankle injured population has yet to be investigated.

6.6 Summary and conclusion

The purpose of this study was to investigate the between-days reliability and inter-rater reliability for the volumetric measurement of the foot/ankle. This study has demonstrated high reliability both between-days and between-raters for this method in measuring the foot/ankle volume. Therefore this method is suitable for objective evaluation of swelling repeatedly in subjects with ankle injuries. The high inter-rater reliability also shows that there will be consistency with this volumetric procedure

when performed by different raters. The higher reliability was obtained in this study because the foot positioning protocol was easy to administer and the subjects reported no difficulties in sustaining the foot position throughout the evaluation.

This study demonstrates that water volumetry is a simple tool that enables accurate measuring of the foot/ankle volume. This method can be used for examining the effect of an intervention in ankle injury/fracture, or to observe the course of a clinical condition by measuring the foot/ankle volume, such as cardiovascular or renal disease.

6.7 Implications of the study results

Ankle injuries are common injuries both in the sporting and in the normal population. Currently research is being undertaken extensively to find an effective intervention for early return to sport and to normal functional level. Among the available clinical outcome tools the researchers look for a highly reliable tool to measure the change in volume repeatedly to identify the effect of an intervention. Considering the need for a highly reliable procedure, this study results demonstrate that the volumetric procedure is a reliable objective tool for the clinicians/researchers who are interested in measuring foot/ankle volume accurately to estimate the magnitude of volume difference in the response to treatment. The high reliability can be achieved by following the same methodology of this study, however accepting that there will be an error of ±3.5ml (SEM) during repeated measurements within the day and ±7ml (SEM) variation during repeated measurements on different days. The error range of this measurement procedure is less when compared with the other studies. Further, the ICC results of this study are useful for estimation of sample size for a foot/ankle

injury intervention study, which follows the similar volumetry methodology and include swelling as an outcome measure.

6.8 Implications for future research

The size of the reduction in ankle swelling in subjects with ankle pathologies needed for a clinically significant change in swelling is still under examination. This size of change in ankle volume would be of benefit both for the physiotherapists in every day practice and for the researchers conducting ankle injuries interventions studies. Therefore future studies need to be performed to determine the relation between swelling and the functional level in subjects with ankle pathologies. This will justify the need for a highly reliable procedure to accurately measure the clinically meaningful volume change in subjects with ankle swelling.

APPENDICES

Appendix 1: Checklist for reliability studies

Checklist for reliability study		
Study details (1st author, year, title, journal, vol. Issue, pg. no.)		
Evaluation criteria		How well were the criteria addressed
Reliability estimate	1. Aim of the reliability study: to measure	
	Instrumental reliability:	
	Reliability of the measurement device	
	Reliability of the rater:	
	Intra or inter-rater?	
	Sufficient details on raters?	
Methodology	2. Study design	
	Was the design explained?	
	Participants	
	Sample size	
	Was justification for sample size provided?	
	Is the population defined properly? (e.g., age, gender etc.,)	
	3. Procedures	
	Were the measurement procedures explained in detail?	
	Number of trials?	
	Were the raters blinded to each other measurements? (inter-rater)	
Statistical analysis of reliability	4. Reliability measures	
	Were combined statistical measures of reliability used?	
	What were the reliability indices used? (Hypothesis, relative, absolute reliability)	
	5. Hypothesis testing:	
	Paired t-test	
	ANOVA	
	6. Relative reliability:	
	Correlation coefficient: Pearson's, Intraclass (ICC)	
	Type of ICC used?	
	(1,1) One-way single measure	
	(1,k) One-way single & average measure	
	(2,1) Two-way random effects model single measure	
	(2,1) Two-way random effects model single measure	
	(2,k) Two-way random effects model average measure	
	(3,1) Two-way mixed effects model single measure	
	(3,k) Two-way mixed effects model average measure	
	Method: Absolute agreement or Consistency	
	7. Absolute reliability:	
	Standard error of measurement	
	Coefficient of variation	
	Bland & Altman 95% limits of agreement	
	Repeatability coefficient	
	Any other statistical methods?	
	Were all participants considered for analysis?	
	Was there any loss in the retest phase?	
	What was the % of loss?	
	Was the loss sufficient enough to cause bias?	
Results	8. Were the results reported properly? (clear & scientific presentation; type of reliability statistic & ICC model & number of trials given, details about variance between participants if correlation was used (Heterogeneous/Homogenous)	
Conclusion	What were the study's conclusions? Instrument/Method/Rater reliable (low/medium/high) & practical use of the instrument/method etc.,	

Appendix 2.1: Ethical considerations

This study was part of a larger study which aimed to investigate the physiotherapy management of acute ankle sprains. The ankle swelling was the primary outcome measure of the larger study in which the swelling was measured repeatedly using the water volumetry method as described in the present study. The ethical approval was obtained (See Appendix 2.1.1) for the larger study, and the consent form and information sheet were approved by the ethics committee (See Appendix 2.1.2 & See Appendix 2.1.3). Similar ethical principles were applied for this present study which included healthy volunteers without any ankle injuries.

Appendix 2.1.1: Ethical approval

Auckland
Ethics Committees

Private Bag 92522
Wellesley Street
Auckland
Delivery Address:
C/O Ministry of Health
3rd Floor, Unisys Building
650 Great South Road, Penrose
Fax (09) 580 9001

Please include the reference no. and study Title in all correspondence/telephone calls.

14th May 2004

Jeyakhanthan Balasundaram,
1/25 Don Croot Street,
Morningside,
Kingsland,
Auckland.

Dear Jeyakhanthan,

Title: Physiostherapy management of acute ankle sprain. PIS/Consent V#3 14/05/2004
Ethics ref: AKY/04/04/082

Thank you for your amendments, received 14th May 2004.

The above study has been given ethical approval by Auckland Ethics Committee Y. Approval is conditional on the Committee being advised when the study is completed.

Certification
It is certified as not being conducted principally for the benefit of the manufacturer and may be considered for coverage under ACC.

Accreditation
This Committee is accredited by the Health Research Council and is constituted and operates in accordance with the Operational Standard for Ethics Committees, March 2002.

Documents Approved:

- Participant Information Sheet — Version # 3 14/05/2004
- Consent Form — Version # 3 14/05/2004
- Advertisement
- Patient Diary
- Questionnaire

It should be noted that Ethics Committee approval does not imply any resource commitment or administrative facilitation by any healthcare provider, within whose facility the research is to be carried out. Where applicable, authority for this must be obtained separately from the appropriate manager within the organisation.

Progress Reports
The study is approved until 31st December 2004. *If this study is not completed by the approved date the researcher must approach the Committee for an extension of approval.*

A final report is also required at the conclusion of the study.

...2

Requirements for SAE Reporting
Please advise the Committee as soon as possible of the following:

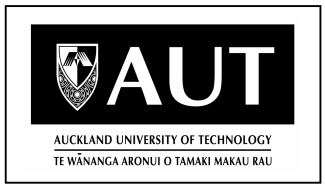
- any study in another country that has stopped due to serious or unexpected adverse events
- withdrawal of investigational product for continued development
- withdrawal from the market for any reason
- all serious adverse events which result in the investigator or sponsor breaking the blinding code at the time of the SAE or which result in hospitalisation or death.

Amendments
All amendments to the study must be advised to the Committee prior to their implementation, except in the case where immediate implementation is required for reasons of safety. In such cases the Committee must be notified as soon as possible of the change.

Yours sincerely,

Diana Yukich
Administrator, Committee Y.

Appendix 2.1.2: Consent form
CONSENT FORM



Title of Project: **The effect *physiotherapy* has on the healing and time to recovery of ankle sprains.**

Project Supervisor: **Wayne Hing.**

Researcher: **Jeyakhanthan Balasundaram.**

- I understand the information that has been given to me and confirm having read the Information for Participants form, for all volunteers taking part in the study on **'**The effect physiotherapy have on the healing and time to recovery of ankle sprains'.
- I have had the opportunity to discuss this study and I am satisfied with the answers that have been given.
- I understand that taking part in this study is voluntary and that I can withdraw at any time without giving reasons and without being disadvantaged in any way. This includes withdrawal of any identifiable information provided at any time prior to the completion of data gathering.
- I …….. (Full name) hereby consent/agree to take part in this study.
- I would like to be sent a summary of the results of the research YES/NO

Participant signature: .....

Date: .....

Project Supervisor Contact Details:

Wayne Hing, School of Physiotherapy, Auckland University of Technology, Tel (09) 917 9999 (x7800), wayne.hing@aut.ac.nz

Or

Jeyakhanthan Balasundaram, Mobile no:021-2172959, jeyakhanthan@hotmail.com.

This study has been approved by the Auckland Ethics Committees on 14th May 2004, until 31st December 2004. Reference no: AKY/04/04/082

Appendix 2.1.3: Information sheet
INFORMATION SHEET

Title of Project: **The effect of *physiotherapy* on the healing and time to recovery of acute ankle sprains.**

Project Supervisor: **Wayne Hing.**

Researcher: **Jeyakhanthan Balasundaram.**

You are invited to take part in a project which will study the effects of *physiotherapy* on the healing process and time to recovery of ankle sprains.

You are asked to read this information sheet before deciding whether or not to accept this invitation.

This research is being conducted by Jeyakhanthan Balasundaram, Master of Health science candidate, Auckland University of Technology under the supervision of Wayne Hing from the School of Physiotherapy, Auckland University of Technology.

Your rights

Your participation is voluntary and can be declined without giving a reason or being disadvantaged in any way. If you accept, you may withdraw yourself or any personal information that you have provided at any time (before data collection is completed) without giving any reason for your withdrawal and without penalty of any sort. All information obtained during this study is confidential will only be identified by a code number known only by the investigators. You will not be identified in any publication resulting from this study.

Information on the Study

Aim:

The aim of this study is to establish if physiotherapy shortens the time of an acute ankle injury, and therefore allow patients to get back to normal daily life faster than standard first aid advise as recommended by the Accident Compensation Corporation.

Protocol:

The study will be carried out at the Auckland University of Technology and participating Physiotherapy Clinics in the North Harbour area. You will complete an 'Initial Ankle Assessment' prior to starting any particular treatment.

The 'Initial Ankle Assessment' consists of an initial clinical evaluation to make sure the injury was due to a mechanical injury and to exclude participants with any additional complicating injuries (i.e., fractures). The injured ankle will be reassessed after 6 days so that it can be correctly graded. To make sure the grading is consistent and reliable two testers, who have both received the same training and who are consistent with the testing techniques, will perform all the clinical assessments.

All the participants will receive the same general advice about the Rest, Ice, Compression, and Elevation (= R.I.C.E.) treatment protocol. You may also take medication such as ibuprofen or panadol for pain relief and as an anti-inflammatory if

you wish to do so. You will be asked to record how many tablets a day you have taken in a supplied diary.

Eligible participants will be randomly allocated, to one of the following two treatment groups.

The *physiotherapy ankle group* will receive 20 minutes of standard physiotherapy treatment on alternate days over the course of a week.

The *control physiotherapy ankle (R.I.C.E.) group* will just receive the standard advice regarding R.I.C.E.

Ankle evaluation: Before the first, the third, the seventh and the eleventh treatment you will receive the same standard evaluation consisting of: 1) An assessment of the volume of the foot and ankle using the water volumetric method (water bath) and 2) an ankle score questionnaire. These two tests will both be repeated one last time on day twenty-four. The participants must also complete a visual assessment scale of perceived pain before each treatment and again one last time on day twenty-four.

You will be asked to write in the supplied diary to what extent you have followed up the medical advice given. The purpose of this is to see if there is any difference between those who are compliant and those who aren't as it may have consequences for the treatment provided. All treatments will be stopped after the 6th treatment. All participants, regardless of which treatment group they were in, will be given the option after day eleven to either receive a further five sessions of physiotherapy or to stop all forms of further treatment.

Time commitment & Travel requirement:
If you participate in this study, your involvement will amount to either approximately 5 hours over a period of 10 days depending on which 'treatment' group you are randomly allocated to.

- For the physiotherapy treatment group:

An initial 1 & 1/2-hour assessment and treatment session followed by 5 sessions of treatment and assessment (approx. one hour), and a final thirty minutes evaluation on day twenty-four.

- For the control physiotherapy ankle (R.I.C.E.) group:

An initial 1 & 1/2-hour assessment and advice followed by 3 sessions of assessment (approx. one hour), and a final thirty minutes evaluation on day twenty-four.

The ankle evaluation will be done at the AUT research lab by the principal investigator. All the participants are required to travel to AUT for all the assessment

sessions for which the travel allowance will be provided. The physiotherapy treatments will be provided free of cost by the physiotherapists at the particular physiotherapy clinics from which the participants are recruited. All the participants will also receive ice pack and compression bandages at no cost.

Risks of the study:
There are minimal risks associated with participation in this study and these will be fully explained to you prior to any participation. Participants will be screened with a medical questionnaire and will be excluded if they have any of the following: fracture, previously sustained sprains to the same ankle, and general health problems that will slow down the normal healing processes.

Compensation:
In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act. ACC cover is not automatic and your case will need to be assessed by ACC according to the provisions of the 2002 Injury Prevention Rehabilitation and Compensation Act. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators.

If you have any questions about ACC, contact your nearest ACC office or the investigator.

Benefits of the study:
Your involvement in this study will allow us to establish whether physiotherapy shorten the time to recovery. This information will allow us to confirm if the current standard treatment is indeed the most effective treatment or if maybe needs to be improved. Potential faster return to working activities in association with information on the cost benefits of the treatment types will be gained from the study.

All the participants will receive a summary of the final results.

Contacts:
If you are willing to participate or you have any questions and wish to discuss anything to do with this study, before or during the study, please contact either:

Wayne Hing, School of Physiotherapy, Auckland University of Technology, Tel (09) 917 9999 (x7800), wayne.hing@aut.ac.nz (or)

Jeyakhanthan Balasundaram, Mobile no:021-2172959, jeybal99@aut.ac.nz

For any concerns regarding the ethical nature or conduct this Study, please contact Madeline Banda, the Secretary of the Auckland University of Technology Ethics Committee, on (09) 917 9999 (x 8044), madeline.banda@aut.ac.nz

If you have any queries or concerns regarding your rights as a participant in this study you may wish to contact a Health Advocacy Trust number, Phone: 0800 555 050

This study has been approved by the Auckland Ethics Committees on 14th May 2004, until 31st December 2004. Reference no: AKY/04/04/082

Appendix 3: Random order table

Random order for volumetric measurement for both raters created using SPSS

SUBJECT	RATER	SUBJECT	RATER	SUBJECT	RATER	SUBJECT	RATER
1	RATER-1	26	RATER-2	51	RATER-1	76	RATER-2
2	RATER-2	27	RATER-1	52	RATER-2	77	RATER-2
3	RATER-2	28	RATER-2	53	RATER-1	78	RATER-1
4	RATER-1	29	RATER-1	54	RATER-2	79	RATER-1
5	RATER-1	30	RATER-2	55	RATER-2	80	RATER-2
6	RATER-2	31	RATER-2	56	RATER-1	81	RATER-1
7	RATER-1	32	RATER-1	57	RATER-1	82	RATER-2
8	RATER-2	33	RATER-2	58	RATER-2	83	RATER-2
9	RATER-1	34	RATER-1	59	RATER-2	84	RATER-1
10	RATER-2	35	RATER-1	60	RATER-1	85	RATER-1
11	RATER-2	36	RATER-2	61	RATER-1	86	RATER-2
12	RATER-1	37	RATER-2	62	RATER-2	87	RATER-2
13	RATER-2	38	RATER-1	63	RATER-1	88	RATER-1
14	RATER-1	39	RATER-1	64	RATER-2	89	RATER-2
15	RATER-1	40	RATER-2	65	RATER-2	90	RATER-1
16	RATER-2	41	RATER-1	66	RATER-1	91	RATER-2
17	RATER-2	42	RATER-2	67	RATER-2	92	RATER-1
18	RATER-1	43	RATER-1	68	RATER-1	93	RATER-1
19	RATER-2	44	RATER-2	69	RATER-2	94	RATER-2
20	RATER-1	45	RATER-1	70	RATER-1	95	RATER-1
21	RATER-1	46	RATER-2	71	RATER-2	96	RATER-2
22	RATER-2	47	RATER-1	72	RATER-1	97	RATER-1
23	RATER-2	48	RATER-2	73	RATER-1	98	RATER-2
24	RATER-1	49	RATER-2	74	RATER-2	99	RATER-1
25	RATER-1	50	RATER-1	75	RATER-1	100	RATER-2

Appendix 4: Results & statistical analysis

Table 4.1: Volumetric measurements of the subjects foot/ankle volume (ml) by rater 1 at 3 different days

Subject	Day1			Day3			Day5		
	Trial 1	Trial 2	Trial 3	Trial 1	Trial 2	Trial 3	Trial 1	Trial 2	Trial 3
1	1484	1475	1477	1478	1473	1482	1483	1480	1488
2	1635	1633	1624	1640	1651	1644	1642	1638	1644
3	1337	1328	1332	1335	1340	1332	1331	1336	1336
4	1279	1277	1285	1281	1277	1272	1291	1283	1281
5	1360	1355	1348	1356	1357	1358	1357	1360	1359
6	1386	1389	1382	1390	1384	1390	1391	1395	1389
7	1609	1608	1615	1604	1609	1609	1606	1609	1611
8	1311	1321	1319	1313	1312	1312	1313	1315	1312
9	1210	1215	1214	1212	1216	1221	1228	1220	1218
10	1523	1527	1527	1521	1526	1527	1527	1529	1526
11	1475	1474	1473	1482	1476	1479	1486	1481	1481
12	1242	1254	1251	1240	1235	1239	1258	1259	1258
13	1428	1428	1432	1440	1443	1442	1442	1440	1448
14	1523	1520	1522	1507	1510	1512	1510	1514	1511
15	1720	1724	1728	1714	1719	1722	1726	1721	1722
16	1322	1328	1325	1345	1340	1343	1338	1335	1335
17	1209	1206	1208	1220	1212	1216	1201	1200	1203
18	1540	1544	1543	1543	1537	1544	1530	1532	1538
19	1680	1672	1672	1666	1672	1672	1660	1666	1662
20	1640	1640	1640	1646	1649	1643	1642	1645	1641
21	1545	1542	1548	1539	1546	1541	1530	1530	1532
22	1654	1661	1662	1662	1657	1660	1666	1662	1664
23	1291	1301	1300	1295	1292	1298	1296	1297	1297
24	1372	1372	1371	1348	1350	1354	1353	1357	1360
25	1194	1200	1197	1200	1202	1193	1191	1185	1190
26	1463	1470	1471	1481	1475	1474	1470	1470	1473
27	1240	1241	1244	1241	1252	1244	1259	1251	1246
28	1431	1434	1430	1419	1414	1420	1430	1435	1433
29	1347	1346	1343	1321	1329	1331	1330	1328	1331
30	1491	1490	1492	1496	1499	1492	1481	1472	1476

Table 4.2: Volumetric measurements of the subjects foot/ankle volume (ml) by rater 2 at 3 different days

Subject	Day1			Day3			Day5		
	Trial 1	Trial 2	Trial 3	Trial 1	Trial 2	Trial 3	Trial 1	Trial 2	Trial 3
1	1490	1479	1470	1481	1470	1476	1473	1481	1477
2	1627	1630	1623	1631	1632	1641	1631	1632	1628
3	1330	1331	1323	1334	1337	1342	1323	1326	1331
4	1280	1275	1278	1281	1271	1278	1276	1285	1260
5	1352	1356	1365	1360	1355	1362	1364	1359	1361
6	1372	1384	1375	1386	1390	1392	1387	1389	1389
7	1614	1618	1617	1614	1609	1608	1611	1609	1608
8	1320	1312	1314	1313	1311	1314	1311	1311	1310
9	1201	1205	1211	1215	1218	1215	1211	1213	1213
10	1530	1529	1530	1530	1534	1528	1522	1519	1523
11	1490	1477	1474	1476	1477	1477	1491	1494	1488
12	1259	1258	1257	1252	1256	1254	1257	1255	1257
13	1420	1425	1427	1441	1444	1442	1448	1445	1441
14	1515	1520	1518	1507	1508	1510	1517	1516	1514
15	1725	1724	1723	1723	1722	1725	1728	1730	1724
16	1311	1318	1323	1338	1342	1340	1338	1335	1339
17	1213	1208	1214	1216	1215	1216	1207	1205	1205
18	1539	1540	1538	1539	1529	1530	1537	1542	1542
19	1675	1673	1672	1674	1682	1676	1681	1673	1677
20	1637	1641	1642	1641	1644	1642	1645	1632	1648
21	1538	1537	1545	1533	1538	1534	1535	1531	1530
22	1646	1652	1656	1659	1658	1662	1660	1664	1661
23	1290	1289	1292	1284	1279	1285	1291	1292	1294
24	1374	1381	1377	1355	1353	1353	1359	1358	1358
25	1200	1200	1202	1191	1195	1194	1203	1195	1208
26	1473	1472	1471	1477	1479	1476	1471	1478	1475
27	1237	1238	1238	1247	1243	1245	1247	1246	1249
28	1420	1423	1427	1415	1413	1417	1439	1441	1435
29	1349	1343	1347	1338	1336	1337	1331	1331	1331
30	1497	1501	1494	1489	1495	1494	1485	1483	1486

Table 4.3 Absolute error (ml) & Percentage error for each trial

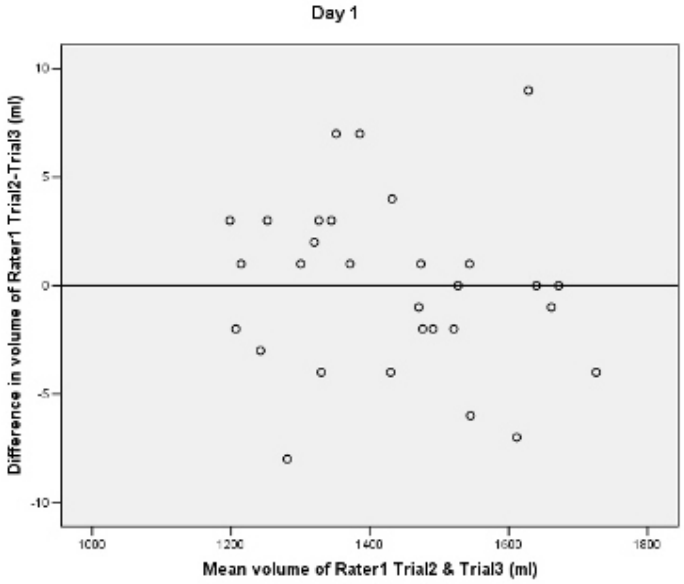
Trial	Immersed object volume (ml)	Displaced volume (ml)	Absolute error (ml)	Percentage error %
1	1110	1109.70	0.30	0.03
2	1110	1108.23	1.77	0.16
3	1110	1108.90	1.10	0.10
4	1110	1110.47	-0.47	-0.04
5	1110	1110.57	-0.57	-0.05
6	1110	1108.75	1.25	0.11
7	1110	1110.88	-0.88	-0.08
8	1110	1108.16	1.84	0.17
9	1110	1110.17	-0.17	-0.02
10	1110	1111.72	-1.72	-0.15
11	1110	1109.65	0.35	0.03
12	1110	1110.20	-0.20	-0.02
13	1110	1108.18	1.82	0.16
14	1110	1110.91	-0.91	-0.08
15	1110	1107.94	2.06	0.19
16	1110	1109.80	0.20	0.02
17	1110	1110.37	-0.37	-0.03
18	1110	1107.90	2.10	0.19
19	1110	1109.66	0.34	0.03
20	1110	1108.97	1.03	0.09
Mean± SD		1109.56 ± 1.13	0.44 ± 1.13	0.04 ± 0.10

Table 4.4 Paired samples *t*-test results between trials within day, between days for both the raters (Rater1 R1 & Rater2 R2) and between raters (R1 & R2) on all the 3 days

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	R1Day1Trial1 - R1Day1Trial2	-1.190	5.286	.965	-3.164	.783	-1.234	29	.227
Pair 2	R1Day1Trial2 - R1Day1Trial3	.068	3.950	.721	-1.407	1.543	.094	29	.926
Pair 3	R1Day1Trial1 - R1Day1Trial3	-1.122	5.784	1.056	-3.282	1.037	-1.063	29	.297
Pair 4	R1Day3Trial1 - R1Day3Trial2	-.699	5.597	1.022	-2.789	1.391	-.684	29	.500
Pair 5	R1Day3Trial2 - R1Day3Trial3	-.417	5.132	.937	-2.333	1.499	-.445	29	.660
Pair 6	R1Day3Trial1 - R1Day3Trial3	-1.116	4.904	.895	-2.947	.716	-1.246	29	.223
Pair 7	R1Day5Trial1 - R1Day5Trial2	.789	4.523	.826	-.900	2.477	.955	29	.347
Pair 8	R1Day5Trial2 - R1Day5Trial3	-.635	3.795	.693	-2.053	.782	-.917	29	.367
Pair 9	R1Day5Trial1 - R1Day5Trial3	.153	4.981	.909	-1.707	2.013	.169	29	.867
Pair 10	R2Day1Trial1 - R2Day1Trial2	-.422	5.438	.993	-2.452	1.609	-.425	29	.674
Pair 11	R2Day1Trial2 - R2Day1Trial3	-.220	4.813	.879	-2.017	1.577	-.250	29	.804
Pair 12	R2Day1Trial1 - R2Day1Trial3	-.641	7.262	1.326	-3.353	2.070	-.484	29	.632
Pair 13	R2Day3Trial1 - R2Day3Trial2	.196	4.777	.872	-1.588	1.980	.225	29	.824
Pair 14	R2Day3Trial2 - R2Day3Trial3	-1.065	3.840	.701	-2.499	.369	-1.519	29	.140
Pair 15	R2Day3Trial1 - R2Day3Trial3	-.869	3.812	.696	-2.293	.555	-1.248	29	.222
Pair 16	R2Day5Trial1 - R2Day5Trial2	.217	4.844	.884	-1.592	2.025	.245	29	.808
Pair 17	R2Day5Trial2 - R2Day5Trial3	.183	6.744	1.231	-2.335	2.702	.149	29	.883
Pair 18	R2Day5Trial1 - R2Day5Trial3	.400	4.418	.807	-1.250	2.050	.496	29	.624
Pair 19	R1Day1Trial1 - R1Day3Trial1	.211	10.878	1.986	-3.851	4.273	.106	29	.916
Pair 20	R1Day1Trial2 - R1Day3Trial2	.703	10.234	1.869	-3.119	4.524	.376	29	.710
Pair 21	R1Day1Trial3 - R1Day3Trial3	.218	8.931	1.631	-3.117	3.553	.133	29	.895

Pair 22	R1Day3Trial1 - R1Day5Trial1	-1.194	9.536	1.741	-4.754	2.367	-.686	29	.498
Pair 23	R1Day3Trial2 - R1Day5Trial2	.294	10.434	1.905	-3.602	4.190	.154	29	.879
Pair 24	R1Day3Trial3 - R1Day5Trial3	.075	7.230	1.320	-2.624	2.775	.057	29	.955
Pair 25	R1Day1Trial1 - R1Day5Trial1	-.983	11.399	2.081	-5.239	3.274	-.472	29	.640
Pair 26	R1Day1Trial2 - R1Day5Trial2	.996	8.621	1.574	-2.223	4.215	.633	29	.532
Pair 27	R1Day1Trial3 - R1Day5Trial3	.293	9.202	1.680	-3.143	3.729	.174	29	.863
Pair 28	R2Day1Trial1 - R2Day3Trial1	-.541	10.382	1.895	-4.418	3.335	-.286	29	.777
Pair 29	R2Day1Trial2 - R2Day3Trial2	.076	10.161	1.855	-3.718	3.870	.041	29	.967
Pair 30	R2Day1Trial3 - R2Day3Trial3	-.769	10.054	1.836	-4.523	2.985	-.419	29	.678
Pair 31	R2Day3Trial1 - R2Day5Trial1	-1.194	7.749	1.415	-4.088	1.700	-.844	29	.406
Pair 32	R2Day3Trial2 - R2Day5Trial2	-1.173	9.903	1.808	-4.871	2.525	-.649	29	.521
Pair 33	R2Day3Trial3 - R2Day5Trial3	.075	7.964	1.454	-2.899	3.049	.052	29	.959
Pair 34	R2Day1Trial1 - R2Day5Trial1	-1.735	11.668	2.130	-6.092	2.621	-.815	29	.422
Pair 35	R2Day1Trial2 - R2Day5Trial2	-1.097	10.565	1.929	-5.042	2.848	-.569	29	.574
Pair 36	R2Day1Trial3 - R2Day5Trial3	-.694	9.699	1.771	-4.316	2.928	-.392	29	.698
Pair 37	R1Day1Trial1 - R2Day1Trial1	.586	8.001	1.461	-2.402	3.573	.401	29	.691
Pair 38	R1Day1Trial2 - R2Day1Trial2	1.354	5.976	1.091	-.877	3.586	1.241	29	.224
Pair 39	R1Day1Trial3 - R2Day1Trial3	1.067	5.687	1.038	-1.057	3.190	1.027	29	.313
Pair 40	R1Day3Trial1 - R2Day3Trial1	-.167	7.062	1.289	-2.804	2.470	-.129	29	.898
Pair 41	R1Day3Trial2 - R2Day3Trial2	.728	7.535	1.376	-2.086	3.542	.529	29	.601
Pair 42	R1Day3Trial3 - R2Day3Trial3	.080	5.820	1.063	-2.093	2.253	.075	29	.941
Pair 43	R1Day5Trial1 - R2Day5Trial1	-.167	8.436	1.540	-3.317	2.983	-.108	29	.914
Pair 44	R1Day5Trial2 - R2Day5Trial2	-.739	6.830	1.247	-3.289	1.811	-.593	29	.558
Pair 45	R1Day5Trial3 - R2Day5Trial3	.080	7.791	1.422	-2.830	2.989	.056	29	.956

Figure 4.1: Bland & Altman's plot for intra-rater reliability within-day for both the rater 1 on day 1



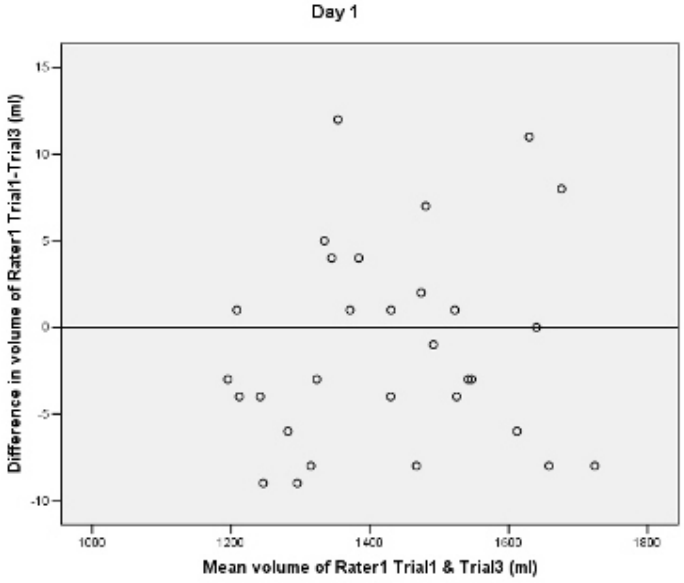
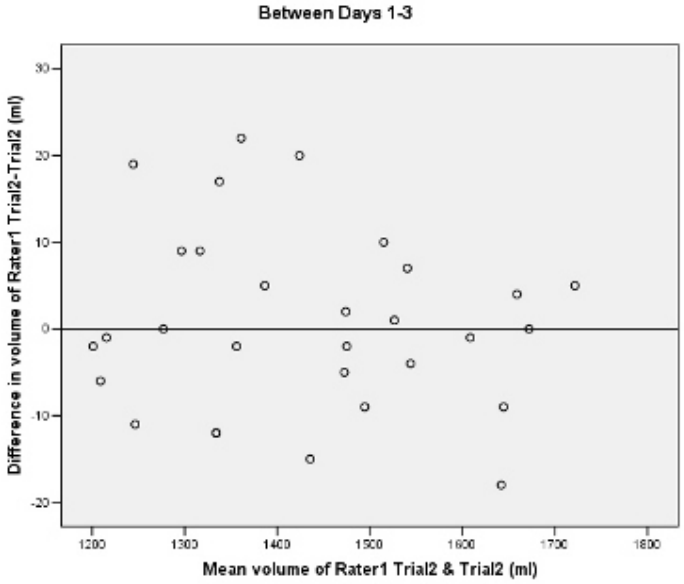


Figure 4.2: Bland & Altman's plot for intra-rater reliability between-days for raters 1



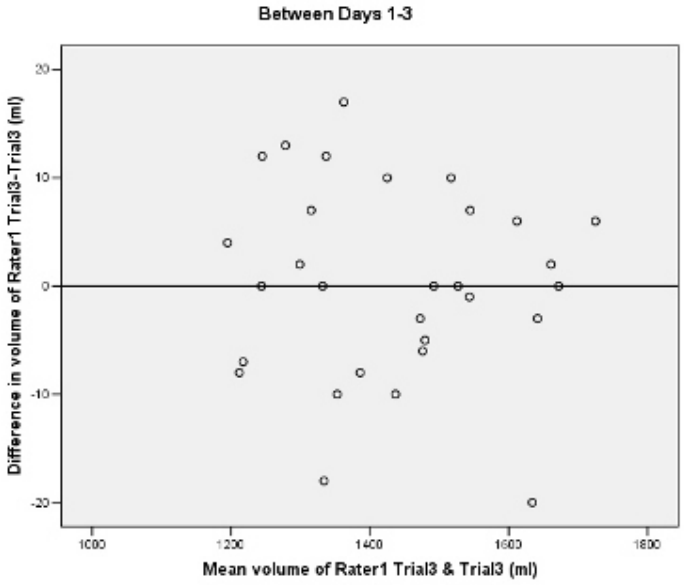
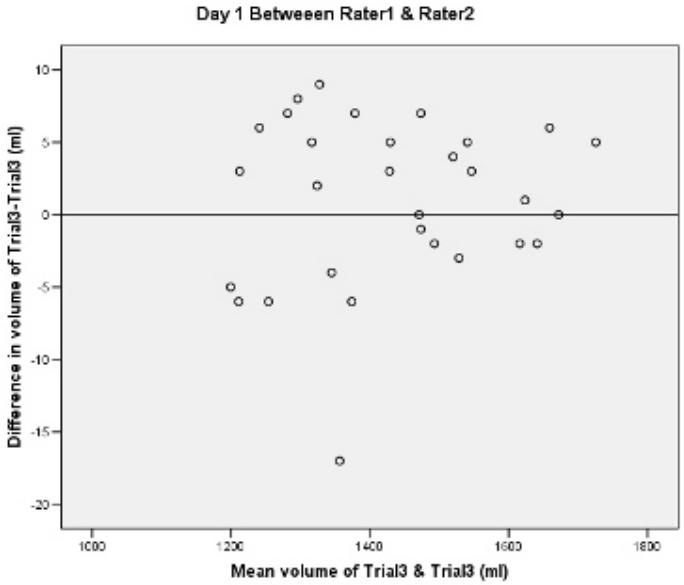
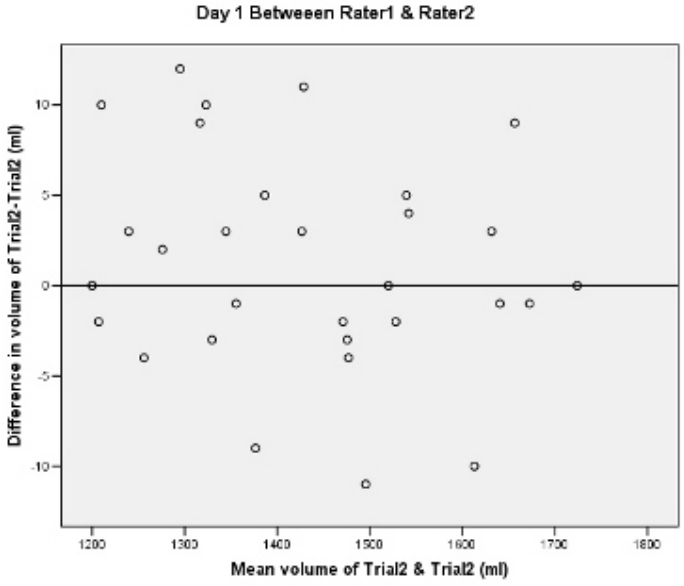


Figure 4.3: Bland & Altman's plot for inter-rater reliability between both the raters day 1





References

Accident Compensation Corporation. (2002). *Managing soft tissue ankle injuries: A summary of recent research*. New Zealand.

Airaksinen, O., Kolari, P., & Miettinen, H. (1990). Elastic bandages and intermittent pneumatic compression for treatment of acute ankle sprains. *Archives of Physical Medicine and Rehabilitation, 71*(6), 380-383.

Airaksinen, O., Partanen, K., Kolari, P. J., & Soimakallio, S. (1991). Intermittent pneumatic compression therapy in posttraumatic lower limb edema: Computer tomography and clinical measurements. *Archives of Physical Medicine and Rehabilitation, 72*, 667-670.

Alexandrou, A. (2001). *Principles of fluid mechanics* (1 ed.). New Jersey: Prentice-Hall Inc.

Almedia, S. A., Williams, K. M., Shaffer, R. A., & Brodine, S. K. (1999). Epidemological patterns of musculoskeletal injuries and physical training. *Medicine and Science in sports and Exercise, 31*(8), 1176-1182.

Altman, D. G., & Bland, J. M. (1999). How to randomise. *British Medical Journal, 319*, 703–704.

Andersson, S., Fredin, H., Lindberg, H., Sanzen, L., & Westlin, N. (1983). Ibuprofen and compression bandage in the treatment of ankle sprains. *Acta Orthopaedica Scandinavica, 54*(2), 322-325.

Atkinson, G., & Nevill, A. M. (1998). Statistical methods for assessing measurement error (reliability) in variables relevant to sports medicine. *Sports Medicine, 26*(4), 217-238.

Balasundaram, J., Hing, W., & Reid, D. (2005). *The reliability of foot and ankle water volumetry.* Unpublished Thesis, Auckland University of Technology, Auckland.

Bednarczyk, J. H., Hershler, C., & Cooper, D. G. (1992). Development and clinical evaluation of a computerized limb volume measurement system. *Archives of Physical Medicine and Rehabilitation, 73*, 60-63.

Berard, A., Kurz, X., & Zuccarelli, F. (1998). Reliability study of the leg-o-meter, an improved tape measure device, in patients with chronic venous insufficiency of the leg. *Angiology, 49*(169-173).

Berard, A., Xavier, K., Zuccarelli, F., & Abenhaim, L. (2002). Validity of the leg-o-meter, an instrument to measure leg circumference. *Angiology, 53*(1), 21-28.

Berard, A., & Zuccarelli, F. (2000). Test-retest reliability study of a new improved leg-o-meter ii, in patients suffering from venous insufficiency of the lower limbs. *Angiology, 51*(9), 711-717.

Bridgman, S. A., Clement, D., Downing, A., Walley, G., Phair, I., & Maffulli, N. (2003). Population based epidemiology of ankle sprains attending accident and emergency units in the west midlands of England, and a survey of UK practice for severe ankle sprains. *Emergency Medicine Journal, 20*(6), 508-510.

Brijker, F., Heijdra, Y. F., van den Elshout, F. J., Bosch, F. H., & Folgering, H. T. (2000). Volumetric measurements of peripheral oedema in clinical conditions. *Journal of Clinical Physiology, 20*(1), 56-61.

Brune, K., Rainsford, K. D., Wagner, K., & Peskar, B. A. (1981). Inhibition by anti-inflammatory drugs of prostaglandin production in cultured macrophages. *Archives of Pharmacology, 36*, 269-278.

Bruton, A., Conway, J. H., & Holgate, S. T. (2000). Reliability: What is it, and how is it measured. *Physiotherapy, 86*(2), 94-99.

Busse, J. W., Bhandari, M., Kulkarni, A. V., & Tunks, E. (2002). The effect of low-intensity pulsed ultrasound therapy on time to fracture healing: A meta-analysis. *Canadian Medical Association Journal, 166*(4), 437-441.

Chalk, J. P., McPoil, T., & Cornwall, M. W. (1995). Variations in foot volume before and after exercise. *Journal of the American Podiatric Medical Association, 85*(9), 470-472.

Chatburn, R. L. (1996). Evaluation of instrument error and method agreement. *The Journal of the American Association of Nurse Anesthetists, 64*(3), 261-268.

Cheah, L. H., Parkin, A., Gilson, P., Elliot, S., & Hall, A. J. (1989). Limb volume measurements in peripheral arterial disease. *Clinical Physical and Physiological Measures, 10*, 75-79.

Chinn, S. (1991). Repeatability and method comparison. *Thorax, 46*(6), 454-456.

Cloughley, W. B., & Mawdsley, R. H. (1995). Effect of running on volume of foot and ankle. *Journal of Orthopaedic and Sports Physical Therapy, 22*(4), 151-152.

Cote, D. J., Prentice, W. E., Hooker, D. N., & Shields, E. W. (1988). Comparison of three treatment procedures for minimizing ankle sprain swelling. *Physical Therapy, 68*(7), 1072-1076.

Cromer, A. H. (1997). *Physics for the life sciences* (2 ed.). New York: McGraw Hill.

de Bie, R. A., de Vet, H. C. W., Lenssen, T. F., van den Wildenberg, F. A. J. M., Kootstra, G., & Knipschild, P. G. (1998). Low-level laser therapy in ankle sprains: A randomized clinical trial. *Archives of Physical Medicine and Rehabilitation, 79*(11), 1415-1420.

Delforge, G. (2002). *Musculoskeletal trauma: Implications for sports injury management*. Illinois: Human kinetics.

Eiff, M. P., & Smith, A. T. (1994). Early mobilization versus immobilization in the treatment of lateral ankle sprains. *American Journal of Sports Medicine, 22*(1), 83-88.

Ekstrand, J., & Tropp, H. (1990). The incidence of ankle sprains in soccer. *Foot and Ankle International, 11*(1), 41-44.

Eliasziw, M., Young, S. L., Woodbury, M. G., & Fryday-Field, K. (1994). Statistical methodology for the concurrent assessment of interrater and intrarater reliability: Using goniometric measurements as an example. *Physical Therapy, 74*(8), 777-788.

Esterson, P. S. (1979). Measurement of ankle joint swelling using a figure of eight. *Journal of Orthopaedic and Sports Physical Therapy, 1*(1), 51-52.

Gabbe, B., & Finch, C. (2001). A profile of Australian football injuries presenting to sports medicine clinics. *Journal of Science and Medicine in Sport, 4*(4), 386-395.

Gerber, J. P., Williams, G. N., Scoville, C. R., Arciero, R. A., & Taylor, D. C. (1998). Persistent disability associated with ankle sprains: A prospective examination of an athletic population. *Foot and Ankle International, 19*(10), 653-660.

Gillespie, W. J., Gillespie, L. D., & Rowntree, K. F. (2004). Musculoskeletal injuries group. In *The cochrane library,issue 1*. Chichester, UK: John Wiley & Sons, Ltd.

Goldie, I. F., Gunterberg, B., & Jacobson, C. (1974). Foot volumetry as an objective test of the effect of antiphlogistic drugs in ankle sprains. *Rheumatology and Rehabilitation, 13*(4), 204-207.

Guskiewicz, K. M., Riemann, B. L., & Onate, J. A. (1999). Comparison of 3 methods of external support for management of acute lateral ankle sprains. *Journal of Athletic Training, 34*(1), 5-10.

Guyton, A. C., & Hall, J. E. (2000). *Textbook of medical physiology* (10th ed.). Philadelphia: W.B. Saunders company.

Hettinga, D. L. (1985). Inflammatory response of synovial joint structures. In J. A. Gould & G. J. Davies (Eds.), *Orthopaedic and sports physical therapy* (pp. 87-117). St. Louis: C. V. Mosby.

Holmer, P., Sondergaard, L., Konradsen, L., Nielsen, P. T., & Jorgensen, L. N. (1994). Epidemiology of sprains in the lateral ankle and foot. *Foot and Ankle International, 15*(2), 72-74.

Hopkins, J. T., & Palmieri, R. (2003). Effects of ankle joint effusion on lower leg function. *Clinical Journal of Sports Medicine, 14*(1), 1-7.

Hopkins, W. G. (2000). Measures of reliability in sports medicine and science. *Sports Medicine, 30*(1), 1-15.

Hunter, J. P., Marshall, R. N., & McNair, P. J. (2004). Reliability of biomechanical variables of sprint running. *Medicine and Science in Sports and Exercise, 36*(5), 850–861.

Kannus, P., & Renstrom, P. (1991). Treatment for acute tears of the lateral ligaments of the ankle. Operation, cast, or early controlled mobilization. *Journal of Bone and Joint Surgery. American Volume, 73*(2), 305-312.

Kaulesar Sukul, D. M., den Hoed, P. T., Johannes, E. J., van Dolder, R., & Benda, E. (1993). Direct and indirect methods for the quantification of leg volume: Comparison between water displacement volumetry, the disk model and the frustum sign model method, using the correlation coefficient and the limits of agreement. *Journal of Biomedical Engineering, 15*(6), 477-480.

Keating, J., & Matyas, T. (1998). Unreliable inferences from reliable measurements. *Australian Journal of Physiotherapy, 44*(1), 5-10.

King II, T. I. (1993). The effect of water temperature on hand volume during volumetric measurement using the water displacement method. *Journal of Hand Therapy, 6*(3), 202-204.

Klabunde, R. E. (2004). *Cardiovascular physiology concepts*. New York: Lippincott Williams & Wilkins.

Laba, E. (1989). Clinical evaluation of ice therapy for acute ankle sprain injuries. *New Zealand Journal of Physiotherapy*, 7-9.

Labs, K. H., Tschoepl, M., Gamba, G., Aschwanden, M., & Jaeger, K. A. (2002). The reliability of leg circumference assessment: A comparison of spring tape measurements and optoelectronic volumetry. *Vascular Medicine, 5*, 69-74.

Leanderson, J., & Wredmark, T. (1995). Treatment of acute ankle sprain. Comparison of a semi-rigid ankle brace and compression bandage in 73 patients. *Acta orthopaedica Scandinavica, 66*(6), 529-531.

Lennihan, R., & MacKereth, M. (1973). Calculating volume changes in a swollen extremity from surface measurements. *American Journal of Surgery, 126*, 649-652.

Ludbrook, J. (2002). Statistical techniques for comparing measurers and methods of measurement: A critical review. *Clinical and Experimental Pharmacology and Physiology, 29*, 527–536.

MacAuley, D. (1999). The European perspective: Ankle injuries: Same joint, different sports. *Medicine and Science in Sports and Exercise, 31*(7 suppl), S409-S411.

Man, I. O. W., Glover, K., Nixon, P., Poyton, R., Terre, R., & Morrissey, M. C. (2004). Effect of body position on foot and ankle volume in healthy subjects. *Clinical Physiology and Functional Imaging, 24*(6), 323-326.

Man, I. O. W., Lapar, G. S., Morrissey, M. C., & Cywinski, J. K. (2003). Effect of neuromuscular electrical stimulation on foot/ankle volume during standing. *Medicine and Science in Sports and Exercise, 35*(4), 630-634.

Martini, F. H. (2004). *Fundamentals of anatomy and physiology* (6th ed.). New Jersey: Pearson Education limited.

Massey, B. (1998). *Mechanics of fluids* (7th ed.). Cheltenham: Stanley Thornes (Publishers) Ltd.

McCulloch, J., & Boyd, V. B. (1992). The effects of whirlpool and the dependent position on lower extremity volume. *Journal of Orthopaedic and Sports Physical Therapy, 16*(4), 169-173.

McGraw, K. O., & Wong, S. P. (1996). Forming inferences about some intraclass correlation coefficients. *Psychological Methods, 1*(1), 30-46.

Michlovitz, S., Smith, W., & Watkins, M. (1988). Ice and high voltage pulsed stimulation in treatment of acute lateral ankle sprains. *Journal of Orthopaedic and Sports Physical Therapy, 9*(9), 301-304.

Moher, D., Jadad, A. R., & Tugwell, P. (1996). Assessing the quality of randomized controlled trials. *International Journal of Technology Assessment in Health Care, 12*, 195-208.

Moholkar, K., & Fenelon, G. (2001a). Diurnal variations in volume of the foot and ankle. *The Journal of Foot and Ankle Surgery, 40*(5), 302-304.

Moholkar, K., & Fenelon, G. (2001b). Normal volume of the foot and ankle. *The Foot, 11*(2), 63-65.

Morrow, J. R., & Jackson, A. W. (1993). How 'significant' is your reliability? *Research Quarterly for Exercise and Sport, 64*(3), 352-355.

Mulligan Concept. (2005). The official international web site. Retrieved 1st October, 2005, from http://www.bmulligan.com/

National Space Biomedical Research Institute. (2004). Static leg volume. Retrieved 12th February, 2004, from http://www.nsbri.org/HumanPhysSpace/focus2/spaceflight-leg.html

Nave, C. R., & Nave, B. C. (1985). *Physics for the health sciences* (3rd ed.). Philadelphia: W.B. Saunders company.

Nilsson, S., & Haugen, G. B. (1981). Volumetry in the evaluation of swelling in the ankle and foot. *Journal of the Oslo City Hospitals, 31*(1), 11-15.

Nyanzi, C. S., Langridge, J., Heyworth, J. R. C., & Mani, R. (1999). Randomized controlled study of ultrasound therapy in the management of acute lateral ligament sprains of the ankle joint. *Clinical Rehabilitation, 13*(1), 16-22.

Pero-System. (2004). Retrieved 12th November, 2004, from http://www.pero-system.de/index_e.htm

Perrin, M., & Guex, J. J. (2000). Edema and leg volume: Methods of assessment. *Angiology, 51*(1), 9-12.

Petersen, E. J., Irish, S. M., Lyons, C. L., Miklaski, S. F., Bryan, J. M., Henderson, N. E., et al. (1999). Reliability of water volumetry and the figure of eight method on subjects with ankle joint swelling. *Journal of Orthopaedic and Sports Physical Therapy, 29*(10), 609-615.

Rankin, G., & Stokes, M. (1998). Reliability of assessment tools in rehabilitation: An illustration of appropriate statistical analyses. *Clinical Rehabilitation, 12*(187-199).

Rucinski, R. J., Hooker, D. N., Prentice, W. E., Shields, E. W., & Cote-Murray, D. J. (1991). The effects of intermittent compression on edema in post acute ankle sprains. *Journal of Orthopaedic and Sports Physical Therapy, 14*(2), 65-69.

Safran, M. R., Benedetti, R. S., Bartolozzi, A. R. I., & Mandelbaum, B. R. (1999a). Lateral ankle sprains: A comprehensive review; part 1: Etiology, pathoanatomy, histopathogenesis, and diagnosis. *Medicine and Science in Sports and Exercise, 31*(7 Suppl), S429-437.

Safran, M. R., Zachazewski, J. E., Benedetti, R. S., Bartolozzi, A. R. I., & Mandelbaum, B. R. (1999b). Lateral ankle sprains: A comprehensive review; part 2: Treatment and rehabilitation with an emphasis on the athlete. *Medicine and Science in Sports and Exercise, 31*(7 Suppl), S438-447.

Seo, A., Kakehashi, M., Uda, S., Tsuru, S., & Yoshinaga, F. (1995). Bioelectrical impedance measuring method for standing load evaluation. *Journal of Occupational Health, 37*(83-87).

Seo, A., Kondo, Y., & Yoshinaga, F. (1997). A portable apparatus for monitoring leg swelling by bioelectrical impedance measurement. *Journal of Occupational Health, 39*, 150-151.

Shrout, P. E., & Fleiss, J. L. (1979). Intraclass correlations: Uses in assessing rater reliability. *Psychological Bulletin, 86*(2), 420-428.

Sims, D. (1986). Effects of positioning on ankle edema. *Journal of Orthopaedic and Sports Physical Therapy, 8*(1), 30-33.

Sloan, J. P., Hain, R., & Giddings, P. (1988). Effect of cold and compression on edema. *Physician and Sports Medicine, 16*, 116-120.

Sloan, J. P., Hain, R., & Pownall, R. (1989). Clinical benefits of early cold therapy in accident and emergency following ankle sprain. *Archives of Emergency Medicine, 6*(1), 1-6.

Stergioulas, A. (2004). Low-level laser treatment can reduce edema in second degree ankle sprains. *Journal of Clinical Laser Medicine and Surgery, 22*(2), 125-128.

Stevens, A., & Lowe, J. (1995). *Pathology*. St. Louis: Mosby.

Stranden, E. (1981). A comparison between surface measurements and water displacement volumetry for the quantification of leg edema. *Journal of the Oslo City Hospitals, 31*, 153-155.

Stratford, P. W., & Goldsmith, C. H. (1997). Use of standard error as a reliability index of interest: An applied example using elbow flexor strength data. *Physical Therapy, 77*(7), 1997.

Taber, C., Contrayman, K., Fahrenbruch, J., LaCount, K., & Cornwall, M. W. (1992). Measurement of reactive vasodilation during cold gel pack application to nontraumatized ankles. *Physical Therapy, 72*(4), 294-299.

Tatro-Adams, D., McGann, S. F., & Carbone, W. (1995). Reliability of the figure-of-eight method of ankle measurement. *Journal of Orthopaedic and Sports Physical Therapy, 22*(4), 161-163.

Thordarson, D. B., Ghalambor, N., & Perlman, M. (1997). Intermittent pneumatic pedal compression and edema resolution after acute ankle fracture: A prospective, randomized study. *Foot and Ankle International, 18*(6), 347-350.

Tierney, S., Aslam, M., Rennie, K., & Grace, P. (1996). Infrared optoelectronic volumetry, the ideal way to measure limb volume. *European Journal of Vascular and Endovascular Surgery, 12*(4), 412-417.

Trochim, W. M. (2004, 01/16/2005). The research methods knowledge base. 2nd Edition. Retrieved 2nd March, 2005, from http://trochim.human.cornell.edu/kb/index.htm

Tsang, K. K. W., Hertel, J., & Denegar, C. R. (2003). Volume decreases after elevation and intermittent compression of postacute ankle sprains are negated by gravity-dependent positioning. *Journal of Athletic Training, 38*(4), 320-324.

van Hamersvelt, H. W., Kloke, H. J., de Jong, D. J., Koene, R. A., & Huysmans, F. T. (1996). Oedema formation with the vasodilators nifedipine and diazoxide: Direct local effect or sodium retention. *Journal of Hypertension, 14*(8), 41-45.

Walter, S. D., Eliasziw, M., & Donner, A. (1998). Sample size and optimal designs for reliability studies. *Statistics in Medicine, 17*, 101-110.

Waylett-Rendall, J., & Seibly, D. S. (1991). A study of accuracy of a commercially available volumeter. *Journal of Hand Therapy, 4*, 10-13.

Weir, J. P. (2005). Quantifying test-retest reliability using the intraclass correlation coefficient and the standard error of measurement. *Journal of Strength and Conditioning Research, 19*(1), 231-240.

Wester, J. U., Jespersen, S. M., Nielsen, K. D., & Neumann, L. (1996). Wobble board training after partial sprains of the lateral ligaments of the ankle: A prospective randomized study. *Journal of Orthopaedic and Sports Physical Therapy, 23*(5), 332-336.

Weston, M., Taber, C., Casagranda, L., & Cornwall, M. (1994). Changes in local blood volume during cold gel pack application to traumatized ankles. *Journal of Orthopaedic and Sports Physical Therapy, 19*(4), 197-199.

Williamson, J. B., George, T. K., Simpson, D. C., Hannah, B., & Bradbury, E. (1986). Ultrasound in the treatment of ankle sprains. *Injury, 17*(3), 176-178.

Woods, C., Hawkins, R., Hulse, M., & Hodson, A. (2003). The football association medical research programme: An audit of injuries in professional football: An analysis of ankle sprains. *British Journal of Sports Medicine, 37*(3), 233-238.

Yeung, M. S., Chan, K. M., So, C. H., & Yuan, W. Y. (1994). An epidemiological survey on ankle sprain. *British Journal of Sports Medicine, 28*(2), 112-116.

Zoch, C., Fialka-Moser, V., & Quittan, M. (2003). Rehabilitation of ligamentous ankle injuries: A review of recent studies. *British Journal of Sports Medicine, 37*(4), 291-295.