Department of Bioengineering

Development of User-Friendly system of Flexible electrogoniometers for use in Total Knee Arthroplasty

By

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Declaration

I declare that this Thesis embodies my own research work and that it is composed by myself. Where appropriate, I have made acknowledgements to the work of others.

Vivek Padmanaabhan Indramohan

Dedication

I would like to dedicate this thesis to *Mother Mira* and *Bhagvan Sri Aurobindo*

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Publication Details

The following Publications arose from this Research

Paper in Peer review Journal

- IndraMohan.V.P, Valsan.G, Rowe.P.J, (2009) Validation of Strathclyde University data logging system (SUDALS); Journal of Medical engineering and technology, vol 33, No: 8, 650-655, November 2009.

Paper in peer reviewed International Conference:

- IndraMohan.V.P, Valsan.G, Rowe.P.J, Development of Strathclyde University data logging system (SUDALS) for use with flexible electrogoniometry - International conference on biomedical electronics and Devices, 2009, Portugal.

Abstracts in peer reviewed International Conference:

- A simple clinical method of recording knee kinematics during functional activity using flexible electrogoniometry and the Strathclyde university data logging system (SUDALS) for use in multi-centre RCT's of TKA – International Conference on Knee Arthroplasty – IMechE (London, 2009).
- An objective functional assessment of knee using flexible electrogoniometry and the Strathclyde University Data Logging System (SUDALS) for use in Total knee arthroplasty (TKA) – XXII Congress of the International Society of Biomechanics (Cape town, 2009).
- Towards phase III, multi-centered RCTs of functional outcome of TKA using flexible electro-goniometry: The challenge for the next decade - IMechE (London, 2009).

Abstract

With an increase in number of people suffering from Knee osteoarthritis, Total knee arthroplasty (TKA) seems to be a promising solution which relieves the patients from pain and restores their functional abilities. Objective functional outcome assessment of the knee following such an intervention is useful in meeting the increasing demand for evidence based practice and evaluating the efficiency of the treatment. A review of the literature indicated that, due to the lack of a clinically relevant, simple, scientific measurement technique, such assessments are seldom carried out in clinical settings. Hence, to enhance clinical research in the field of orthopaedics and to facilitate a routine clinical appraisal of individual patients and the intervention they have received, a simple, portable, robust, unobtrusive, useful and reliable tool which allows clinical staff to study the behaviour of patients and acquire sufficient information regarding their knee joint movement during various activities of daily living (ADL) was developed.

The project aimed to produce 'A user friendly version of flexible electrogoniometers'; namely, Strathclyde University Data Logging System (SUDALS). The newly developed system was tested quantitatively for its reliability, reproducibility and validity during various ADL's such as level walking, getting in and out of chair, stair ascend, stair descend and deep squatting and the system was also tested qualitatively for its usability by involving focus group comprising of research nurses and AHP's. The results of these studies showed that, the newly developed system has a good resolution and is capable of quantifying angular displacements to the nearest 0.15° with a maximum inaccuracy of 3° to 5° in extreme conditions. There is a good repeatability and reproducibility in the data recorded by the system. The maximum/minimum knee flexion angles recorded by the system during various ADL's are within the values published in the literature. From these studies, it was concluded that, SUDALS is a user-friendly system and this version of flexible electrogoniometers with a few additional improvements can be used as a clinical tool to assess the functional outcomes of the knee following TKA.

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Table of Concepts

S.No	Concept	Definition
1.	Accuracy	It is defined as the maximum difference that will exist between the actual value and the indicated value at the output of an instrument.
2.	Data Bit	Number of bits used to represent one character of data.
3.	Hysteresis	It is defined as the measure of the capability of an instrument to follow the changes of the input parameter regardless of the direction in which the change is made.
4.	Precision	It refers to the ability of an instrument to produce consistent results when performing multiple measurements on the same sample.
5.	Reliability	It is the degree to which an instrument measures the same way each time when used under the same condition with same subjects.
6.	Reproducibility	It refers to the ability of an instrument to obtain consistent measurement results when measuring the same sample at different times or by different users or by using different measuring systems of same type.
7.	Stability	It is the stability of an instrument to produce a stable signal over a definite period of time under static conditions.
8.	Validity	It refers to the ability of an instrument to measure what it claims to measure.
9.	Word	It is defined as group of bits of fixed size.

Table of Acronyms

S.No	Abbreviations Used	Acronym
1.	AAMC	American Association of Medical College
2.	ADC	Analog to Digital Converter
3.	ADL	Activities of Daily Living
4.	AHP	Allied Health Professional
5.	ARM	Advanced RISC Machine
6.	CAT	Computerised Axial Tomography
7.	CAMARC	Computer Aided Movement Analysis in a Rehabilitation Context.
8.	CFI	Canadian foundation for Innovation
9.	CPU	Central Processing Unit
10.	CRF	Clinical Research Facility.
11.	CSO	Chief Scientific Office(r)
12.	CTU	Clinical Trial Unit
13.	DAC	Digital to Analog Converter
14.	DAQ	Data Acquisition
15.	DCE	Data Circuit terminating Equipment
16.	DTE	Data Terminal Equipment
17.	EBP	Evidence Based Practice
18.	EBM	Evidence Based Medicine
19.	EEPROM	Electrically Erasable Programmable Read Only Memory
20.	FDA	Food and Drug Administration.
21.	FSR	Force Sensing Resistor
22.	GCRC	General Clinical Research Centre.
23.	GPIO	General Purpose Input-Output
24.	GUI	Graphical User Interface
25.	HDA	Health Development Agency
26.	HMO	Health Maintenance Organisations
27.	IADL	Instrumental Activities of Daily Living
28.	IC	Integrated Circuit
29.	ICC	Interclass Correlation Coefficient
30.	ISR	Interrupt Service Routine
31.	IR	Infra Red
32.	LAPSE	Long term Ambulatory Physiological Surveillance Equipment.
33.	LSB	Least Significant Bit.
34.	MCU	Microcontroller Unit
35.	MIPS	Million Instructions Per Second
36.	MRI	Magnetic Resonance Imaging
37.	MRC	Medical Research Council.
38.	MSB	Most Significant Bit
39.	NCCR	National Centre for Clinical Research Resources.
40.	NHS	National Health Service

S.No	Abbreviations Used	Acronym
41.	NIH	National Institute of Health
42.	NICE	National Institute for Health and Clinical Excellence
43.	NSAID's	Non-Steroidal Anti Inflammatory Drugs
44.	OA	Osteoarthritis
45.	Op-Amp	Operational Amplifier
46.	PC	Personal Computer
47.	PCB	Printed Circuit Board
48.	PET	Positron Emission Tomography
49.	PLL	Programmable Logic Loop
50.	POT	Potentiometer
51.	RCT	Randomised Controlled Trials
52.	REP	Replicating Effective Program
53.	RISC	Reduced Instruction Set Computer
54.	ROM	Read Only Memory
55.	RS:232	Recommended Standard 232
56.	SD	Standard Deviation
57.	SEM	Standard Error of Measurement
58.	SRAM	Static Random Access Memory
59.	TENS	Transcutaneous Electrical Nerve Stimulation
60.	THR	Total Hip Replacement
61.	TJR	Total Joint Replacement
62.	TKA	Total knee arthroplasty
63.	UART	Universal Asynchronous Receiver Transmitter
64.	UKCRC	United Kingdom Clinical Research Collaboration
65.	VHA	Veterans Health Administration
66.	WHO	World Health Organisation
67.	WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index

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Section 7.1: Training CD and Functioning of SUDALS

Section7.2: Consent Forms, Subject Information sheet of Chapter 7, Questionnaires and Interview questions

Section 7.3: Interview Audio

Appendix 8: Ethics forms.

Synopsis

Knee osteoarthritis is a degenerative condition associated with a fixed flexion deformity and loss of full flexion and this is secondary to osteophyte formation, soft tissue contracture, bone loss and deformity. With an increase in number of people suffering from such a degenerative condition, total knee arthroplasty has been established as a permanent solution and a valuable procedure for the management of patients with disabling knee osteoarthritis. Total knee arthroplasty primarily aims to relieve pain and limitation in knee movement, restore the knee functionality and improve the quality of life of an individual.

However, when practicing an evidence based approach, the evaluation of effectiveness of such an intervention in an objective manner is carried out by scientifically recording the angular displacement of the knee during a range of functional activities. Reviewing the literature shows that, such an objective functional assessment of the knee following total knee arthroplasty is carried out on a routine basis in a research environment and is seldom carried out in clinical settings. The author therefore decided to develop a user-friendly system of flexible electrogoniometers, which can be used by any non-technical professional with minimal training in multi centred clinical trials aiming the evaluation of post-operative rehabilitation. The first prototype of the user-friendly system of flexible electrogoniometer, namely; SUDALS was designed and developed as part of this research work and this is explained in detail in the chapters one to nine of this thesis.

The important phases involved in the development and testing of the prototype are described in detail in chapters 3, 4, 5, 6 and 7. All these phases were accomplished within a definite time frame. The overall time taken to complete all the experimental work and data analysis reported in this thesis was 32 months. The maximum time taken for the design and development phase (including the selection and purchase of the required electronic components from U.S.A) as illustrated in chapter 3 was 18 months. Following the development phase, the system was calibrated and bench tested prior to its usage in dynamic environments. It was possible to accomplish the calibration and bench-testing phase (as described in chapter 4) by a time period of 3 months. In an other 3 months time period, the system was also dynamically tested (as reported in the chapter 5) on 10 normal subjects during various functional activities such as level walking, getting in and out of chair, stair ascend, stair descend and deep squatting and was also validated against a gold standard (Vicon system). In addition to this, the system was also tested for reliability on 10 normal

subjects against the commercially available system during various above mentioned functional activities as reported in chapter 6. The maximum time taken for obtaining the results reported in this chapter was 4 months. Finally, the clinical usability of the developed system was tested by incorporating a user-feedback study as reported in chapter 7. The time taken to complete this study was 4 months. Also, a summary of the time taken for accomplishing the tasks reported in chapters 3 to 7 is given below.

S.No	Chapters	Time taken for designing, developing and testing the SUDALS
1.	Chapter 3	18 months.
2.	Chapter 4	3 months.
3.	Chapter 5	3 months.
4.	Chapter 6	4 months.
5.	Chapter 7	4 months

This then forms the basis of the entire research work reported here in this thesis.

Chapter 1 – Literature review

1.1 Introduction

This chapter presents a critical review of the literature related to the research work undertaken. Two important themes are discussed here; the first theme elucidates 'The UK health care system and health care research' and the second theme explains about the 'Movement which is a defining element of animal life'. The former is discussed in detail in the sections 1.2 to 1.7 and the latter is discussed in the sections 1.8 to 1.15.

1.2 The UK health care system and health care research – The past and present

'*Is health care art or science?*' – is a highly intellectual question. Though it may sound very simple, strictly speaking; it is a complex and debatable question and such a question cannot be answered without reviewing the literature and analysing how the concept of health care has been practiced in the past and how it is being currently practiced due to the advances in basic science and technology.

Reviewing the history reveals that, during the middle Ages, despite the availability of valuable diagnostic and treatment services, the concept of health care was merely considered as an art and seems to have been practiced on non-scientific grounds. For instance, illnesses not cured by home remedies were left to be cured naturally and were controlled using spiritual values although the outcomes of such remedies were often fatal. (Steichen, 2002; Bronzino, 1992) This feudal concept of healthcare was challenged by the Renaissance, during which scientific principles were applied to the clinical art and the art of surgery or healthcare was elevated to join medicine as a branch of health science by scholars like Vesalius, Harvey, Morgagni, Laennec and Paré. During the same period, with the accumulation of knowledge from different sources, the idea of multidisciplinary speciality was born and in certain disciplines like; orthopaedics, ophthalmology, urology, gynaecology, etc., the concept of team work was also introduced whereby; the physicians and the surgeons worked together in diagnosing and

providing treatment to the patients. (Steichen, 2002; Bronzino, 1992) Incorporation of such a dynamic idea of clinical diagnostic-therapeutic practice units enhanced effective communication among clinicians, scientists, teachers and students, enabling trainees to visualize the application of science and various other disciplines in daily clinical practice. It also benefited the patients by providing them both the diagnostic and therapeutic procedures under one common roof and by utilising the available resources efficiently and economically. The multi-disciplinary transformation that has taken place in chemistry, physics, engineering, microbiology, physiology, pharmacology, etc. at the turn of the 19th century, characterised by intense interdisciplinary cross-fertilization has aided medical research in developing techniques for the diagnosis and treatment of diseases. (Steichen, 2002; Bronzino, 1992)

The most significant innovation of X-rays for orthopaedics was in 1895 by W.K. Roentgen and this caused a chain reaction of innovation including many other new discoveries in medical technology as outlined in table 1.1. Consequently modern technology came into existence in most urban hospitals and following the second world war, contribution of advanced electronics in the development of biomedical instruments and imaging techniques such as; diagnostic ultrasound imaging, computerised axial tomography (CAT), magnetic resonance imaging (MRI) and positron emission tomography (PET) and the ability to monitor the electrical behaviour of central nervous system facilitated the clinicians to accurately measure and document the body functions with reduced observer error. Further, the onset of powerful and effective atomic science promoted the discovery of radiopharmaceuticals and appropriate nuclear instrumentation to detect and display the activity of these elements. Simultaneously, developments in biomaterials also encouraged the technologists to provide prosthetic devices to replace defective human organs. Artificial heart valves, blood vessels and artificial heart are few examples of innovative developments to be mentioned during this period. (Soames, 2003)

Year	Discovery
1895	Discovery of X-rays by W.K Roentgen.
1900	Discovery of different blood groups and their incompatibility.
1903	Discovery of ECG by Willem Einthoven.
1913	Discovery of Sodium Citrate to prevent blood clotting.
1927	Introduction of Drinker respirator.
1930's	Discovery of Sulphanilamide to reduce cross infections among patients.
1940's	Discovery of Penicillin.

Table1.1: Discoveries in medical technology

From the above discussions, it is evident that the field of health care which was conventionally practiced, merely as an art is now emerging into a technique which is based on evidences, experiments, measurements and facts. However, when bridging the gap between a discovery and its implementation in practice, evidence based practice (EBP) is considered to be a gold standard for cutting edge patient care and effective practice.

1.3 Science – An art of evidence, facts and truth

The philosophical origin of EBP extends back to mid-19th century from the work of Archie Cochrane and over the past two decades it has attracted more and more attention in the medical community. EBP is a concept which insists on a clinical practice based on scientific inquiry, conscientious, explicit and judicious use of current evidence so as to; improve medicine and health care, make precise decisions regarding the care of individual patients and integrate clinical expertise with patient values. (Vos et al., 2002; Homes, 2006; Bergstrom, 2008; Sackett, 1996)

Though researchers have insisted on the implementation of EBP when making clinical decisions in the care for individual patients or groups of patients (Sackett et al., 1996), reviewing the literature reveals that, integrating evidence into practice is not that easy in reality due to various constraints such as; lack of financial incentives, unawareness of the availability of evidence based interventions by many of the health care purchasers and inadequate guidance in designing a user friendly intervention for specific populations (Kilbourne et al., 2007 & Bergstrom, 2008). Many agencies such as

the U.S National Institutes of Health, Veterans Health Administration (VHA) and the agency for healthcare research and quality have been trying to overcome such issues and bridge the gap between research and practice by implementing a number of training programs and effective interventions to improve the quality in health care. (Kilbourne et al., 2007 & Bergstrom, 2008) Nevertheless, such interventions are said to mainly target the academic settings and due to variations in the outcome observed on testing an intervention in research settings and community based organizations only a few have been said to be disseminated in non-academic organizations (Kilbourne et al., 2007). This in turn reflects on a need for implementing an effective health services intervention in both clinical and research environment.

One of the first translational frameworks, 'the replicating effective program (REP)' sought to address this critical link between research and practice by implementing evidence based interventions into community based settings. It was developed by the US centres for disease control and prevention in 1996. Based on the belief that training professionals makes them more skilled in using the best research to provide most effective and efficient health care to patients, REP has combined various strategies such as intervention training, packaging and technical assistance to accomplish the objective and maximize the chances for sustaining the interventions. (Nabulsi, 2007) Although EBM is practiced in the US, there is not much in the literature on how EBM is implemented in European countries. In countries like Germany and France, hierarchical and central government policies seem to be influencing the development of guidelines and EBM. (Vos et al., 2002) However, in Netherlands, the Professional medical association such as the Dutch General Practitioner Association has taken the responsibility of developing EBM. In the UK, the Health Development Agency (HDA) is supporting the National Health Services (NHS) to set their priorities for practicing research commissioning activities with respect to the evidence based medicine agenda and facilitate changes in front line practice. Similar to the frameworks developed in the USA, in the UK, the HDA together with the National Co-ordinating Centre for Health Technology Assessment and National Institute for Health and Clinical Excellence (NICE) have proposed various guidelines to bridge the gap between the research and practice. As

part of this collaboration, the research into practice program was set up in the year 2001; (Getting Evidence into practice to reduce health inequalities – www.nice.org.uk)

1. To develop a more systematic approach in reviewing the primary research literature to provide answers for decision makers in the NHS on the most cost-effective interventions.
2. To work with professional groups with suitable skills and knowledge and provide appropriate training strategies at all stages of dissemination to implementation.
3. To develop user-friendly interventions adaptable to particular communities, organisations and localities and
4. To involve peers at all stages of disseminating best practice so as to improve the health services and help the NHS staff to make sustainable changes in the delivery of health care. (Speller & Kelly, 2003 – www.nice.org.uk)

Due to such initiative approaches taken by the above mentioned agencies; currently, different branches of medicine such as; adult medicine, child health, surgery, pathology, pharmacotherapy, nursing, general practice, dentistry and other branches of applied science including biomedical engineering, have started incorporating evidence based approaches in their routine practices; however, its positive impacts in these areas are yet to be validated. (Homes et al., 2006; Sackett et al., 1996) Along side the medical sector, the 'proof of concept' studies are now being adopted by biotechnology and pharmaceutical industries to evaluate the different stages of a product development. (www.acmedsci.ac.uk/images/publication/pscr.pdf - October 2003)

In summary, research and experimentation is the root of science and since science provides objective and precise facts as the basis for decision making, health care researchers and clinicians need to pursue EBP as an effective tool to meet the increasing demand for improved services and the accurate low cost clinical measurements to support them. In this way, health care will progress from an art to science.

1.4 Clinical Measurement and issues for measurement in clinical environment

Measurement of any clinical parameter (physiological or psychological) is a fundamental evaluation procedure. It should be designed for a wide range of clinical applications and

should apply scientific knowledge in measuring such parameters. Such measures are of interest for the clinician and other medical professionals, as they would assist them in providing an efficient prognosis and an improved treatment. (Geurts et al., 1991; Rozendal, 1989) Parameters such as; temperature, blood pressure, pulse rate, respiration rate etc… are some of the commonly measured physiological factors in the clinical environment. However, the ability to move is a fundamental characteristic of any animal including the human and restoration of movement is a basic aim of orthopaedics and physical rehabilitation. Hence, researchers have been keen to study and measure goal directed movements of human beings. Current advancements in medical technology have facilitated measurements pertaining to mobility, joint range of motion (ROM), gait analysis or movement analysis by orthopaedic surgeons and rehabilitation health professionals in a clinical environment. However, literature seems to reveal the existence of certain practical issues in the implementation of such measurements in daily practice. Some of these issues are listed below: (Rozendal, 1990, Leo and Woltring, 1990, Bussmann and Stam, 1998, Mulder et al., 1998, lea et al., 1995; Smith, 1982)

1. The use of non – goal specific measurement techniques: For example, some of the movement analysis techniques such as the 3D motion analysis system aim in measuring impairment without providing any information pertaining to the disability – which is the underlying cause of the impairment.
2. Lack of techniques addressing the required clinical question: Research reveals the existence of disagreement between the availability of many new and advanced procedures for gait analysis and the application of these techniques on a routine basis in a clinical context. The reason for such discrepancy is that, the gait analysis procedures in the labs aim at assessing the motor behaviour in terms of functions; whereas, many clinical questions in the field of rehabilitation medicine need answers pertaining to balance and ambulation skills rather than detailed kinetic or kinematic data.
3. General attitude of physicians and clinicians: With advancement in measurement technology, analysis of gait has seen rapid growth over the last 20 years. However, literature reviews report the existence of a wide spread perception among clinicians and orthopaedic surgeons that movement analysis is too

complex for clinical practice resulting in the use of clinical examination and observational gait analysis for evaluating the outcomes of their intervention (Rozendal, 1990, Leo and Woltring, 1990, Bussmann and Stam, 1998, Mulder et al., 1998, lea et al., 1995; Smith, 1982)

4. Time Consumption: Evaluation of the data from certain measurement techniques such as movement analysis has been reported to be a time consuming process.
5. Lack of space, money and expertise seems to be accountable for a part of lack of clinical application of advanced clinical measurement techniques.
6. Inefficiency of certain researchers in retrieving information from qualitative measurement findings.
7. Existence of claims against the validity of current measurement techniques for assessing desired outcomes.
8. Lack of technical awareness among the clinicians to be familiar with the technology involved in digital signal processing has resulted in a gap between what one can measure and what one desires to know.
9. Use of subjective protocols such as observational techniques and questionnaires in the assessment of motor dysfunctions results in subjective outcomes with low reliability and sensitivity.
10. Inability of the researchers in effectively using the available instruments, leading to inter-rater and intra-rater errors. For example: many researchers have used electrogoniometer, for measuring the range of motion of various joints such as hip, knee, ankle, etc…. However, research reports the usage of this transducer especially in terms of attachment procedures so as to minimize the errors due to misalignment of this device. (Rowe et al., 2001, 2005, Rozendal, 1990, Leo and Woltring, 1990, Bussmann and Stam, 1998, Mulder et al., 1998, lea et al., 1995; Smith, 1982). This in turn reflects on the proper usage of the device in producing accurate outcomes.

To overcome the above mentioned issues in clinical measurement, in 1990, a consortium of British, French, Dutch and Italian partners comprising of people from various disciplines such as academia, public-health and industrial sector proposed a project known as CAMARC (Computer Aided Movement Analysis in a Rehabilitation Context),

which aimed to assess the existing knowledge in specific area of clinical measurement such as movement analysis and standardise the test protocols and address the issues hindering its use as an effective clinical measurement. With the onset of this project, relevant digital signal processing algorithms were implemented to minimize the time spent by clinicians on analysing the data corresponding to such measurements. In addition to this, the project also analysed the marketing potential of new instrumentation and facilitated the implementation of design criteria for new devices. Though the scope of this project was reported to be pre-competitive, it has addressed vital issues involved in the clinical measurement and bridged the gap between laboratory and rehabilitation clinics. (Leo and Woltring, 1990)

1.5 Clinical Research – The past, present and Future

The advances in medical research, technology and improved health care are inextricably linked by a component of medical health research known as Clinical research. Clinical research embraces a series of studies involving frequent patient interactions, clinical knowledge, detection, diagnosis, therapeutic interventions including clinical trials and health services research so as to produce valuable information for understanding human diseases, preventing and treating illness, and promoting health. Despite the enormous benefits offered by clinical research, reviewing the literature reveals a recent decline in clinical research and hence, the production of clinical research to incorporate into practice seems to have become a serious issue (Future of Clinical Research: www.aaas.org/spp/rd/ch29.pdf & www.ngpharma.eu.com). Between 1990-1999, the clinical research summit called by American Association of Medical Colleges (AAMC) together with American Medical Association and the Wake Forest University school of medicine brought together focus groups comprising of five clinical research physicians with different levels of experience along with non-physician clinical researchers, basic scientists, patients and patient advocates, the corporate and government purchasers of health care to fulfil the urgent demand for revitalisation of clinical research and identify and resolve the issues affecting the progression of clinical research.

The report from the working group of Academy of Medical Sciences shows the existence of a translational barrier between basic discoveries and converting those discoveries into patient beneficial innovations leading to serious weakness in areas of clinical research and experimental medicine. The UK has become an unattractive location for clinical trial over the last decade partly due to the increasing regulatory burden on clinical research. Further, the revolution in the field of genetics and molecular biology, together with fragmented research trial capacity, prolonged start-up times, low patient recruitment rates have also made the UK an unappealing site for investment in clinical trials, despite the UK being previously recognised as an international centre for its contribution to clinical research and development. (Bell, 2003 & Strengthening Clinical Research - www.acmedsci.ac.uk/images/publication/pscr.pdf - October 2003)

1.5.1 Factors resulting in the decline of Clinical research

Various factors preventing the growth of clinical research as reported by the AAMC focus groups and other associations such as; Health Maintenance Organisations (HMO), National Institute of Health (NIH), National Centre for Research Resources (NCCR) and General Clinical Research Centre (GCRC) are summarized below (Strengthening Clinical Research - www.acmedsci.ac.uk/images/publication/pscr.pdf - October 2003, Future of Clinical Research: www.aaas.org/spp/rd/ch29.pdf, Bell 2003)

1. Incomplete knowledge about clinical research among the public, leading to relatively small number of participants volunteering in clinical research trials.
2. Irregular track record of data regarding the effective utilisation of resources invested by stake holders.
3. Insufficient funding and financial constraints resulting in unsustainable clinical research system.
4. Issues related to dynamic work force.
5. Lack of co-ordination between HMO's, academic medical centres, public health organisations, schools of nursing and schools of medicine.
6. Unclear dynamic agenda for clinical research.
7. Lack of research networks.

8. Inappropriate infrastructure and facilities.
9. Inappropriately trained clinical scientists and
10. Increase in complex legal and ethical issues.

1.5.2 Steps taken by the stake holders to improve the existing situation

A number of recommendations have been reported in the literature for overcoming the obstacles that limit the ability to undertake experimental research and clinical trials in the United Kingdom. A national network for clinical research within the NHS has been established to coordinate large clinical trials between different clinical or research centres and track the resources required to create the necessary infrastructure. Although the NHS is responsible for making knowledge based decisions, promoting clinical research facilities and clinical trial units, the funds allocated within the NHS research and development to directly support the clinical research for the benefit of the health service has been reported to be only £ 70 million per annum. (Strengthening clinical research: www.acmedsci.ac.uk/images/publication/pscr.pdf, Future of Clinical Research: www.aaas.org/spp/rd/ch29.pdf , www.ngpharma.eu.com, Bell, 2003)

In 1994, when the NHS research and development programme was initially started, NHS decided to spend 1.5 % of its turnover for clinical research activities. However, despite its preset target, currently only 0.1% of NHS turnover is being used for such activities and research reveals that this is considerably less than the amount spent by other nationally supported health care systems. Although major academic institutions integrate clinical research activities with the NHS, supporting such activities without appropriate financial support wouldn't be feasible for these institutions. Hence as a remedial approach, nowadays the clinical research activities within the NHS are integrated with private sectors such as the biotechnology and pharmaceutical industries (the two major dominating industries in UK). With an overall contribution of these industries to research and development (37%) the research and development activities are said to bloom compared to other industries. (Strengthening clinical research: www.acmedsci.ac.uk/images/publication/pscr.pdf, Future of Clinical Research: www.aaas.org/spp/rd/ch29.pdf , www.ngpharma.eu.com, Bell, 2003)

Despite, the concerns expressed about the UK as an unattractive location for clinical trials, significant amounts of basic and clinical research in universities and NHS facilities are being supported by companies. In addition to the financial support, these companies play a major role in providing significant intellectual input to their academic partners. Further, the coordination of clinical trials throughout Europe enhances the potential of investment and minimises the unrealistic constraints on research activities placed by European Clinical Trials Directive. Though some of the solutions suggested above would help in overcoming the problems related to inappropriate infrastructure, facilities and financial support, (Strengthening Clinical Research: www.acmedsci.ac.uk/images/publication/pscr.pdf, Future of Clinical Research: www.aaas.org/spp/rd/ch29.pdf, www.ngpharma.eu.com, Bell,2003) the effective functioning of a clinical trial unit also depends upon the availability of dynamic work force, trained and educated professionals in the area of clinical research. However, reviewing the literature reveals an existence of difficulty in recruiting and retaining research staff and a substantial need for long term support and training among health care professionals to undertake the research activities and participate in routine patient care within the NHS. Having known the value of clinical research and the importance of training the health care professionals to undertake such research activities, the next stage is to figure out the ways of implementing and organising such training programmes. Due to the various constraints mentioned above, such programmes are not solely carried out by the NHS. Instead, the NHS co-ordinates with private industries (such as the biotechnology and pharmaceutical industry) which play a crucial role in providing research training to these health care professionals and making them skilful in the field of clinical research and experimental medicine (Strengthening Clinical Research: www.acmedsci.ac.uk/images/publication/pscr.pdf, Future of Clinical Research: www.aaas.org/spp/rd/ch29.pdf, Bell, 2003) Further, inclusion of clinical research as part of the curriculum for nurses, physicians and other health professionals would be useful in strengthening the work force required for clinical research.

Other than UK, many other developed countries like; Canada and U.S.A are also facing organisational weakness in the area of clinical research. However, similar to UK, these countries are also trying to practice clinical research on a regular basis by

introducing new packages to support the development of large clinical trial networks and substantial infrastructure. For example: In Canada, the medical research council was replaced by the Canadian Institute of Health Research and Canadian Foundation for Innovation (CFI) and in U.S.A, an analogue of the National Institute for Health was developed to effectively utilise the resources for clinical research and redirect the funds in favour of clinical research. Though the packages recommended for one country may not be applicable to the clinical research crisis in another country, research reveals that, the parallel developments in the health care research in one country acts as a source of intelligence and an instructive basis for comparison (Strengthening Clinical Research: www.acmedsci.ac.uk/images/publication/pscr.pdf, Future of Clinical Research: www.aaas.org/spp/rd/ch29.pdf, Bell,2003)

In recent years, a partnership of academic, charitable, commercial and government organizations (UK Clinical Research Collaboration (UKCRC)) has been set up to establish the UK as a world leader in clinical research by harnessing the full potential of the NHS. (www.ukcrc.org/publications.December 2006) In addition to this, a substantial amount of financial support by external funding bodies and partnership industries has been given to build up the infrastructure supporting clinical research facilities adjacent to or within the NHS. This has encouraged experimental medicine in the UK which in turn has resulted in many clinical research facilities and clinical trial units in and around UK. The Glasgow Clinical Research Facility (CRF) can be considered as an encouraging example. The Glasgow CRF aims to centralise the research services with the ongoing change in the legal and regulatory environment, to offer new levels of support to investigation and patients across the city. The Glasgow CRF was set up in 2006 with an NHS clinical research grant agreement with Chief Scientist Office (CSO) and collaboration with higher education comprising of Universities of Glasgow, Strathclyde, Paisley and Glasgow Caledonian. The Glasgow CRF provides support in terms of trained research staff, expertise for conducting clinical trials and dedicated clinical research space. In addition to this, they also offer help with designing a protocol, support statistical design and management of clinical data. Examples of other clinical research facilities in UK include; Birmingham Wellcome trust Clinical Research Facility, Edinburgh Wellcome trust Clinical Research Facility, Southampton Wellcome trust

Clinical Research Facility, Sheffield Wellcome Clinical Research Facility and Clinical Research Centre Tayside. (http://www.glasgowcrf.org.uk/links.htm).

Despite such developments in the field of clinical/medical research, lack of efficient researchers and failure to train adequate number of researchers in the arena of clinical science seems to be an area for discussion in developed countries and is reported to be one of major cause for limiting the clinical research effort. Hence, a solution to overcome this issue is required and this is discussed in the following section. (Strengthening Clinical Research: www.acmedsci.ac.uk/images/publication/pscr.pdf, Future of Clinical Research: www.aaas.org/spp/rd/ch29.pdf, www.ngpharma.eu.com, Bell.J 2003)

1.6 Involving nurses and AHP's in clinical research

Nearly 700,000 nurses, midwives and specialist community public health nurses and more than 70,000 allied health professionals (AHP) are registered to work in the UK. Nurses and AHP play a vital role within the NHS by contributing significantly for clinical research and providing frontline services and support to patients (www.Health.org.uk/publications/consultation_responses/nurses_in_clinical.html-March 2007, Bell, 2003) However, such teams do not get enough opportunities, support and training to pursue a career in clinical trials and population based health research.

The UK clinical research collaboration (UKCRC) sub-committee for nurses in clinical research has recommended new clinical research career structures for nurses (www.ukcrc.org/publications.December 2006) and AHP's and it aims to develop a highly skilled workforce of trained clinical researchers and educators within the context of a rapidly changing UK healthcare environment. The committee has started examining the current role of nurses and AHP's as researchers and educators and investigating the barriers that are preventing them from reaching their full potential in these areas. (www.ukcrc.org/publications.December 2006) It recognizes the broad range of research skills needed by nurses and AHP's and envisages a more flexible career structure by combining clinical and academic work as the norm for those who wish to pursue a research career at all levels. This would ultimately produce research leaders of the future

in which a larger number of graduate nurses and AHP's would be active in high quality clinical and other health related research at various levels.

The main advantage of incorporating nurses and AHP's in clinical research is that, they can bring distinctive views of the patients to the research. These views offer additional benefits to patient care, and at the same time, such insights help to produce relevant outcomes and address any practical methodological issues. (www.ukcrc.org/publications.December 2006) Whilst, there are a number of nurses and AHP's undertaking key roles in the delivery of clinical research, literature shows that many of the research positions offered to these professionals are temporary and opportunities for career development are limited. Consequently, the number of nurses and AHP's with sufficient experience, qualification and permanence to lead clinical research projects is limited. Greater emphasis is required on the clinical applications of research, using multi-professional research teams comprising of clinicians, nurses and allied health professionals to develop research from bench to bedside. The table 1.2 below shows the number of research settings in which nurses and AHP's are currently involved and the pros and cons of each setting. (www.ukcrc.org/publications.December 2006)

S.No	Research settings	Advantages	Disadvantages
1.	University departments	Strong academic basis with established research interests and methodological expertise.	Less opportunity for clinical practice and patient focused research.
2.	Clinical Research Areas: Wards, clinics and departments.	Access to funded research projects with some training.	Little academic supervision and poor career prospects.
3.	Research Networks	These networks offer considerable opportunities for nurses to work within multidisciplinary research teams with specified clinical networks.	There seems to be no problem for nurses and AHP's working in such a research setting. But these networks are costly and therefore limited to major research areas such as stroke and cancer.
4.	Clinical research facilities for experimental medicine.	These units have high quality bio-medical science and established methodological expertise. Opportunities to work with multidisciplinary research are offered to the nurses.	However, currently such research works carried out by the nurses and AHP's are very little and most research is in the area of biomedical or pharmaceutical science.
5.	Primary Care	Possibility for nurses to work on ad-hoc research projects in primary care supported by research grants or external funding agents.	Little opportunity for training or career progression.
6.	Contract research facilities.	Here the nurses are involved in the day to day running of many clinical trials of new medicines or new indications for older products.	However, such research is protocol driven and offers limited education and training in research methodology and is carried out under short term contract. As a result, integration into a clinical career would be difficult.

Table1. 2: Research settings involving Nurses and AHP's

Currently, with an increase in use of modern electronic devices in fast-paced health care environments, the research necessitates that the nurses and AHP's working in these arena should be capable of using such devices in their routine clinical research practice. Though these professionals are proficient in the safe and effective usage of medical technology in health care environments, the expected standard for handling research related medical devices such as advanced measurement tools can be accomplished only by suitably resigned equipment, relevant education and in-service training provided by the hospitals employing them. Further, it would be advisable, if the responsibility of keeping these professionals updated with the upcoming technological developments in the field of biomedicine is taken up by the hospitals employing them (supported by the CRF partners), as it would be convenient for these professionals to spend equal amount of time in their routine clinical practice and engaged in different forms of clinical research. (O'connell et al., 2007, strengthening clinical research: www.acmedsci.ac.uk/images/publication/pscr.pdf - October 2003). Figure 1.1 shows the organization of a typical CRF with in a hospital environment.

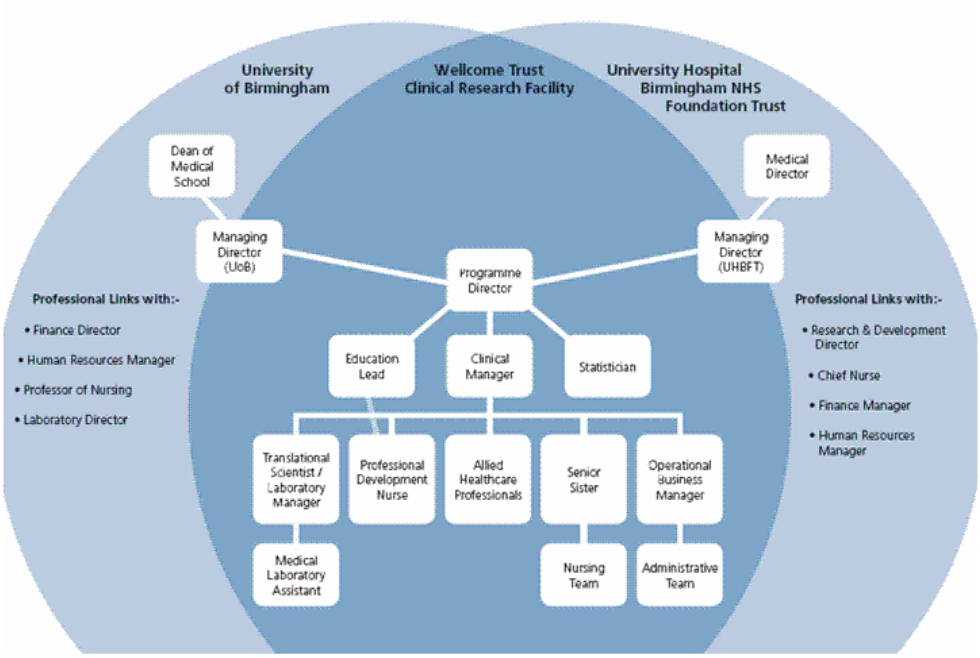


Figure 1.1: CRF within a hospital environment - http://www.crf.bham.ac.uk/

The increasing demand for research nurses and AHP's to perform high quality research and the critical role of clinical research nurse and AHP's in all phases of clinical trial makes research training mandatory for these professionals. In addition to this, the research centres such as clinical trials units, academic units and biomedical research centres often supported by partnerships between the NHS and universities enable a wide range of research that involves nurses and AHP's and develops research capacity in both these professions. With an increase in total number of NHS nurses and AHP's involving in research and with an ability to operate at the highest levels of research, the CRF in Glasgow is equipped with the necessary clinical infrastructure and research nurses and AHP's to conduct high quality clinical research. The research nurses working in all the above mentioned CRF's have common responsibilities and offer numerous services including "Meticulous implementation of protocol procedures, accurate data and specimen collection, accurate recording and documentation of procedures, assistance with screening, questionnaires, study design and trial coordination". (http://www.glasgowcrf.org.uk/links.htm). Hence, involving these professionals in clinical research would not only make their professional lives more challenging, but at the same time it would also help the clinician / researcher to improve the methodology adopted based on their feedback.

1.7 Summary

In summary, the following conclusions for the future implementation of clinical orthopaedic research can be assumed.

- Although the remarkable innovation in the field of basic and applied medical technology in the 20th century has led to improvements in the field of medicine, the health care system still seems to be in a developmental state.
- Clinical research will be strongly regulated and governed and will mostly be scientific in nature.
- The gold standard for evidence based practice will be multi centred Randomized Controlled Trials (RCT's) of effectiveness.

- Single and subsequent multi centred RCT's will increasingly be undertaken using the resources of CRF's and clinical trial units.
- Area of clinical practice such as orthopaedics without wide research networks will be supported to undertake multi centred RCT's by local CRF's.
- Orthopaedic research will be funded in a variety of forms including industrial, clinical, academic, research council and charitable funding bodies. But in order to be cost effective and regulated, the resources offered by local CRF's should be used.
- Research nurses and AHP's will be involved in research activities and this will become part of their job responsibilities and collaboration between CRF's and academic institutions will enable these professionals to work in different research activities in addition to their routine clinical duties.
- Such collaborations will result in frequent interactions between research nurses, clinical scientists, AHP's and academicians such as research fellows and bioengineers which will enhance their knowledge in both clinical and engineering aspects.
- The ability of these professionals to work within a medical technology sector also depends on the specific research protocol oriented training given to them in the operation of medical devices or measurement tools. Such training sessions can be organised either within the CRF or at the academic institution with which these professionals intend to work.
- Also, the medical devices or the measurement tools designed for routine clinical practice by non-technical professionals such as research nurses and AHP's should be simple and user friendly in nature and this has to be taken in to account by the device manufacturers.
- Orthopaedics is fundamentally about removing pain and restoring function to patients through surgery and rehabilitation. The goal is pain free normal movement. As yet orthopaedics and the clinical measurement of functional movement have had little priority or practical expression in the work of CRF's.

- If orthopaedic research is to flourish it must make use of clinically relevant movement analysis techniques which can be routinely used by nurses and AHP's with suitable training in the local CRF's participating in a multi centre trial.

1.8 Movement – A defining element of animal life

"Human function is an elusive entity"

The ability to move is the defining element of the animal kingdom. The development of functional movement and maintenance of functional skills throughout the life span with or without using tools are important facts of human beings (Durward et al., 1999). In modern life, functional movements or goal-directed movements are necessary for safety, survival, mobility, occupation, leisure, health and fitness and their presence or absence is intimately related to our well-being. (Martin, 2002, Carlsoo, 1972) Functional movement takes place throughout our life span and contributes to our complete development as individuals. Motivation to move is inborn and the ability to move increases and diminishes across the life span. (Durward et al., 1999)

Functional movement is therefore an essential and fundamental part of our behaviour and it is highly advisable to take care of such movements as they are the major determinants of health today. However, when movement is inhibited and becomes less efficient, we may be less able to meet our day to day needs. As a result, the functional independence of an individual is reduced. Such restriction in movement can have serious effects on our general health and in some circumstance can be life threatening. However, relatively little is known about functional movement. In recent years, systematic attempts have been made to study the laws governing human motion using the methods of modern science and technology. This is reportedly due to the clinical demand for highly objective and persuasive information related to human movement. (Martin, 2002, Carlsoo, 1972, Whittle, 1991) Over the last 30 years the remarkable developments in medical and measurement technology in biomechanics has facilitated clinicians and rehabilitation health professionals by providing them with relevant and meaningful information pertaining to normal or abnormal human gait, range of motion of a joint etc… The need for such information arises from a number of factors including the demand for increased understanding of joint kinematics in orthopaedics, the assessment of the efficacy of therapeutic measures; (physical, surgical or pharmacological) and the diagnosis of a number of joint related conditions. Thus, quantifying functional activity of an individual

in a living environment not only helps to describe pathological function and assess the impact of treatment, but at the same time it also provides objective information pertaining to the effectiveness of treatment. (Martin, 2002) There are a number of different instruments for quantifying functional outcomes. However to date literature doesn't suggest any standard method or instrument to assess such outcomes in a living environment and the production of one presents a considerable challenge to the clinical biomechanics research community. (Whittle, 1991)

1.9. Activities of daily living & Factors affecting Activities of daily living

The ability to accomplish specific goal directed movements, in order to carry out the activities of daily living (ADL) and functional activities is highly important for an individual to be independent. Most of the movements associated with ADL and functional abilities are voluntary movements and research reveals that these movements diminish as the individual grows older (Martin, 2002, Delbono, 2003). In addition to this, a research survey on disability and old age, (Littbrand et al., 2006, McMillan & Nichols, 2005) reports that; in Europe, out of 30 million disabled people, 70% are aged above 60. Time related natural changes between the second and seventh decades of life, alters the mechanical properties of the ligaments, increases stiffness of the joints, decreases the muscle strength to about 30% and reduces the muscle area by 40% leading to limitations in walking, diminished proprioception, reduced lower limb strength and various neurologic and non-neurologic age related changes. This in turn results in gait disorders and impairments, eventually leading to reduced joint mobility and range of motion (Littbrand et al., 2006, McMillan & Nichols, 2005). In addition to such naturally occurring physiological changes, various other factors such as physical work demanding occupations, severe injuries at specific joints, genetic predisposition and certain customarily practiced ADL's such as kneeling and squatting can result in wearing of the articular cartilage and capsular thickening of that corresponding joint. (McMillan & Nichols, 2005) The ability of individuals to accomplish their ADL is increasingly affected by these disease processes and makes the individual increasingly dependent on others.

1.10 Understanding Disability

The inability of an individual to meet his/her personal, social or occupational requirements is defined as disability. (Demeter, 2003) A disability doesn't necessarily have to be related to an identifiable impairment or health condition. Instead, "An impairment or medical condition often contributes to disability". (Demeter, 2003) A reappraisal study based on a survey by Badley et al. in 1978 revealed that stroke, all forms of arthritis and circulatory disorders are the most important causes of severe disability and onset of disability is not merely due to the naturally occurring age related changes, but also due to other occupational and environmental factors as mentioned in section 1.9. Further, this study identifies lower limb osteoarthritis as one of the underlying causes of impairment and disabling condition whereby, individuals have difficulties in performing the ADL. (Creamer et al., 2000) In the UK more than 6 million adults (www.arthritiscare.org.uk) have OA affecting their knees and about 16.3% of the proportion is severely or very severely disabled with a prevalence rate of 18.67 per 1000 population (www.agingsociety.org) and in the U.S.A, nearly 12.1% of the population aged 25 and above have such a degenerative condition (www.agingsociety.org)

OA being closely associated with my current research, in the subsequent paragraphs, its epidemiology, various diagnostic and treatments available for OA and the outcomes of such treatments will be discussed in detail.

1.11 Osteoarthritis

1.11.1 Definition and Types

The term osteoarthritis is derived from the combination of the three Greek words; *osteo* meaning *of the bone*, *arthro* meaning *the joint* and *itis* meaning *inflammation*. The world health organization (WHO, 2000) defined osteoarthritis as:

"A condition characterized by focal areas of loss of articular cartilage within synovial joints associated with hypertrophy of bone (osteophytes and subchondral bone sclerosis) and thickening of capsule".

Such a degenerative process which was traditionally considered to be slowly progressive is now viewed as a dynamic process that develops episodically due to various environmental, genetic and biomechanical stresses.

There are two types of osteoarthritis. Osteoarthritis is defined as primary when it occurs without any known cause, and as secondary when it is caused by obesity, hormone disorders, repeated trauma or surgery to the joint structures leading to demonstrable abnormality in the anatomy and mechanics of the joint. More and more evidence is accumulating that most osteoarthritis in the middle-aged and elderly is secondary in nature and occurrence of primary osteoarthritis is rare. However, research by Haq et al., 2003 reveals that in women, primary OA is more common due to hormonal changes (Priestley and Rabiee, 2001, www.agingsociety.org, WHO, 2000). Since, a detailed explanation about the pathophysiology of OA is beyond the scope of this thesis, the etiology risk factors, pathophysiological processes and disease outcome are summarized in the figure shown below.

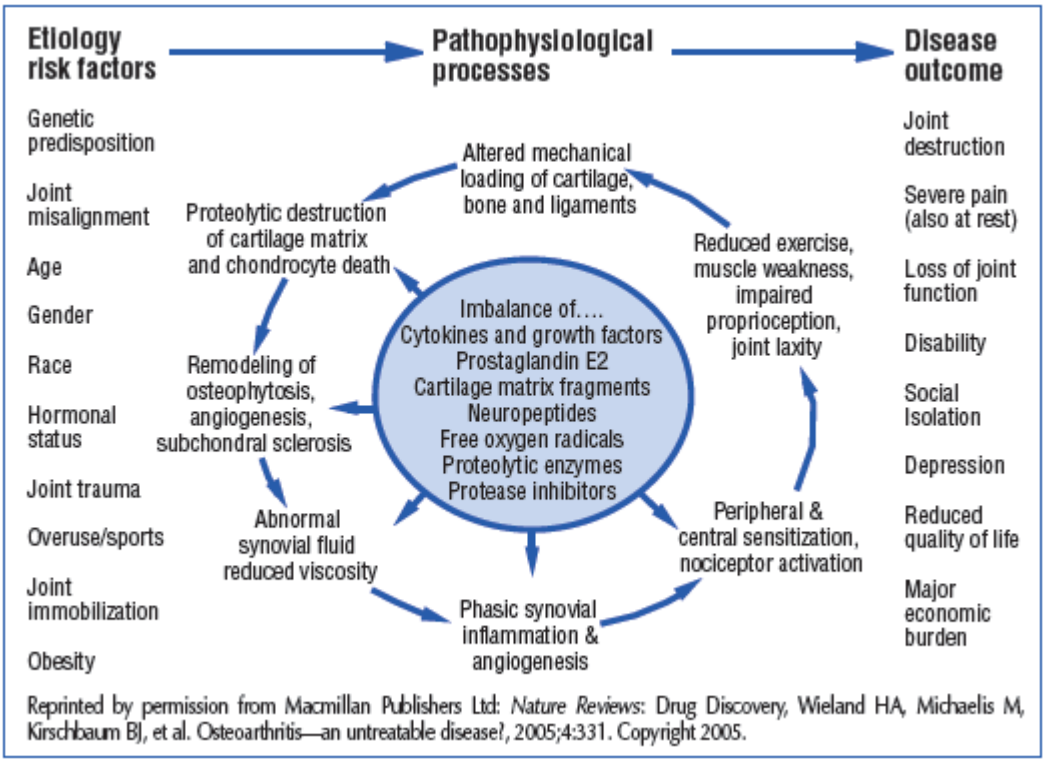


Figure 1.2: Pathophysiology of OA

1.11.2 Epidemiology

Osteoarthritis is considered to be a major cause of disability affecting people of all ages. However, higher percentage of elderly population (46%) aged 65 and above are said to be more prone to this condition. On the other hand, a survey report by the national academy on aging society shows that, nearly 48% of the population under the age of 65 (including almost 200,000 children) has osteoarthritis (www.agingsociety.org, WHO, 2000). Among which, 12.1% of the population are in their second and third decades of life and 36% of the population are aged between 45 and 64. In the U.K, up to 550,000 people have been diagnosed with severe knee osteoarthritis and research reveals that 2 million people have visited their general practitioner in the previous years because of this degenerative condition. In addition to this, in England and Wales, nearly 1.75 million people have been diagnosed with symptomatic osteoarthritis. Similarly in the U.S.A it is reported that, one of every 12 people have osteoarthritis. As the incidence of osteoarthritis seems to affect individuals irrespective of age, (more common in older adults) there is an increasing number of people at risk of osteoarthritis in western countries like U.S.A, U.K, etc. Development of osteoarthritis is also effected by ethnic and racial groups. (www.agingsociety.org, WHO, 2000) The percentage of people with osteoarthritis; especially in the hip and hand joints in china and those of Chinese origin in the U.S.A is very small compared to knee osteoarthritis. In Beijing, 46.6% of the elderly women have knee osteoarthritis compared to its prevalence in the U.S.A – 34.8% (Zhang et al., 2001). This could be due to various genetic factors, other day to day occupational activities, nutritional factors and also due to impact of different lifestyles. From the above discussion, it's very evident that the incidence and prevalence rate of OA is high across the globe and as a result, a very high percentage of the NHS budget is likely to be used to provide long term care for OA patients in the future. Decision related to the design of OA services take into account the impact of OA on an individual and on the economy of the country (www.agingsociety.org, WHO, 2000). This is discussed in the following section.

1.11.3 Impact of OA on individual and economy

OA has adverse impact on physical, mental and social well being of an individual and it's a leading cause of substantial physical disability and functional impairment. According to a 1999 health research survey, a high percentage of population (50%) suffering from knee OA, have difficulties in carrying out activities such as kneeling, stooping and crouching and more than 30% of adults diagnosed with OA found it very difficult to walk a quarter of a mile. As pain and physical limitations increases, osteoarthritic patients develop different ways of modifying their behaviour and movements so as to reduce the demands on their knees. Further, they are also subjected to emotional distress to a greater extent and they rate themselves as poorly or fairly healthy. (Priestley and Rabiee, 2001, www.agingsociety.org, WHO, 2000)

As physical limitations increases, it becomes difficult to carry out basic household duties. Hence, people with OA accomplish their ADL and instrumental activities of daily living (IADL) such as taking medications, shopping, preparing meals, using the phone etc… by seeking assistance from their spouse or relatives. Research shows substantial amount of evidence pertaining to various other concomitant diseases such as hypertension, metabolic and nutritional disorders, musculoskeletal, connective tissues, bone and gastrointestinal system disorders associated with OA. This in turn has motivated various researchers to focus their interest on identifying different diagnosis techniques to study the early development of such a disabling condition and provide permanent remedial measures to individuals suffering from OA through gene therapy and other biological cures. (Priestley and Rabiee, 2001, www.agingsociety.org, WHO, 2000)

However, until such one cure is found, OA will continue to significantly affect the quality of life of many individual. Based on a research survey conducted by "The Association of the British Pharmaceutical Industry", OA influences the economy of a country significantly. With an initial investment of £ 341 million on drugs and other medications, £ 566 million has been spent for general hospital and GP consultation and in addition to these expenses, with the increase in number of joint replacements (80,000 hip/knee replacements) in UK every year, the cost of operations to replace hip and knee joint was estimated to be £ 405 million; increasing the overall cost to the NHS and social

service to £ 5.5 billion. Even Though this is the overall cost of arthritis, OA is reported as the largest component of this overall expenditure. Due to such significant impacts, early diagnosis and effective management of OA seems to be highly recommended. (http://orthoinfo.aaos.org/brochure/thr_report.cfm?Thread_ID=18)

1.11.4 Diagnosis of Osteoarthritis

As far as the diagnosis of the osteoarthritis is concerned, no single test is available for this degenerative disorder. The physician generally diagnoses the disease by combining various methods. Initially, the clinical history of the patient is obtained and the description of various conditions and symptoms that have changed over time helps the physician to understand the severity of the disease. (Johanson et al., 2004) This would also help the physician to know, whether the patient has had any other medical problems or medications which should be considered during the treatment of osteoarthritis. Following the preliminary diagnosis, the clinician carries out a detailed investigation involving examination of the muscle strength, reflexes and general health of the patient, including the pain in the affected joints, ability of the patient to walk, bend and carry out ADL. (Johanson et al., 2004)

Difficulties in performing the above activities by the patients would lead to tertiary stage of diagnosis, which involves x- rays, magnetic resonance (MRI) and computer tomography (CT) imaging of the joints so as to get a better picture of the joint damage, cartilage loss and severity of osteoarthritis. Even Though radiographic techniques are cheap, easily available and provide a permanent record, they cannot be used for measuring the disease progression because, they reveal details only about the narrowing of joint space. Further, reviewing the literature reveals that, MRI is only useful in assessing meniscal and ligament tear in knee and they are not used currently for diagnosing preclinical osteoarthritis. Though CT imaging has advantages compared to plain radiographic techniques, it cannot be used on a routine basis in a clinical environment. On the other hand, radionuclide imaging reveals very limited anatomical details and hence it's considered to be inadequate in assessing disease progression. Currently, a combination of the above techniques together with various questionnaires are

being used by clinicians for measuring the disease progression and assessing the functional outcomes of an intervention to ascertain the impact of OA on the lifestyle of individuals. (Johanson et al., 2004, Demeter et al., 2003)

1.11.5 Managing Osteoarthritis

From the above discussion, it is evident that, OA not only affects the physical, mental and financial well being of an individual, but also affects the society and economy of the country to a greater extent. Therefore, efficient management of OA is essential. There are various osteoarthritis management interventions in clinical practice. These interventions are decided based upon the severity of the disorder and they are planned uniquely for each individual. These include; proper education, weight loss techniques, exercises and physiotherapy programmes (Non-drug pain relief), medications for pain relief and surgery (MacAuley, 2004). Given that, OA has such a remarkable economic impact, the selection of suitable management techniques which could relieve the patients from the distress of OA is highly valuable. Some of the approaches are described below and the guidelines given by NICE for the management of OA in adults are shown in figure 1.3 and 1.4:

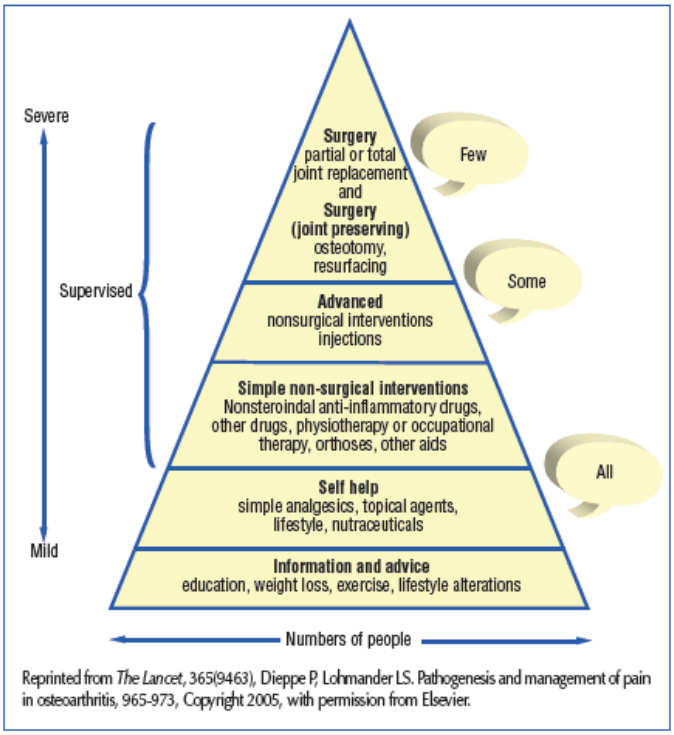


Figure 1.3: Various stages in the management of OA

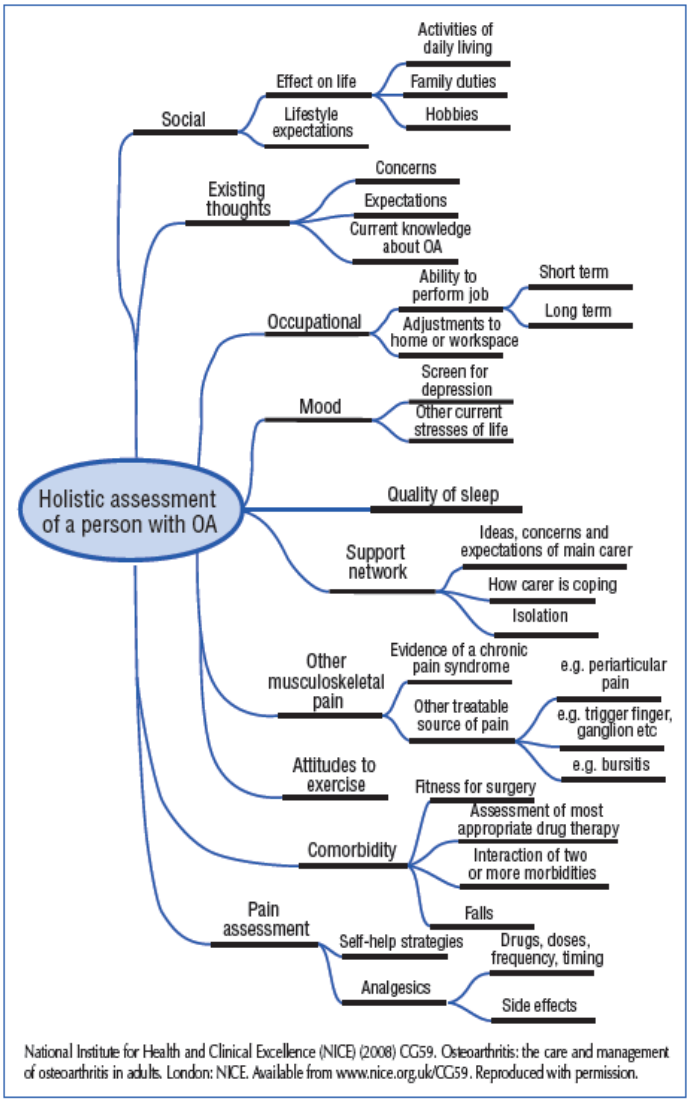


Figure 1.4: Guidelines provided by NICE for the management of OA

Education: In OA, patient education and social support is considered to be a low cost and an effective way to decrease pain and reduce the amount of medicines used. Further, interaction between health professionals and patients, concerning treatment instructions can improve treatment and self care. Research shows that, the functional outcomes of people participating in such programs are likely to be positive. This kind of self management program gives better understanding of disease progression to the patients, increases their self confidence and helps them to remain active and develop an ability to control the disease and manage the pain. This in turn, helps the patients to cope

physically, emotionally, mentally and to live an active and independent life. (http://www.emedicine.com/orthoped/topic384.htm)

Exercises: Exercise is considered to be one of the best treatments during the early stages of OA. Some of the most popular types of exercises for people with OA include; swimming, water aerobics and walking. Though such exercises can increase flexibility, improve the range of motion, reduce weight and promote general physical fitness, the chances of these exercises being performed by patients with acute osteoarthritic pain and significant functional loss are reduced. Prescription of such exercises by a doctor or physical therapists is limited and will depend on the joints involved and their stability (Jordan et al., 2003, MacAuley, 2004)

Weight Control: Individuals who are obese or overweight have increased stress on their weight bearing joints. (http://www.emedicine.com/orthoped/topic384.htm). This in turn can worsen their injury and limit their mobility. Hence, during the early stages, when an individual is being diagnosed with OA, the patient with the help of a dietician and regular exercises should try to reduce weight so as to prevent the further development of the disease.

Non-Drug pain relief: There are various non-drug pain relief techniques available for osteoarthritic patients. Some of them are as listed below: (Jordan et al., 2003, MacAuley, 2004)

- Applying hot or cold pack; increases blood flow, reduces inflammation, numbness or stiffness and relieves pain.
- Alternatively, small electronic devices are also being used to apply direct mild electric pulses to the nerves underlying the painful area. As a result, the pain messages transmitted to the brain is being blocked and the pain perception is modified. This is known as transcutaneous electrical nerve stimulation (TENS).

- On the other hand, increasing the blood flow and bringing warmth to the painful or stressed joints with the help of a massage therapist familiar with the problem of the disease is another pain relief approach.

Medications for pain relief: Depending upon a number of factors such as the patient medical history, potential side effects of the medication and the intensity of pain the doctors prescribe medicines to osteoarthritic patients. However, literature reports the lack of drugs that can treat OA directly. Most of the drugs prescribed by the doctors are pain relievers that help to ease some of the pain and reduce inflammation associated with OA. In addition to these medicines, several other medications such as topical pain-relieving creams, sprays and rubs are also being used by osteoarthritic patients on doctors' prescription. Such products are applied directly to the surface of the skin above the affected joints. The specific ingredients in these products distract the brains' attention from the joint pain by stimulating the nerve endings. Alternatively, certain other pain relieving creams deplete a particular neurotransmitter substance present in the painful joints and also block the pain inducing chemicals called prostaglandins, thereby interrupting the pain messages sent to the brain and reducing the inflammation in the affected joint. (http://www.emedicine.com/orthoped/topic384.htm, MacAuley, 2004)

Though these medications may not be as effective as the actual pain killer drugs, the side effect of these topical pain relieving creams are reported to be minimal. The commonly used medicines in the treatment of OA include; acetaminophen, non-steroidal anti-inflammatory drugs (NSAID's), tramadol, mild narcotic pain killers, corticosteroids and hyaluronic acid substitutes. While most of these drugs are available only with a doctor's prescription, certain commonly used pain relieving drugs such as acetaminophen are available even without a prescription. However, the research reveals the existence of certain potential concerns to be borne in mind when using these drugs. Interaction of some medication with one another can increase the risk of drug side effects. Commercially, a large variety of NSAID's are available and each chemical has different reaction and slightly different effect on the body. Moreover, due to this peculiar nature of NSAID's, when used along with other drugs, they alter the way in which these other drugs are being used or eliminated by our

body. (http://www.emedicine.com/orthoped/topic384.htm, Jordan et al., 2003, MacAuley, 2004)

Long term use of NSAID's by people who have heart disease is strongly discouraged by the food and drug administration (FDA) – U.S.A, as this might increase the chance of a heart attack or stroke. On the other hand, natural or man-made corticosteroids, which are powerful anti-inflammatory hormones, are generally not recommended for more than 2 or 4 treatments per year. Depending upon the type of joint being affected by OA, certain visco-supplement products such as hyaluronic acid substitutes are also being used as a substitute for normal joint component involved in joint lubrication and nutrition. Such products are generally used for knee joints. The general side effects reported in the literature include; stomach irritation, kidney dysfunction, serious gastrointestinal problems including ulcers, bleeding, perforation of the stomach or intestine, heartburn, diarrhoea, fluid retention and to the worst scenario, certain drugs like Tramadol (Ultram) include the potential for addiction. (http://www.emedicine.com/orthoped/topic384.htm, Jordan. et al., 2003, MacAuley, 2004) However, following healthy eating habits such as avoiding stomach irritants such as tobacco, caffeine and alcohol, avoiding medications in empty stomach (unless prescribed) and in some cases, use of certain other medications along with NSAID's could be taken to coat the stomach or block stomach acids, would help in minimizing the potential side effects rather than completely eliminating them.

Surgery: The above explanation gives us a clear picture that, the medications used for the treatment of OA can provide temporary relief of pain and don't focus on completely curing OA or improving the functional outcome of the patients. There is an imbalance between the resources spent on drugs and patient satisfaction. Under these circumstances, Total joint replacement (TJR) is considered as a permanent remedy. However, the decision to use surgery depends on several factors including the age, occupation, level of disability, pain intensity and degree to which OA affects the lifestyle of an individual. (http://www.emedicine.com/orthoped/topic384.htm, Jordan et al., 2003, MacAuley, 2004) The first osteotomy on an ankylosed hip was performed by Barton in 1826,

followed by total hip arthroplasty performed by Wiles in 1938, and by Walldius, who pioneered the development of the hinged design of total knee arthroplasty in 1950.

In TJR, the affected joint is replaced with an artificial joint made of metal alloys, high density plastic or ceramic materials shaped to restore the joint movement and function. The design of such joints is based on the weight, sex, age and activity level of the patients undergoing the surgery. Joint replacement surgery aims to alleviate pain, minimize complications and maximize the functional abilities of an individual by removing the debris (loose pieces of bones and cartilage) from the affected joints and providing relief from pain. Further, reviewing the literature shows that, such procedures have grown dramatically over the past 35 years, improving the quality of life for millions of patients. (http://www.emedicine.com/orthoped/topic384.htm, Jordan et al., 2003, MacAuley, 2004) Although it's not necessary for all osteoarthritic patients to undergo surgery, it is usually performed on those patients who require bone resurfacing and repositioning. Generally, the surgery is thought to fulfil its aim and is positive in more than 9 out of 10 people, there are certain post-operative complications that need to be taken into account. Research reports the prevalence of asymptomatic deep vein thrombosis in 50 -70% of people and occurrence of infection in 1- 2.5% of cases undergoing total knee arthroplasty. Other complications include; loosening and dislocation of prosthesis, prosthetic breakage, wear and nerve injury.

Despite such post-operative complications, most patients undergo a knee replacement to regain their original knee functionality and accomplish their ADL independently.

1.12 Functional outcome measurement following total knee arthroplasty (TKA)

From the above discussions, it is evident that knee arthroplasty is established for management of patients with disabling knee OA and a large number of patients are undergoing this valuable procedure. (Liebenson, 2007; Myles et al., 2002; Boonstra et al., 2006; Rowe et al., 2001, 2005)

Though a number of studies have confirmed the ability of knee arthroplasty to remove pain and improve the quality of life together with an increase in the general mobility of individuals, reviewing the literature reveals the persistence of post-operative back-related

problems and knee scar pain, which in turn restricts the individuals in performing certain activities such as kneeling, squatting, etc. In addition to this, it has also been reported that, the outcomes of kinematic assessment of knee joint range of motion during activities such as; timed up and go test, 6m walk and stair ascent prior to TKA continued post surgery. Consequently, to address these functional deficits, post-surgical rehabilitation is recommended. (Liebenson, 2007; Myles et al., 2002; Boonstra et al., 2004; Rowe et al., 2001, 2005)

At this point of time many orthopaedic and rehabilitation health professionals aim to restore the joint motion of their clients by promoting rehabilitation of functional activities. It is believed that the status of the joint can be ascertained by measuring the active and passive joint range in static/supine positions. Nevertheless, such measures are reported to exhibit poor inter-tester reliability and concurrent validity and have not been shown to reflect the actual functioning of the joint during functional activities exhibited by individuals during ADL. (Rowe et al., 2001) Measurement of dynamic knee joint range of motion during functional activities is seldom performed in the clinical setting. Hence, to meet the increasing demand for EBP, a standard method to measure the dynamic behaviour of a joint during a number of activities in a clinical environment, required to be established by the rehabilitation community. Currently, the assessment techniques available for this purpose include: questionnaire based assessment, assessment based on clinical gait analysis, X ray, physical examination, photography and video systems. The former technique makes use of knee scoring questionnaires such as the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Knee Society Clinical Rating System, American Society of orthopaedic surgeons' clinical rating systems and Harris Index (Rowe et al., 2005). Even Though these questionnaires are popular, easy to administer and characterize the overall performance of an individual, research reveals that they are highly subjective, unsuccessful in detecting the change in function due to the overlap of questions in the main scale with subscale and do little to reveal any objective information regarding the actual restoration of the knee function achieved by an individual while performing ADL. (Boonstra et al., 2006)

On the other hand, have photography and video based analysis of subjects after knee replacement provides information pertaining to knee joint kinetics and

estimates the implant loading, research reveals that these are expensive, complex and time consuming processes and generally have only been used in laboratory settings for small populations. (Rowe et al., 2005) Further, these systems are reported to be sensitive to range of errors and to overcome such issues, highly trained individuals with good knowledge of normal and pathological gait are required. (Begg et al., 1989) Most of the studies carried out in the past, measured the functional activities of a subject in a laboratory environment and research shows that the result of such studies varies to a greater extent than those from studies conducted in an unconstrained free living environment. (Bussman et al., 1995) Therefore, in order to evaluate the functional activity of the lower limb, following an intervention(especially a surgery), a simple user-friendly system with improved data collection technique that allows monitoring of the lower-limb activity in a free living environment is needed. Such objective information can be used for clinical decision making (about the type of treatment) and to assess the clinical effectiveness of an existing treatment. However, there are criteria for selecting the appropriate measurement technique based on each of their advantages and disadvantages as shown in table1.3. (Bontrager; 1998, Whittle; 1991; Steele et al., 2003; Lea et al., 1995)

Selection Criteria	Questionnaire Assessment	Functional assessment in Laboratory Environment	Functional assessment in Non-laboratory Environment.
Validity	YES	YES	YES
Reliability	YES	YES	YES
Possibility for Bias	YES	YES	NO
Highly Subjective	YES	NO	NO
Highly Objective	NO	YES	YES
Preferred method for clinician and Researcher.	NO	NO	YES

Table1. 3 – Criteria for selecting an appropriate measurement technique

With the advancement in medical technology, such requirements are fulfilled by making use of assessment techniques comprising of sensors such as Pedometers/step counters, Inclinometers, accelerometers, gyroscopes and flexible electrogoniometers. Such body mounted transducers are commonly used in combination with data acquisition systems and the selection of sensors as part of the assessment technique depends on the specific application. However, each of these sensors has certain limitations and they have to be borne in mind when selecting the sensors for a particular application (Huddleston.J et al., 2006). These limitations are listed below in table 1.4.

S.No	Sensors/ Transducers	Applications	Limitations	Authors/ Year
1.	Electronic Dual Digital Inclinometer	Used in measuring joint repositioning sense of knee.	This device cannot be used for studies involving dynamic motion of knee	Stewart, Sleivert, 1998; Luinge, Veltink, 2005.
2.	Gyroscopes	Used in measuring the orientation of human body segments	• This device can be used only in combination with accelerometers. • Need to integrate the angular velocity to obtain the desired output. • Need additional filtering hardware or software algorithms. • Possibility of integration and inclination errors. • No information regarding the usage of this sensor in the measurement of flexion/extension of knee so far.	Cikajlo, Bajd, 2003; Kuan Zang et al., 2003
3.	Accelerometers	Used in measuring the orientation of human body segments	• Less accurate for movements with relatively large accelerations. • Do not give complete description of orientation. • Parameters measured are subjected to errors due to vibration. • Analyzing the output signal depends on the positioning of the sensor.	Cikajlo, Bajd, 2003; Kuan Zang et al., 2003; Steele et al., 2003.

Table 1.4: Limitations of various body mounted transducers

S.No	Sensors/ Transducers	Applications	Limitations	Authors/ Year
4.	Pedometers/Stepcounters	Used for measuring the mobility of individuals.	• Designed specifically for waist and ankle only. • Doesn't provide data pertaining to the functionality of knee in particular and less sensitive to small improvements in walking activity.	Kuan Zang et al., 2003; Steele et al., 2003.

Table 1.4: Limitations of various body mounted transducers

In recent years, flexible electrogoniometers have been used widely for assessing the angular motions of the joints and this transducer has gained in clinical popularity due to its stable, accurate, precise and reproducible nature in assessing the effectiveness of rehabilitation interventions and measuring the functional outcomes of post-operative patients (Rowe et al., 2001). The flexible electrogoniometer reveals information pertaining to the functional ability of the subjects undergoing clinical interventions and helps the health professionals involved to improve the quality of their rehabilitation program. (Steele et al., 2003; Rowe et al., 1989) However, these transducers are fragile and have to be attached to the joints of interest carefully, so as to yield accurate results. Hence, they cannot be operated by untrained staff without appropriate training. (Myles et al., 2001; Rowe et al., 1989, 2001)

1.13 Flexible electrogoniometer

A Flexible electrogoniometer (Rowe, 1989) is a modern instrument which provides clinicians and researcher's objective data corresponding to human locomotion and it's the most common direct joint measurement method and continues to gain in popularity when used to assess the function of patients following total joint replacement. This transducer adopts the technique of goniometry which is commonly used in physical therapy for

assessing the range of motion of joints, especially in individual's suffering from any medical conditions which could limit their joint motion or in case of patients following a rehabilitation intervention. The measurement of functional range of motion of joint angle provides an objective way to document normal and pathological gait pattern, which in turn can be used as references for outcome measures following clinical treatment (Rowe et al., 2001). Currently, flexible electrogoniometers are widely used in many applications. However, prior to using the transducer in an application, various characteristics of the flexible electrogoniometers have to be studied with respect to the literature and these are explained in detail in the following paragraphs.

Precision or repeatability: The precision of flexible electrogoniometer refers to the degree of reproducibility of a measurement made by the transducer. Various researchers have reported on the precision of the transducer when used in different applications. In a study involving the assessment of lumbar spine sagittal kinematics of healthy subjects using an electrogoniometer, Thoumie et al. (1997) reported the repeatability of the transducer to be ±1° for an angular movement of ±90°. Similarly, in an application involving the measurement of functional asymmetries of the lower limb using electrogoniometry, Maupas et al., 2002 reported the intra-sensor reproducibility (during walking) to be 1.4°±1.1° (range: 0-3.5°). Another practical application of electrogoniometers was in the measurement of postures and movements during repetitive work by Kristensen et al. (2001). The researchers used biaxial electrogoniometers for recording the flexion-extension and deviation angles of right and left wrist and concluded that the precision of the goniometer as a mean measured over 90° from neutral position to be ±1.5°.

Accuracy: The accuracy of the flexible electrogoniometer is the maximum difference that will exist between the actual value and the indicated value at the output of the transducer. Maupas et al. (2002) investigated the application of this transducer in measuring the functional asymmetries of the lower limb and reported that, the accuracy of electrogoniometer is 1.3±1.1°(Range 0 - 4°). On the other hand, Hazlewood et al. (1995) reported the accuracy of electrogoniometer to be within 3 degrees when used as a

measurement tool for passive movement and gait analysis. Similarly, Brumagne et al. (1999) reported that, the accuracy of the electrogoniometer was 0.42° when used for measuring the range of pelvic tilting in determining the lumbosacral repositioning accuracy. However, the researchers concluded that the accuracy of the transducer varies, depending upon the anatomical joint in which the device is used.

Reliability: Reliability is the degree to which the flexible electrogoniometer measures the same way each time when it is used under the same condition with same subjects. The first author's to report on the reliability of goniometric measurements were, Hellebrandt et al. in 1949 (Gogia et al., 1987). The author's tested the reliability of a simple goniometer when used in shoulder, elbow, radioulnar and wrist joints. They concluded that, there is a high degree of reliability when the range of motion of specified joints are being measured by well-trained physical therapists. Similarly, studies by Hamilton and Lachenbruch (Gogia et al., 1987) reported that the reliable information of the hand joint function when using this device could be obtained with the help of an individual therapist capable of making accurate repeated observations. However, they did not report anything on the inter-rater reliability of measurements. Also, certain author's have carried out reliability study, comparing two different types of electrogoniometers namely; flexible electrogoniometer and potentiometric goniometers. One such investigation by Tesio et al. (1995) involved the comparison of kinesiological advantages between these two different types of goniometers and concluded that; with better adaptation to all body parts, flexible electrogoniometer are more reliable compared to potentiometric goniometers.

In another study by Goodwin et al., the authors aimed to compare the reliability and interchangeability of 3 types of goniometers: universal, fluid and electrogoniometer and reported that, the use of electrogoniometer reduced the variability between testers and interchangeability of goniometers is not preferable (Gogia et al., 1987). The result of their studies also suggested that, the interclass correlation coefficient for electrogoniometer is slightly higher than videotaping. The results of the above studies seem to be similar to those reported by Rothstein et al., where the authors found a high inter-tester reliability when using the device in a clinical setting for measuring the elbow flexion/extension and knee flexion (Gogia et al., 1987). However, the inter-tester

reliability for knee extension has been reported to be poor by these researchers. As far as the reliability of the device with respect to upper/lower extremity joints are concerned, a study by Boone et al. (Gogia et al., 1987) shows greater reliability for three upper extremity motions than for lower extremity motions. However, the inter-tester reliability of goniometric measurements of the major joints of upper and lower extremities has been reported to be high in the studies carried out by Mayerson and Milano (Gogia et al., 1987).

Validity: Validity refers to the ability of an instrument to measure what it claims to measure. Rowe et al. (2001) carried out the validation of Flexible electrogoniometer against Vicon system and the authors reported a high degree of concurrent validity between the two systems. However, minor differences (in the order of 2 or 3 degrees) were observed between the results of the electrogoniometer and Vicon system in terms of mean range of motion, mean maximum and mean minimum angles, mean pattern of motion and the range of motion, which according to the authors are clinically acceptable. Similarly, Jamshidi and Smith; 1996 compared their findings with angular data collected by video camera and showed that angular displacement of the knee joint in people with abnormal knee extensor muscle tone measured using electrogoniometer is valid and reliable. Further, the validation study carried out by these researchers showed that, movement under an angle of 35° in the x-x plane corresponding to the frontal plane of the knee; do not modify the measurement in the sagittal plane. As a result, the author's suggest that an asymmetry of 35° in the frontal movement of knee varus-valgus does not interfere with the measurement of flexion-extension amplitude.

Hysteresis: Hysteresis is the measure of the capability of the flexible electrogoniometer to follow the changes of the input parameter regardless of the direction in which the change is made. Research carried out by Rowe et al., 2001 reveals the presence of small hysteretic effect when the device is manipulated in different directions. The authors have reported a maximum hysteretic effect of 1.2° or 1.1% for an excursion range of 10° to 120°. Also the researchers have predicted a maximum increase in the hysteretic effect to 1.5% with an increase in the measuring range. However, with functional activities

involving joint movements with a range less than 100° in most of the clinical testing, a maximum hysteretic effect of 1° is said to be expected (Rowe et al., 2001).

Stability: Signal stability of flexible electrogoniometer is the ability of the transducer to produce stable signal over a definite period of time under static conditions. The stability of the signal produced by the device under various static positions; 0°, +90° and -90° has been reported to be stable over an hour and doesn't seem to vary more than 0.2% of the measured range (Rowe et al., 2001).

Other Features of the transducer: The other miscellaneous features of the transducer include its simplicity, usability, cost-effectiveness and amount of time taken to administer the device and acquire the information pertaining to clinical relevance. Many researchers have used the flexible electrogoniometers in different applications and have revealed their experience in using the device. Myles et al. (2001) used this device to record the maximum and minimum knee flexion-extension angle and knee excursion during 11 functional activities and the author's suggested that, electrogoniometry had proven to be a simple, cheaper, quicker and reproducible method of quantifying functional range of movement and producing an objective measurement of Knee function, compared to conventional gait analysis. Further, the instrument seems to have provided unique insight into the function of the knee joint during a range of activities. The authors have reported the device to be simple to operate, comfortable to wear, minimally invasive and acceptable to patients despite few technical issues. However, the author's have not mentioned in detail about the technical difficulties experienced by them and have concluded by reporting, flexible electrogoniometer as a suitable outcome measure for research and audit. Similarly, Rowe et al., (1989) used flexible goniometers to record the flexion-extension angles of both hips and knees in patients who have undergone total hip replacement. Following the usage of this instrument, the author's have concluded that this transducer has proven to quantify the functional status of patients who have undergone total hip replacement (THR). The authors have felt that the use of the transducer is simple and economical within the clinical environment. Further, the results obtained from these transducers have proven to be reliable compared to those obtained from Harris index.

However, from author's point of view, this device is a practical, readily accessible and clinically useful measurement system, provided; appropriate care is taken in handling and mounting the transducers during specific applications. At the same time, Walker et al. (2001), used this device in assessing the function of knee in Osteoarthritis and concluded that, the flexible electrogoniometer accurately measures the functional range of motion during various activities of daily living such as walking, stair climbing and rising from a chair and the system is relatively inexpensive and easy to use in a non-laboratory setting with minimal inconvenience to the patients. Similar to Rowe et al. (2005) who used electrogoniometry in determining the knee joint movement during functional activities and joint range of motion, these researchers have recommended the use of this system as an objective tool for evaluating different surgical techniques for TKR.

Errors: Similar to other transducers, flexible electrogoniometers also suffer from certain application and characteristic errors resulting in a difference between the measured value and the true value and various researchers have reported the existence of such errors with respect to flexible electrogoniometers as discussed below.

Rowe et al., 2001 have reported the presence of little variations between and within the electrogoniometers at different times, on different days due to certain manufacturing defects of the device resulting in systematic errors from -1° to +2° over a measurement range of 100°. These results are similar to the findings of Shiratsu and Coury; 2003, who have reported a maximum error of the transducer to be less than ±3°. Also, the study carried out by Rowe et al. sheds light on the substantial errors given by these transducers, when they are subjected to abduction-adduction angles equal to or greater than 40 degrees and simultaneous flexion or extension. However, the device has not been reported to be affected by environmental pollutants, heat, convection currents or noise and the authors have suggested its use in variety of Hospital environments. In addition to these errors, certain researchers, Kettelkamp et al., 1970, Stal.M et al., 1999; have also reported errors produced by the device due to skin artifacts and as a remedial measure Rowe et al., 2001 have recommended the use of attachment plastic strips and Velcro straps to avoid the application errors due to the soft tissue movement, skin artifacts and improper attachment of the device resulting in their slippage and inaccurate

joint angle measurement. In another application involving the use of electrogoniometers in the measurement of postures and movements during repetitive work by Kristensen et al. (2001), the authors have revealed the presence of crosstalk of the goniometers when used in measuring the flexion/extension and abduction/adduction of the wrist joint to be 8% in neutral position, 77% in extreme supination and -32% in extreme pronation (Stal et al., 1999, Kristensen et al., 2001) Similarly, Yen & Radwin (1999) used flexible electrogoniometers in measuring the upper extremity joint angles - wrist, elbow and shoulder of dominant limb during five different industrial jobs. As part of this study, flexion-extension and ulnar-radial deviation of wrist and shoulder and flexion-extension of elbow was measured and the researchers have figured out an error of less than 5% for wrist and elbow and an error of less than 10% was obtained for shoulder following the calibration of joints within a range of motion for each task. However, this estimation does not seem to match with the results reported by Stal.M et al. and Kristensen et al. In a study involving the assessment of lumbar spine sagittal kinematics of healthy subjects, Thoumie et al. (1997) have reported crosstalk between the electrogoniometer channels to be equal to or less than 1° for a lateral bending of less than 30 degrees. Many researchers have considered the transducer as a simple and convenient tool for use in clinical studies and list of these applications is summarised below in table 1.5.

S.No	Transducer	Application	Authors
1	Electrogoniometer	Used in the study of knee motion in normal gait	Kettlekamp et al. – 1970.
2	Goniometer	Total knee motion knee goniometry.	Townsend et al. – 1977.
3	Goniometer	Reliability and validity of Goniometric measurements at the knee.	Gogia et al. 1987.
4	Flexible electrogoniometer	Used to record the Flexion-extension angles of both hips and knees in patients who have undergone total hip replacement.	Rowe et al. – 1989.
5	Goniometer	Clinical Methods of Goniometry – A comparative study. Here it has been used in measuring the elbow flexion-extension.	Goodwin et al. – 1992.
6	Electrogoniometers	Used as passive movement measurement tool.	Hazlewood et al. – 1995.
7	Flexible electrogoniometers / Potentiometric goniometers.	Kinesiological advantages of FG with PG.	Tesio et al. – 1995.
8	Electrogoniometer	Clinical Measurement of spasticity – Comparison of electrogoniometric and videotape analyses.	Jamshidi et al. – 1996.
9	Electrogoniometer	Assessment of wrist movement.	Rawes et al. -1996.
10	Electrogoniometer	Used in the assessment of lumbar spine sagittal kinematics of healthy subjects during a dynamic test.	Thoumie et al. – 1997.
11	Flexible electrogoniometer	Used in the continuous measurement of joint angles – wrist, elbow and shoulder of dominant limb during five different industrial jobs.	Yen, Radwin – 1998.
12	Electrogoniometer	Used in determining lumbosacral repositioning accuracy	Brumagne et al. – 1999.
13	Electrogoniometers	Used to quantify a rower's ankle, knee, hip, and elbow flexion / extension angles.	Hawkins - 1999

S.No	Transducer	Application	Authors
14	Electrogoniometer	Used for detecting Asymmetric leg activity in healthy subjects during walking.	Maupas et al. – 1999.
15	Flexible electrogoniometer	Used in the measurement of knee joint kinematics in gait and other functional activities.	Rowe et al. – 2000.
16	Electrogoniometer	Passive knee angular displacement data was collected by using an electrogoniometer.	Smith et al. – 2000.
17	Flexible electrogoniometer	Used to record the maximum and minimum flexion-extension angle and flexion-extension excursions of both knees during 11 functional activities.	Myles et al. - 2001
18	Electrogoniometers	Used in the direct technical measurement of postures and movements during repetitive work.	Kristensen et al. – 2001.
19	Flexible electrogoniometer	Validation of Flexible electrogoniometer against vicon system as a measure of joint kinematics.	Rowe et al. – 2001.
20	Flexible electrogoniometer	Used in assessing the function of knee in Osteoarthritis.	Walker et al. – 2001.
21	Flexible electrogoniometer	Validation of equinometer with goniometers - Ankle measurement.	Weaver et al. 2001.
22	Flexible electrogoniometer	Used in measuring the functional asymmetries of the lower limb.	Maupas et al. – 2002.
23	Flexible electrogoniometer	Reliability & Accuracy of different sensors of FEG.	Shiratsu, Coury et al. – 2003
24	Flexible electrogoniometer	Used in the measurement of wrist and forearm positions.	Hansson et al. – 2004.
25	Flexible electrogoniometer	Used in measuring knee, hip angles and angular velocities.	Boonstra et al. – 2006.
26	Electrogoniometer	Used for recording the elbow movement.	Burns et al. - 2005
27	Electrogoniometer	Used in determining the effect of TKA on joint movement during functional activities and joint range of motion.	Rowe et al. – 2005.
28	Electrogoniometers	Used in determining the joint angles during the golf swing.	Teua et al. – 2006.

Table 1.5: Applications of flexible electrogoniometers

1.14 Data acquisition system used with flexible electrogoniometers

From the above discussion, it is clear that, while the errors exhibited by the device seem to vary depending upon the application and the anatomical joint in which the device has been used, the device has found widespread research use. In contrast, it has found little use in regular clinical evaluations such as; audit, arthroplasty or multi centre RCT's. For all of the above mentioned applications, the flexible electrogoniometers have to be used in conjunction with a data acquisition system. The errors reported by the researchers are not necessarily solely due to the transducer, but these errors may also be due to the data logging device used in conjunction with these transducers. None of these researchers have studied or reported about the data logging system used with these transducers. A flexible electrogoniometer being a transducer; converts the physiological signal to an electrical signal. As a result, this electrical signal needs further processing and has to be converted into a usable form, so that the information can be used by the clinicians for patient evaluation. This necessitates the use of a portable data logger in conjunction with such transducers for recording the motion of the joints during dynamic functional activities. Originally, passive recorders such as analogue tape recorders and non-programmable electronic tape recorders were used for recording the physiological signal along with the time signal. However; these devices have been reported to be complex, large and expensive in contrast to the compact event recorders and the real time data loggers of today. (Mulvey, 1986)

Real time data loggers have the ability to record; process and store the data in a semi-conductor memory and the idea of real time data collection seem to have developed from the idea of continuous recording ECG signals based on microprocessor controlled real time monitors. Following this, many such devices were developed to monitor the physiological signals together with physical activity. One such example is the development of long term ambulatory physiological surveillance equipment (LAPSE) by Karagozoglu and MacGregor. (Mulvey, 1986) Though the primary aim for the development of LAPSE was in collecting ECG data together with physical activity of an individual, this research laid a strong foundation and provoked other researchers to develop several non-programmable electronic recorders in the other

areas of biomedical engineering. With the availability of low power microprocessors and their support circuits, various microprocessor controlled data logging instruments were developed and some of the early devices developed for different applications by various researchers are summarized in table1.6 (Mulvey, 1986)

S.No	Researchers	Year	Microprocessor	Memory		Application
				Data	Program	
1.	Craig	1981	CDP1802	1/8K	1K	Heart rate monitor
2.	Skoldstrom & Holmer	1981	CDP1802	4K	1/4 K	Heart rate monitor
3.	Miles & Rule	1981	6100	4.5K	Not specified	Physiological monitor
4.	Fernie & Holden	1983	CDP1802	4 K	Not specified	Activity patterns
5.	Pincroli & Tresca	1983	NSC 800	4K	4K	Heart rate - variability monitor
6.	Thakor et al.	1984	CDP1802	2K	2K	Arrhythmia monitor
7.	Oxford Systems	1985	NSC 800	16K	8K	Oesophageal PH Monitor
8.	Vitalog Corp	1985	6100	8K	3.5K	Physiological Monitor
9.	Cumming et al.	1986	NSC 800	24K	24K	Weight Shift Monitor

Table1.6: Early data logging devices developed for different applications

The new microprocessor controlled data collection systems are said to offer a significant advance in data collecting capability, both in terms of the range of data that can be collected and the endurance of the collection system. Many such devices are being currently used along with a wide range of transducers such as flexible electrogoniometers, accelerometers and strain gauges for mobility assessment, recording of plantar pressure etc. (Zhu et al., 1991). The research carried out by Huddleston et al., 2006 proposed a system to be used in conjunction with flexible electrogoniometers known as IDEEA. IDEEA is an intelligent device for energy expenditure and activity system, which was developed for measuring the energy expenditure of the individuals during various ADL. Though the system has been validated and tested for measuring the flexion of the knee during various ADL, the device has not been tested for its usability and has not been studied for its accuracy/reliability against a commercially available system. While, wireless communication is finding its way into various medical technological applications (Zhang & Liu, 2004), similar to other data acquisition systems, IDEEA also seems to be a hardwired system. Currently, the commercially available Biometrics data loggers are used with flexible electrogoniometers. However, the literature doesn't report the validity and success of any such units. (Anderson, Lyons, 2001; Tesio et al., 1995) Consequently, a promising solution is required to address the above issues and the lack of such a simple to use system may explain why electrogoniometry has not found more widespread use.

1.15 Conclusion

The following conclusions towards the need for a user friendly objective functional assessment tool to measure the knee outcomes following TKA can be assumed:

- The ability to move and goal directed movements are the basic backbone of human beings.
- Such movements are said to be affected by time related naturally occurring physiological changes or by various occupational and environmental factors.

- Millions of people through out the world, irrespective of race, sex and age have been affected due to such phenomena's. Which in turn has led the present generation emerge into, '*The decade (2000 to 2010) of bone and joint'*.
- Among; stroke, other forms of arthritis and circulatory disorders, lower limb OA has affected more than 6 million people in the UK with increased pain, disability, movement impairment and reduced quality of life. Consequently, the overall medical expenses of the NHS have increased to £ 5.5 billion. Hence, management of OA becomes crucial.
- In terms of a permanent solution, TKA is believed to relieve pain and restore the mobility of patients.
- However, when practicing evidence based approach, the above assumption holds true only if the efficiency of the intervention is evaluated by objectively assessing the functional outcome of the knee joint in an unconstrained environment as preferred by most of the clinicians and researchers today.
- Currently, no specific pre-clinical diagnosing technique for OA is available and expensive and time consuming assessment techniques together with subjective questionnaires are being used for assessing the functional outcomes of such interventions.
- Flexible electrogoniometers can be considered as a promising solution, compared to all the other sensors available for such applications and currently, these transducers have gained in clinical popularity in assessing the effectiveness of rehabilitation interventions and measuring the functional outcomes of post-operative patients in unconstrained environments. However, these transducers have to be used in conjunction with data acquisition systems for such applications.
- Though various data loggers have been used with these transducers for various applications, literature doesn't report on the validity, usability and clinical applicability of these data acquisition systems.

- Further, the research doesn't reveal any novel development of a simple user friendly data logging system for use with flexible electrogoniometers in assessing the functional outcomes of the knee following the knee arthroplasty.

'*This in turn merits further research in this area'*

1.16 Summary

In summary then, it is evident that OA has significant impact on the voluntary movements of individuals, making them more dependent by restricting their ADL's. With advancements in medical technology, TKA seems to be a most promising remedy for OA. However, objective functional outcome assessment following such an intervention is necessary to study the efficiency of the treatment and to know the extent to which it has benefited the osteoarthritic patients. Further such assessments would also assist EBP. The principle of goniometry seem to have been used and tested by several researchers since 1949 to current date and flexible electrogoniometers have been reported to be reliable, accurate and provide non-obtrusive measurement of human locomotion in an unconstrained environment. Certain author's have reported errors due to skin artifacts and soft tissue influence. But such errors can be overcome by following suitable attachment procedures as mentioned by Rowe et al. (2001, 2005). In addition to this, the whole concept of using flexible electrogoniometry can be simplified further by improving the functionality of the data logger currently used with flexible electrogoniometers whereby pushing a button would start, stop, collect multiple data sets and transmit the same without any physical contact between the subject and the operator. Such a simple system of flexible electrogoniometry should be able to be used by any research nurse or AHP in a multi centered clinical trial evaluating post-operative rehabilitation and would facilitate an efficient way of collecting and extracting large streams of data, making it suitable for clinical research and clinical measurement in an unconstrained environment.

1.17 Aim and Objectives of the Research

Aim: The aim of this research was to design, develop and evaluate a user friendly system of flexible electrogoniometry for use in Total Knee Arthroplasty.

Objectives: The following objectives were set in relation to the aim.

- To design and develop a data logging system capable of recording, analyzing and transmitting the knee joint angles (flexion/extension) during a range of functional activities without any physical contact with the subjects.
- To validate the system against the standard vicon system for a range of functional tasks associated with the activities of daily living.
- To test the above developed system for Inter and Intra rater reliability during various functional activities and
- To make the system much more user friendly and economic for clinical applicability so as to facilitate its use by research nurse and other allied health professionals.

Chapter 2 – Methods: The Functional testing system

2.1 Rationale

Given that OA has a significant economic impact and a large number of Individuals are undergoing knee replacement every year, evaluation of these individuals following TKA becomes important. With the multitude of the techniques available, it is essential to have a clinically acceptable and objective method of assessing the outcomes of TKA. Although clinical assessment scores provide a simple, inexpensive and easily set up method of assessment suitable for routine clinical use, they are less than ideal due to their subjective nature, floor and ceiling effect and lack of sensitivity to post operative rehabilitation. Hence, an objective and sensitive functional assessment tool is required. Biomechanical analysis techniques such as 3D motion analysis are accurate and sensitive, but are reported to be expensive and time consuming to perform. Hence, these techniques are restricted to the study of small numbers of patients in specialist research centres. While it is recognized that such techniques and facilities are becoming more wide spread, it is unlikely that resources will be available to allow their routine use for the assessment of TKA.

Hence, a system capable of studying the behavior of patients during various ADL such as walking, getting in and out of a chair, stair ascend and descend and a deep squat may provide sufficient information regarding mobility or actual functioning of the knee joint following TKA to allow a routine clinical appraisal of individual patients and the intervention they have received. If this hypothesis could be validated and the system were to be inexpensive to purchase and simple to operate by any non-technical person; it could form the basis for routine clinical assessment of TKA. Such a system would allow the comparison of data from multi centre trials and provide a standard method of assessment. In order to achieve this, the system must fulfill the following design criteria:

1. The system must be simple to operate, inexpensive, portable, robust and unobtrusive.
2. Testing should be rapid and effective in order to include as many patients as possible and reduce patient discomfort.

3. The System should be able to investigate the patient activities (ADL) in an unconstrained environment / free living environment.
4. The system should be designed for use with a non-technical operator.
5. Data processing and analysis should be semiautomatic or automatic in order to reduce operator time and errors and in order to increase patient turnover.
6. The output of the system should be reliable, reproducible, objective and meaningful to medical staff and sufficiently accurate for clinical use.

A review of available systems indicated that a flexible electrogoniometer was a suitable transducer with a commercial data recording system. However, the operation of the system by non-technical staff has rarely been attempted and such systems are only being used in research centres. They have not found routine use in clinical centres. The author therefore decided to develop a system which would be capable of routine use by research nurses or AHP's in the clinical environment. The system could then be evaluated in terms of reliability and reproducibility of the data. Further, such a system could be validated against a Gold standard system and the relative advantages and disadvantages of the system could be investigated. Finally, the system could be used in practice by research nurses and AHP's allowing them in a structured way to comment on its suitability for use by them and to provide feedback for a second phase prototype with possible commercial and clinical application. This then forms the basis of the work reported in the following sections of this chapter and the thesis.

2.2 Overall System Design

2.2.1 An Overview of the system

A functional system; namely, Strathclyde University Data logging System (SUDALS) capable of recording data pertaining to the flexion/extension of the knee during various ADL's has been developed taking into account the various design criteria as mentioned in the chapter1. SUDALS is exclusively designed for use with flexible electrogoniometers. SUDALS can be interfaced with two flexible electrogoniometers and four footswitches / force sensing resistors (FSR's). The SG150 type flexible electrogoniometers (manufactured by the Biometrics Ltd – Gwent) measures the flexion/extension angles when attached to the lateral border of the knees and the footswitches placed under the heels and toes of both the feet are used as event markers. These measuring instruments are interfaced to the SUDALS using thin flexible cables provided by the Biometrics Ltd. The output from flexible electrogoniometers and the foot switches are given to the signal conditioning circuits and following the signal conditioning, the analogue outputs of these instruments are converted to a digital form using a 12 bit Successive approximation type analog to digital converter (A/D). The signal conditioning circuits employed in the system design is described in detail in chapter 3.

The output from each instrument is read at a sampling rate of 50 Hz and following A/D conversion; the values are stored in a 32KB x 16K SRAM and transmitted via wireless RS232 transmitter to a laptop, which has an RS232 receiver connected to its serial port. Software written at the laptop end using Graphical user interface (GUI - Matlab) then displays the recorded data/results on the monitor. The program allows the user to view each and every recording and save those of interest. Also the program facilitates the user to enter individual subject details and store the recorded data with respect to each individual in the form of Excel files, which can then be analysed further at the user discretion. The system has been used to investigate the knee flexion/extension during normal gait, stair ascents and descents, sitting and rising from a chair and a deep squat in normal subjects. Also, the system developed has been validated against the gold

standard (Vicon system) and tested for reliability with respect to the commercial system (Biometrics). Further, the system was tested for its user friendly nature by making use of a qualitative approach. These methods are individually explained in detail in chapters 5 to 7 respectively.

2.2.2 Flexible electrogoniometers

The unique design of flexible electrogoniometers was originally developed by Professor A.C. Nicol. (Nicol, 1987) The flexible electrogoniometers (SG 150) used in this study were those manufactured by Biometrics Ltd – Gwent – UK. A flexible electrogoniometer is a transducer that converts an angular displacement about a joint (a joint angle) into an electrical signal. The transducer consists of a thin flexible strain gauged shim (100 mm long) which connects the two end blocks as shown in the Figure 2.1. The distal end block is sprung with 20 mm of play to prevent tension on the measurement shim and damage to the instrument. The gauges run the entire length of the shim on either side and are wired in a half Wheatstone bridge configuration (Figure 2.2). The principle used is to summate the strain applied to the shim. As reported by Professor A.C. Nicol, the unique feature of the instrument is that *'the output angle is independent of the shape of the strip within the plane of measurement and the output is linearly proportional to the angle subtended by one end relative to the other end'*. (Nicol, 1988) Similarly, the rotations around the other axes and translations of the end pieces of the electrogoniometer do not theoretically produce a change in the output voltage due to the equal and opposite distortions of the gauges.

Figure 2.1: Flexible electrogoniometer

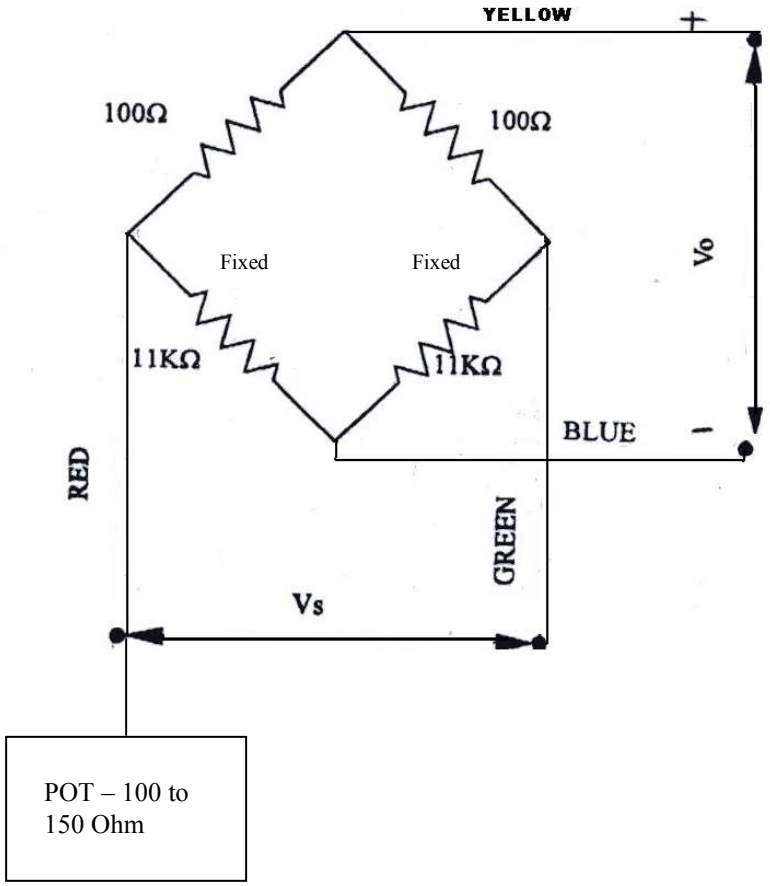


Figure 2.2: Wheatstone bridge used in flexible electrogoniometer

To prevent any kind of damage to the strain gauged shim and injury to the subjects, the shim is placed in a loosely fitted metal spring. The resulting electrogoniometer is; light, flexible and has no specific centre of rotation. Further, the self centring feature of the instrument and the ability of the transducer to measure angular joint motion independent of the instantaneous position of the joint centre make it possible to use the instrument accurately at the polycentric knee joint; provided, that the two end plates of the instrument are mounted proximal and distal to the joint centre.

2.2.3 Force sensing resistors

Force sensing resistors or foot switches are devices which exhibits a decrease in resistance with an increase in the force applied to the active surface.

The FSR's used in this study is Model 402 with a 12.5 mm diameter circle and with solderable tabs (Interlink electronics). The FSR consisted of 3 layers as shown in the Figure 2.3. The superficial layer is a flexible substrate with printed semiconductor. In between the spacer adhesive and rear adhesive layers is the conductive layer comprising of electrodes. The device operates with a supply voltage of 5V and based on the instruction given by the manufacturers, a measuring resistor (Rm) or a current limiting resistor of 1KΩ is used in conjunction with the FSR to operate the device in this application (Figure 2.4). The footswitches are attached to the soles of the feet of the test subjects using hypoallergenic attachment tape. Four FSR's are used, two for each foot, one under the heel and the other under the metatarsal region. The FSR's are interfaced with the SUDALS via thin flexible cables and the resulting system was easily applied and unobtrusive to the test subjects. These footswitches proved inexpensive and were relatively resistant to the high forces generated under the soles of the feet.

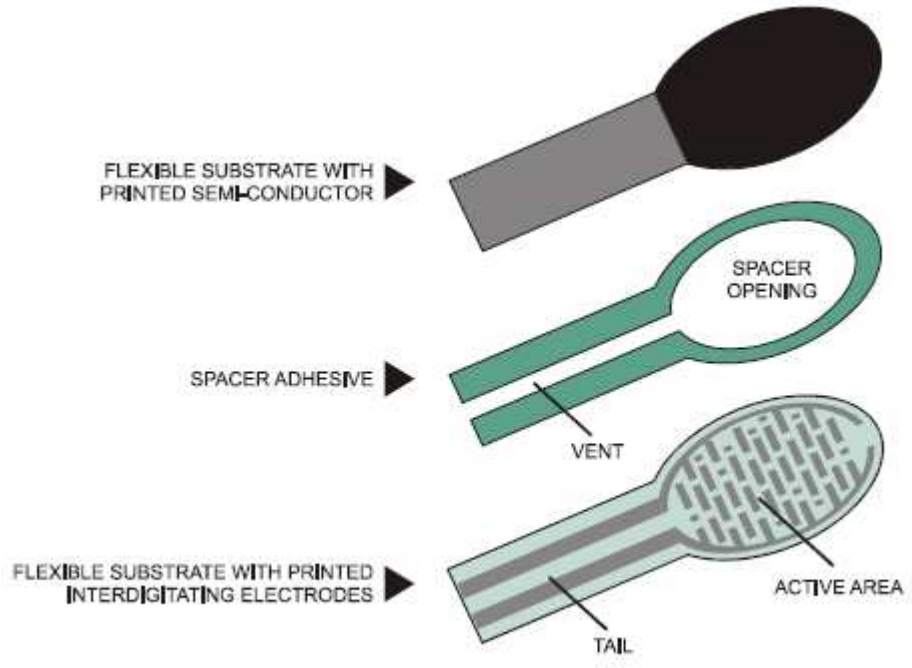


Figure 2.3: Layers of a FSR.

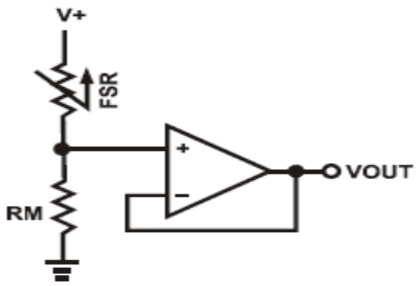


Figure 2.4: Application circuit of a FSR

2.2.4 Attachment of Electrogoniometers to Subject

A couple of factors must be taken into account in providing a comfortable, accurate and non-restrictive method of attaching the electrogoniometers to the subject. Prior to attaching the electrogoniometer to the subjects, the instrument is prepared. This includes the attachment of the electrogoniometers to two light weight plastic strips fastened to the ends of the shim as shown in Figure 2.5. The plastic strips reduce to acceptable levels the errors caused by skin movement. The plastic strips used here are made up of a polyethylene material, whose dimensions were 165 mm x 30 mm x 1 mm (length x breadth x thickness). The prepared electrogoniometers are attached using double sided medical grade tape laterally to the shank and thigh of individuals via these plastic strips.

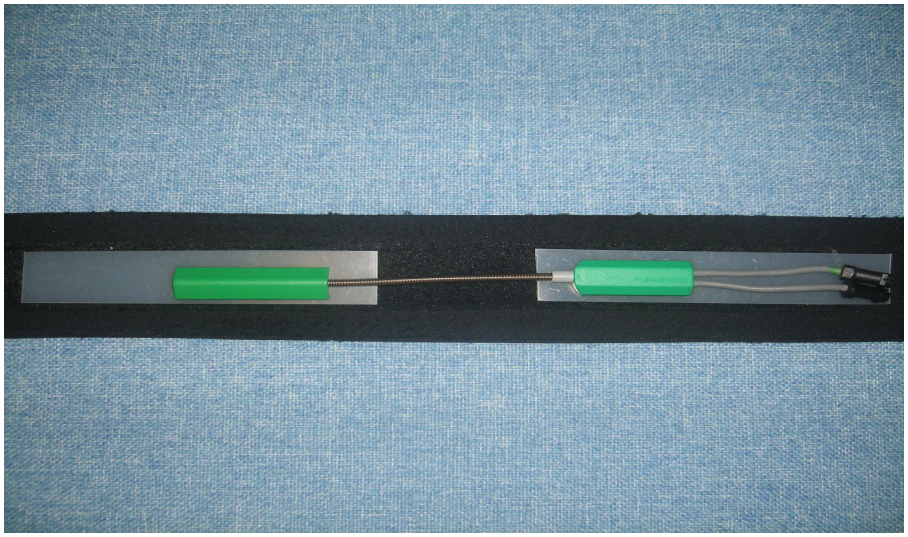


Figure 2.5: Attachment of plastic strips to the flexible electrogoniometers

The distal telescopic end block is placed in parallel to an imaginary line between the head of the fibula and the lateral malleolus and the proximally fixed end block is placed in parallel to an imaginary line between the greater trochanter and the lateral condyle of the femur (Piriyaprasarth, 2008). These attachments are further secured by making use of Velcro straps around the thigh and shank areas, to ensure that the devices aren't dislodged due to any fabric movements. These straps are also useful in holding the connection cables from the electrogoniometer and the four FSR's in place. Since the transducer is mounted in the sagittal plane of the knee, the primary output of the device represented the flexion-extension angle of the knee. (Figure 2.6) The device has a secondary output for measuring the abduction/adduction, but this measurement channel was not included in the design of this study. The attachment system held the instruments firmly in position and proved comfortable to wear and relatively unobtrusive. Following the attachment of the devices to the subject, the instruments were connected to the SUDALS box which was hooked on to a waist belt worn by the subjects.

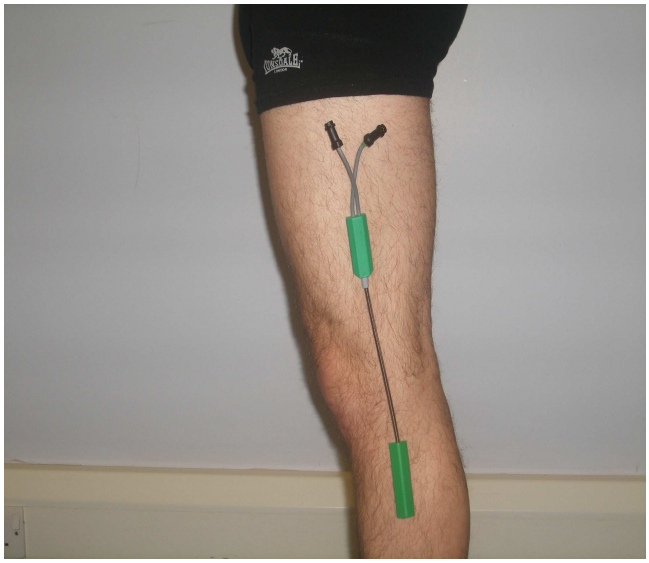


Figure 2.6: Attachment of flexible electrogoniometer to the subject.

2.3 Overview of design of Strathclyde University Data Logging System (SUDALS)

This section provides a general description and the essential capabilities of the SUDALS device. A more detailed description of the data logging system – SUDALS and the way in which it operates is given in chapter 3.

2.3.1. Hardware

A data logger is typically a portable battery-operated device that has memory for programs and data and is controlled by a micro-processor. SUDALS uses the latest microprocessor technology and was designed to be capable of acquiring, processing, storing and analysing electrical signals from flexible electrogoniometers and force sensing resistors at regular intervals. The hardware designed here aims to minimise power consumption and to be as compact as possible. Some of the design choices that these aims raised are discussed in chapter 3. The overall system developed is shown in figure 2.7 (Scale – 40%) and the simplified block diagram of the data logger hardware is shown in figure 2.8.

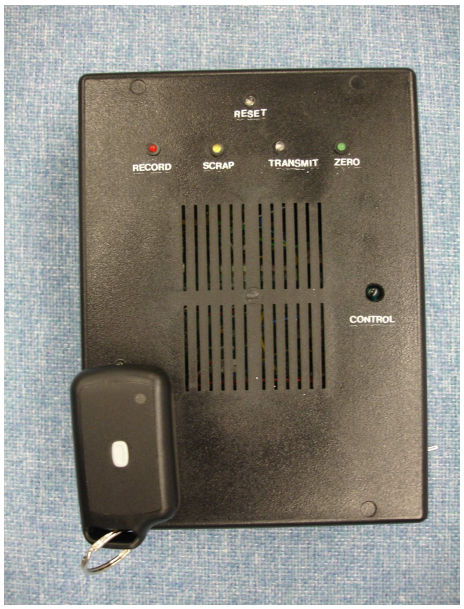


Figure 2.7: The developed system – SUDALS.

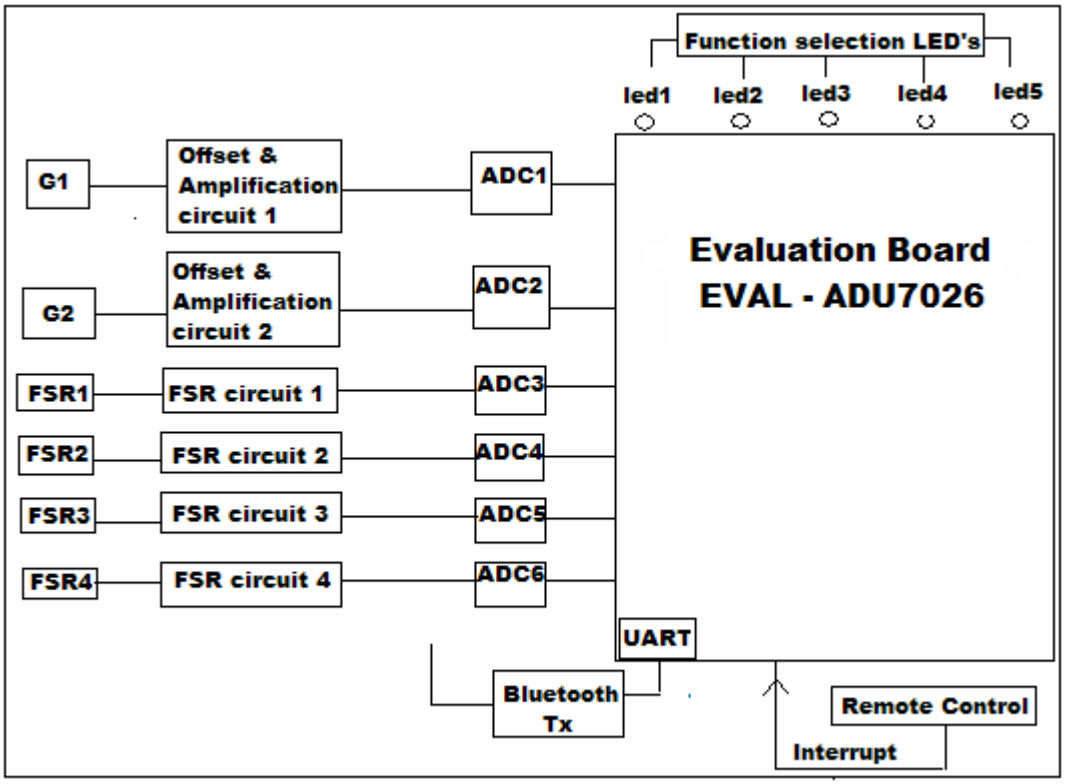


Figure 2.8: Simplified hardware Block Diagram of SUDALS

Where G = Goniometer, FSR = Foot switch, ADC = analog to digital converter, UART = universal asynchronous receiver transmitter and Tx = Transmitter.

The hardware can be sub-classified into various functional blocks each representing a stage in the process of acquiring signals from the sensors to data storage. These functional blocks are:

a) Offset and amplification circuit 1 & 2

These blocks acquire signal from the sensors and conditions the signal into a form suitable for input to the ADC and then to the microcontroller which is considered as the central processing unit (CPU) of the data logger.

These modules are mainly confined to signal conditioning of the input signals and consist of analogue circuits. In addition, these modules also consist of offset implementation circuits which are used for zeroing the flexible electrogoniometers following their attachment to the subjects.

b) FSR Circuits

Based on the manufacturers' specification, suitable current limiting resistors are used in conjunction with the FSR's to make use of the sensors for event marking application. Slight pressure on the FSR causes the signal to transit from low to high and back to low when the pressure is removed.

c) Analogue to Digital Converters (ADC)

The signals from all these sensors are analogue in nature. Hence, before passing on the signals to the microcontroller, these signals have to be digitized. This was carried out using the on chip 12 bit successive approximation type analogue to digital converter.

d) ADUC7026

The digitised signals from the ADC are then passed to the multifunctional 32 bit microcontroller – ADUC7026 for further processing. The functioning and features of this microcontroller are explained in detail in section 3.1.6 in chapter 3.

e) Wireless data transmission

The processed signals from these sensors are stored in a 32 kB x 16 K on board external static RAM (SRAM). The data from the external memory is transferred at intervals to a personal computer via a bluetooth transmitter (HDWBTRS232 – wireless RS232 Transceiver**)** interfaced with the Eval ADUC7026 via the universal asynchronous transmitter (UART) terminal provided on board and a transmitter line driver ADM202.

f) Interrupt Service Routine (ISR)

The interrupt service routine to the microcontroller was given via an infra red remote control (which acts as an infra red transmitter and external trigger) interfaced with the general purpose input-output port of the microcontroller via an infra red receiver and a dual monostable multivibrator 4528.

2.3.2 Firmware

The way in which, the data logger records and processes data is defined by a program resident in a 62 kilobytes flash/EEPROM which is part of the microprocessor board. Unlike the programs held in RAM (known as software), this program (firmware) can only be changed by erasing and reprogramming the EEPROM. This section briefly describes the overall structure of the firmware and the operation of the firmware is explained in detail in chapter 3.

The firmware at the microcontroller end is only concerned with the operation of the data logger. Depending upon the specific application and other features available within the microcontroller, the firmware is written. Basically, the aim was to make use of a single interrupt service routine to perform five different functions pertaining to the process of data collection:

a) Zero the flexible electrogoniometers interfaced with the data logger.
b) Record the signals from all the sensors connected to six different channels.
c) Delete a recording if necessary.
d) Transmit the data recorded via bluetooth to a personal computer (PC) and
e) Reset the whole system prior to the next set of data collection.

Initially, when the system is connected to the sensors and switched on, the system is ready to zero the sensors. Once, a single recording is completed, then the system facilitates the user to make use of other functions such as; scrapping the recorded data 'if needed', collect a second or subsequent set of data or else to transmit the collected data via the wireless technology and reset the entire system for the next set of data collection. Each of these above mentioned functions can be accomplished by providing an ISR to the microcontroller to start or stop that specific function via an Infra red remote control transmitter and receiver interfaced with the microcontroller, when the LED corresponding to that function illuminates. Since, all these functions operate within a loop arrangement; the user can perform single recording or multiple recordings, transmit, zero and scrap the data all with a single key fob type Infra red remote control. The system functional flowchart is as shown in figure 2.9.

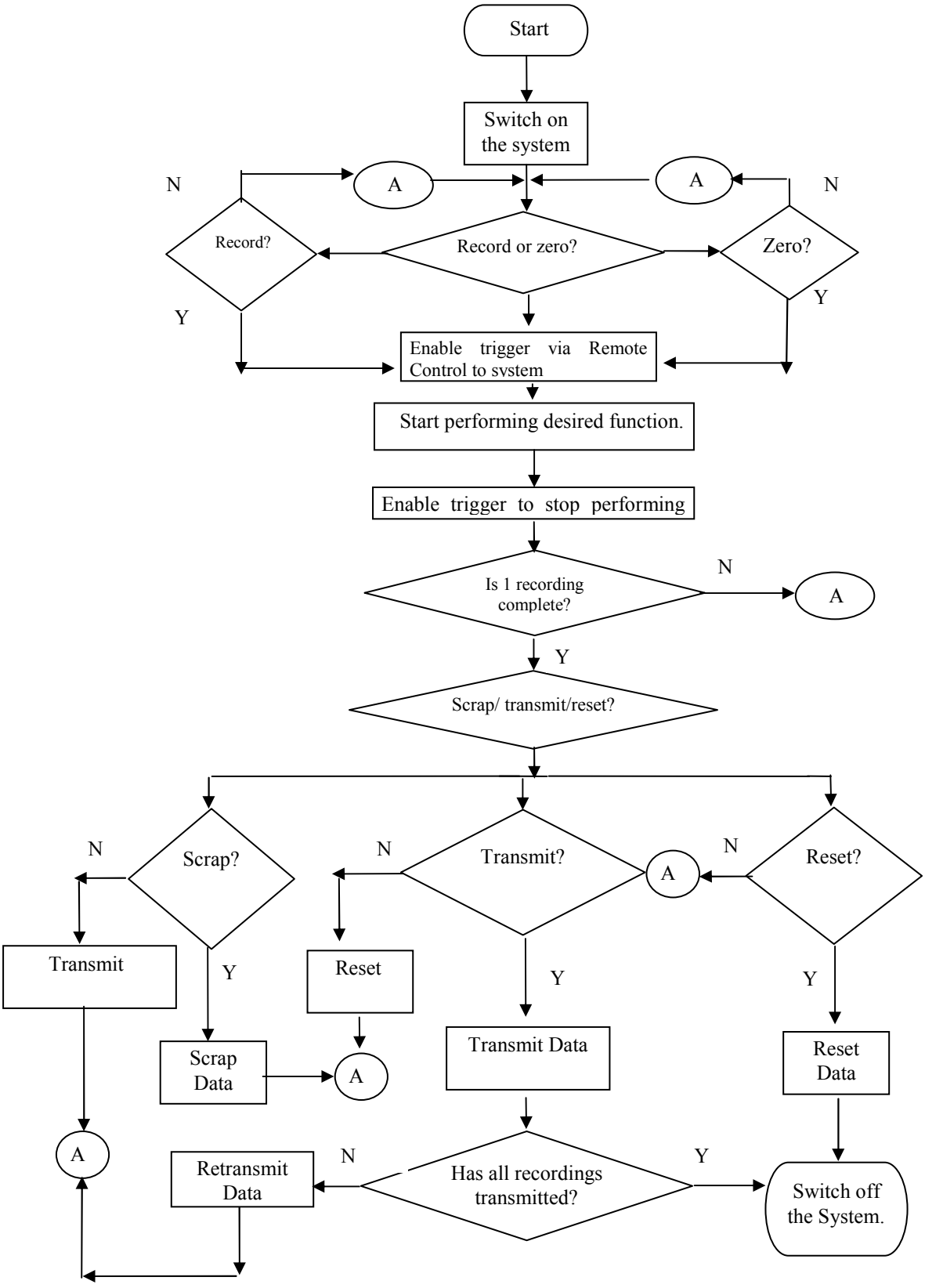


Figure 2.9: System firmware flowchart

In addition to this, an indication of memory full condition and a function time out indication are also included. The data recorded and transmitted via bluetooth to the PC is then recovered with help of software / graphical user interface (GUI) written in MATLAB 7.0. This software allows one to get the data recorded, display the same in the sequence in which they are recorded and then save the data in the format of MS-Excel files, which can be then analyzed. The firmware and the software codes used in this application are given in section 4.3 and 4.4 of electronic Appendix 4.

2.3.3 Physical Construction

The main aim behind the construction of the data logger is to incorporate all the components in a single light weight plastic box which can be worn on a waist belt. A box made of ABS plastic, with an internal dimension of 197x145x55mm was chosen for this application. The size of the evaluation board used for this application decided the size of the data logger box. Further, the provision for signal conditioning circuits and battery pack is also taken into account in deciding the dimension of the box. In the design of SUDALS; 3 signal conditioning circuits are being used. Two circuits corresponding to the conditioning of the input signals from the sensors, zeroing the flexible electrogoniometers and ISR are individually soldered on two strip boards and the third circuit pertaining to the power supply and transmission are separately soldered on to another strip board. The availability of the on board foot prints for external memory and latch interface eliminated the need for additional circuitry for memory interface. The sensors are interfaced to the microcontroller via the evaluation board using six lemo connectors as shown in figure 2.10. Further, the bluetooth transmitter adapter was interfaced with the transmitter line driver and to the UART terminals via a D-connector. All these components including the sensors are powered using 6 x 1.2 V AA high wattage batteries of 2500 mah, which are enclosed in a plastic holder within the data logger box. In addition, there is also a provision for recharging the batteries, similar to the car battery charger which enables the batteries to be recharged without removing them from the system. The overall weight of the data logger box including the battery pack is 583.2 g. The general specification of the data logging system is given in Table 2.1.

Figure 2.10: Lemo connectors for interfacing the sensors to the data logger.

1. Mass:	583.2 g
2. Dimension:	197x145x55mm
3. Box:	ABS plastic
4. Microcontroller:	ADUC7026
5. Clock Source:	32.768 kHz watch crystal to drive the PLL clock which in turn generates 45 MHz.
6. Data memory:	32kB x 16 SRAM
7. Program memory:	62 kilobytes flash/EEPROM
8. Power supply:	6 x 1.2 V 2500 mah AA Nickel Metal Hydride (NiMH) batteries
9. ISR:	One interrupt to the microcontroller via Infra red transmitter
10. Data recovery unit:	PC with GUI software
11. Communication:	HDWBTRS232 – wireless RS232 Transceiver Data transfer rate 19200 baud.

Table 2.1: General specification of SUDALS

2.3.4 Wireless communication link

The RS-232 wireless communication link provides the means of connecting the data logger to the host PC for the purpose of recovering the recorded data (from all the sensors) from the external memory (SRAM) and transmitting it to a PC.
The evaluation board EVAL- ADUC7026 has a provision for serial communication via the UART terminals and the RS232 dongle cable (provided by the manufacturers)

connects the UART terminals with the serial port of the PC. This concept is being modified by making use of a HDWBTRS232 – wireless RS232 Transceiver. The transceiver kit has two wireless adapters. One can be used as a transmitter adapter (master) and the other can be used as a receiver adapter (slave). Figure 2.11 below, shows various parts and specifications of the adapter.

1 Power LED	2 Link LED	3 Slide switch	4 RS232 connector
5 Mini USB Connector	6 Reset button	7 Antenna connector	

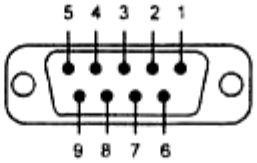
Specification	Description
Antenna Gain	Chip antenna max. 1 to 2 dBi
Power Supply	+5 to +6 V DC
Current Consumption	Max. 90 mA
Operation Temperature	-20°C to +75°C
Dimensions	35 mm (W) x 65 mm (D) x 16 mm (H)

Figure 2.11: Specification of Bluetooth Transceiver.

The pin diagram of the female DB9 connector on the transmitter adapter is listed below in figure 2.12. (Where, DTE stands for data terminal equipment and DCE stands for data circuit terminating equipment).

Based on the above information and the details provided by the manufacturers (via personal communication), the modification of the serial communication to a wireless

communication is carried out by shorting the pins 1, 4, 6, 7 and 8 of the male D connector at the data logger end. Further, the pins Rx and Tx of the UART terminal on the evaluation board are connected to pins 3 and 2 of the D connector and the adapter is powered via pin 9 and is grounded via pin 5.



Pin	DTE Signal	DTE to DCE Direction	DCE to DTE Direction	Description
1	CD	Input	Output	Not connected
2	RxD	Input	Output	Received data
3	TxD	Output	Input	Transmitted data
4	DTR	Output	Input	Not connected
5	GND	N/A	N/A	Signal ground
6	DSR	Input	Output	Not connected
7	RTS	Output	Input	Request to send
8	CTS	Input	Output	Clear to send
9	Vcc	Input	Input	Power supply

Figure 2.12: Pin details of the Female DB9 Connector

However, these adapters have to be configured in their respective master and slave modes using the manufacturers' instructions prior to using these adapters for the required application. This is carried out by connecting each adapter to the serial port of two laptops individually and running the configuration file (section 2.1 – electronic Appendix 2) downloaded from the manufacturers' website. This enables one to check for the factory settings of the adapters and modify the baud rate as per the requirements. During the configuration of the adapters, the switch on one of the adapters connected to the laptop is set facing towards the antenna (DTE or Master adapter) and the switch on the other adapter is set facing towards the RS232 connector (DCE or Slave adapter). During the configuration, the adapters are powered by connecting them to the USB port of the laptops via the cable provided by the manufacturers. Following the instructions given in the manual, a Hyper Terminal file is created and the properties of the COM port in which

the adapters are connected are set similar to the default factory settings (section 2.1 – electronic Appendix 2). Then, various characters are given as input in the master laptop Hyper Terminal file and the echo is observed in the file opened in the receiver laptop. For example: giving an input 'A' in the master file echoes 'A' in the receiver file. This established a communication link between both the adapters and subsequently the respective adapters can be used for transmitting and receiving data. By default, the factory settings of the COM port are: Baud rate: 19200 bps, Data bit: 8, Parity: none, Stop bit: 1, Flow control: hardware or none. These default factory settings are being currently used in the wireless communication link to transmit the data recorded. However, the manufacturers have given a provision for increasing or decreasing the communication baud rate and this can be carried out during the configuration of the adapters.

2.4 Routine Deployment

The procedure used during routine deployment of the data logging system together with the transducers is described here in this section. Such a procedure aims to obtain reliable signals from the system and also to ensure that the signals obtained are free from artefacts and that the system doesn't cause any level of discomfort to the subject throughout the data collection period. These aims are achieved by carefully preparing and suitably attaching the transducers to the subject using the previously reported attachment protocol. The deployment procedure is as explained below:

The flexible electrogoniometers are prepared as explained in section 2.1.4 and following the preparation, the flexible electrogoniometers together with these plastic strips are attached on to the subjects by means of double sided medical tape affixed to the posterior side (facing the subject) of the plastic strips. Prior to the experiment, the 'subject information sheet' is given to the participant and informed written consent is obtained from the participants. Also, the participants are requested to wear shorts or knee length skirt and remove shoes and socks so that their lower limbs and soles of their feet are accessible and visible (shoes and socks are replaced following the equipment attachment to avoid dislodgment of the connections). The participants are asked to sit / lie

on a bed and 2 flat footswitches (FSR sensors) are taped to the soles of each foot – one on the heel area and the other at the 1st or the 2nd metatarsal area. Then the socks are replaced to keep the cables and footswitches in place. Now the participants are asked to stand with their lower limbs as straight as possible and the electrogoniometers are attached to the lateral border of the individuals' lower limb using plastic strips with double sided tape. Care is taken to ensure that the green end plates are anatomically positioned and aligned as described in *section 2.1.4* and by means of visual alignment; care is taken to ensure that the green end blocks are placed at an equal distance from the approximate centre of the knee joint. The plastic strip attached to the upper end block (fixed end block) points towards the hip joint and the plastic strip attached to the lower end block (telescopic end block) points towards the ankle joint centre. An additional support is given by wrapping Velcro straps around plastic strips; one at the thigh and one at the shin and the cables from the footswitches are looped into the straps to prevent any kind of trip hazard.

The belt and pouch to hold the data logger are then fitted and approximately adjusted according to the waist size of the subjects. The cables from the transducers and the bluetooth transmitter adapter are connected to the data logger and then the system is switched on and the data pertaining to the flexion/extension of the knee during various ADL are recorded and transmitted. The connection protocol and standard operating procedure of the data logger are given in section 2.2 – electronic Appendix 2 and a video of the functioning of the SUDALS is given in section 7.1 – electronic Appendix 7.

Chapter 3: Methods – Development of Strathclyde University Data logging System (SUDALS)

This chapter is a continuation of the general description of the data logger given in chapter 2. The data logger hardware together with the firmware/software used in the design of SUDALS is explained in detail in this chapter. The design strategy and the methods used to interface the data logger with the transducers are also described here. Finally, the pros and cons of the adopted hardware elements and the methodology are highlighted in the discussion section towards the end of this chapter.

3.1 Data-logger Hardware

The hardware block diagram of the SUDALS is as shown in figure 3.1

3.1.1 Signal Conditioning Module

Generally, any analogue signal has to be manipulated in such a way that, it meets the requirements of the next stage for further processing and in the development of SUDALS, the analog signals from both the flexible electrogoniometers and the FSR's have to be conditioned before passing on the signals to the A/D converter so as to make the output of the sensors compatible with the A/D converter. The output of the flexible electrogoniometer (Wheatstone bridge) is a differential output ranging from -5V to +5V for a full range movement of -150º to +150º. However, the A/D converter accepts inputs in the range of 0 to + 2.5 V. This necessitated the need for stepping down the output of the goniometer to make it compatible with the A/D converter and this is achieved by making use of an 8 pin instrumentation amplifier INA118 as shown in figure 3.1.

The output of the instrumentation amplifier is determined by the equation: $Vout = G((Vin_+) - (Vin-))$. Where, $G = [1 + (50\ K\Omega / Rg)]$ and Rg is the gain resistor. From the above relations it is evident that, the output of the amplifier depends upon the selection of suitable gain resistor. Using a gain resistor of 820Ω, gives a gain of 61.9, and yields an output voltage ranging from 0.60V to 1.85 V for an operating range of

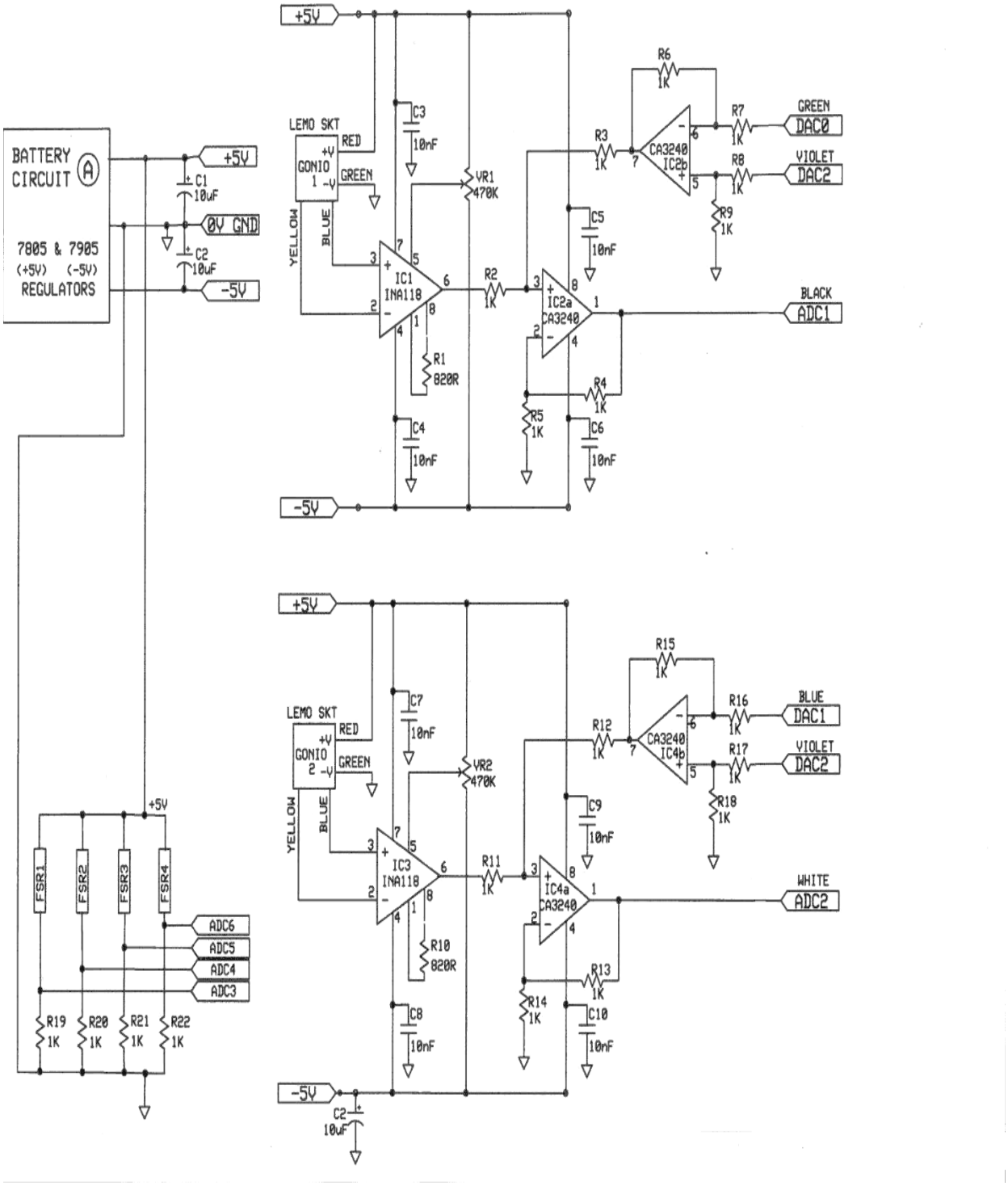


Figure 3.1 – SUDALS Circuit diagram

-150º to + 150º and an output of 1.25 V, with the goniometer placed in a neutral position. A 470 Kilo ohm potentiometer (POT) is connected to the Vref or pin 5 of the INA118, to eliminate the dc offsets. The hardware circuit also has the flexible electrogoniometer zeroing circuit interfaced with the instrumentation amplifiers, using operational amplifiers CA3240 and the output from both the flexible electrogoniometers is interfaced with the respective analog channels – ADC1 and ADC2 as shown in figure 3.1.

3.1.2 Zeroing Module: Op-Amp CA3240 is an 8 pin integrated circuit (IC) that combines the advantages of metal oxide semiconductors and bipolar transistors. The zeroing circuit operates on the basic principle that, when the digital output of an ADC channel (ADC1) is given to a DAC channel (DAC0), the analog output from the DAC channel is the same as the input given to the ADC channel. If the output of the DAC0 is applied to the inverting terminal of the Op-Amp (CA3240) and if the non-inverting terminal of the Op-Amp (CA3240) is supplied with a constant voltage corresponding to the zero value (as shown in figure 3.2), then the resulting output, when summed together with the actual analog input value to the ADC1, gives us the required zeroing value, irrespective of the analog input. As mentioned above in section 3.1.1, in neutral position, the output of flexible electrogoniometer is 1.25 V. Hence, this value is used as the zeroing value and is supplied to the non-inverting terminals of the CA3240 via DAC2. The output of the DAC2 is set to a constant 1.25 V at the microcontroller end via the firmware. Ideally, this is achievable by calibrating the ADC1 and DAC0 channels, which is explained in detail in Chapter 4. The same procedure is repeated for ADC2 – DAC1 channels.

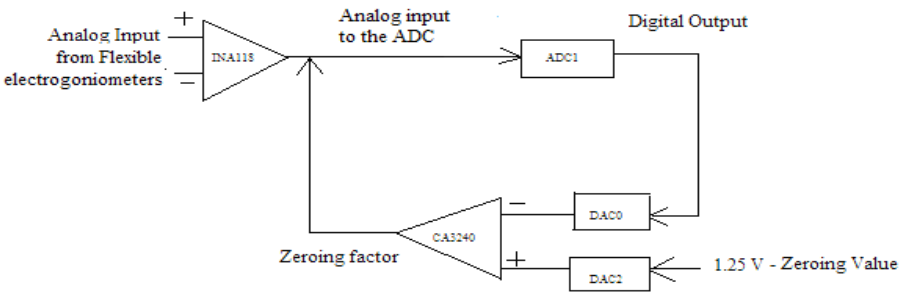


Figure 3.2: Zeroing Module Concept

In addition to this, the FSR's are interfaced with the analog channels ADC3, 4, 5 and 6 respectively as shown in figure 3.1. These sensors are connected in series with a current limiting resistor as prescribed by the manufacturers. As mentioned in chapter 2, other than the instrumentation amplifiers and the Op-Amp 3240's, the hardware circuit also consists of the transmitter line driver ADM202, a monostable multivibrator CD4528 and a DC-DC converter used for specific applications as explained below.

3.1.3 Transmitter Line driver module: The ADM202 is a 2 channel RS232 line driver / receiver pair designed to operate from +5V D.C and facilitates data transmission at a rate of 120 kilo bits per second. The Schematic of the transmitter line driver used in SUDALS is shown in figure 3.3. The instructions for connecting the transmitter line driver with the UART terminals are obtained from the manufacturers (Analog devices) and the way in which ADM202 is connected with the UART is shown in figure 3.4.

3.1.4 IR detector and Monostable multivibrator: The IS1U60 is a 3 pin, infrared detector which has the features of the preamplifier and demodulator in one unit and designed to receive signals from the IR remote control units. The receiver operates from +4.7V to +5.3 V D.C and is designed to respond to vertical acceptance angles of 30° and horizontal acceptance angles 60°.

The CD4528 is a dual monostable multivibrator, which can accept a falling edge input pulse and provide an output pulse of wide range of widths. The IC operates from -0.5 V - +18 V D.C and the pulse duration and accuracy of the output signals are determined by the external timing components Rx and Cx. A relation to calculate the pulse width is given by: Pulse Width = K * Rx * Cx; where, K = 0.42, if the supply voltage is 5V D.C. In SUDALS, Rx - 100 KΩ and Cx - 4.7 μf are being used to provide a rising edge pulse width of 190 ms to the microcontroller.

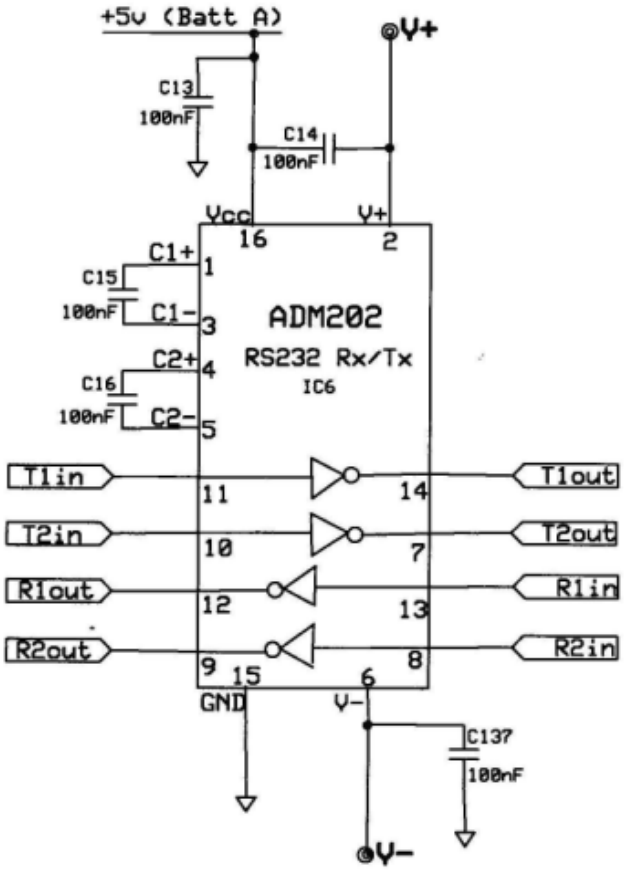


Figure 3.3 – Transmitter line driver.

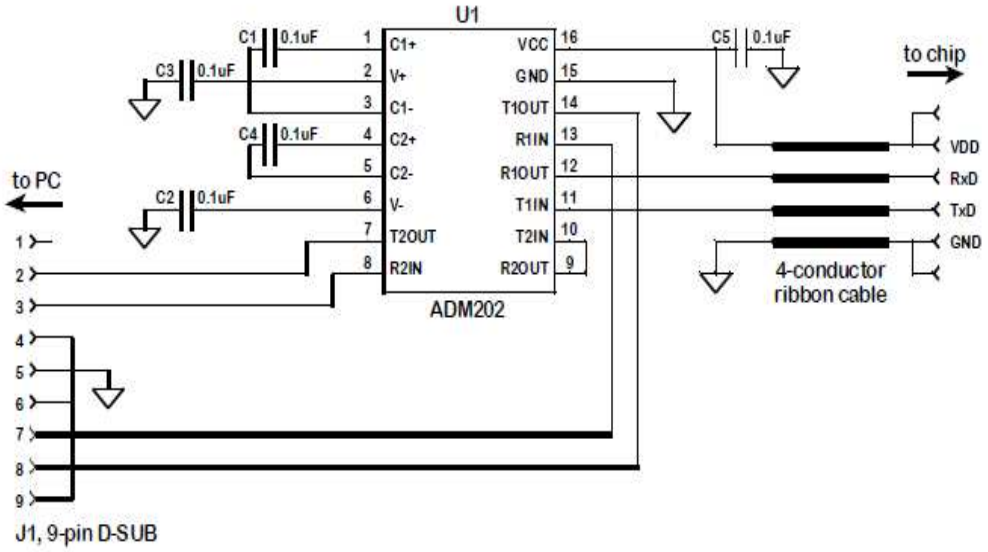


Figure 3.4 – Diagram illustrating the connection of transmitter line driver with the on board UART terminals.

The main objective of using a monostable multivibrator CD4528 in conjunction with the infra red receiver IS1U60 is to provide an ISR of specified pulse width to the microcontroller. Hence, the output of the IR detector is given as input to (pin 5) the multivibrator and the external timing components are tied to the respective pins as specified in the truth table and data sheet provided by the manufacturers (PDF document number 3 – section 3.1 – electronic Appendix 3). Further the output of the multivibrator (the required ISR pulse) is interfaced with the microcontroller via the general purpose input-output port P0.4 as shown in figure 3.5.

3.1.5 EVAL – ADUC7026

EVAL-ADUC7026 is an evaluation board developed by microcontroller manufacturers (Keil) that allows one to quickly get started with new microcontroller architecture. The silk screen view of the evaluation board EVAL-ADUC7026 is shown in figure 3.6. The ADUC7026 evaluation board has following features:

1. 9V power supply regulated to 3.3 V on board.
2. 4 pin UART header - which enables to connect the evaluation board to a serial port of a PC via RS-232 interface cable.
3. Reset / Download / IRQ 0 push buttons.
4. External memory and latch footprint.
5. Power indicator / general purpose LED's and
6. 32.748 kHz watch crystal which drives the on chip PLL circuit to generate the 45 MHz clock for the microcontroller. All these components are mounted on a 2 layer PCB.

In addition to the features mentioned above, the evaluation board also has many other features such as the emulation interface, external references, etc. However, for the development of SUDALS, only certain important segments of the evaluation board are being used and they are explained in the subsequent sections. The different segments of

the board used in the development of SUDALS are marked as connectors; J1, J2, J3, J4 and J5 as shown in figure 3.6.

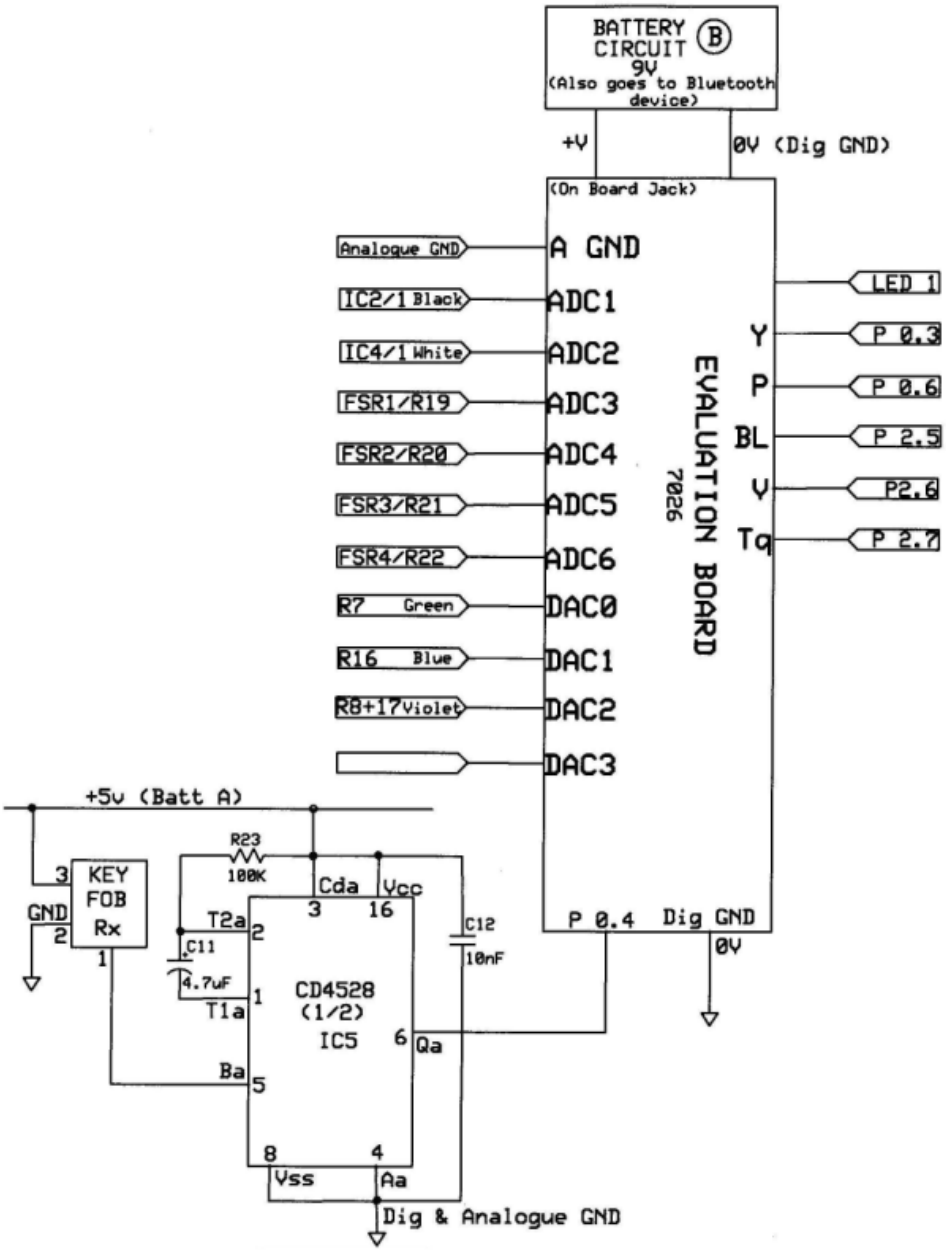


Figure 3.5: GPIO used in interfacing the Evaluation board with Monostable Multivibrator

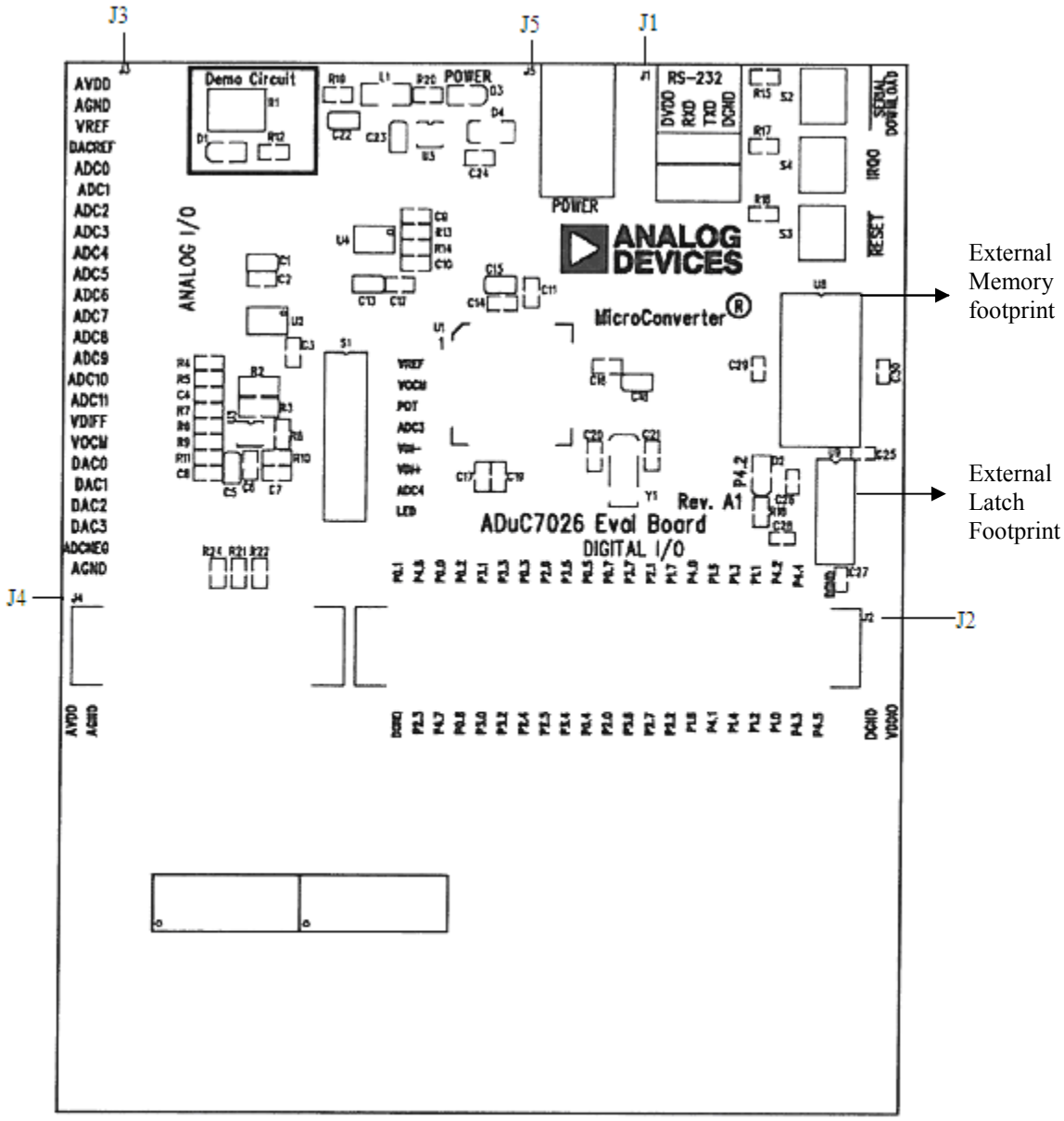


Figure 3.6 – ADUC7026 Evaluation Board Silk Screen (Technical documentation – EVAL –ADUC7026)

J1 Connector: The serial input and serial output lines (P1.1 and P1.0) of ADUC7026 are connected to the UART terminals via connector J1 and these terminals can be interfaced with the serial port of the PC using the RS-232 interface cable. This cable is required to facilitate direct connection of the ADUC7026 to the PC serial port. However, the cable supplied should be connected to the board correctly, i.e. DVDD is connected to DVDD and DGND is connected to DGND.

J2 Connector: J2 is a digital input / output connector which provide external connections for all general purpose input-output ports (GPIO's). The details of the pin functions are given in section 4.1 – electronic Appendix 4.

J3 Connector: J3 is an analog input / output connector which provide external connections for all the ADC inputs. All the conditioned analog inputs are interfaced with the microcontroller via this connector. In addition to this, they also provide external connections to the DAC outputs and reference inputs. The details of the pin functions are given in section 4.1 – electronic Appendix 4.

J5 Connector: This connector permits the connection of a 9V power supply adapter (provided by the Manufacturers) to power the evaluation board. However, in SUDALS, the power supply circuit designed, replaces the adapter and provides the power required to operate the evaluation board. This is explained towards the end of this section. The 9V supply is regulated via an on board linear voltage regulator to produce an output of 3.3 V to drive the digital side of the board. Further, the same output is filtered to supply, the analog side of the board (PDF document number 1&4 – section 3.1 – electronic Appendix 3). There is also a provision to interface an external memory and latch to the microcontroller via the footprints provided on the evaluation board. These footprints are for a 32 kB x 16 K external SRAM and a 16 bit D latch. As prescribed by the manufacturers, CY7C1020CV33 (external memory) and 74LVT16373AGG (latch) are used in the design of SUDALS. The external memory connections are shown in figure 3.7. All these above components are internally connected with the microcontroller ADUC7026 as shown in figure 3.8.

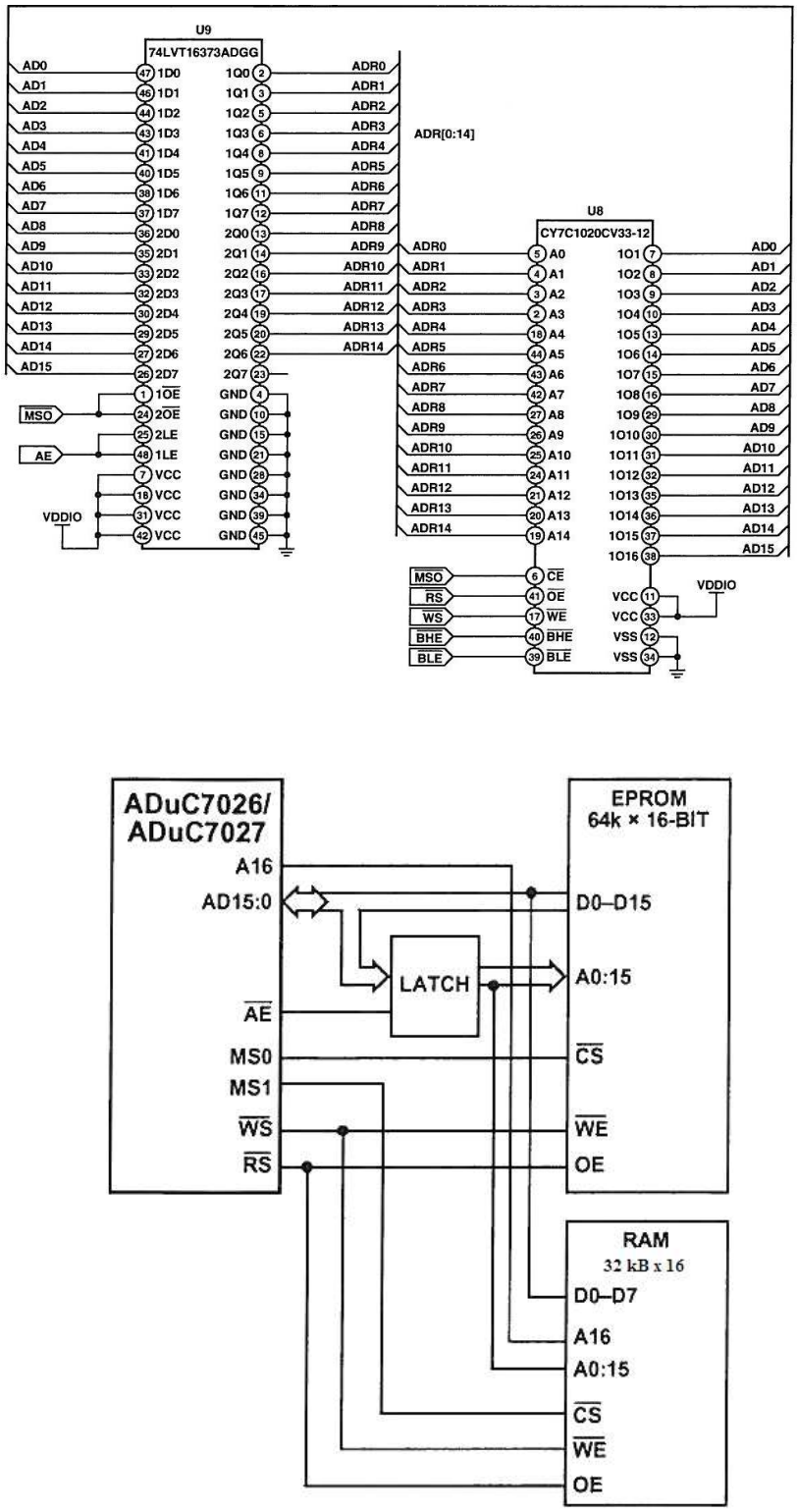


Figure 3.7: External memory connections.

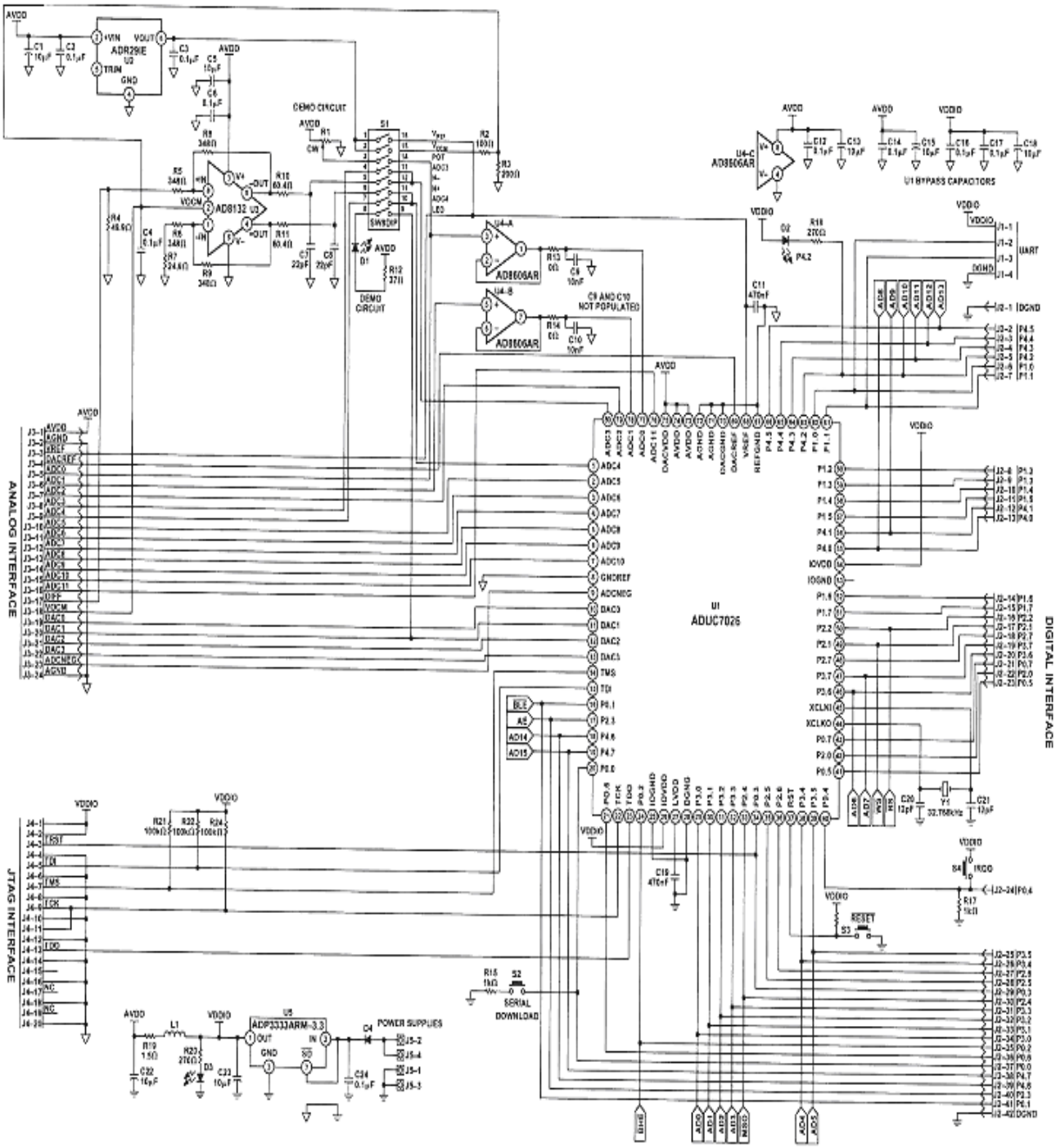


Figure 3.8 – Internal wiring schematic of the Microcontroller in EVAL-ADUC7026
(Technical documentation – EVAL –ADUC7026)

3.1.6 Microcontroller ADUC7026:

The ADUC7026 is a multifunctional 32 bit microcontroller unit (MCU), which has fully integrated high performance multi-channel 12 bit data acquisition system (ADC's) and Flash/EE memory on a single chip. All these devices operate from an on-chip oscillator and a programmable logic loop (PLL) generating a high frequency clock of 41.78 MHz. Further, this clock is routed internally via a programmable clock divider, to generate the frequency required for the operation of the MCU core. The microcontroller core is an ARM7 32 bit RISC machine. Where, ARM is an acronym for advanced RISC machine and RISC is an acronym for reduced instruction set computer. The peak performance of the MCU is about 41 million instructions per second (MIPS). In-circuit serial download of the firmware and serial transmission of the data from the microcontroller is facilitated by the UART interface port interfaced with the microcontroller. The pin details and the functional block diagram of the ARM core is as shown in figure 3.9 and 3.10.

Following the signal conditioning, the outputs from the sensors are passed on to the MCU core via the analog interface channels and multiplexer for further data processing. The 12 bit SAR type A/D converter converts the inputs from the analog channels to corresponding digital values and stores the digital values in the specified memory locations. Appropriate commands given to the microcontroller via the firmware downloaded to the MCU via the UART serial port and the ISR provided by the infra red key fob remote control, allows the MCU to perform various other functions such as zeroing, scrapping the recorded data, transmitting the recorded data via bluetooth to a PC and resetting the whole system. An overview of this functionality has already been discussed in the firmware flow chart in chapter 2. Further, looking at the functional block diagram of the MCU reveals that, the microcontroller ADUC7026 has various functional segments. However, in the development of SUDALS, only certain functional segments are used to serve the desired application and those segments are included in the firmware by initialising suitable addresses to the corresponding application oriented registers and downloading them to the MCU.

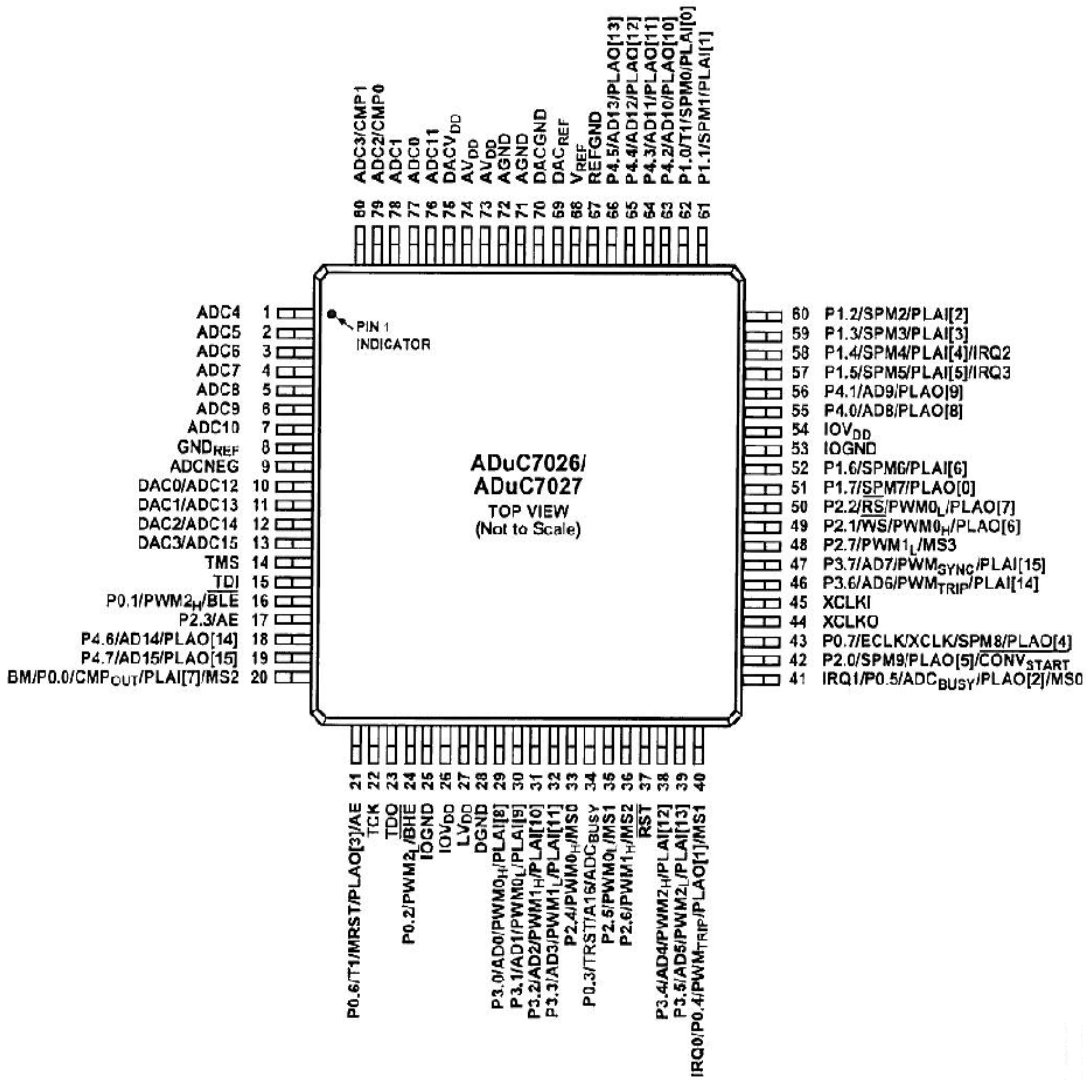


Figure 3.9: Pin diagram of ADUC7026

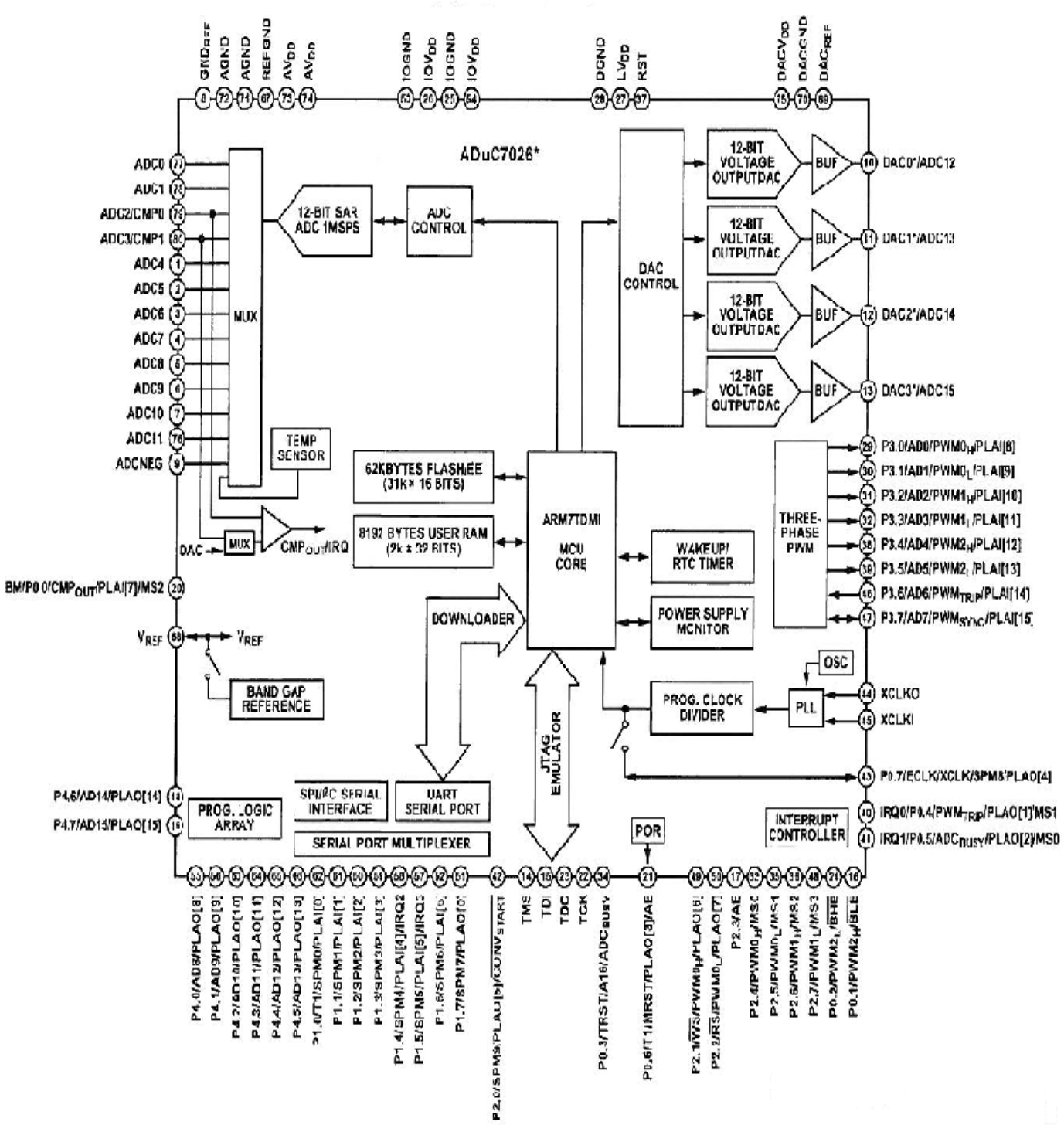


Figure 3.10: Functional block diagram of ADUC7026

The application oriented registers used in the development of SUDALS are; ADC registers, DAC registers GPIO registers, UART registers, Reset registers, ISR registers, Timer registers and external memory registers. The details about the selection of registers and assigning suitable addresses in the development of SUDALS are explained in detail in section 4.1 – electronic Appendix 4. All the hardware components mentioned above, including the evaluation board, are powered using the application oriented power supply unit designed for SUDALS.

3.1.7 Power supply unit:

For the specific application, 6 high wattage (2500 mah) 1.2 V AA Ni-mh (Nickel metal hydride) batteries are used in conjunction with a VWRAS1 – SIP DC-DC converter. The DC-DC converter is an 8 pin IC, which accepts input voltage in the range of 4.5 V to 9.0 V D.C and provides a regulated ± 5V D.C voltage. In the design of the power supply circuit for SUDALS, the output of the battery pack (7.2V) is given as input to the DC-DC converter, which in turn yields an output of ±5V. All the components in the hardware circuit, other than the evaluation board and the transmitter adapter can be operated with a voltage in the range of +5V D.C and -5V D.C. Though the evaluation board was powered initially using the external 9V D.C adapter provided by the manufacturers, on testing, it was found that the evaluation board can be powered and efficiently operated using 7.2 V supplied by AA batteries. Also, the bluetooth transmitter adapter requires an operating voltage of +5V to +9V. Hence, these two components are powered directly from the output of the AA batteries. The pin details and specifications of the DC-DC converter are given in PDF document number 2 – section 3.1 – electronic Appendix3.

3.2 Data logger firmware

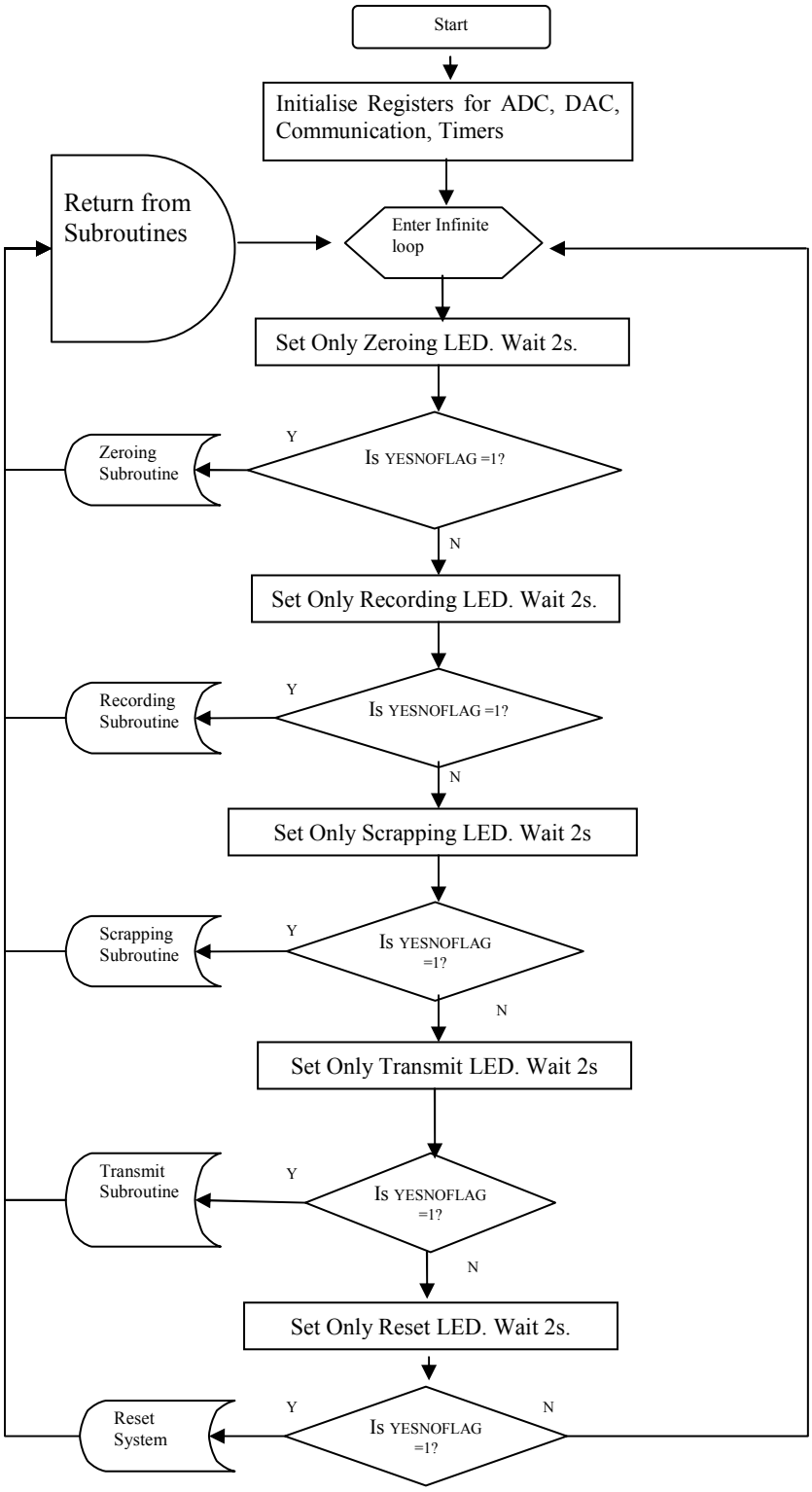
The firmware logic included in the development of SUDALS is explained in detail as a step by step procedure. Prior to writing the firmware, the keil micro vision project software (given by the manufacturers) required for interfacing the evaluation board with the PC and for converting the codes written in a user friendly language (C) to Hex codes, had to be installed in the PC used for this application. The various syntaxes required for the operation of the MCU are obtained from the sample firmware codes, which comes along with the software installed. However, since the software installation CD is copyright protected, it's not been included in the appendix. As mentioned already, the firmware written enables the microcontroller to perform five different functions (record, scrap, transmit, reset and zero) pertaining to the process of data collection. The functions such as; recording, transmitting and scraping are written as subroutines and they are called as part of the main program when required. The subroutines corresponding to various functions are included in the header file of the program and various status flags such as; yes-no flag, stop flag, busy flag, scrap flag, record flag, Calib flag, transmit flag and reset flag are assigned to the respective subroutines to check for application oriented conditions. Basically, the status of all these flags are initially kept low (0) and once the conditions are satisfied, the status of the flag are made to go high (1). Within the main program, various timers, GPIO ports and other application oriented registers are initialised by providing suitable addresses. This is explained in detail in section 4.1 – electronic - Appendix 4.

3.2.1 Firmware Logic employed in SUDALS

The firmware logic employed in the operation of SUDALS; to perform five different functions pertaining to the process of data collection is explained here in this section. Following the initialisation of the desired registers (Appendix 4), these registers are employed as part of the routine firmware with a suitable logic to serve the desired application. This firmware is then serially downloaded to the MCU by interfacing the UART terminals of the evaluation board via the RS232 interface cable provided by the manufacturers. The five main subroutines corresponding to the five functions of

SUDALS (zero, record, scrap, transmit and reset) are illustrated in the form of flowcharts and the explanation of overall firmware code used in this application is given in section 4.2 – electronic Appendix 4.

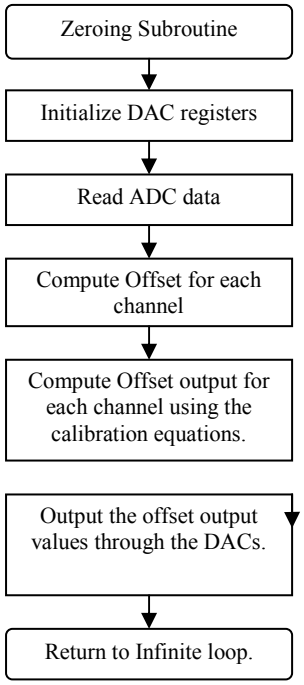
Main Logic flowchart



In the main program, all the application oriented registers as mentioned in section 3.1.6 are initialised and the user is given an option to select the functions using a key fob remote control. Once, a function is selected, then the status of the flag corresponding to that specific function is set high and simultaneously, the status flag (Yesno) corresponding to the external interrupt provided by the user is also checked and the control is transferred to the corresponding functional subroutine. A delay of 2 seconds is provided to select a desired function and if the user hasn't selected the function, then at the end of 2 seconds, an audio beep is provided to indicate the function time out and the control is transferred to the next function in the menu.

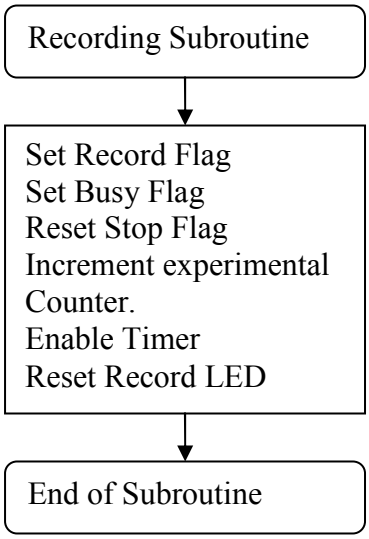
- Zeroing Subroutine:

In this subroutine, the offset function to 'zero' the flexible electrogoniometers is implemented by making use of the DAC registers and the ADC-DAC calibration equation. Once the zeroing value is taken into account, the control from this subroutine is transmitted to the main program.



- Recording Subroutine

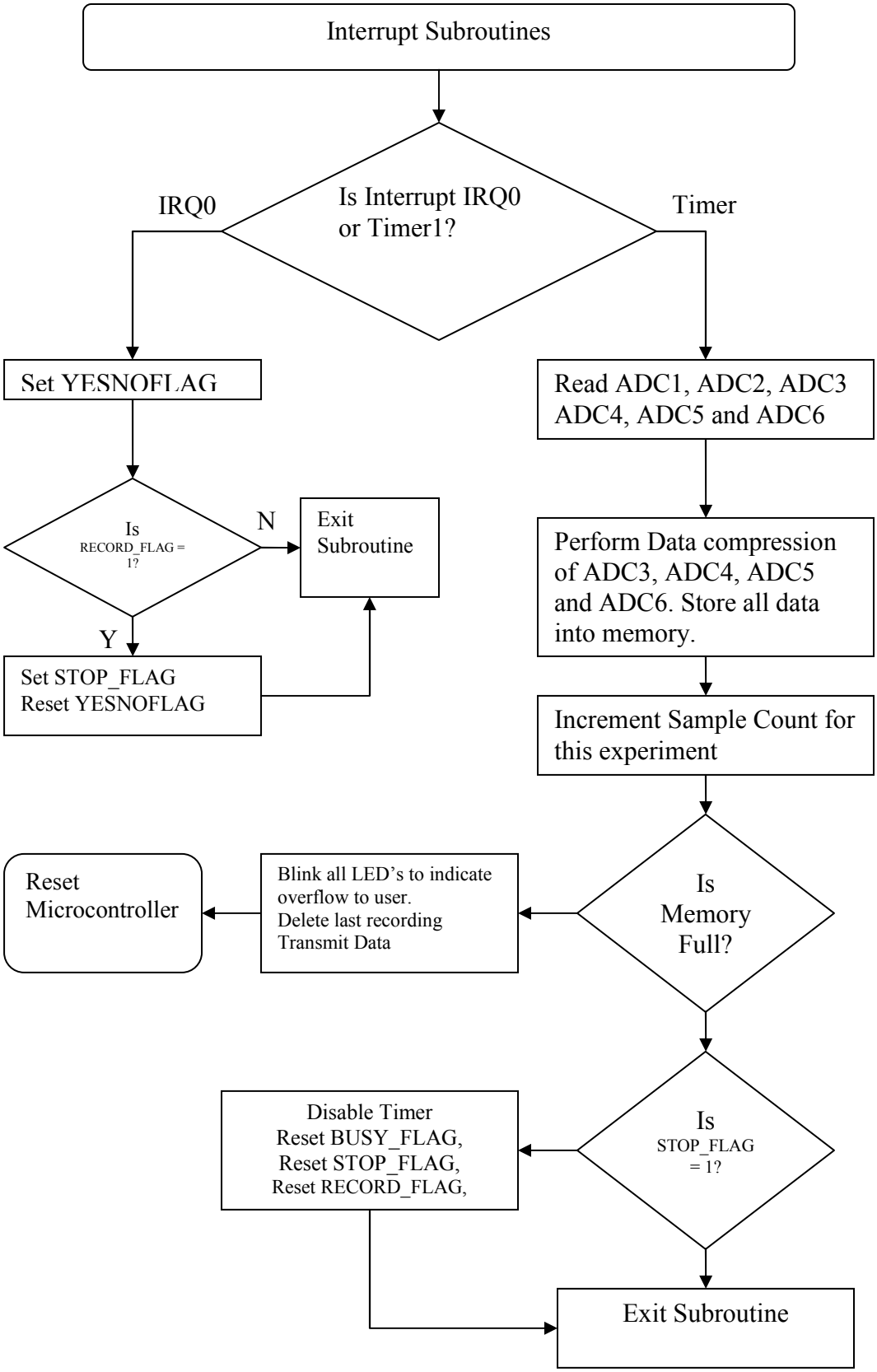
This subroutine is executed, if the recording function is selected from the menu function. Within the subroutine the RECORD FLAG is set and this is used within the IRQ0 subroutine to detect when the system is recording. The BUSY_FLAG is also set; this ensures that no other function can be selected as long as the recording is going on. The EXPERIMENTAL_COUTNER is incremented by one since one more experiment has been started and the timer is then enabled to start recording the data at the specified sampling rate. And finally the recording LED is switched off to let the user know that the recording has commenced.



- IRQ Handler and Sampling routine

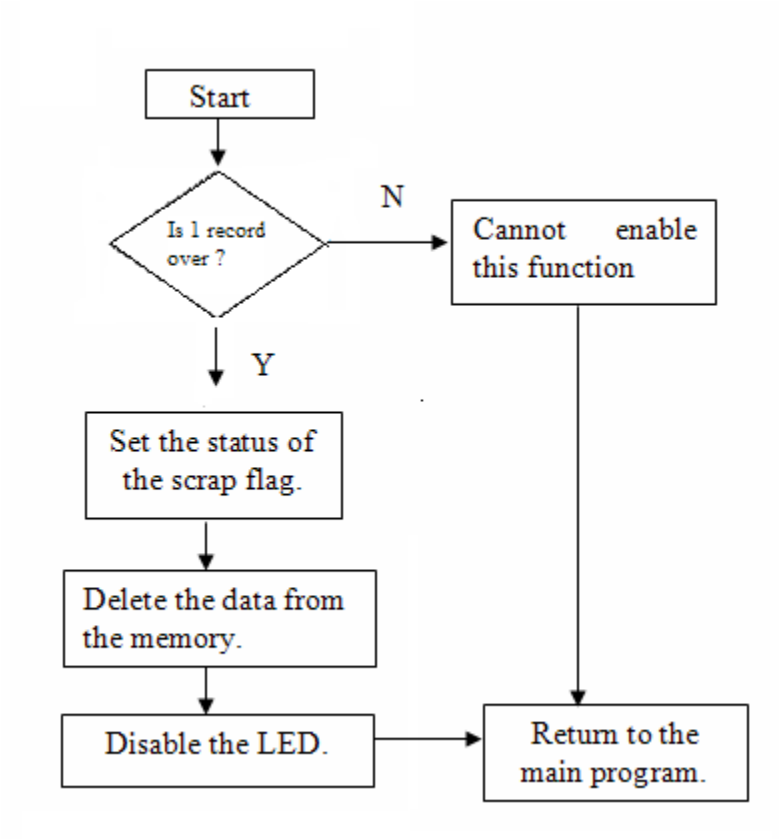
In this subroutine, handling of an ISR and timer interrupt is taken into account and once a specific function is selected via the external interrupt request given to the microcontroller, then this status is marked via the Yesno flag and the microcontroller performs the desired function by entering the function oriented subroutine. Since, the timer interrupt is also handled within this subroutine, if the

record function is selected, then the data from all the ADC channels are sampled and the data is stored in the external memory. Once the record function is selected, then the user has to stop the recording by providing the ISR to the MCU. So the status of the STOP FLAG is set suitably prior to and following the selection of the record function. To make an effective use of the available memory space, the data from the FSR channels are compressed to a single channel data and this process of data compression is implemented as part of this subroutine and in addition to this, a 'memory full' condition check is also carried out. If the memory becomes full, then the recording process is disabled and all the data other than the current recording is automatically transmitted to the PC and the system is reset.


Interrupt Subroutines
Is Interrupt IRQ0 or Timer1?
IRQ0
Timer
Set YESNOFLAG
Read ADC1, ADC2, ADC3 ADC4, ADC5 and ADC6
Is RECORD_FLAG = 1?
N
Exit Subroutine
Y
Set STOP_FLAG
Reset YESNOFLAG
Perform Data compression of ADC3, ADC4, ADC5 and ADC6. Store all data into memory.
Increment Sample Count for this experiment
Is Memory Full?
Blink all LED's to indicate overflow to user.
Delete last recording
Transmit Data
Reset Microcontroller
Is STOP_FLAG = 1?
Disable Timer
Reset BUSY_FLAG,
Reset STOP_FLAG,
Reset RECORD_FLAG,
Exit Subroutine

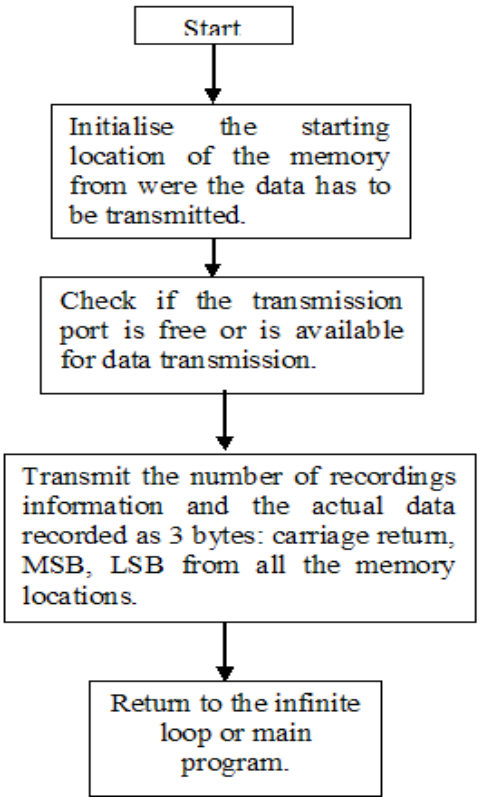
- Delete or Scrap Subroutine

The delete or scrap subroutine is included as part of the routine menu function and is used for scrapping a recorded function. The scrapping function is enabled if and only if a single recording has been made. Hence, if a recording is completed and if the user is not satisfied with the recording made, it can be deleted by choosing the scrap function via the external IRQ. Once, this function is selected, the microcontroller deletes the information stored in the memory location and transfers the control to the beginning of the menu function routine.



- Transmit subroutine

The transmit function is included as part of the menu function routine. Prior to data transmission, the availability of the transmission port is checked along with the status of the communication port. Once, these conditions are satisfied, then the information pertaining to the number of recordings, length of each recording, carriage return, MSB data and LSB data is transmitted from all the memory locations and the control is returned to the main function.



All the above firmware written in a user friendly language (C language) is then converted into a Hex file and is serially downloaded into the flash/EEPROM of the microcontroller. This enables us to make use of SUDALS to collect and transmit data pertaining to the flexion/extension of the knee. The transmitted data is then retrieved at the PC end using the front end software as explained below.

3.2.2 Front-end Software

Following the data collection, the recorded data is transmitted wirelessly to the PC, where the data is received by the receiver adapter connected to the serial port of the PC. The data from the serial port is then read and processed using software written in Matlabs' Graphical User Interface Development Environment (GUIDE).

Appearance of the front end of the GUI is show in figure 3.14. The main objective of writing this software is; to read the data from the serial port of the PC, display the total number of recordings made numerically and graphically in the same sequence with the relevant record number and enable the user to save these recordings together with the record details as individual Excel files for future analysis. The front end presents the user with buttons, pop_up menus, slider bars and graphs. The buttons enable the users to connect, disconnect, read, save, and enter subject and recording details. While the only data processing tool built into the GUI is the possibility for offset correction, there is possibility for developing and including more advanced signal processing tools to the user in the future. The pop_up menus enable the user to select either of the two calibrated goniometers that are used during the experiment and the slider allows the user to browse through the different records of the experiment. The graphs present the signals recorded during the different experiments. The following section gives a more detailed explanation of the functionality of the different controls.

Software Algorithm:

- Initially, all the variables required for retrieving the data from the serial port are initialised using the 'handles' command. This includes, the initialisation of the serial communication port, baud rate, input buffer size, flow control, size of the data storage array, etc.
- As shown in figure 3.11, various control buttons such as connect, subject details, Get data, Record details, Save, Disconnect and Offset are used for carrying out certain application oriented functions during the data retrieval. These are the main functions

corresponding to data retrieval and the software written here is for executing these functions. The logic involved in the execution of each function is explained here in this algorithm.

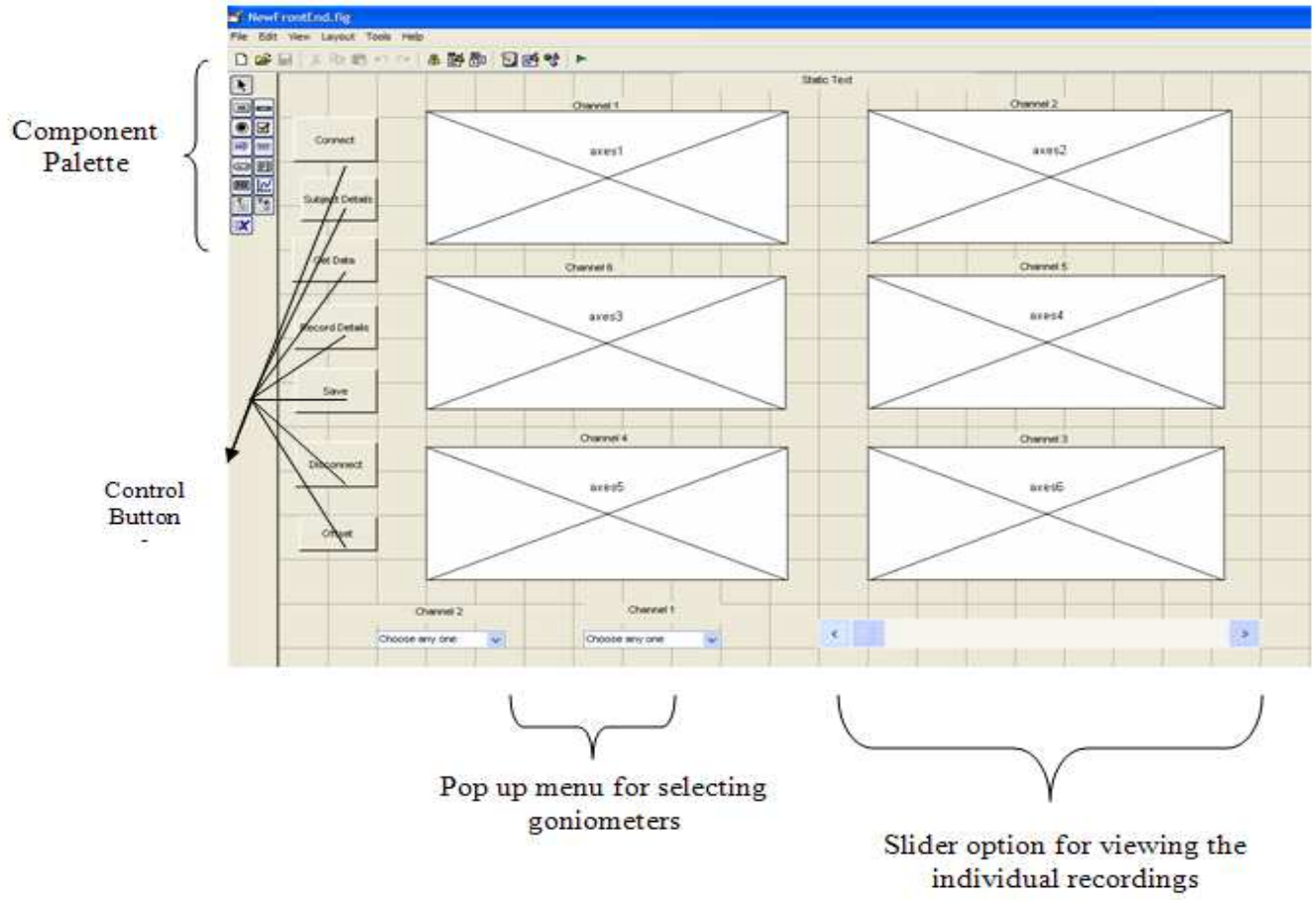


Figure 3.11: GUI Layout editor

Connect and Disconnect function: When the 'Connect' function is enabled, the status of the serial port at the PC end is sent to the microcontroller, which then transmits the data (if the function is selected at the microcontroller end) and the data transmitted is temporarily stored in the 'input buffer'. Similarly, when the 'Disconnect' function is enabled, then the serial port is closed and this indicates to the microcontroller that the serial port is not ready for receiving any data. If this function is enabled, the other control buttons cannot be enabled and all the other functions related to data retrieval

are disabled. Hence, as a rule of thumb prior to data transmission, the Connect function should be enabled.

Get Function: Once the Connect function has been enabled and the microcontroller has finished the data transmission, the Get function can be enabled. This displays all the data recorded from the 6 channels along with their record number in the areas marked 'axes1, 2, 3, 4, 5 and 6' as shown in figure 3.11. The graph displayed in the areas marked 'axes 1 and 2' correspond to the knee flexion/extension data and these data are displayed in degrees.

Basically, when this function is enabled, the data stored in the input buffer is retrieved by the software and following this the recombination of the data takes place. As mentioned in the *Transmit subroutine*, the data transmitted is in the form of two 8 bits. Hence, prior to displaying this information, the data has to be recombined into a 16 bit value. In addition to this, the carriage return that was also transmitted along with the data has to be eliminated and the actual data has to be extracted in its original form prior to displaying the data.

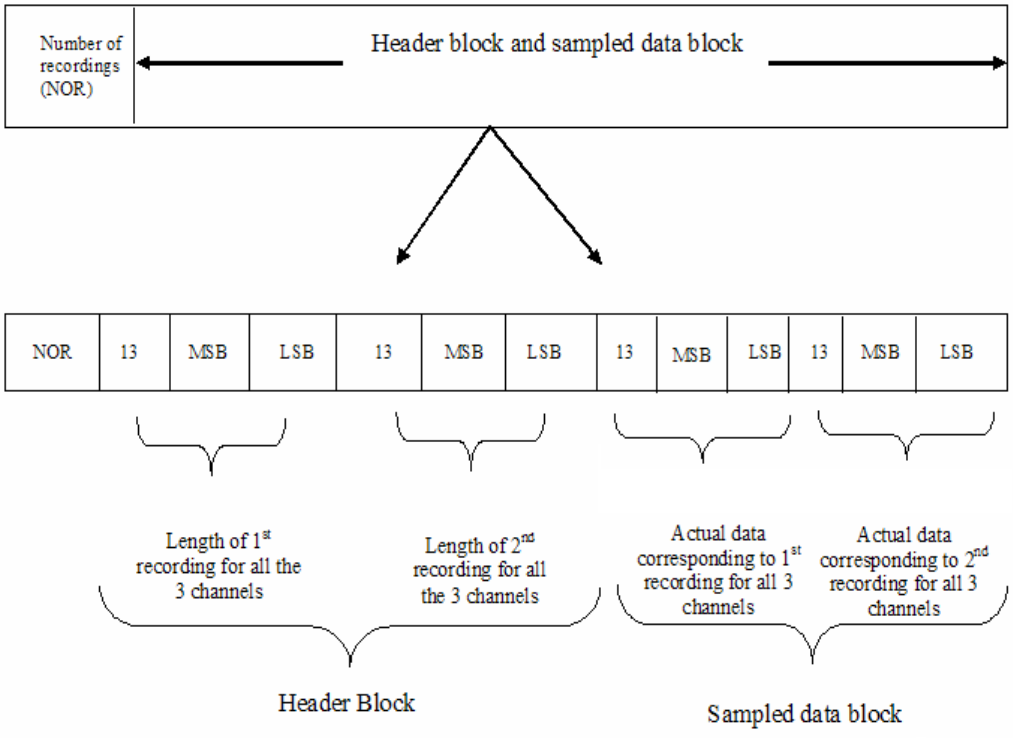


Figure 3.12 – Format of the array comprising of recombined data in case of two recordings.

Also due to arbitrary recording time for each activity, the actual data corresponding to each recording and each channel has to be extracted individually following the recombination. All the recombined data is stored in an array in a specific format as shown below in figure 3.12. Following the data extraction from the array, the data corresponding to the FSR channels; 3, 4, 5 and 6 which are in a binary format are converted to a suitable format for display and all the recordings are displayed graphically.

Pop up Menu and Offset function: This function allows one to select the desired goniometers used for recording the knee flexion/extension data. Three different goniometers are currently being used along with SUDALS and selecting two of the three goniometers via the pop menu option automatically includes the calibration equation corresponding to the goniometers selected for the different calculations performed in the program. The offset function allows the user to correct for offset issues associated with the anatomically defective knee. In such cases, the user will be able to add the known offset angle directly to the data retrieved by making use of this function. For example, if someone has a fixed flexion contracture of 10 degrees, the zero position will be 10 degrees from neutral. But the data can be corrected by adding or subtracting (left knee/ right knee) 10 degrees to all values recorded.

Slider, Subject and Record details function: The displayed graphs can be individually viewed with the help of the slider option provided (shown in figure 3.14) and together with the individual record details and subject details, the information pertaining to the recordings made can be stored in a directory (created with the same name of the subject) as individual excel files corresponding to each activity or recording. The entire software code used in this application is given in section 4.4 in electronic Appendix4.

3.3. Result

The selection of suitable hardware together with an application oriented firmware and software codes have resulted in the development of a simple to use, light weight,

portable, multi-channel, remote controlled and wireless data acquisition system (figure 3.13) for use with flexible electrogoniometers that can be used in assessing the functional outcomes of the knee.

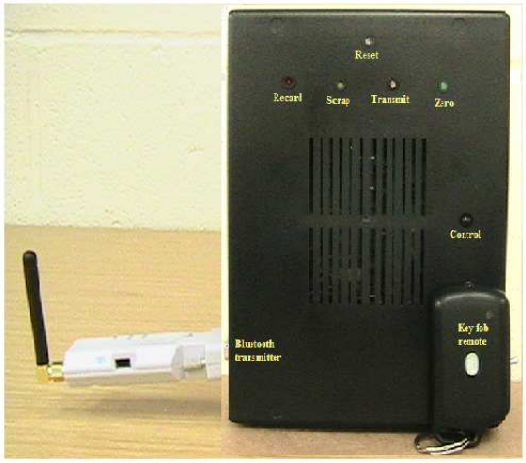


Figure3.13: A simple to use, light weight, remote controlled and wireless data acquisition system (SUDALS)

3.4 Discussion

The design of SUDALS described in this chapter has emerged in an attempt to meet the rationale of this research work and to bridge the gap mentioned in the literature. Though the main aim has been achieved in this development phase, the design of the data collecting system is a balance between what is required and what was available at the time of this development phase. A working prototype has been produced to test the thesis hypothesis. But further development and refinement of the system will be required before a clinical product is developed for manufacture and routine use. As a result, the work reported here forms part of a continuing programme of research and the device developed and tested during this project will provide the basis for further development of the system.

This section describes the objectives underlying the design of SUDALS and explains how some of the design choices were made. The main objective set at the beginning of the design phase was to design a simple to use system for use with flexible electrogoniometry, which has the potential to record the knee flexion/extension data and transmit the same via wireless to a PC with no or minimal technical issues. In addition to the wireless data transmission, if the system has an additional feature of controlling the whole process of data collection remotely, then the system would be much simpler to operate whereby, clicking a single button will allow the user to perform a desired function pertaining to data collection without any difficulty.

When it comes to a data acquisition system used in conjunction with body mounted transducers, the system should be compact, light weight and portable. The primary objective was to design the data logging system by making use of the microcontroller ADUC7026 alone (a 40 pin surface mount IC of dimension 6mm x 6mm). However, the microcontroller being a surface mount IC, it is not possible to use the IC without a suitable IC holder and such holders were subsequently not found to be provided by the IC manufacturers, during the time of purchase of the IC. The microcontroller was a new generation of chip in 2006 and much of the support required for its use proved not to be available from the manufacturers at the time. Though such holders could have been purchased from certain third party manufacturers, the holders were very expensive and without knowing the actual efficiency, operation and the extent to which the IC would be useful for our application, it wasn't worth investing a lot of money for the IC holders. Moreover, the lack of availability of micro soldering facilities for such surface mount IC's within the Bioengineering Unit of University of Strathclyde resulted in the use of an evaluation board and the current size (LxBxH) of the SUDALS is basically due to the size of this evaluation board. The dimension of the ABS plastic box chosen was based on the dimension of the evaluation board and most of the electronic components used in the hardware design of SUDALS are single IC's soldered on a strip board. The main aim of selecting the electronic components explained in this chapter was to meet all the requirements pertaining to signal conditioning, facilitate remote control operation of the whole process of data collection and enable wireless data transmission. The instrumentation amplifier used here for signal conditioning purposes

was simple to use and the documentation provided by the manufacturers explained the procedure of selecting the suitable gain resistors, which in turn provided the desired output for this application. In a different application, another version of the INA118 instrumentation amplifier has been used by Pfister et al., 1989 to develop a 3 channel pressure monitor system and the authors haven't reported any drawbacks of these amplifiers. However, the prototype could in future be reduced in size to 38 x 37 x 18 mm, if manufactured on large scale with IC holders and specific PCB boards.

Similarly, the idea of using the IR key fob remote control implemented here in the design of SUDALS is a simple and novel idea that fastens the process of data collection without the need for any physical contact with the subject wearing the data logger. Though there may be many remote control system used in the process of data collection, reviewing the literature doesn't reveal the use of any such key fob remote controller with respect to flexible electrogoniometry. However, suitable electronic components had to be used with the IR receiver IC to interface the device with the microcontroller and provide an external interrupt trigger to the MCU. This was achieved by making use of the monostable multivibrator as shown in figure 3.5. The objective behind interfacing the output of the IR receiver IC with the monostable multivibrator was to provide an ISR to the microcontroller. Generally, an external interrupt required to trigger the microcontroller should be a rising edge pulse with a low to high transition state. However, when the IR receiver IC was tested initially, the output of the IC was a falling edge pulse with a high to low transition state. As a result, the output of the receiver IC had to be interfaced with the multivibrator, so as to obtain the required signal to trigger the MCU.

Another idea implemented here in the design of the SUDALS is the calibration circuit used for zeroing the flexible electrogoniometers. Using a combination of unique hardware circuit together with software seems to be a novel one and reviewing the literature doesn't reveal the use of any such concepts. This concept proved to be efficient when tested in static conditions (explained in chapter 4); however its actual performance can be known only when tested in dynamic conditions. Although the hardware for the zeroing circuit could have been designed using simple operational amplifiers, dual Bimos operational amplifier (Op-amp 3240) were used in the design of the hardware circuit for

this application to save space. The device provides high input impedance; a wide common mode input voltage range and allows a wide output voltage swing. This in turn reduces the requirement of other miscellaneous components for designing this circuit. Hence, taking into account, the simplicity, power consumption issues and space constrains within the data logger box, the idea of using two of these Op-amps instead of four ordinary Op-amps, met our desired application and addressed the above issues. The space constrain issue within the data logger box was mainly due to the size of the evaluation board. Despite that the evaluation board served the actual purpose, there are pros and cons with respect to the usage of this evaluation board. Considering the advantages of the board; the manufacturers have designed the board in such a way that it allows one to start using the microcontroller by following the instructions given by the manufacturers in the manual and technical documentation. Hence, it is possible for an Instrumentation engineer new to microcontrollers to be able to get started with this development kit. Also, the sample firmware codes given in the software installed, gave an idea of setting suitable addresses to the application oriented registers available. In fact, using the development kit also avoided micro soldering, approaching external people for downloading the firmware to the MCU and converting the user language code to machine language code. At the same time, the main limitation of using the evaluation board is concerned with the memory issues. The microcontroller ADUC7026 has very limited in built memory and so this necessitated the use of an external memory. However, in the footprint provided on the evaluation board for using an external memory, only a 32kB x 16 SRAM (as prescribed by the manufacturers) can be used.

This in turn has resulted in a system with a less memory capacity than is ideal and currently possible. So, if data from all the sensors are sampled at 50 Hz and recorded from all the 6 channels, the memory would be saturated in less than 5 minutes. This is the main limitation of the EVAL-ADUC7026. May be if the manufacturers had prescribed another version of SRAM with increased capacity, then the system could have been used to record data for a longer duration. Otherwise, if the microcontroller was used as such without an evaluation board, a high capacity SRAM's could have been interfaced to the microcontroller via the peripheral input ports. However, most of the human activities are high frequency activities and when assessing the functional outcome

activities such as walking, in and out of a chair etc. the amount of time required to record such activities would be less than a minute. This still allows us to use the system in conjunction with flexible electrogoniometers for assessing the functional outcomes of knee surgery.

As a promising solution, the issues associated with the external memory have been reduced by implementing the idea of data compression and simultaneous recording and data transmission. The concept of data compression is applied only to the FSR channels, where the data from all the four FSR channels are compressed to a single channel data (as explained in the IRQ subroutine in section 4.2 – electronic Appendix 4). As a result, even though the data from all the six channels are simultaneously recorded and sampled, the amount of space that will be occupied in the memory to store the information from all the six channels will be same as the amount of space required to store the information from only three channels. Such data compression techniques have also been used in the design of three channel pressure monitor system by Pfister et al., 1989 and the technique seem to have worked efficiently without any problem.

Similarly, the idea of recording a set of activities for a specific period of time (less than 5 minutes), storing the same and transmitting the data is similar to the concept of simultaneous data recording and transmission. This approach will not only be a solution for the memory issue but will also be useful in checking the reliability of the system operation, the recording carried out and the data collected, unlike the non-wireless systems where the user has to wait until all the recordings are completed to transfer the data to the PC. In such situations, if the user is unhappy with the data collected, then the subject has to perform all the activities again which will be a waste of time. The idea of wireless data transmission implemented here in the design of SUDALS, was obtained from the serial RS232 interface cable provided by the manufacturers. In addition to the transceiver adapters, inclusion of a transmitter line driver seems to be mandatory as the line driver actually interfaces the UART terminals of the evaluation board with the wireless adapter and enables us to transmit the data stored in the external memory of the evaluation board via these adapters to a PC. Using the wireless adapters proved to be simple, economical and avoided the hassles of building a separate wireless hardware circuit. By following the manufacturer's instruction, the adapters were paired and

configured with the microcontroller, which then resulted in wireless transmission of data. However, the adapters are high power draining devices and consume a large amount of power. Hence, suitable precautionary measures had to be taken to ensure proper functioning of the device when used in actual application.

This was carried out by designing an efficient power supply circuit with DC-DC converters, voltage regulators and high wattage batteries. All the components including the sensors are powered using 6 1.2 V AA Nimh 2500 mah batteries. These batteries are said to last for 1 hour with a maximum current discharge of 2500 mA. However, the maximum power consumption of all the components including the transmitter adapter is 160 mA. So, if all the batteries are fully charged, then the system can be used for collecting data for a maximum time of 8 hours to 10 hours approximately and such components have been used in designing power supply circuit supporting high power draining applications (Kao et al., 1995, Lin et al., 2004). Though the use of high wattage batteries has resolved the power consumption issues, inclusion of 6 AA batteries within the data logger box seem to have resulted in a little bulky system, weighing 140 grams (table 2.1) more than the commercially available system. One of the alternatives for the AA cells is the zinc-air cells which occupy only half the volume of the alkaline cells. However, with these cells dual power supply method has to be adopted to ensure adequate data protection. In addition to the trade-off in the size of the data logger and the lack of sufficient memory (due to the use of evaluation board), the microcontroller itself had certain limitations which led to a compromise in the logic designed for the operation of SUDALS. The way the current logic works is based on the single trigger concept given by the remote controller to the microcontroller via the GPIO port pin 0.4. This is the only pin available at the microcontroller end, which can accept external trigger ISR. Though there are other pins which can accept ISR, these pins are multifunctional and using these pins could activate other unwanted functions of the MCU. As a result, using a single trigger makes the data logger operate in a multi functional loop. So, even if the user doesn't wish to perform a specific function, the user has to wait until the prompt for that specific function finishes, to enable the required function and this can result in an unwanted delay in between the function selection. However, the indication of all the available functions in a sequence would allow any non-

technical person to operate the system with minimal training and enable to collect and transmit data in few minutes.

In summary, despite the availability of a commercial data logging system for use with flexible electrogoniometry, there is not enough literature illustrating the design concepts of the data collecting system and the commercially available system doesn't facilitate remote control operation and wireless data transmission. Even, if such systems exist, then the literature doesn't report on the clinical applicability and usability of such a system. Hence, before releasing the developed system for general use, it was necessary to test the system for its accuracy, reproducibility, validity, reliability and usability. This was carried out by performing a series of experiments within the Bioengineering unit of University of Strathclyde. These experiments together with their results and discussion are explained in detail in the chapters 4, 5, 6 and 7.

Chapter 4 – System Testing

Following the development of SUDALS, prior to releasing the system for general use, the system developed was subjected to various bench tests and calibrations to validate its output.

The essential aim of testing the developed system is to remove any faults in the hardware, firmware and software and to check that the data logger meets the desired objectives. Generally, when testing the efficiency of a computer based system, the hardware and software testing can be distinguished easily. However, when testing a microcontroller based system, the software and hardware are closely interrelated and this distinction becomes blurred. Hence, testing the firmware or software automatically reflects on the extent to which the hardware is being tested and it also gives an idea about the overall performance of the system. On the other hand, the concept of testing occurs throughout the writing of the firmware / software and at each and every stage of the software design, all the possible logical errors are taken into account and its ensured that the questions; 'does the program behave as expected and does the program do what is required' are always answered during the software design stage itself. Similarly, when we try to interface a sensor with a newly developed data collecting system, the accuracy of the equipment and the extent to which the device serves its desired objective has to be checked prior to its usage in a practical application oriented environment. All these parameters were taken into account when testing the system. Prior to subject testing, bench testing of the overall system was carried out and this was divided into various stages as explained in each methods section of this chapter.

4.1 Methods

4.1.1 Implementation of Zeroing Circuit

This section explains the calibration of the ADC and DAC channels involved in the zeroing module described in section 3.1.2 of chapter 3. Prior to implementing the zeroing function and interfacing the output of the sensors to the A/D channels, the A/D and D/A channels were tested / calibrated. The results obtained from this test are tabulated in the results section of this chapter.

With the flexible electrogoniometers placed in the neutral position, the analog channels ADC1 and ADC2 were calibrated against the digital channels DAC0 and DAC1, by giving various analog inputs ranging from 0 to 2.5 V (input range of the A/D converter) in increments of 0.1 V by varying the 470 KΩ POT connected to the INA118. The analog inputs given are individually recorded and serially transmitted to the PC to calculate the digital equivalent of the analog input by averaging 500 data points corresponding to each of the recordings made. The input given and the output obtained are related in terms of the regression equation. Similarly, digital inputs varying from 000 to FFF are given to the DAC channels 0 and 1 via the firmware written and the analog output given at these channels is measured using a multimeter. The calibration figures and the corresponding equations are as shown below:

The equations obtained from the analog channels are in the form of: $Y = mX + c$; i.e.

ADC1 = m_1* Analog voltage0 + C ---------- Equation 1.

ADC2 = m_2* Analog voltage1 + C ---------- Equation 2.

Where, ADC1 and ADC2 is the required digital output.

Similarly, the equations obtained from the digital channels are in the form of:

$Y = mX + c$; i.e.

Analog voltage0 = m_1* DAC0 + C ---------- Equation 3.

Analog voltage1 = m_2* DAC1 + C ----------Equation 4.

Where, DAC0 and DAC1 are the digital values given as inputs.

Rearranging Equation 1 gives us:

Analog voltage0 = {(ADC1-C)}/m_1----------Equation 5.

Similarly, rearranging equation 2 gives us:

Analog voltage1 = {(ADC2-C)}/m_2----------Equation 6.

Substituting Equation 5 in Equation 3 and Equation 6 in Equation 4, we have:

DAC0 = {(ADC1 – 2C)}/ m_1^2 ----------Equation7.

$DAC1 = \{(ADC2 - 2C)\} / m_2^2$ ----------Equation8.

Equations 7 and 8 are the required calibration equations used for zeroing and are included in the firmware. If the SUDALS system is correctly calibrated, then the system should give an output of 0 to 4095 computer units with an input range of 0 to 2.5 Volts, irrespective of the initial (zero) voltage of that range.

4.1.2 Bench test for studying the overall system characteristics (Accuracy, Precision, Linearity, Percentage Error)

Secondly, a bench test was carried out to study the system characteristics such as accuracy, precision/repeatability and hysteresis. When two different systems are interfaced together, one of the systems has to be calibrated in terms of the other, for efficient system utilization. In this study, the flexible electrogoniometer was interfaced with a 12 bit A/D converter of the SUDALS. The electrogoniometer was attached to the arms of a 350 mm plastic protractor using micropore around the end plate and the protractor arm and was attached to the A/D converter via connection leads. The A/D converter transforms the electrical voltage from the electrogoniometer into a computer number ranging from 0 computer units equivalent to 0 volts to 4095 computer units equivalent to 2.5 volts. With this arrangement, the electrogoniometer was displaced through a range of angles varying from 0° to 150° back through 0° to – 150° and back to 0° in ten degree increments using the protractor. The output from the electrogoniometer was recorded for 6 seconds at 50 Hz in each position yielding 300 readings. To minimize the interference of noise that could have been present during the recording, the initial and the final 50 data points were not considered and of the 300 data points obtained, the mean of the central 200 readings was calculated. With an interval of 1 hour, the above procedure was repeated and the data obtained from this trial was used for determining the precision of the system by calculating the standard deviation of the 200 readings around the mean value for that increment. SUDALS has 2 analog channels to which the electrogoniometer can be connected. Hence, the above procedure was repeated with both the channels using 3 different electrogoniometers (SG150 manufactured by Biometrics Ltd Gwent) on two different occasions to determine their influence on the recorded

angular displacements. The applied input angle in degrees(X) was related to the recorded output in computer units(Y) using regression analysis as shown in figure 4.5 – figure 4.10 in the results section of this chapter. This equation relates the input to the output. In our case we wanted the SUDALS to measure the angle from the electrogoniometer, i.e. we know the output, but want to calculate the input. Hence, the equation was rearranged to obtain the input X in terms of degrees from the output Y in computer units. The line of best fit through the data for all the three electrogoniometers, when connected to both the channels were obtained individually and were then averaged to obtain two single slopes and constants corresponding to channel1 and 2.

4.1.3 Static bench testing

Following the calibration of the flexible electrogoniometers with the data logger, prior to dynamic subject testing, static bench testing was carried out. Similar to the above procedure, the electrogoniometer was attached to the arms of a 350 mm plastic protractor using micropore around the end plate and the protractor arm and was attached to the A/D converter via connection leads. Then, the electrogoniometer was displaced through various known angles such as; 0°, 60°, 90°, 130° and 150 °. During this, the position of the flexible electrogoniometer was recorded by the data logger and finally towards the end, all the data recorded were transmitted to the PC via wireless communication and the data was saved using the front end software and then analysed. The results obtained from this test are as tabulated in the results section of this chapter.

4.2 Results

4.2.1 Results of the ADC-DAC channel calibration

The results of the ADC-DAC channel calibration are presented in the form of Tables (4.1 to 4.4) and are also illustrated in the Figures 4.1 to 4.5 in this section.

ADC1 – Channel	
Voltage	Computer units
0	0.6
0.1	171
0.2	340
0.3	496
0.4	662
0.5	829
0.6	1000
0.7	1158
0.8	1337
0.9	1501
1.0	1664
1.1	1839
1.2	2004
1.3	2173
1.4	2329
1.5	2507
1.6	2668
1.7	2821
1.8	2990
1.9	3158
2.0	3329
2.1	3497
2.2	3669
2.3	3819
2.4	3989
2.5	4095

Table 4.1 – Calibration of ADC1 with DAC0

ADC2 - Channel	
Voltage	Computer Units
0	0.5
0.1	166
0.2	316
0.3	491
0.4	663
0.5	819
0.6	976
0.7	1154
0.8	1306
0.9	1478
1.0	1643
1.1	1798
1.2	1969
1.3	2131
1.4	2301
1.5	2460
1.6	2612
1.7	2784
1.8	2944
1.9	3129
2.0	3283
2.1	3443
2.2	3669
2.3	3777
2.4	3933
2.5	4073

Table 4.2 - Calibration of ADC2 with DAC1

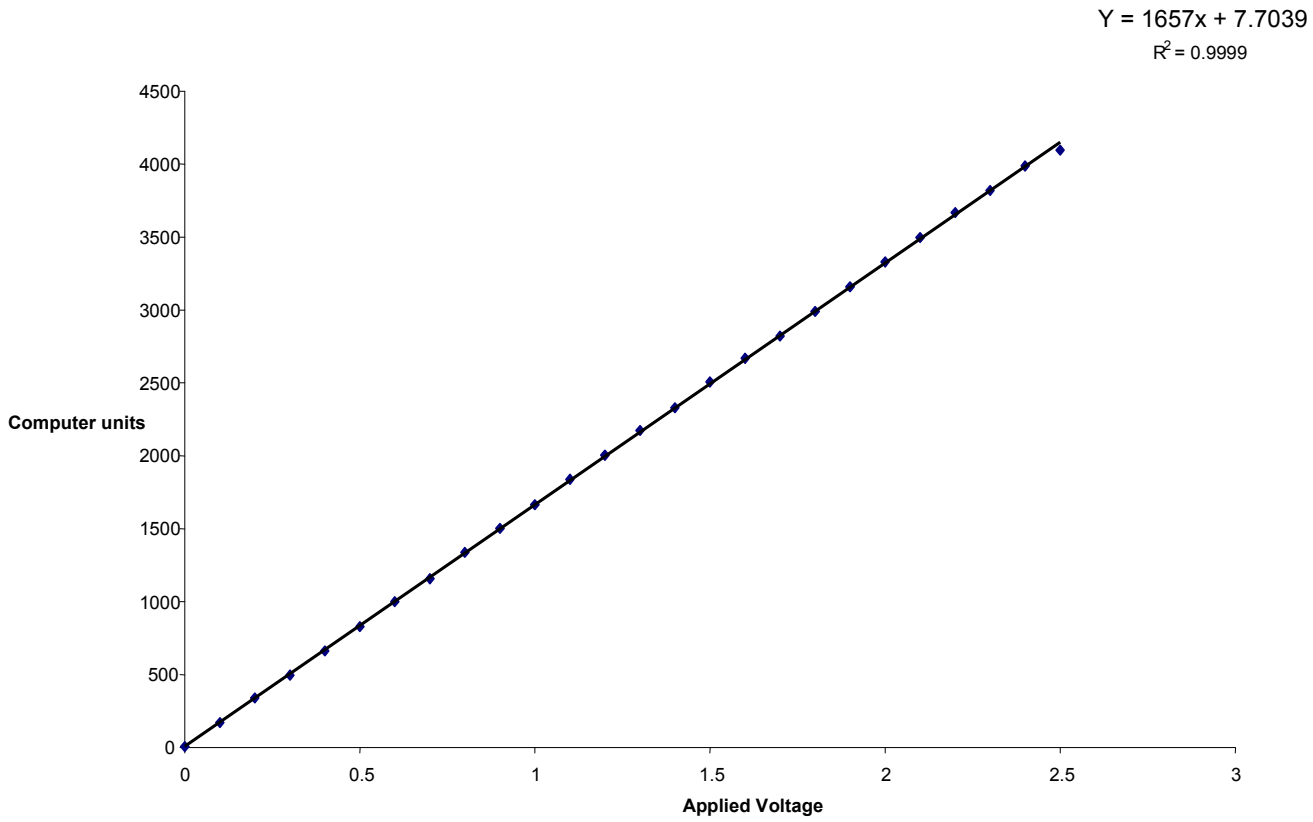


Figure 4.1 – Calibration Chart of ADC1 with DAC0 (where the unit of Y-axis values is in Computer Units).

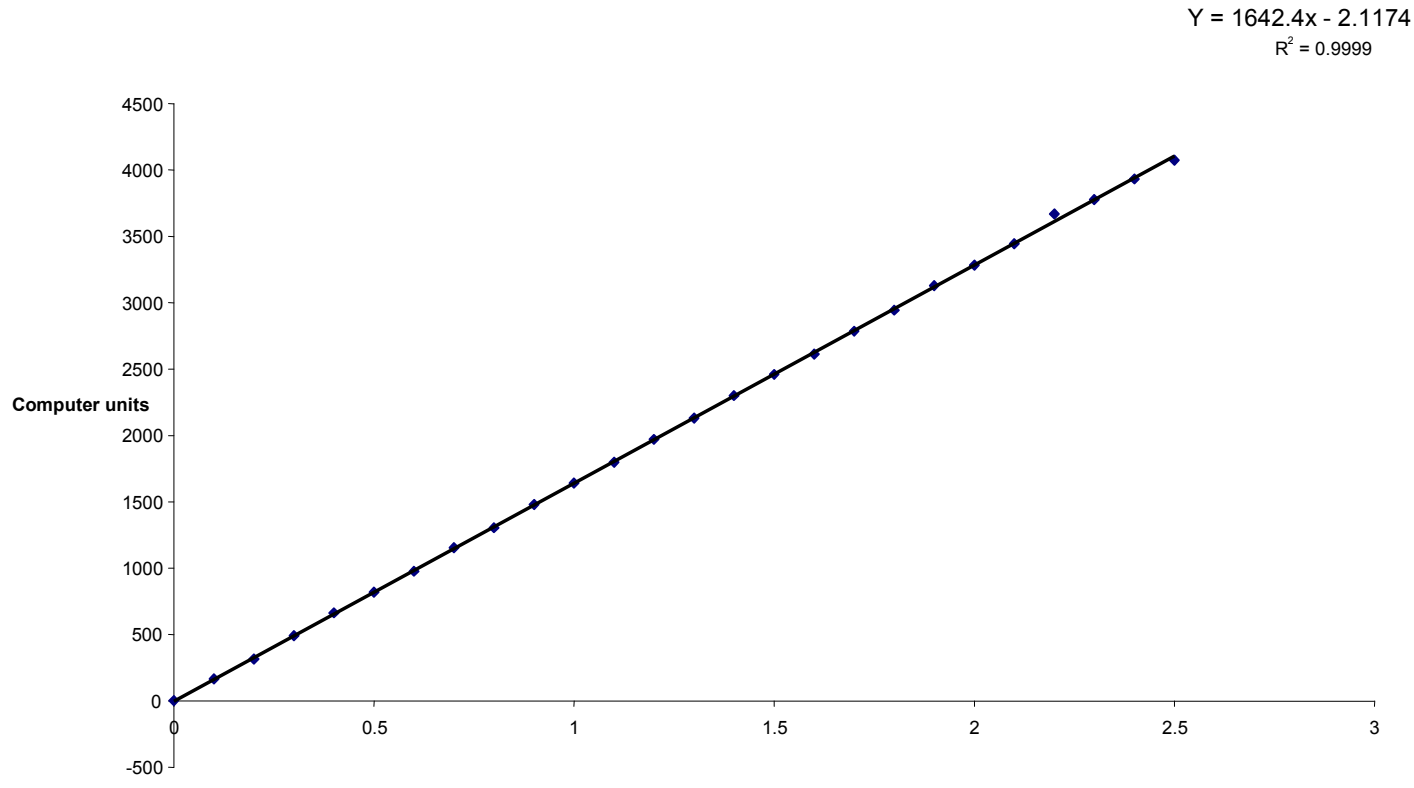


Figure 4.2- Calibration Chart of ADC2 with DAC1 (where the unit of Y-axis values is in Computer Units).

	DAC0 Channel	
Decimal equivalent	Digital Input	Analog Output
0	0	0.01
256	100	0.16
512	200	0.31
768	300	0.46
1024	400	0.61
1280	500	0.77
1536	600	0.92
1792	700	1.08
2048	800	1.23
2304	900	1.39
2560	A00	1.54
2816	B00	1.70
3072	C00	1.85
3328	D00	2.00
3584	E00	2.16
3840	F00	2.31
4096	FFF	2.46

Table 4.3 - Calibration of DAC0 with ADC1

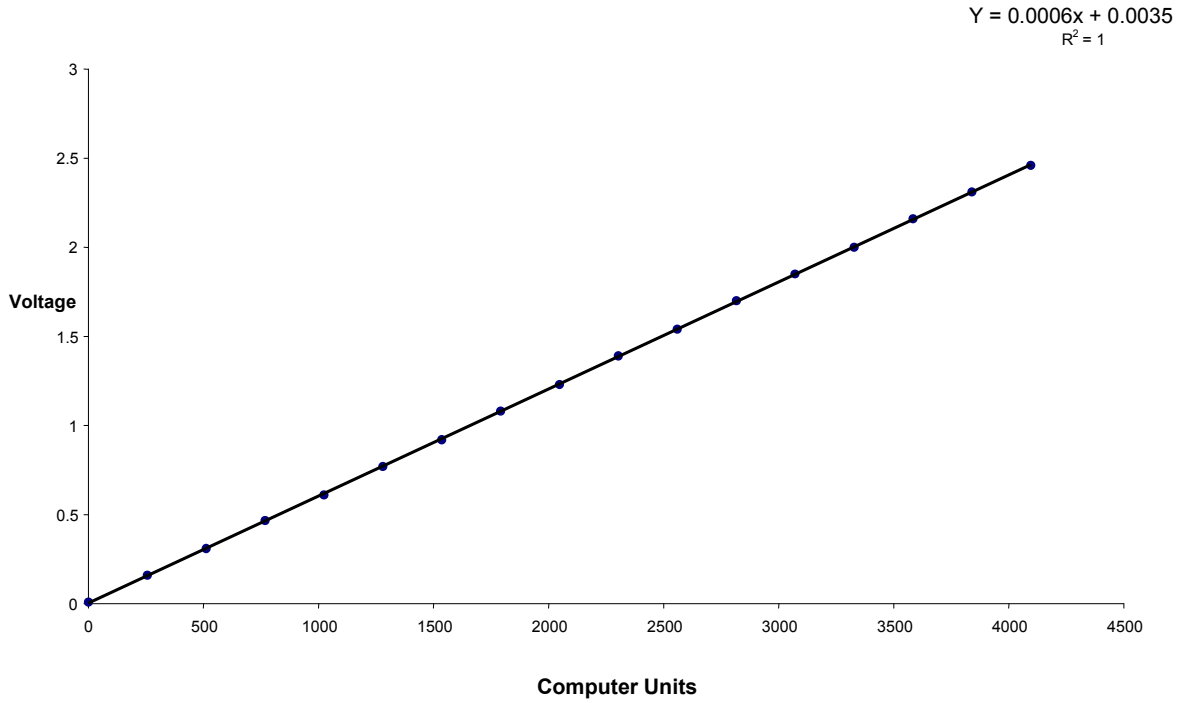


Figure 4.3 - Calibration Chart of DAC0 with ADC1 (where the unit of Y-axis values is in volts).

	DAC1 Channel	
Decimal Equivalent	Digital Input	Analog Output
0	0	0
256	100	0.27
512	200	0.31
768	300	0.46
1024	400	0.61
1280	500	0.77
1536	600	0.92
1792	700	1.08
2048	800	1.23
2304	900	1.39
2560	A00	1.54
2816	B00	1.70
3072	C00	1.85
3328	D00	2.00
3584	E00	2.16
3840	F00	2.31
4096	FFF	2.46

Table 4.4 - Calibration of DAC1with ADC2

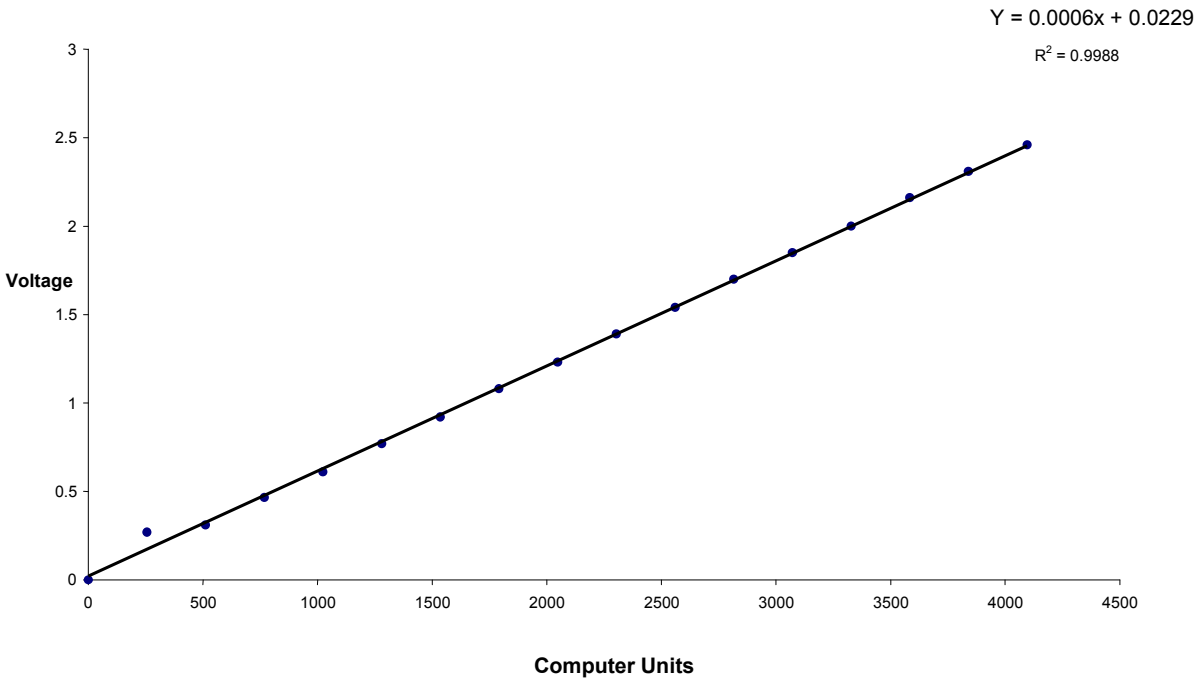


Figure 4.4 – Calibration chart of DAC1 with ADC2, (where the unit of Y-axis values is in volts).

4.2.2 Results of the system characteristics

The calibration equations obtained for all the three flexible electrogoniometers with respect to both the ADC channels 1 and 2 during two different trials are tabulated in table 4.5 and table 4.6 and the calibration figures obtained from these test are illustrated in figures 4.5 to 4.10 and 4.11 to 4.16. Also, the actual data obtained from all the three flexible electrogoniometers with respect to both the ADC channels 1 and 2 are tabulated in table 4.7 to 4.12.

	Goniometers	Slope	Intercept
Channel 1	G1	-0.1517	315.95
	G2	-0.1510	315.91
	G3	-0.1547	318.54
Mean		**-0.152**	**316.80**
Channel 2	G1	-0.1534	309.32
	G2	-0.1518	311.09
	G3	-0.1568	317.54
Mean		**-0.154**	**312.60**

Table 4.5 – Calibration equations of the goniometers – Trial 1

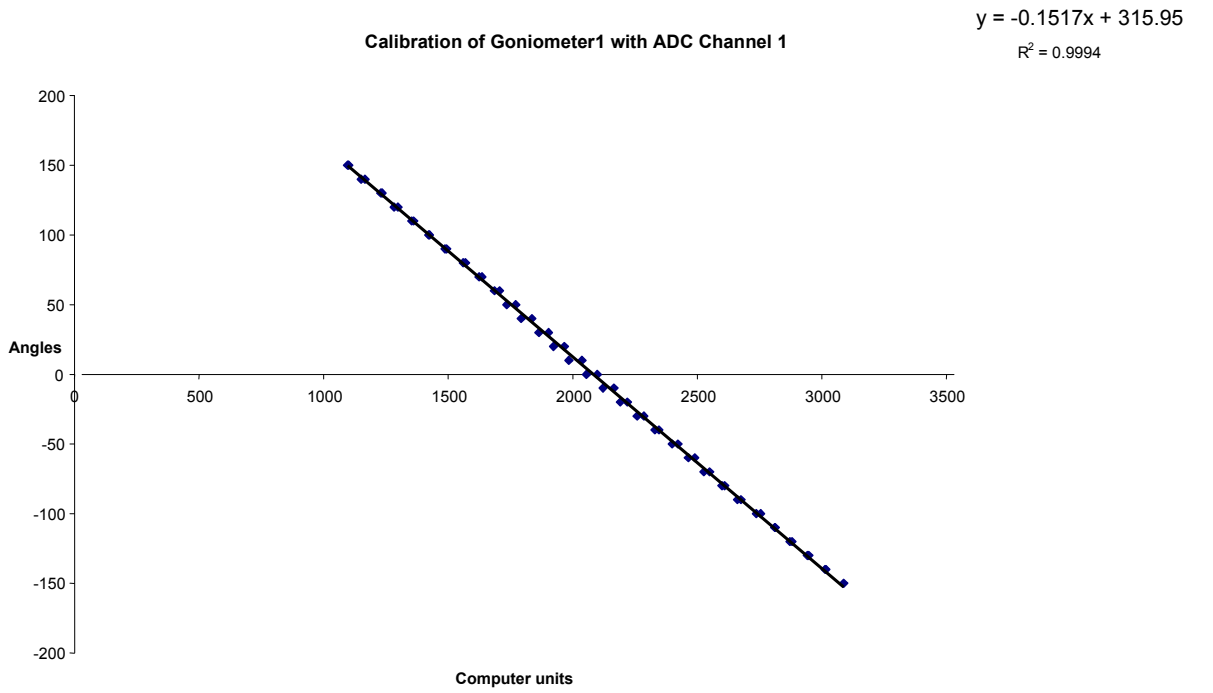


Figure 4.5: Calibration graph of Goniometer 1 with ADC Channel 1 – Trial 1 (where the unit of Y-axis values is in Degrees).

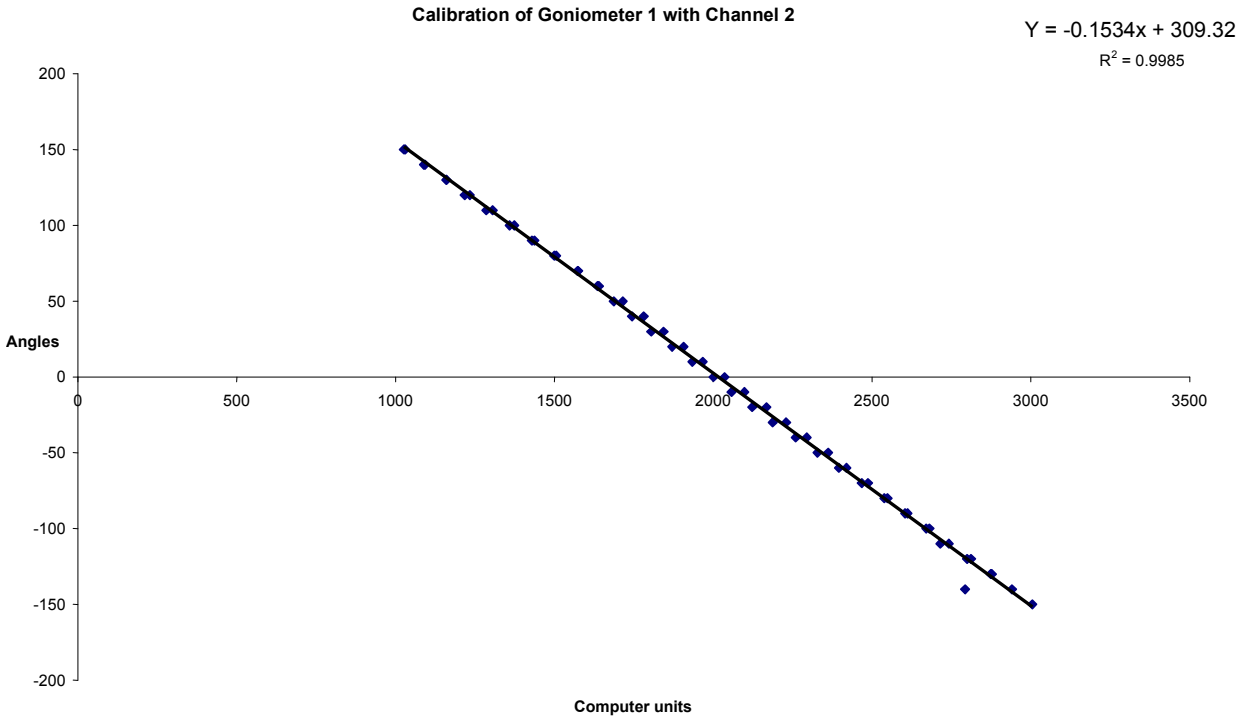


Figure 4.6: Calibration graph of Goniometer 1 with ADC Channel 2 – Trial 1 (where the unit of Y-axis values is in Degrees).

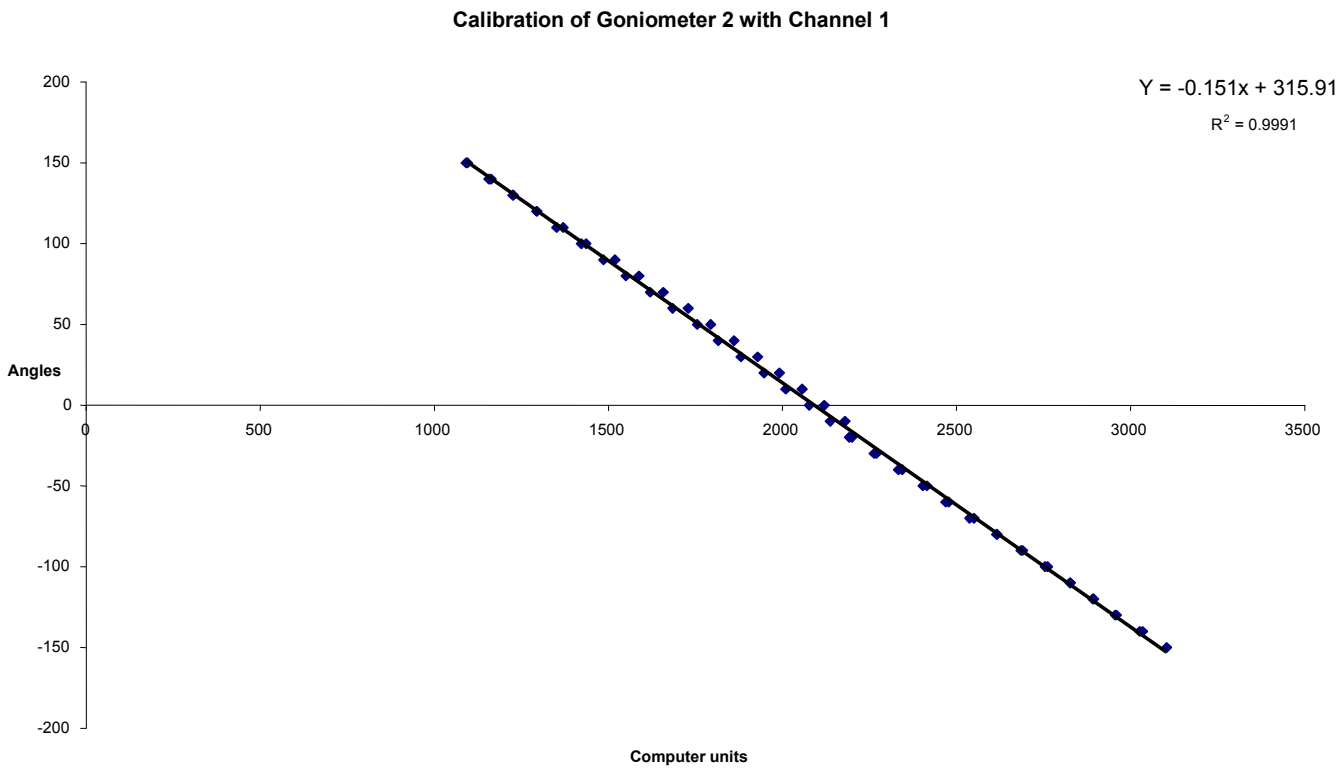


Figure 4.7: Calibration graph of Goniometer 2 with ADC Channel 1 – Trial 1 (where the unit of Y-axis values is in Degrees).

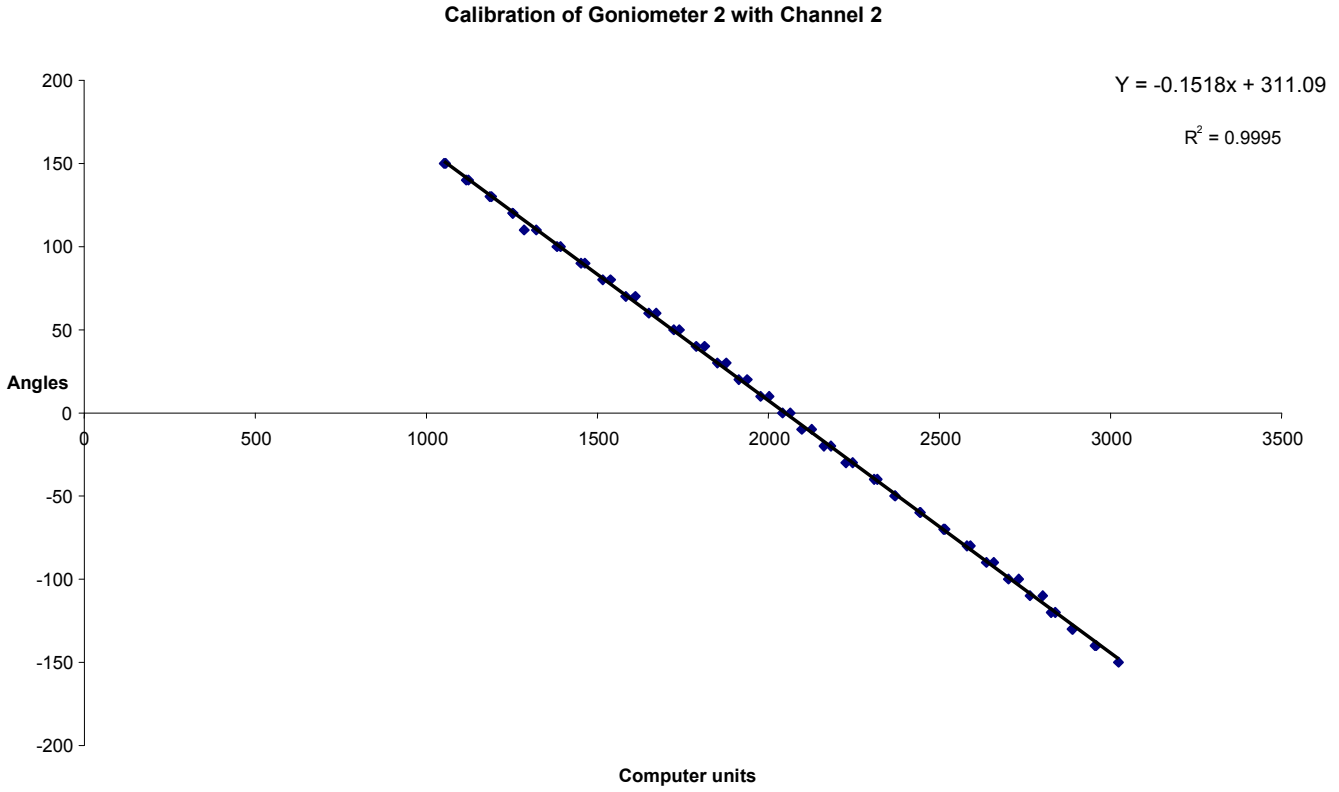


Figure 4.8: Calibration graph of Goniometer 2 with ADC Channel 2 – Trial 1 (where the unit of Y-axis values is in Degrees).

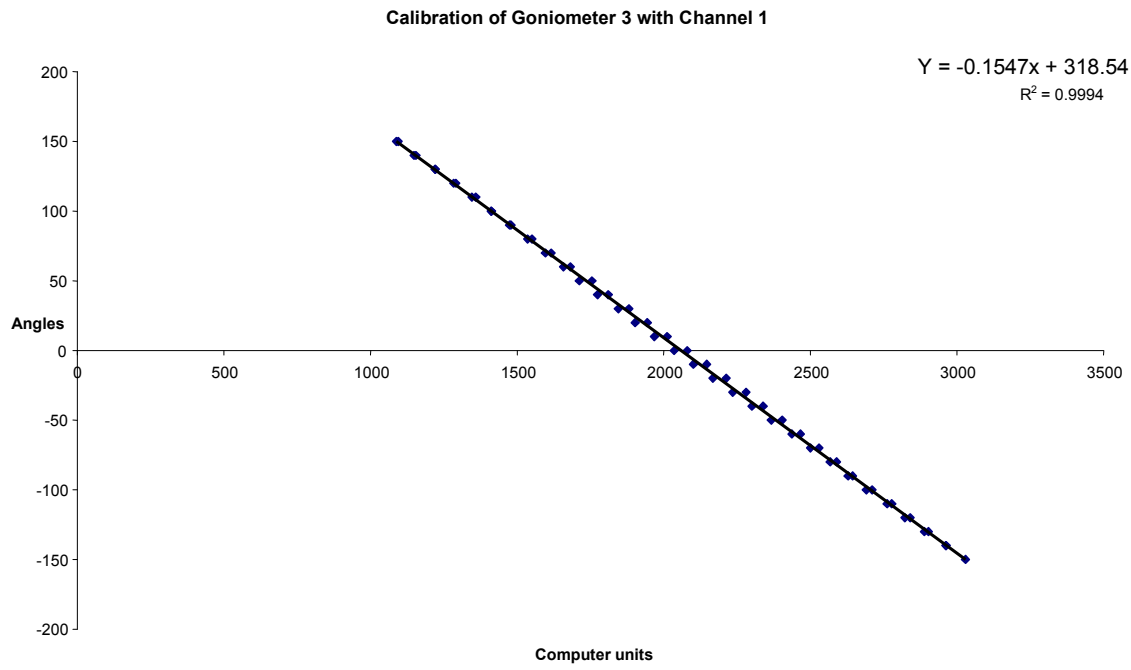


Figure 4.9: Calibration graph of Goniometer 3 with ADC Channel 1 – Trial 1 (where the unit of Y-axis values is in Degrees).

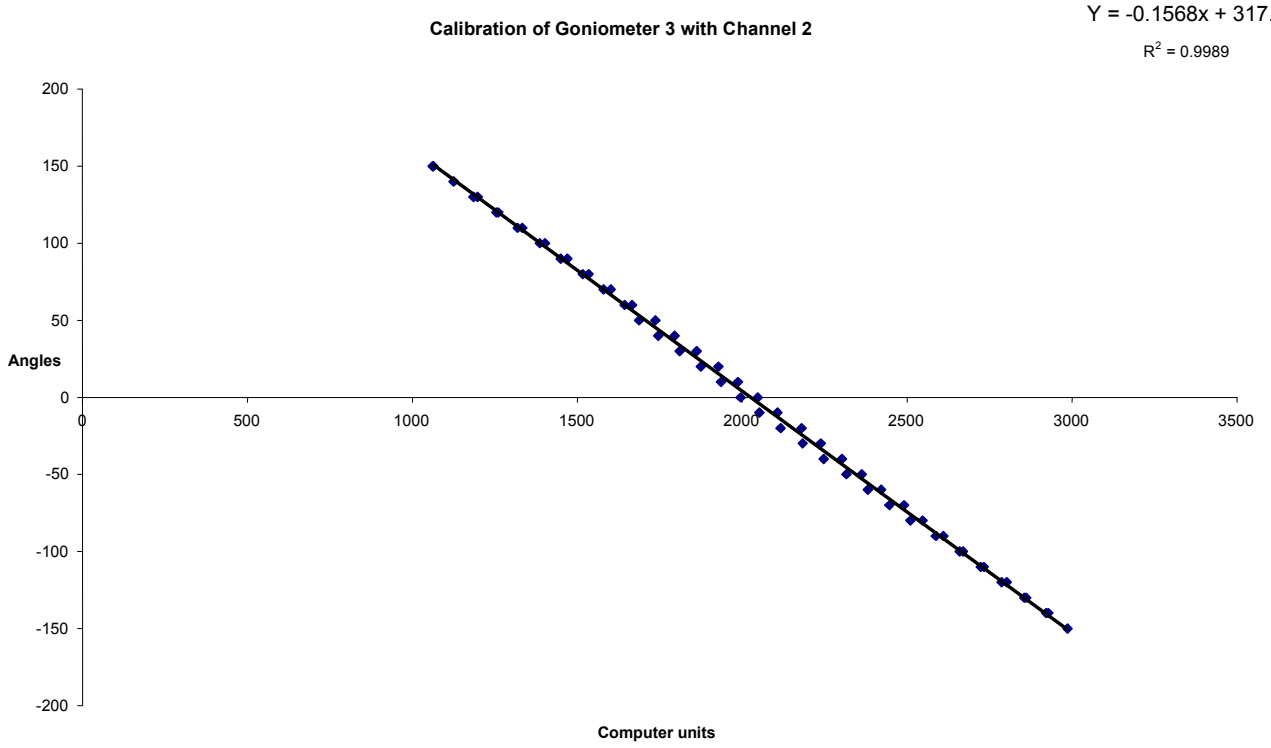


Figure 4.10: Calibration graph of Goniometer 3 with ADC Channel 2 – Trial 1 (where the unit of Y-axis values is in Degrees)

	Goniometers	Slope	Intercept
Channel 1	G1	-0.151	310.47
	G2	-0.154	317.95
	G3	-0.155	316.43
Channel 2	G1	-0.156	309.39
	G2	-0.157	312.95
	G3	-0.157	317.60

Table 4.6 – Calibration equations of the goniometers – Trial 2

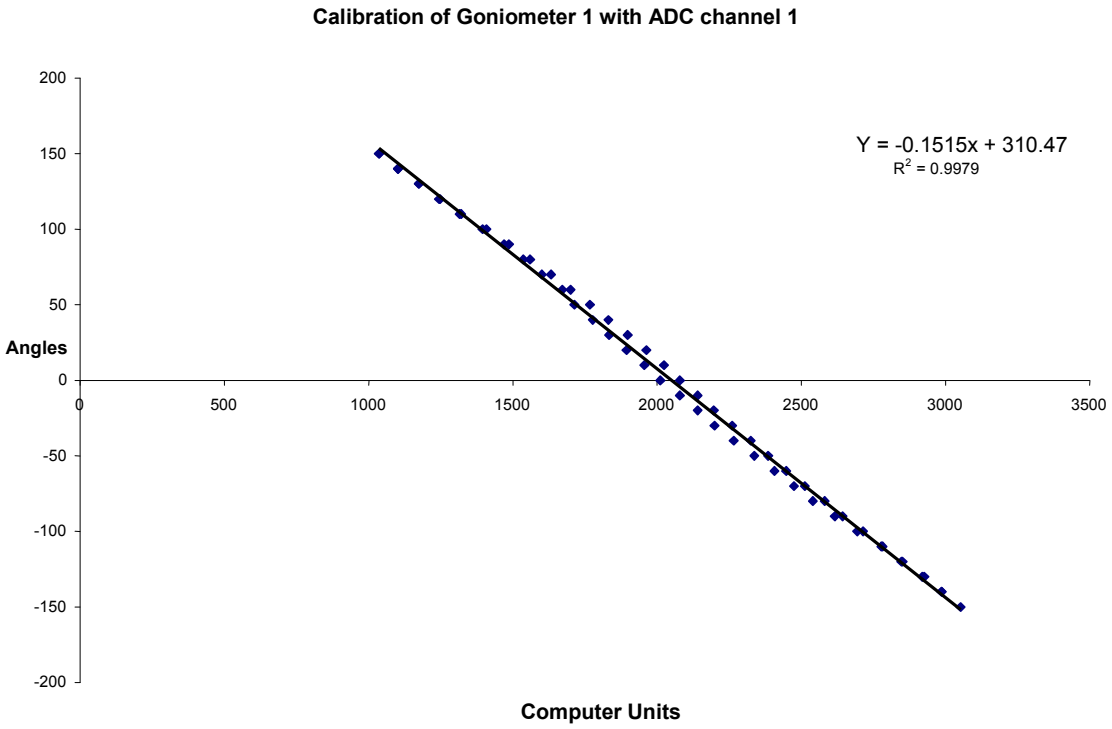


Figure 4.11: Calibration graph of Goniometer 1 with ADC Channel 1 – Trial 2 (where the unit of Y-axis values is in Degrees).

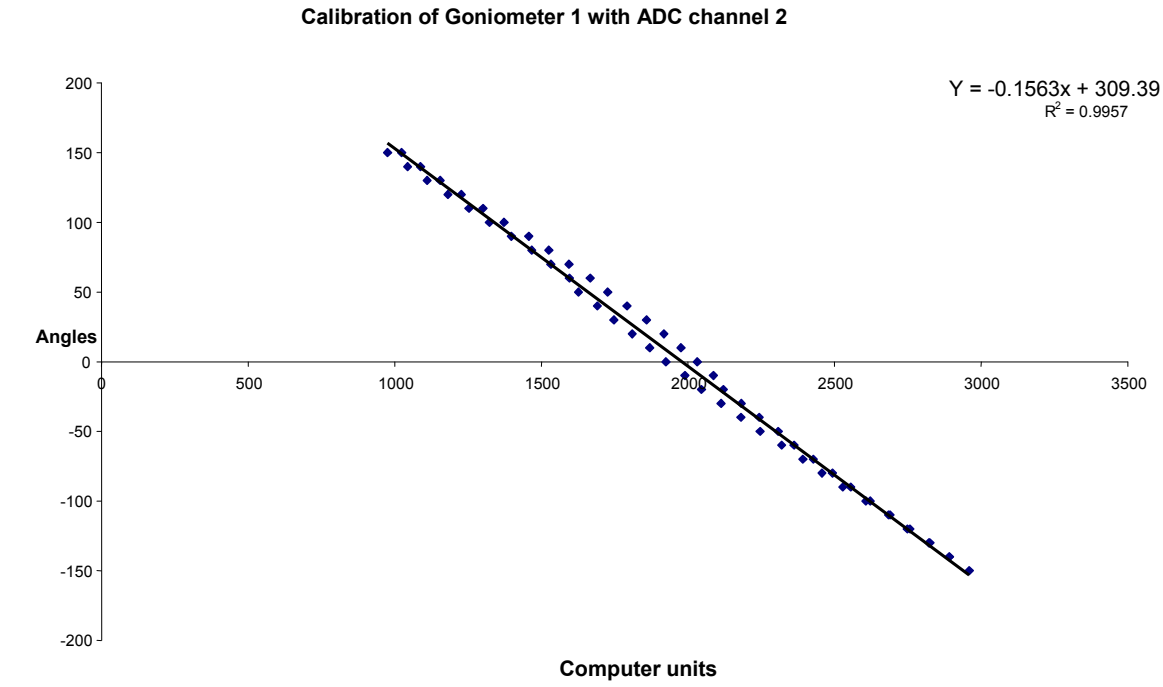


Figure 4.12: Calibration graph of Goniometer 1 with ADC Channel 2 – Trial 2 (where the unit of Y-axis values is in Degrees).

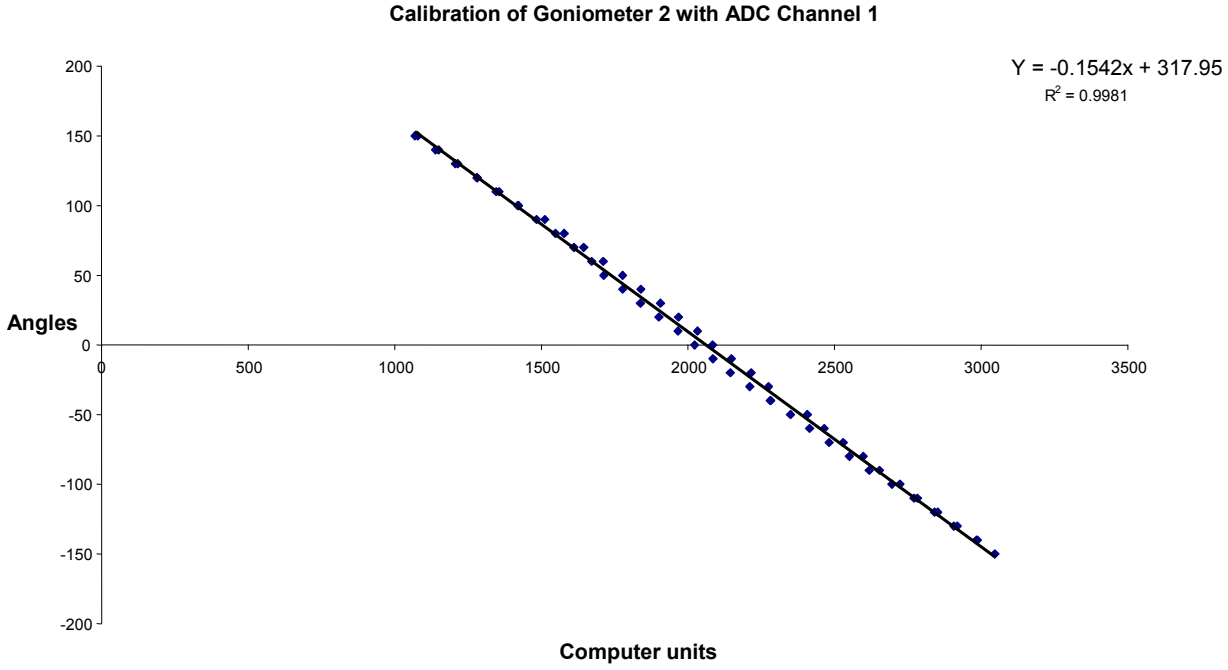


Figure 4.13: Calibration graph of Goniometer 2 with ADC Channel 1 – Trial 2 (where the unit of Y-axis values is in Degrees).

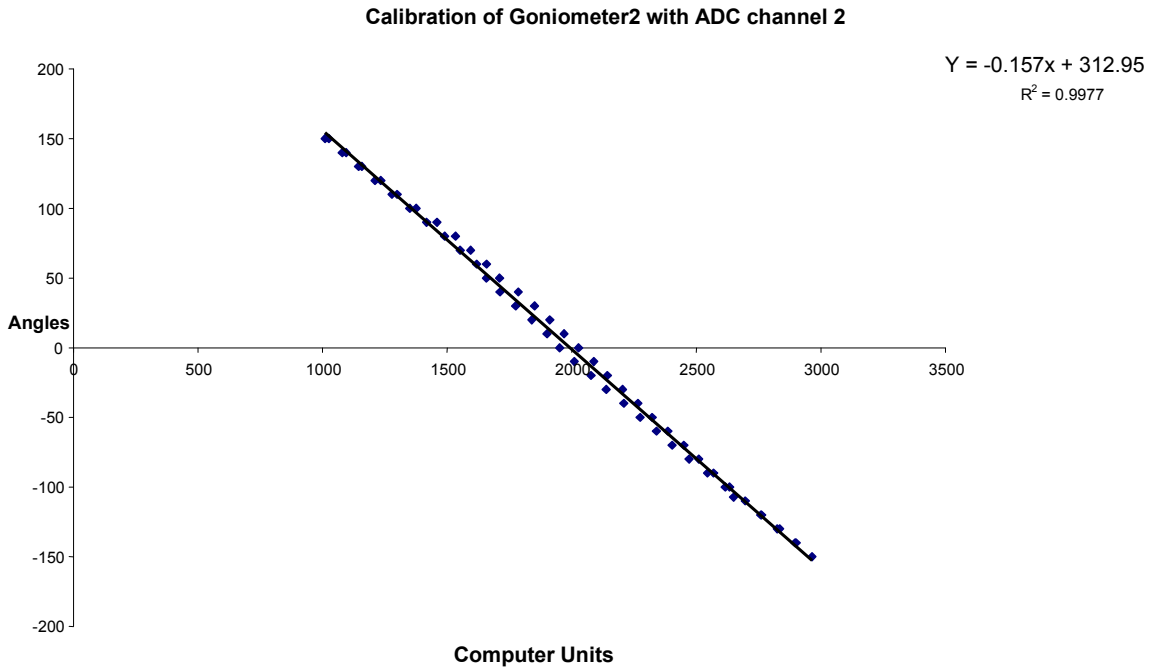


Figure 4.14: Calibration graph of Goniometer 2 with ADC Channel 2 – Trial 2 (where the unit of Y-axis values is in Degrees).

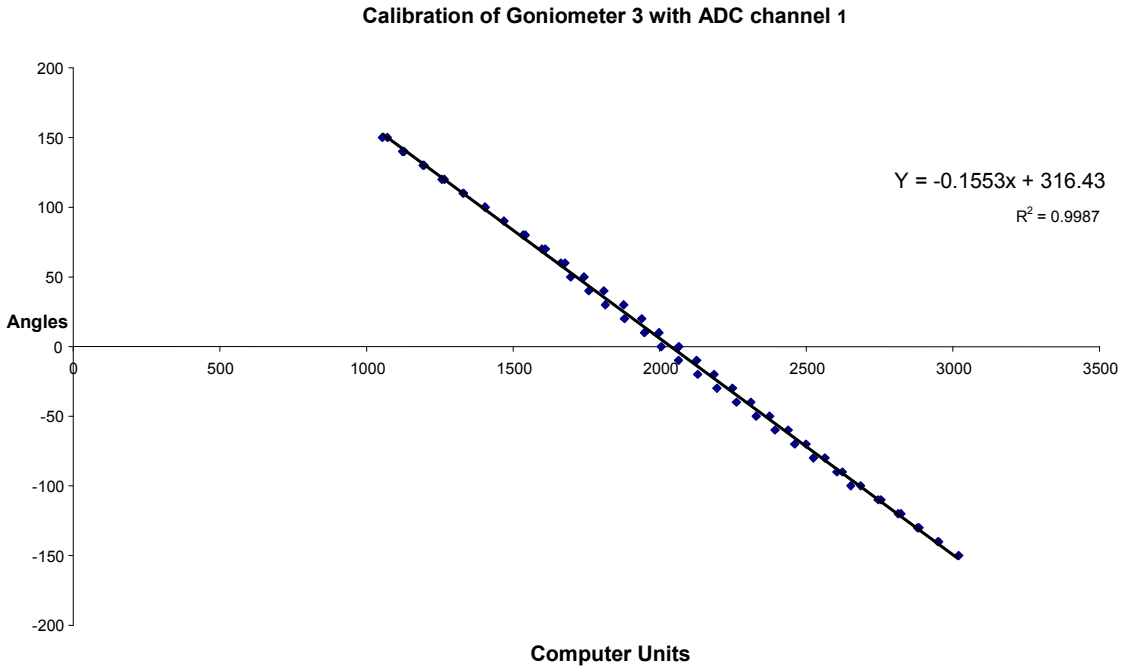


Figure – 4.15: Calibration graph of Goniometer 3 with ADC Channel 1 – Trial 2 (where the unit of Y-axis values is in Degrees).

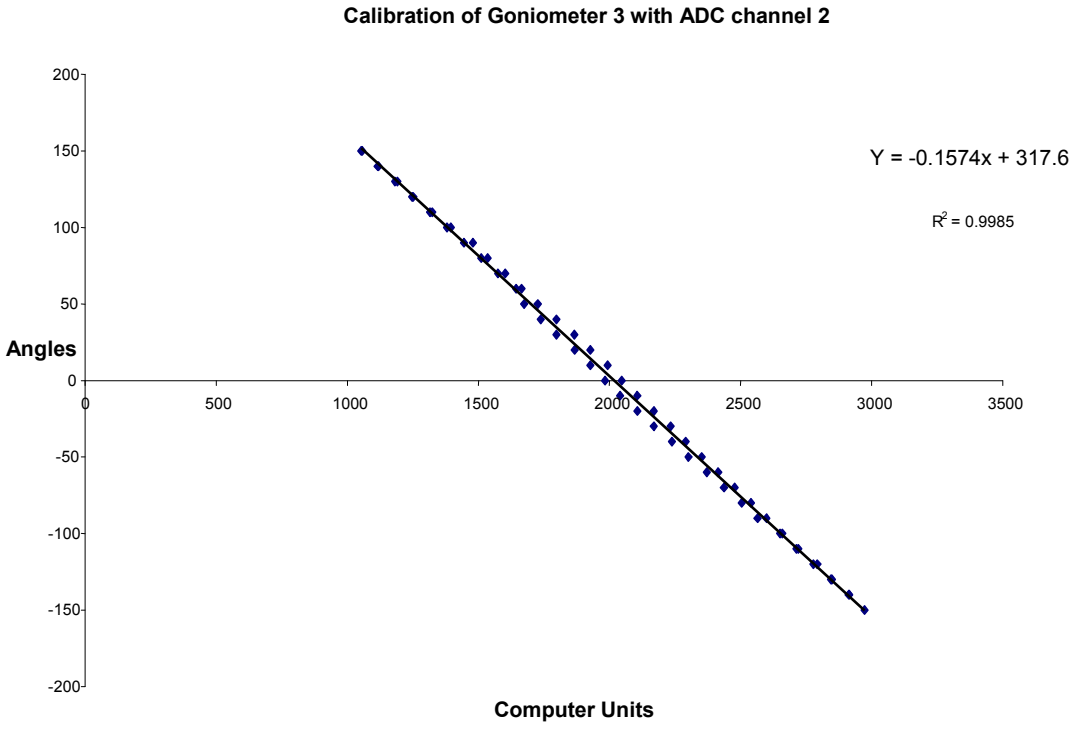


Figure – 4.16: Calibration graph of Goniometer 3 with ADC Channel 2 – Trial 2 (where the unit of Y-axis values is in Degrees).

Input - X	Output - Y	Output - X'	Difference	Absolute error
150	1035	154	-3.9	3.9
140	1101	144	-3.9	3.9
130	1175	133	-2.8	2.8
120	1248	122	-1.7	1.7
110	1320	111	-0.7	0.7
100	1408	97	2.6	2.6
90	1486	85	4.5	4.5
80	1560	74	5.7	5.7
70	1632	63	6.7	6.7
60	1699	53	6.9	6.9
50	1767	43	7.1	7.1
40	1831	33	6.8	6.8
30	1898	23	6.9	6.9
20	1962	13	6.7	6.7
10	2024	4	6.1	6.1
0	2079	-4	4.4	4.4
-10	2141	-14	3.8	3.8
-20	2197	-22	2.3	2.3
-30	2260	-32	1.9	1.9
-40	2324	-42	1.7	1.7
-50	2385	-51	0.9	0.9
-60	2448	-60	0.4	0.4
-70	2512	-70	0.2	0.2
-80	2581	-81	0.7	0.7
-90	2643	-90	0.0	0.0
-100	2714	-101	0.9	0.9
-110	2782	-111	1.1	1.1
-120	2851	-122	1.7	1.7
-130	2926	-133	3.1	3.1
-140	2986	-142	2.1	2.1
-150	3052	-152	2.2	2.2
-140	2987	-142	2.3	2.3
-130	2919	-132	2.0	2.0
-120	2847	-121	1.0	1.0
-110	2777	-110	0.4	0.4
-100	2694	-98	-2.3	2.3
-90	2617	-86	-4.0	4.0
-80	2540	-74	-5.6	5.6
-70	2474	-64	-5.6	5.6
-60	2407	-54	-5.8	5.8
-50	2338	-44	-6.3	6.3
-40	2265	-33	-7.3	7.3
-30	2199	-23	-7.3	7.3

Input - X	Output - Y	Output - X'	Difference	Absolute error
-20	2140	-14	-6.2	6.2
-10	2079	-4	-5.6	5.6
0	2011	6	-5.9	5.9
10	1956	14	-4.3	4.3
20	1893	24	-3.7	3.7
30	1834	33	-2.8	2.8
40	1777	41	-1.4	1.4
50	1713	51	-1.1	1.1
60	1672	57	2.6	2.6
70	1601	68	1.8	1.8
80	1537	78	2.2	2.2
90	1470	88	2.0	2.0
100	1394	99	0.5	0.5
110	1315	111	-1.5	1.5
120	1245	122	-2.2	2.2
130	1174	133	-2.9	2.9
140	1102	144	-3.8	3.8
150	1037	154	-3.7	3.7

Mean difference	0.0	Mean Absolute difference	3.3
Maximum difference	-7.3	Maximum Absolute Difference	7.3
		Standard deviation of Differences	2.1

Table 4.7: Data table of Goniometer 1 and ADC Channel 1 (where the unit of Difference and Absolute errors is in Degrees).

Input -X	Output - Y	Output - X'	Difference	Absolute error
150	1069	153	-3.4	3.4
140	1139	142	-2.5	2.5
130	1207	132	-2.0	2.0
120	1281	121	-0.5	0.5
110	1356	109	1.0	1.0
100	1422	99	1.3	1.3
90	1512	85	5.1	5.1
80	1579	75	5.4	5.4
70	1645	64	5.6	5.6
60	1711	54	5.9	5.9
50	1777	44	6.1	6.1
40	1839	34	5.6	5.6
30	1906	24	6.1	6.1
20	1968	14	5.6	5.6
10	2033	4	5.6	5.6
0	2084	-4	3.5	3.5
-10	2148	-13	3.5	3.5
-20	2215	-24	3.8	3.8
-30	2275	-33	3.1	3.1
-40	2283	-34	-5.8	5.8
-50	2407	-53	3.4	3.4
-60	2465	-62	2.4	2.4
-70	2530	-72	2.4	2.4
-80	2598	-83	2.9	2.9
-90	2653	-91	1.5	1.5
-100	2722	-102	2.2	2.2
-110	2783	-112	1.5	1.5
-120	2852	-122	2.3	2.3
-130	2918	-132	2.5	2.5
-140	2987	-143	3.1	3.1
-150	3047	-152	2.3	2.3
-140	2984	-143	2.5	2.5
-130	2907	-131	0.7	0.7
-120	2841	-120	0.5	0.5
-110	2771	-110	-0.3	0.3
-100	2696	-98	-1.9	1.9
-90	2618	-86	-3.9	3.9
-80	2551	-76	-4.4	4.4
-70	2482	-65	-5.0	5.0
-60	2414	-55	-5.4	5.4
-50	2349	-45	-5.5	5.5
-40	2281	-34	-6.1	6.1
-30	2211	-23	-6.9	6.9
-20	2145	-13	-7.1	7.1

Input -X	Output - Y	Output - X'	Difference	Absolute error
-10	2085	-4	-6.3	6.3
0	2023	6	-5.9	5.9
10	1967	15	-4.6	4.6
20	1901	25	-4.8	4.8
30	1838	34	-4.5	4.5
40	1778	44	-3.8	3.8
50	1713	54	-3.9	3.9
60	1672	60	-0.2	0.2
70	1611	70	0.4	0.4
80	1548	79	0.8	0.8
90	1483	89	0.7	0.7
100	1419	99	0.8	0.8
110	1346	111	-0.6	0.6
120	1281	121	-0.6	0.6
130	1216	131	-0.7	0.7
140	1150	141	-0.8	0.8
150	1079	152	-1.9	1.9

Mean difference	0.0	Mean Absolute difference	3.2
Maximum difference	-7.0	Maximum Absolute Difference	7.0
		Standard deviation of Differences	2.0

Table 4.8: Data table of Goniometer 2 and ADC Channel 1 (where the unit of Difference and Absolute errors is in Degrees).

Input - X	Output - Y	Output - X'	Difference	Absolute error
150	1055	153	-2.9	2.9
140	1124	142	-2.2	2.2
130	1193	131	-1.4	1.4
120	1257	121	-1.3	1.3
110	1329	110	-0.2	0.2
100	1404	98	1.5	1.5
90	1469	88	1.6	1.6
80	1542	77	2.9	2.9
70	1610	67	3.4	3.4
60	1677	56	3.9	3.9
50	1742	46	4.0	4.0
40	1809	36	4.5	4.5
30	1878	25	5.1	5.1
20	1939	15	4.7	4.7
10	1998	6	3.8	3.8
0	2066	-4	4.3	4.3
-10	2126	-14	3.7	3.7
-20	2185	-23	2.9	2.9
-30	2248	-33	2.7	2.7
-40	2311	-42	2.5	2.5
-50	2375	-52	2.4	2.4
-60	2438	-62	2.2	2.2
-70	2499	-72	1.7	1.7
-80	2564	-82	1.7	1.7
-90	2623	-91	1.0	1.0
-100	2685	-101	0.7	0.7
-110	2754	-111	1.4	1.4
-120	2823	-122	2.0	2.0
-130	2884	-132	1.6	1.6
-140	2952	-142	2.1	2.1
-150	3020	-153	2.7	2.7
-140	2949	-142	1.7	1.7
-130	2879	-131	0.8	0.8
-120	2813	-121	0.6	0.6
-110	2745	-110	0.0	0.0
-100	2652	-95	-4.5	4.5
-90	2605	-88	-1.9	1.9
-80	2524	-76	-4.4	4.4
-70	2460	-66	-4.3	4.3
-60	2393	-55	-4.7	4.7
-50	2329	-45	-4.7	4.7
-40	2262	-35	-5.1	5.1
-30	2195	-24	-5.5	5.5
-20	2130	-14	-5.7	5.7

Input - X	Output - Y	Output - X'	Difference	Absolute error
-10	2064	-4	-5.9	5.9
0	2006	5	-5.0	5.0
10	1948	14	-4.0	4.0
20	1880	25	-4.6	4.6
30	1815	35	-4.7	4.7
40	1758	43	-3.5	3.5
50	1697	53	-3.0	3.0
60	1663	58	1.7	1.7
70	1599	68	1.7	1.7
80	1534	78	1.7	1.7
90	1469	89	1.5	1.5
100	1405	98	1.6	1.6
110	1331	110	0.2	0.2
120	1266	120	-0.1	0.1
130	1196	131	-0.9	0.9
140	1127	142	-1.5	1.5
150	1072	150	-0.2	0.2

Mean difference	0.0	Mean Absolute difference	2.6
Maximum difference	-5.8	Maximum Absolute Difference	5.8
		Standard deviation of Differences	1.6

Table 4.9: Data table of Goniometer 3 and ADC Channel 1 (where the unit of Difference and Absolute errors is in Degrees).

Input - X	Output - Y	Output - X'	Difference	Absolute Error
150	1023	150	-0.1	0.1
140	1088	140	0.0	0.0
130	1155	129	0.6	0.6
120	1227	118	1.9	1.9
110	1301	107	3.5	3.5
100	1373	95	4.7	4.7
90	1457	82	7.9	7.9
80	1525	71	8.6	8.6
70	1595	60	9.6	9.6
60	1666	49	10.8	10.8
50	1726	40	10.2	10.2
40	1792	29	10.6	10.6
30	1858	19	10.9	10.9
20	1918	10	10.3	10.3
10	1976	1	9.3	9.3
0	2032	-8	8.2	8.2
-10	2087	-17	6.8	6.8
-20	2121	-22	2.2	2.2
-30	2182	-32	1.7	1.7
-40	2243	-41	1.3	1.3
-50	2308	-51	1.5	1.5
-60	2362	-60	0.0	0.0
-70	2427	-70	0.3	0.3
-80	2493	-80	0.5	0.5
-90	2555	-90	0.4	0.4
-100	2622	-101	0.8	0.8
-110	2689	-111	1.3	1.3
-120	2757	-122	2.0	2.0
-130	2825	-133	2.7	2.7
-140	2891	-143	3.0	3.0
-150	2959	-154	3.7	3.7
-140	2892	-143	3.1	3.1
-130	2822	-132	2.2	2.2
-120	2748	-121	0.6	0.6
-110	2684	-111	0.6	0.6
-100	2607	-98	-1.6	1.6
-90	2528	-86	-4.0	4.0
-80	2458	-75	-5.0	5.0
-70	2392	-65	-5.3	5.3
-60	2319	-53	-6.7	6.7
-50	2246	-42	-8.2	8.2
-40	2181	-32	-8.5	8.5
-30	2113	-21	-9.0	9.0
-20	2046	-10	-9.6	9.6

Input - X	Output - Y	Output - X'	Difference	Absolute Error
-10	1989	-1	-8.5	8.5
0	1925	9	-8.6	8.6
10	1870	17	-7.3	7.3
20	1810	27	-6.6	6.6
30	1748	36	-6.4	6.4
40	1691	45	-5.3	5.3
50	1627	55	-5.4	5.4
60	1595	60	-0.3	0.3
70	1533	70	-0.2	0.2
80	1467	80	-0.4	0.4
90	1398	91	-1.4	1.4
100	1323	103	-3.0	3.0
110	1253	114	-4.0	4.0
120	1181	125	-5.3	5.3
130	1110	136	-6.5	6.5
140	1044	147	-6.8	6.8
150	976	158	-7.6	7.6

Mean difference	0.1	Mean Absolute difference	4.6
Maximum difference	10.9	Maximum Absolute Difference	10.9
		Standard deviation of Differences	3.5

Table 4.10: Data table of Goniometer 1 and ADC Channel 2 (where the unit of Difference and Absolute errors is in Degrees)

Input - X	Input - Y	Input - X'	Difference	Absolute Error
150	1025	153	-2.8	2.8
140	1095	142	-1.7	1.7
130	1157	132	-1.8	1.8
120	1234	120	0.3	0.3
110	1299	109	0.6	0.6
100	1375	97	2.6	2.6
90	1459	84	5.8	5.8
80	1534	72	7.7	7.7
70	1594	63	7.3	7.3
60	1659	53	7.4	7.4
50	1711	44	5.6	5.6
40	1786	33	7.5	7.5
30	1851	22	7.8	7.8
20	1912	13	7.4	7.4
10	1969	4	6.5	6.5
0	2028	-6	5.7	5.7
-10	2089	-15	5.5	5.5
-20	2143	-24	3.9	3.9
-30	2204	-34	3.5	3.5
-40	2266	-43	3.3	3.3
-50	2323	-52	2.4	2.4
-60	2386	-62	2.3	2.3
-70	2450	-73	2.5	2.5
-80	2510	-82	1.9	1.9
-90	2569	-91	1.3	1.3
-100	2634	-101	1.5	1.5
-110	2697	-111	1.5	1.5
-120	2762	-122	1.8	1.8
-130	2835	-133	3.3	3.3
-140	2901	-144	3.7	3.7
-150	2965	-154	3.8	3.8
-140	2896	-143	3.0	3.0
-130	2825	-132	1.8	1.8
-120	2759	-121	1.3	1.3
-110	2650	-104	-5.9	5.9
-100	2617	-99	-1.2	1.2
-90	2545	-87	-2.6	2.6
-80	2471	-76	-4.2	4.2
-70	2403	-65	-4.9	4.9
-60	2340	-55	-4.9	4.9
-50	2275	-45	-5.2	5.2
-40	2209	-34	-5.6	5.6
-30	2139	-23	-6.7	6.7
-20	2078	-14	-6.3	6.3

Input - X	Input - Y	Input - X'	Difference	Absolute Error
-10	2010	-3	-7.0	7.0
0	1952	6	-6.3	6.3
10	1901	14	-4.3	4.3
20	1839	24	-4.1	4.1
30	1775	34	-4.2	4.2
40	1712	44	-4.1	4.1
50	1657	53	-2.8	2.8
60	1618	59	0.9	0.9
70	1552	69	0.5	0.5
80	1490	79	0.8	0.8
90	1418	91	-0.7	0.7
100	1351	101	-1.3	1.3
110	1278	113	-2.7	2.7
120	1211	123	-3.3	3.3
130	1144	134	-3.9	3.9
140	1078	144	-4.3	4.3
150	1010	155	-5.0	5.0

Mean difference	0.3	Mean Absolute difference	3.8
Maximum difference	7.8	Maximum Absolute Difference	7.8
		Standard deviation of Differences	2.1

Table 4.11: Data table of Goniometer 2 and ADC Channel 2 (where the unit of Difference and Absolute errors is in Degrees)

Input - X	Output - Y	Output - X'	Difference	Absolute error
150	1057	151	-1.5	1.5
140	1119	142	-1.8	1.8
130	1191	130	-0.3	0.3
120	1251	121	-0.8	0.8
110	1325	109	0.7	0.7
100	1395	98	1.8	1.8
90	1479	85	5.1	5.1
80	1535	76	3.9	3.9
70	1602	66	4.4	4.4
60	1665	56	4.3	4.3
50	1727	46	4.0	4.0
40	1797	35	5.2	5.2
30	1867	24	6.1	6.1
20	1927	14	5.7	5.7
10	1993	4	6.0	6.0
0	2047	-5	4.5	4.5
-10	2106	-14	3.8	3.8
-20	2170	-24	3.8	3.8
-30	2233	-34	3.9	3.9
-40	2291	-43	3.0	3.0
-50	2352	-53	2.6	2.6
-60	2415	-63	2.5	2.5
-70	2478	-72	2.5	2.5
-80	2540	-82	2.2	2.2
-90	2599	-92	1.6	1.6
-100	2659	-101	1.0	1.0
-110	2720	-111	0.7	0.7
-120	2793	-122	2.1	2.1
-130	2849	-131	0.9	0.9
-140	2913	-141	1.0	1.0
-150	2973	-150	0.4	0.4
-140	2915	-141	1.4	1.4
-130	2845	-130	0.4	0.4
-120	2777	-120	-0.3	0.3
-110	2713	-109	-0.5	0.5
-100	2651	-100	-0.3	0.3
-90	2565	-86	-3.8	3.8
-80	2505	-77	-3.3	3.3
-70	2437	-66	-4.0	4.0
-60	2371	-56	-4.4	4.4
-50	2301	-45	-5.4	5.4
-40	2238	-35	-5.3	5.3
-30	2169	-24	-6.2	6.2
-20	2107	-14	-6.0	6.0

Input - X	Output - Y	Output - X'	Difference	Absolute error
-10	2041	-4	-6.4	6.4
0	1983	6	-5.6	5.6
10	1928	14	-4.2	4.2
20	1868	24	-3.7	3.7
30	1798	35	-4.7	4.7
40	1738	44	-4.2	4.2
50	1674	54	-4.2	4.2
60	1644	59	1.0	1.0
70	1575	70	0.2	0.2
80	1511	80	0.0	0.0
90	1445	90	-0.3	0.3
100	1381	100	-0.5	0.5
110	1315	111	-0.8	0.8
120	1247	121	-1.5	1.5
130	1182	132	-1.8	1.8
140	1116	142	-2.2	2.2
150	1054	152	-2.0	2.0

Mean difference	0.0	Mean Absolute difference	2.8
Maximum difference	-6.4	Maximum Absolute Difference	6.4
		Standard deviation of Differences	1.9

Table 4.12: Data table of Goniometer 3 and ADC Channel 2 (where the unit of Difference and Absolute errors is in Degrees)

4.2.3 Results of the Static Bench test

G1 - Ch1	Input	Output	Difference	Absolute Error
	0	3	-3	3
	60	62	-2	2
	90	93	-3	3
	150	155	-5	5
Average			-3.2	3.2
Maximum			2	5

(a)

G1 - Ch2	Input	Output	Difference	Absolute Error
	0	0.3	-0.3	0.3
	60	58	2	2
	90	90	0	0
	150	153	-3	3
Average			-0.3	1.3
Maximum			2	3

(b)

G2 - Ch1	Input	Output	Difference	Absolute Error
	0	-2	2	2
	60	55	5	5
	90	87	3	3
	150	151	-1	1
Average			2.2	2.7
Maximum			5	5

(c)

G2 - Ch2	Input	Output	Difference	Absolute Error
	0	0.16	-0.1	0.1
	60	57	3	3
	90	88	2	2
	150	154	-4	4
Average			0.2	2.2
Maximum			3	4

(d)

G3 - Ch1	Input	Output	Difference	Absolute Error
	0	-5	5	5
	60	55	5	5
	90	87	3	3
	150	151	-1	1
Average			3	3.5
Maximum			5	5

(e)

G3 - Ch2	Input	Output	Difference	Absolute Error
	0	-4	4	4
	60	56	4	4
	90	89	1	1
	150	152	-2	2
Average			1.7	2.7
Maximum			4	4

(f)

Table 4.13: Static Bench test of Goniometers; G1, G2 and G3 with Analog Channels Ch1 and Ch2 (All values are in degrees)

4.3 Discussion

The main objective of conducting a series of experiments explained here in this chapter was to test the behaviour of the electrogoniometers when used with SUDALS. Prior to the commencement of the calibration procedure and static trial bench-testing of the system, the output of all the ADC channels were checked individually using an oscilloscope to ensure that there is no interference or cross-talk between the electrogoniometer and foot switch channels. The results of the ***ADC-DAC calibration*** show a good linearity between the ADC-DAC channels. However, the calibration of DAC1 channel with ADC2 channel shows a little variation in the linearity close to zero volts as illustrated in figure 4.4. When a digital value of 100 units is given as input to the DAC channel, the system gives an analog output of 0.27 V instead of 0.16 V. At the same time such variation is not observed when the channels are calibrated vice-versa. One of the possible reasons for this variation in linearity among these channels could be due to minor manufacturing defects. On the other hand, analysing the results of the ***system characteristics*** indicate that there is a standard deviation of 2° to 3.5° (which corresponds to 4° to 7° for 95% confidence interval) of the measurement range for all the three electrogoniometers irrespective of the channels to which they are connected. The mean values demonstrated good linearity between the true input angles applied to the protractor and the measured output values recorded in computer units as shown in figures 4.5 to 4.10 and 4.11 to 4.16. The averaged equation of the line of best fit for Goniometer 1 - channel 1 was Y = (-0.1515 * X + 310.47) and for Goniometer 1- channel 2 the equation was Y = (-0.1563*X + 309.39), indicating that there were 0.15° generated per computer unit (or approximately 7 computer units per degree) and that at 0° the computer would obtain a reading of 310 units. The mean absolute error for all the electrogoniometers was between 3° to 5°. This means that the system is able to quantify angular displacement to the nearest 0.15° with a maximum inaccuracy of 3° to 5° in extreme conditions (such as; hysteresis effect, manufacturing defects of the sensor or physical imperfections of ADC/DAC). The results of the repeated trial (trial 2) were similar to those obtained from trial1, indicating that there were no variation in the calculated slope of the line (0.15°

generated per computer unit). However, with different goniometers, small variations were found in the intercept of the line. When goniometer 1 was calibrated with the channel 1, the intercept obtained is 310 computer units, but when the goniometers 2 and 3 were calibrated with the same channel, the variation in the intercepts was from 316 to 317 computer units. Similarly, when goniometer 1 was calibrated with channel 2, the intercept obtained is 309 computer units, but when the goniometers 2 and 3 were calibrated with the same channel, the variation in the intercepts was 312 to 317 computer units (i.e. less than a degree), with the mean absolute error similar to those obtained in trial 1.

Further, examination of figures 4.5 to 4.10 and 4.11 to 4.16 indicates the presence of a very small hysteretic effect and this is particularly noticeable around zero degrees where the curve appears to 'open up' slightly. This effect seems to be very prominent especially in figure 4.14, which is the second set of data obtained from Goniometer 2, when calibrated with ADC channel 2. Similarly, analysing the tables 4.7 to 4.12 reveals the existence of maximum absolute errors varying from 7° to 10° in extreme conditions. However, in case of the third goniometer (G3), the maximum absolute errors for the ADC channels 1 and 2 are only in the order of 6°. Such errors can be due to two possible reasons. One, due to the A/D converter and second, due to the manufacturing defects of the goniometers. If the errors were solely due to the A/D converters, then the error exhibited by G3 should also be similar to those exhibited by the other two goniometers. However, this not being our case, the possibility of such errors can be due to the second reason. Also, such errors could be due to the hysteresis set in the device. The results of the test for accuracy and precision correspond to the second trial which was carried out just within an hour of completion of the first trial. Hence, the hysteresis set within the goniometers could have influenced the results and this is evident from the figure 4.14 and in the future, such bench tests should be carried out by providing sufficient time between the repeat trials, so that the possibility of errors due to hysteresis can be eliminated. In addition to this, on analysing the results for differences ***between the electrogoniometers*** calibrated on two different occasions on the same day, variation among the coefficients of the electrogoniometers was 0.003 degree per computer unit for channel 1 and 0.001 degree per computer unit for channel 2, representing an error of 2°

for channel 1 and an error of 0.6° for channel 2 when measuring 100°. On the other hand on analysing the results for differences ***within the electrogoniometers*** calibrated on two different occasions on the same day, a little variation in the calibration coefficients was observed. For channel 1, the coefficients of electrogoniometer 2 varied from 0.151 to 0.154 and the coefficients of other two electrogoniometers remained the same. However, for channel 2, there were variations in the coefficients of electrogoniometer 1 (from 0.153 to 0.156) and 2 (from 0.152 to 0.157) and the coefficients of the third electrogoniometer remained the same. The variation in the slopes of the electrogoniometers will be introducing systematic errors varying from 2° to 3° over a measurement range of 100°.

As mentioned above, during the bench tests, the electrogoniometers were manipulated through a range of angular displacements using a plastic protractor and reviewing the literature reveals the accuracy of such protractors to be less than a degree. Research also reveals the existence of a slight non-linearity in the Poisson's ratio of the material used for designing the central shim of the electrogoniometer resulting in 'Hysteresis effect'. Due to such an effect the flexible electrogoniometer follows the changes in the input parameter irrespective of the direction in which the changes occur. As a result, for functional activities involving a joint movement of less than or equal to100°, one can expect a hysteretic effect of 1° to 1.6° (Rowe et al., 2001, Sato.T.D.O et al., 2008). Such an effect seems to be very prominent around 0° (neutral position) especially when the device is subjected to repeated trials within short period of time. However, by increasing the time intervals (more than 1 hour) between the repeat trials or measurements errors due to hysteresis effect can be minimised. Also, such errors can be kept small if the device is not subjected to flexion angles greater than 100°.Though the occurrence of systematic errors with the use of different electrogoniometers is not known, literature suggests that these variations between and within the electrogoniometers at different days or different times may be due to certain manufacture differences. (Rowe et al., 2001) and the absolute errors shown by the system when used in conjunction with the flexible electrogoniometers may be due to these defects within the electrogoniometer.

The effect of such variations between the goniometers (or the errors reported above) is reflected in the results of the ***static bench tests*** as shown in table 4.13.

Unlike goniometer 1 and 2, goniometer 3 shows a variation of ± 3° to 5° in its output, in an undisturbed position irrespective of the channel to which it is being connected. In a similar undisturbed position, goniometer 1 and 2 connected to channel 2 shows a very little variation of 0.3° and 0.16°. However, when the goniometers are subjected to other angular displacements replicating the actual knee flexion during various ADL such as normal gait, in and out of chair and deep squat (60°, 90° and 150°), the output of all the three goniometers varied from ±2° to 5° irrespective of the channels.

Although the bench-tests indicated absolute errors up to 5°, the r^2 value for the line of best fit for the all electrogoniometers was > 0.99 indicating a highly significant and linear correlation between the input and output. Regardless of such variations, research reveals the use of electrogoniometer in a variety of hospital settings, as it is not affected by environmental pollutants such as heat, electrical interference, convection currents or noise (Rowe et al., 2001). The developed system was further tested for concurrent validity, reliability and clinical usability using various protocols which are explained in detail in chapters 5, 6 and 7. However, when used in ideal conditions on a Bench, the SUDALS system and electrogoniometers are capable of recording joint function extension to within a few degrees and in worst cases less than 5°.

Chapter 5 – Testing SUDALS for Test-Retest reliability Concurrent Validity and Inter-subject Variability

The calibration of the flexible electrogoniometers with SUDALS, presented in the previous chapter indicated the static characteristics of the transducer and the developed system. Test-retest reliability is 'concerned with whether a test or way of taking measurements will tend to produce the same result upon repeated administrations' (Polgar & Thomas, 1988) and validity is concerned with the ability of the device to measure what it is suppose to measure. Hence, to study the overall system performance under dynamic conditions, SUDALS was tested during 6 ADL (walking, getting into the chair, getting out of the chair, stair ascend, stair descend and deep squat) and was also validated (concurrent validation) against the Gold standard Vicon system. This was carried out by recruiting ten healthy volunteers for reliability studies (6 males and 4 females) and three healthy volunteers for validity studies (1 male and 2 females) within the Bioengineering Unit of University of Strathclyde. Since all the participants were from the Bioengineering Unit, their consent to participate in the study was obtained by personally handing over the information sheet and the consent forms (electronic Appendix 5) a week or two in advance to the actual commencement of the experiment. All the details such as the exclusion criteria, the date, time and place of testing were outlined in the information sheet given to the volunteers. A risk assessment of this protocol and a safety inspection of the developed system were carried out by the respective committee within the Bioengineering Unit of the University of Strathclyde and ethical approval was granted by the University of Strathclyde Bioengineering Unit Ethics Committee. A copy of the ethical approval obtained for this study is included in the electronics appendix 8 of this thesis. All testing took place in the Biomechanics laboratory in the Bioengineering Unit of the University of Strathclyde. The purpose of these experiments was to test the general characteristics of the developed system in dynamic conditions. Therefore, the gender, mass and height of subjects were not considered important and collection of this information was not deemed integral to the purpose of this pilot study. The methodology adopted in this experiment, together with the results and outcomes of this experiment are explained in detail in this chapter.

5.1 Methods

5.1.1 Test for Test-retest reliability:

Test – retest reliability was tested by carrying out a pilot study with 10 young normal healthy subjects (age range 24 to 30 years). The data pertaining to the flexion/extension of the knee of the subjects was collected via the body mounted transducer (flexible electrogoniometer) interfaced with SUDALS and without any kind of special preparation of the skin, the devices were attached to the participants as explained in the routine deployment in section 2.4 and 2.2.4. All the 10 subjects were asked to perform the following 6 activities at their selected speed –

1. 7 m level walking
2. Getting in to a standard Chair (410mm from floor to seat)
3. Getting out of a standard chair (410mm from floor to seat)
4. Ascending 4 step flight of stairs - 180-190mm riser, 270-300mm tread.
5. Descending 4 step flight of stairs - 180-190mm riser, 270-300mm tread.
6. Deep squatting (complete cycle from stand to sit and from sit to stand)

Prior to the commencement of the activities, with the goniometers attached to their knees, the participants were asked to stand as straight as possible without bending their knees and the goniometers were zeroed via SUDALS. Following this, the participants were asked to perform the level walking at their selected speed. The starting point and the destination point for the level walking were marked on the floor and the participants were asked to walk from the starting point to the destination point and then back to the starting point. This was recorded as two individual recordings and on completion of the level walking the next set of activities as listed above was performed by the participants sequentially. All these activities were recorded as individual recordings. On completion of all six activities, the seven recordings corresponding to these activities were transmitted to the PC and were inspected and saved as individual excel files prior to the next set of data collection. The system was reset and the goniometers were zeroed and the above procedure was repeated for an additional two times for reproducibility purposes. Start and stop commands were given at the beginning and completion of each task.

Further, the event marking was taken into account by the FSR's attached to the toes and heels of each subject and this information was used to select the start and end of the gait cycles of the activities recorded by the system. However, the beginning of the non-cyclic activities such as getting in and out of chair and deep squatting were obtained by visually making note of the point at which the output of the flexible electrogoniometer changed from 0° (neutral position) to a continuous increasing knee flexion angles. Similarly, the ending points of these cycles were obtained by making note of the point at which the output of the device changed from the decreasing knee flexion angles to 0° (neutral position) representing that the cycle is complete and the device is in its neutral position. This procedure was adopted for analysing all the results reported in all the chapters of this thesis. All the 21 excel files (7 recordings with three repeats) corresponding to each participant were then analyzed for maximum / minimum knee flexion/extension and knee excursion at the PC end. The attachment of all the devices on the participants during the experiment is as shown in the functional block diagram in figure 5.1.

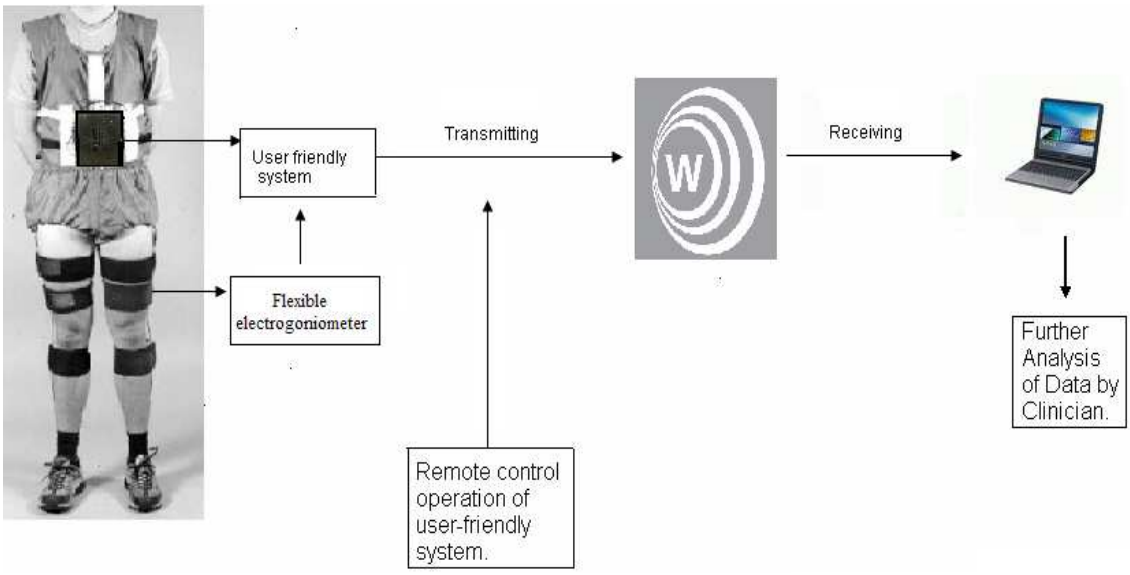


Figure 5.1

5.1.2 Test for Concurrent validity:

Tests for concurrent validity were carried out by simultaneously recording the knee movement during level walking using an 8 camera Vicon movement analysis system (Oxford Metrics Ltd) and flexible electrogoniometry.

Vicon System: The vicon system is an 8 camera motion analysis system used for collecting kinematic and kinetic data about various anatomical joints within a gait laboratory by setting up a capture area using these cameras. The cameras emit infared light which is reflected back from retro-reflective markers worn by the subject. The reflected light is then detected by the cameras and the Vicon software reconstructs the three dimensional co-ordinates of the markers. However, prior to usage the system had to be calibrated to determine the axes set up for the test area and varying test volumes using static and dynamic calibration techniques. In static calibration, a fixed L-shaped bar with markers in know postions was used to calibrate the test area. It was positioned on two sides of force plate 2 within the gait lab. This arrangement allows the vicon software to determine the axes setup for the test area. In dynamic calibration, a wand was used to calibrate the varying test volumes. The wand contains 2 marker set at a specific distance apart. It was moved through the test area for around 15 seconds while the vicon system continuously recorded the marker positions and from this the position of all the eight cameras was determined.

Since, this study specifically investigates the knee joint, a lower limb marker set was used. The spherical reflective markers were 14mm in size and where either attached as part of a cluster or as individual markers. The thigh and shank clusters consisted of 4 markers attached to a plastic cuff, slightly rounded to lie flat against the shape of the leg. Velcro straps were looped round the thigh and shank and then the plastic cuff was stuck to these. Waist markers with 4 markers attached via double sided tape were worn as a waist belt. Finally the foot markers used were 5 individual markers stuck directly to the skin. These markers covered the medial and lateral meleolus, calaneous, 1^{st} and 5^{th} metatarsal joint. To ensure minimal movement and good visibility of these markers, no individual markers were used specifically to mark the bony landmarks of either the knee or hip joint. Instead, clusters of 4 were used on the thigh, shank and waist

so that at least 3 markers were visible for the calculations and the hip, knee and ankle joint centres were calculated as virtual points in relation to these clusters.

Static trials:

Static trials with the subject standing upright and still on the force plate were recorded to input the calibration points for the right and left ASIS and sacrum of the pelvis and the right and left epicondyle at the knee joint. The epicondyles were marked as accurately as possible on the skin of the subject's knee using a pointer which contains 2 reflective markers the position of the mentioned landmarks were recorded in reference to the appropriate clusters. The landmarks of the hip are referenced to the waist markers and the knee landmarks to the thigh clusters. The static trials were used to record the position of the bony landmarks of the knee and hip in relation to cluster markers and were used within the bodybuilder program to calculate the knee joint centre (KJC) and hip joint centre (HJC). The hip, knee and ankle joint centres are then used to calculate the flexion angles of the knee joint.

Validation methodology: Three normal subjects (one male and two females, age range 24 to 30 years) were recruited for this study. A set of retro-reflective markers were attached to the hip, thighs, knees, shanks and feet for gait analysis and the developed system of electrogoniometry was attached to the volunteers as explained above. Both the systems were synchronized by attaching 4 FSR's (2 FSR'S were attached to the toe and another 2 were attached to the heel) to one foot (either right or left) of the subjects. Whereby, one pair of foot switches were connected to the vicon and the other pair were connected to the SUDALS.

The subjects were asked to start walking using the foot to which all the four FSR's were attached and the data pertaining to the flexion/extension of the knee was recorded from both the systems simultaneously during six free-speed walks across a 7-metre section of level vinyl flooring. Each cycle began with a heel strike and terminated with the next heel strike. This information was used to synchronize the starting and ending of the gait cycles recorded by both the systems. The results from the vicon were filtered and were smoothed with the in-built filters and were then time normalized to

percentage of gait cycle and compared with the results from SUDALS as shown in the results section of this chapter.

5.2 Results

The data collected and transmitted using SUDALS during these ADL's were then filtered at the PC end using a 4^{th} order low pass Butterworth filter at a cut-off frequency of 6 Hz and a sampling frequency of 50 Hz to eliminate the noise present in the data and the data were further analyzed for maximum and minimum knee angle. The excursion (maximum knee angle – minimum knee angle) of the knee during these activities for each individual was obtained by calculating the difference between the maximum angle and minimum angle. This procedure was carried out for both the left and right knees and was then averaged to provide the group mean. Since each participant performed the functional tasks at their own pace, comparison of the individual angle versus time plots by simple overlay is not possible and therefore, the data segment for each functional task for each participant was time normalized using an interpolation programme (written by Prof. Philip Rowe in MS-Excel and Turbo Pascal) similar to other normalization procedures used by other researchers in the literature (Van der linden et al.., 2008). This normalized each participant's data segment for both knees for each activity into 100 % points giving an angle versus percent of the movement trace. The standard cycles averaged over 3 (repeat trials) time normalized gait cycles of all the participants obtained by SUDALS during all the 6 ADL's are shown below along with an averaged cycle for the group in figure 5.2 to 5.25. Tables 5.1 to 5.18 show the correlation of the data pertaining to all the repeat trials from all the participants using a Pearson correlation coefficient and the mean and the maximum absolute difference (error) in the data obtained from different trials. Similarly, the average maximum and minimum knee flexion and the knee excursion for all the ADL's are tabulated in table 5.19a, 5.19b and 5.19c. Further, the maximum knee flexion values for the above mentioned ADL's published within the literature is given in table 5.19d. Since, the repeat trial data obtained from both the knees were similar, only the repeat trial data pertaining to the maximum/minimum right knee flexion and right knee excursion are presented here in this chapter.

Subjects	Trial1	Trial2	Trial3	Abs (D_{1-2})	Abs (D_{2-3})	Abs (D_{1-3})
S1	-5.6	-6.2	-7.2	0.6	1.0	1.6
S2	0.2	1.5	2.3	1.3	0.8	2.1
S3	-6.9	-4.3	-3.5	2.6	0.8	3.4
S4	0.0	-1.5	-1.2	1.5	0.3	1.2
S5	0.2	2.3	1.6	2.1	0.7	1.4
S6	0.9	1.5	0.5	0.6	1.0	0.4
S7	-0.7	-1.7	-0.8	1.0	0.9	0.1
S8	-3.1	-1.2	-5.3	1.9	4.1	2.2
S9	-0.1	-1.5	-1.6	1.4	0.1	1.5
S10	0.3	1.5	0.8	1.2	0.7	0.5
			Mean Difference	1.4	1.0	1.4
			Maximum Difference	2.6	4.1	3.4
			Pearson's R	0.85	0.88	0.80

Table 5.1: Repeat trials: Minimum Right Knee flexion angles (in degrees) during level walking; Where; Abs (D_{1-2}), Abs (D_{2-3}), Abs (D_{1-3}) are absolute differences (in degrees) between trials 1-2, 2-3 and 1-3.

Subjects	Trial1	Trial2	Trial3	Abs (D_{1-2})	Abs (D_{2-3})	Abs (D_{1-3})
S1	45.2	41.4	43.5	3.8	2.1	1.7
S2	61.5	63.6	58.7	2.1	4.9	2.8
S3	74.8	70.5	75.6	4.3	5.1	0.8
S4	73.2	71.9	68.5	1.3	3.4	4.7
S5	58.2	52.6	56.7	5.6	4.1	1.5
S6	83.4	87.2	82.6	3.8	4.6	0.8
S7	83.5	80.6	85.4	2.9	4.8	1.9
S8	62.3	57.2	60.9	5.1	3.7	1.4
S9	53.1	56	52.3	2.9	3.7	0.8
S10	64	60.2	65.6	3.8	5.4	1.6
			Mean Difference	3.6	4.2	1.8
			Maximum Difference	5.6	5.4	4.7
			Pearson's R	1.0	0.90	1.0

Table 5.2: Repeat trials: Maximum Right Knee flexion angles (in degrees) during level walking

Subjects	Trial1	Trial2	Trial3	Abs (D_{1-2})	Abs (D_{2-3})	Abs (D_{1-3})
S1	50.8	47.6	50.7	3.2	3.1	0.1
S2	61.3	62.1	56.4	0.8	5.7	4.9
S3	81.7	74.8	79.1	6.9	4.3	2.6
S4	73.2	73.4	69.7	0.2	3.7	3.5
S5	58.0	50.3	55.1	7.7	4.8	2.9
S6	82.5	85.7	82.1	3.2	3.6	0.4
S7	84.2	82.3	86.2	1.9	3.9	2.0
S8	65.4	58.4	66.2	7.0	7.8	0.8
S9	53.2	57.5	53.9	4.3	3.6	0.7
S10	63.7	58.7	64.8	5.0	6.1	1.1
			Mean Difference	4.0	4.7	1.9
			Maximum Difference	7.7	7.8	4.9
			Pearson's R	0.90	0.90	1.0

Table 5.3: Repeat trials: Right Knee excursion angles (in degrees) during level walking

Subjects	Trial1	Trial2	Trial3	Abs (D_{1-2})	Abs (D_{2-3})	Abs (D_{1-3})
S1	-1.0	-2.5	0.8	1.5	3.3	1.8
S2	-2.7	-4.2	-2.3	1.5	1.9	0.4
S3	-1.8	-1.4	-1.6	0.4	0.2	0.2
S4	-4.8	-4.2	-2.4	0.6	1.8	2.4
S5	2.3	1.4	3.5	0.9	2.1	1.2
S6	-1.3	-1.5	-1.2	0.2	0.3	0.1
S7	-3.9	-4.2	-3.4	0.3	0.8	0.5
S8	-7.1	-6.4	-6.8	0.7	0.4	0.3
S9	-5.5	-3.5	-4.3	2.0	0.8	1.2
S10	-5.3	-4.5	-3.6	0.8	0.9	1.7
			Mean Difference	0.9	1.3	1.0
			Maximum Difference	2.0	3.3	2.4
			Pearson's R	0.90	0.90	1.0

Table 5.4: Repeat trials: Minimum Right Knee flexion angles (in degrees) during getting into the chair

Subjects	Trial1	Trial2	Trial3	Abs (D_{1-2})	Abs (D_{2-3})	Abs (D_{1-3})
S1	84.1	88.2	85.1	4.1	3.1	1.1
S2	106.9	104.2	102.8	2.7	1.4	4.1
S3	101.7	98.7	103.5	3.0	4.8	1.8
S4	113.7	108.9	110.3	4.8	1.4	3.4
S5	101.6	98.9	100.5	2.7	1.6	1.1
S6	107.2	104.3	103.6	2.9	0.7	3.6
S7	121.1	118.2	120.6	2.9	2.4	0.5
S8	105.2	100.3	102.5	4.9	2.2	2.7
S9	113.7	115.2	110.3	1.5	4.9	3.4
S10	104.6	102.8	106.5	1.8	3.7	1.9
			Mean Difference	3.1	2.6	2.3
			Maximum Difference	4.9	4.9	4.1
			Pearson's R	1.0	0.90	1.0

Table 5.5: Repeat trials: Maximum Right Knee flexion angles (in degrees) during getting into the chair

Subjects	Trial1	Trial2	Trial3	Abs (D_{1-2})	Abs (D_{2-3})	Abs (D_{1-3})
S1	85.0	90.7	84.3	5.7	6.4	0.7
S2	109.6	108.4	105.1	1.2	3.3	4.4
S3	103.5	100.1	105.1	3.4	5.0	1.5
S4	118.5	113.1	112.7	5.4	0.4	5.8
S5	99.3	97.5	97.0	1.8	0.5	2.2
S6	108.5	105.8	104.8	2.7	1.0	3.6
S7	125.1	122.4	124.0	2.7	1.6	1.0
S8	112.3	106.7	109.3	5.6	2.6	2.9
S9	119.2	118.7	114.6	0.5	4.1	4.5
S10	109.9	107.3	110.1	2.6	2.8	0.1
			Mean Difference	3.2	2.8	2.7
			Maximum Difference	5.7	6.4	5.8
			Pearson's R	1.0	0.90	1.0

Table 5.6: Repeat trials: Right Knee excursion angles (in degrees) during getting into the chair

Subjects	Trial1	Trial2	Trial3	Abs (D_{1-2})	Abs (D_{2-3})	Abs (D_{1-3})
S1	0.1	1.5	3.4	1.4	1.9	3.3
S2	3.3	4.2	2.3	0.9	1.9	1.0
S3	1.0	0.7	1.5	0.3	0.8	0.5
S4	4.3	3.6	2.5	0.7	1.1	1.8
S5	-1.3	-1.5	-3.2	0.2	1.7	1.9
S6	3.8	2.4	3.4	1.4	1.0	0.4
S7	-1.5	-2.3	-4.2	0.8	1.9	2.7
S8	-2.3	-4.0	-3.3	1.7	0.7	1.0
S9	1.9	2.4	1.4	0.5	1.0	0.5
S10	2.5	2.6	4.3	0.1	1.7	1.8
			Mean Difference	0.8	1.4	1.5
			Maximum Difference	1.7	1.9	3.3
			Pearson's R	0.90	0.90	0.80

Table 5.7: Repeat trials: Minimum Right Knee flexion angles (in degrees) during getting out of the chair

Subjects	Trial1	Trial2	Trial3	Abs (D_{1-2})	Abs (D_{2-3})	Abs (D_{1-3})
S1	88.6	89.2	93.2	0.6	4.0	4.6
S2	110.0	109.3	113.5	0.7	4.2	3.5
S3	111.8	107.5	110.2	4.3	2.7	1.6
S4	130.1	129.3	128.4	0.8	0.9	1.7
S5	107.0	110.5	108.4	3.5	2.1	1.4
S6	114.4	110.0	115.4	4.4	5.4	1.0
S7	129.8	126.5	132.1	3.3	5.6	2.3
S8	83.0	85.4	79.4	2.4	6.0	3.6
S9	129.6	125.4	128.3	4.2	2.9	1.3
S10	119.6	120.5	123.2	0.9	2.7	3.6
			Mean Difference	2.5	3.7	2.5
			Maximum Difference	4.4	6.0	4.6
			Pearson's R	1.0	1.0	1.0

Table 5.8: Repeat trials: Maximum Right Knee flexion angles (in degrees) during getting out of the chair

Subjects	Trial1	Trial2	Trial3	Abs (D_{1-2})	Abs (D_{2-3})	Abs (D_{1-3})
S1	88.5	87.7	89.8	0.8	2.1	1.3
S2	106.6	105.1	111.2	1.5	6.1	4.6
S3	110.9	106.8	108.7	4.1	1.9	2.2
S4	125.8	125.7	125.9	0.1	0.2	0.1
S5	108.3	112.0	111.6	3.7	0.4	3.3
S6	110.6	107.6	112.0	3.0	4.4	1.4
S7	131.3	128.8	136.3	2.5	7.5	5.0
S8	85.2	89.4	82.7	4.2	6.7	2.5
S9	127.7	123	126.9	4.7	3.9	0.8
S10	117.1	117.9	118.9	0.8	1.0	1.8
			Mean Difference	2.5	3.4	2.3
			Maximum Difference	4.7	7.5	5.0
			Pearson's R	1.0	1.0	1.0

Table 5.9: Repeat trials: Right Knee excursion angles (in degrees) during getting out of the chair

Subjects	Trial1	Trial2	Trial3	Abs (D_{1-2})	Abs (D_{2-3})	Abs (D_{1-3})
S1	13.3	11.0	14.5	2.3	3.5	1.2
S2	15.3	13.6	12.4	1.7	1.2	2.9
S3	14.6	12.8	13.5	1.8	0.7	1.1
S4	15.5	14.3	12.5	1.2	1.8	3.0
S5	12.8	15.2	12.0	2.4	3.2	0.8
S6	24.8	22.4	23.0	2.4	0.6	1.8
S7	24.7	25.6	21.8	0.9	3.8	2.9
S8	16.5	17.9	10.5	1.4	7.4	6.0
S9	30.4	28.4	29.5	2.0	1.1	0.9
S10	7.3	5.4	4.7	1.9	0.7	2.6
			Mean Difference	1.8	2.4	2.3
			Maximum Difference	2.4	7.4	6.0
			Pearson's R	1.0	0.90	1.0

Table 5.10: Repeat trials: Minimum Right Knee flexion angles (in degrees) during stair ascend

Subjects	Trial1	Trial2	Trial3	Abs (D_{1-2})	Abs (D_{2-3})	Abs (D_{1-3})
S1	45.6	49.2	45.2	3.6	4.0	0.4
S2	69.2	71.3	68.6	2.1	2.7	0.6
S3	101.3	99.2	103.4	2.1	4.2	2.1
S4	96.2	99.4	100.1	3.2	0.7	3.9
S5	78.6	79.3	80.5	0.7	1.2	1.9
S6	97.0	102.3	98.6	5.3	3.7	1.6
S7	118.4	120.2	123	1.8	2.8	4.6
S8	84.5	82.5	85.6	2.0	3.1	1.1
S9	97.1	95.6	99.3	1.5	3.7	2.2
S10	100.8	103.4	102.5	2.6	0.9	1.7
			Mean Difference	2.5	2.7	2.0
			Maximum Difference	5.3	4.2	4.6
			Pearson's R	1.0	1.0	1.0

Table 5.11: Repeat trials: Maximum Right Knee flexion angles (in degrees) during stair ascend

Subjects	Trial1	Trial2	Trial3	Abs (D_{1-2})	Abs (D_{2-3})	Abs (D_{1-3})
S1	32.3	38.2	30.7	5.9	7.5	1.6
S2	53.9	57.7	56.2	3.8	1.5	2.3
S3	86.7	86.4	89.9	0.3	3.5	3.2
S4	80.7	85.1	87.6	4.4	2.5	6.9
S5	65.8	64.1	68.5	1.7	4.4	2.7
S6	72.2	79.9	75.6	7.7	4.3	3.4
S7	93.7	94.6	101.2	0.9	6.6	7.5
S8	68.1	64.6	75.1	3.4	10.5	7.1
S9	66.8	67.2	69.8	0.4	2.6	3.0
S10	93.6	98.0	97.8	4.4	0.2	4.2
			Mean Difference	3.3	4.4	4.2
			Maximum Difference	7.7	10.5	7.5
			Pearson's R	1.0	1.0	1.0

Table 5.12: Repeat trials: Right Knee excursion angles (in degrees) during stair ascend

Subjects	Trial1	Trial2	Trial3	Abs (D_{1-2})	Abs (D_{2-3})	Abs (D_{1-3})
S1	4.2	6.5	8.3	2.3	1.8	4.1
S2	19.2	17.4	19.5	1.8	2.1	0.3
S3	9.9	11.4	10.7	1.5	0.7	0.8
S4	12.4	11.6	11.9	0.8	0.3	0.5
S5	19.8	23.4	21.5	3.6	1.9	1.7
S6	11.5	9.6	12.6	1.9	3.0	1.1
S7	20.9	24.3	22.5	3.4	1.8	1.6
S8	13.5	12.8	15.7	0.7	2.9	2.2
S9	18.0	20.4	23.1	2.4	2.7	5.1
S10	5.5	7.6	8.3	2.1	0.7	2.8
			Mean Difference	2.0	1.8	2.0
			Maximum Difference	3.6	3.0	5.1
			Pearson's R	0.90	1.0	1.0

Table 5.13: Repeat trials: Minimum Right Knee flexion angles (in degrees) during stair descend

Subjects	Trial1	Trial2	Trial3	Abs (D_{1-2})	Abs (D_{2-3})	Abs (D_{1-3})
S1	56.5	57.2	60.1	0.7	2.9	3.6
S2	82.9	80.2	84.2	2.7	4.0	1.3
S3	94.1	96.3	95.3	2.2	1.0	1.2
S4	72.7	75.4	73.4	2.7	2.0	0.7
S5	73.9	76.4	74.8	2.5	1.6	0.9
S6	79.4	78.8	75.6	0.6	3.2	3.8
S7	100.3	104.3	103.2	4.0	1.1	2.9
S8	91.6	93.5	94.3	1.9	0.8	2.7
S9	70.7	73.6	72.8	2.9	0.8	2.1
S10	80.0	82.3	79.7	2.3	2.6	0.3
			Mean Difference	2.3	2.0	1.9
			Maximum Difference	4.0	4.0	3.8
			Pearson's R	1.0	1.0	1.0

Table 5.14: Repeat trials: Maximum Right Knee flexion angles (in degrees) during stair descend

Subjects	Trial1	Trial2	Trial3	Abs (D_{1-2})	Abs (D_{2-3})	Abs (D_{1-3})
S1	52.2	50.7	51.8	1.5	1.1	0.4
S2	63.7	62.8	64.7	0.9	1.9	1.0
S3	84.2	84.9	84.6	0.7	0.3	0.4
S4	60.3	63.8	61.5	3.5	2.3	1.2
S5	54.1	53.0	53.3	1.1	0.3	0.8
S6	67.9	69.2	63.0	1.3	6.2	4.9
S7	79.3	80.0	80.7	0.7	0.7	1.4
S8	78.1	80.7	78.6	2.6	2.1	0.5
S9	52.7	53.2	49.7	0.5	3.5	3.0
S10	74.5	74.7	71.4	0.2	3.3	3.1
			Mean Difference	1.3	2.2	1.7
			Maximum Difference	3.5	6.2	4.9
			Pearson's R	1.0	1.0	1.0

Table 5.15: Repeat trials: Right Knee excursion angles (in degrees) during stair descend

Subjects	Trial1	Trial2	Trial3	Abs (D_{1-2})	Abs (D_{2-3})	Abs (D_{1-3})
S1	-6.5	-8.2	-10.0	1.7	1.8	3.5
S2	-2.0	-3.6	-2.3	1.6	1.3	0.3
S3	-5.1	-6.8	-3.5	1.7	3.3	1.6
S4	-4.5	-7.2	-5.6	2.7	1.6	1.1
S5	0.5	1.5	2.4	1.0	0.9	1.9
S6	-4.8	-6.2	-5.6	1.4	0.6	0.8
S7	-1.9	-3.2	-2.6	1.3	0.6	0.7
S8	-5.4	-7.3	-3.5	1.9	3.8	1.9
S9	-8.6	-9.4	-7.4	0.8	2.0	1.2
S10	-10.3	-8.4	-9.3	1.9	0.9	1.0
			Mean Difference	1.6	1.7	1.4
			Maximum Difference	2.7	3.8	3.5
			Pearson's R	0.90	0.90	0.90

Table 5.16: Repeat trials: Minimum Right Knee flexion angles (in degrees) during squatting

Subjects	Trial1	Trial2	Trial3	Abs (D_{1-2})	Abs (D_{2-3})	Abs (D_{1-3})
S1	98.4	96.3	98.5	2.1	2.2	0.1
S2	131.0	135.3	133.2	4.3	2.1	2.2
S3	138.7	142.5	139.4	3.8	3.1	0.7
S4	125.5	123.6	124.2	1.9	0.6	1.3
S5	93.0	96.3	98.2	3.3	1.9	5.2
S6	125.2	122.4	126.2	2.8	3.8	1.0
S7	103.1	106.3	102.4	3.2	3.9	0.7
S8	129.0	127.4	125.3	1.6	2.1	3.7
S9	105.5	108.7	104.6	3.2	4.1	0.9
S10	107.2	105.4	109.4	1.8	4.0	2.2
			Mean Difference	2.8	2.8	1.8
			Maximum Difference	4.3	4.1	5.2
			Pearson's R	1.0	1.0	1.0

Table 5.17: Repeat trials: Maximum Right Knee flexion angles (in degrees) during squatting

Subjects	Trial1	Trial2	Trial3	Abs (D_{1-2})	Abs (D_{2-3})	Abs (D_{1-3})
S1	104.9	104.5	108.5	0.4	4.0	3.6
S2	132.9	138.9	135.5	6.0	3.4	2.6
S3	143.7	149.3	142.9	5.6	6.4	0.8
S4	130.0	130.8	129.8	0.8	1.0	0.2
S5	92.5	94.8	95.8	2.3	1.0	3.3
S6	130.0	128.6	131.8	1.4	3.2	1.8
S7	105.0	109.5	105.0	4.5	4.5	0.0
S8	134.4	134.7	128.8	0.3	5.9	5.6
S9	114.1	118.1	112.0	4.0	6.1	2.1
S10	117.4	113.8	118.7	3.6	4.9	1.3
			Mean Difference	2.9	4.0	2.1
			Maximum Difference	6.0	6.4	5.6
			Pearson's R	1.0	1.0	1.0

Table 5.18: Repeat trials: Right Knee excursion angles (in degrees) during squatting

Standard Right knee cycles for 10 normal subjects during level walking

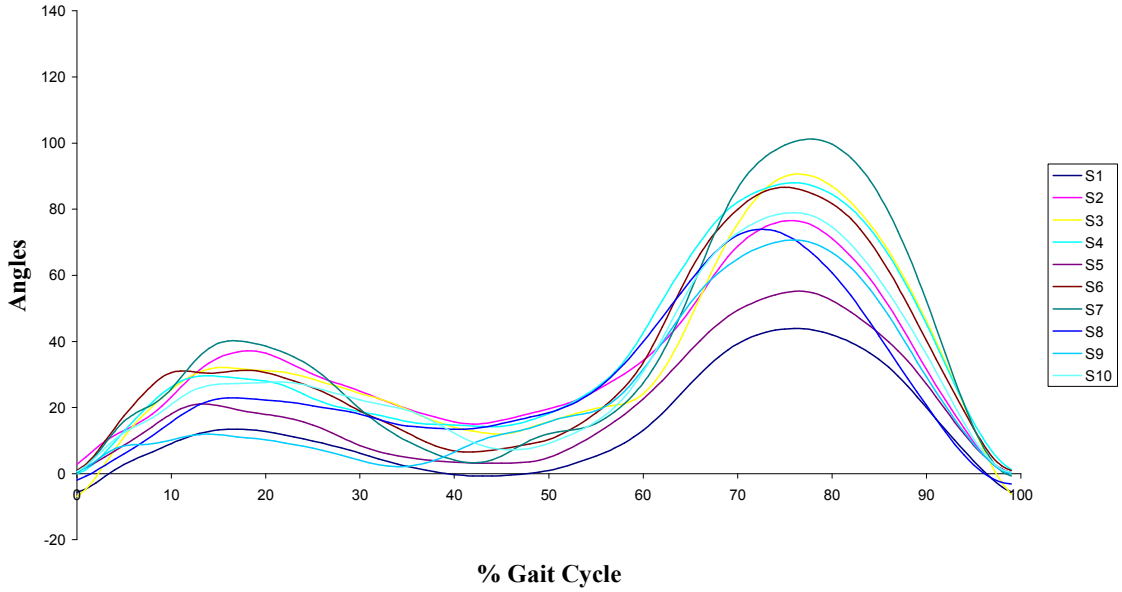


Figure 5.2

Average Standard cycle of Right knee for 10 normal subjects during level walking

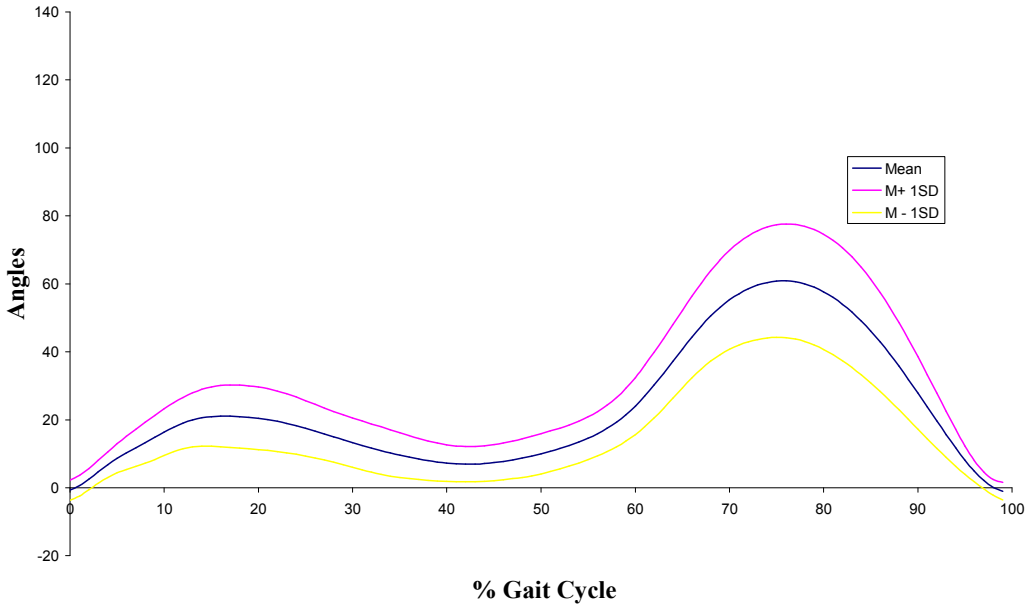


Figure 5.3

Note: All the Y axis – Angles reported in this chapter are in Degrees.

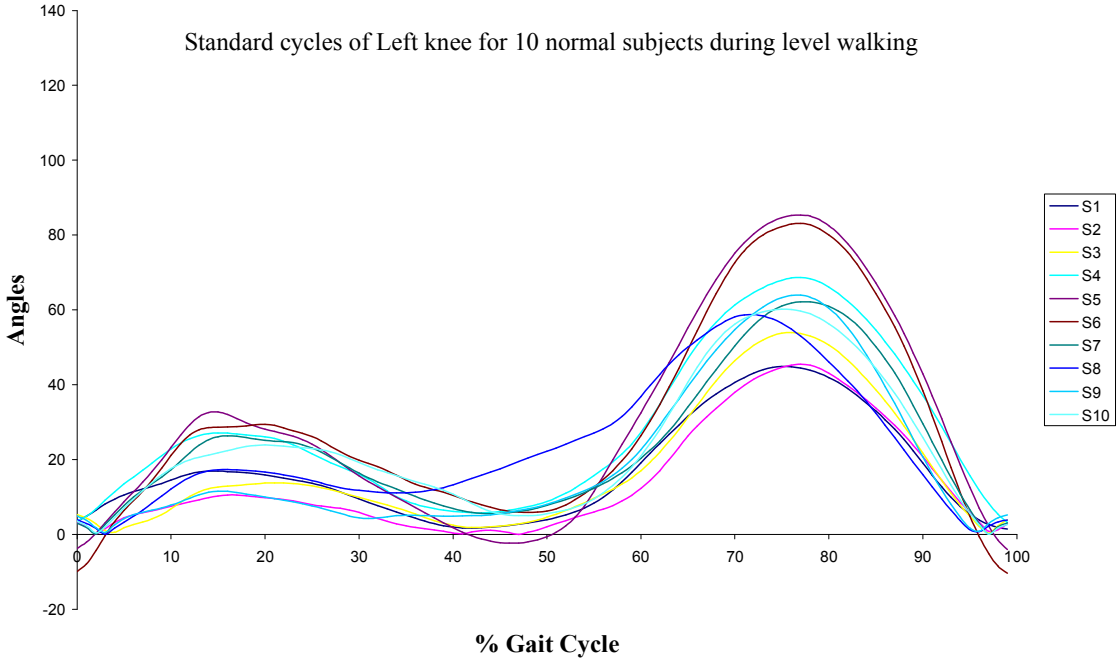


Figure 5.4

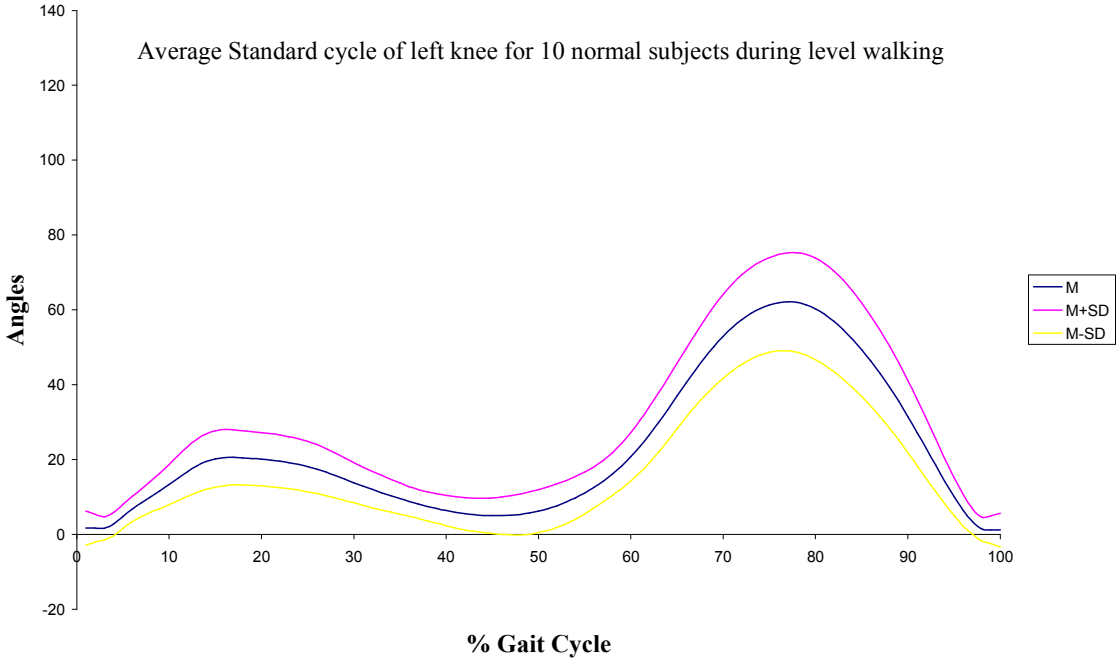


Figure 5.5

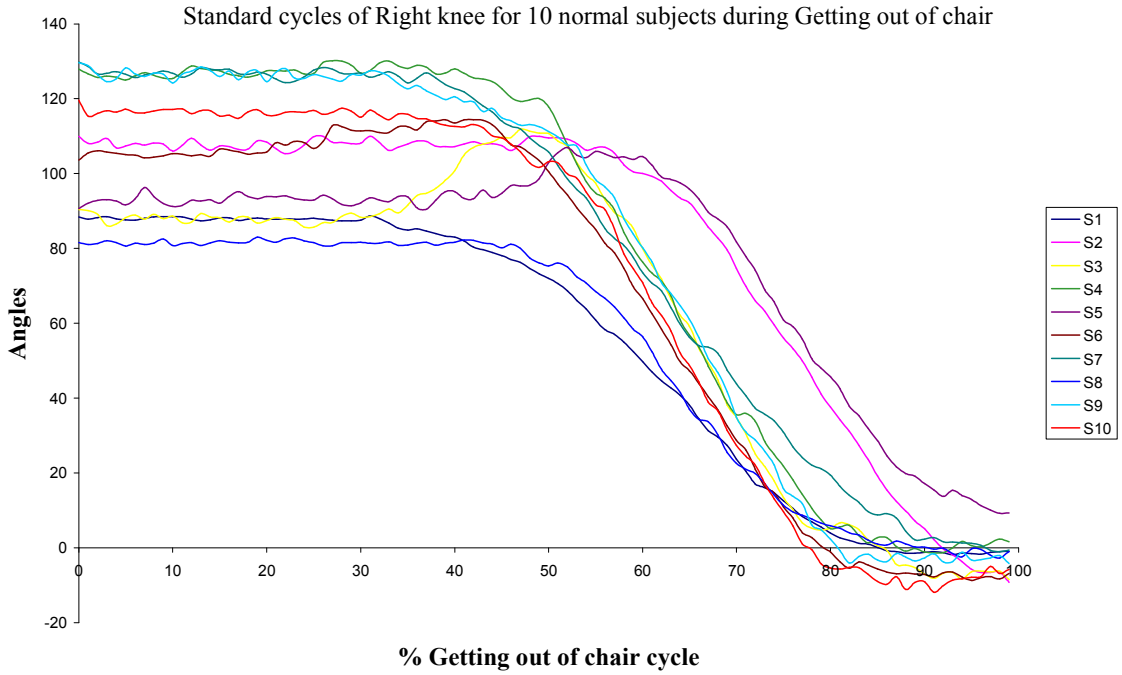


Figure 5.6

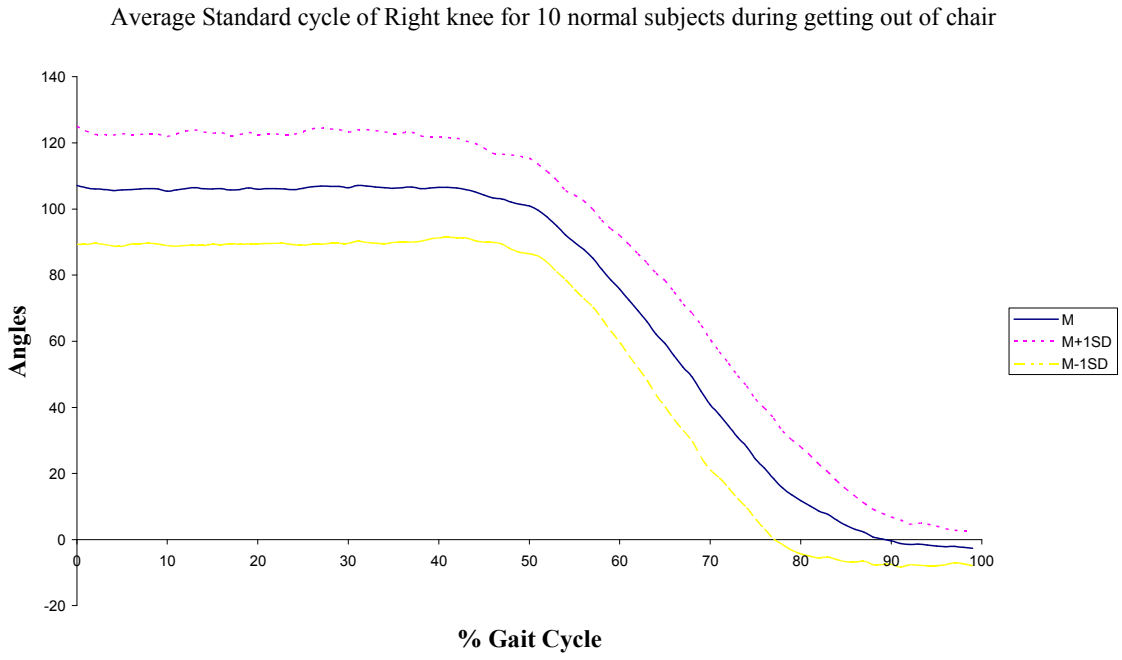


Figure 5.7

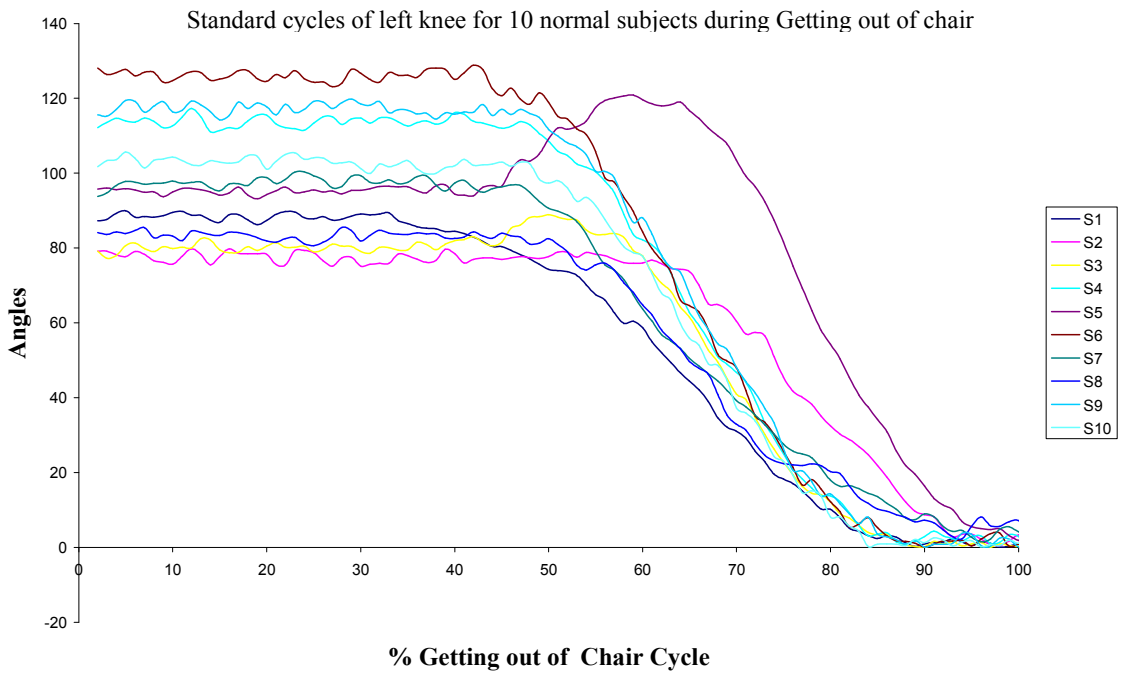


Figure 5.8

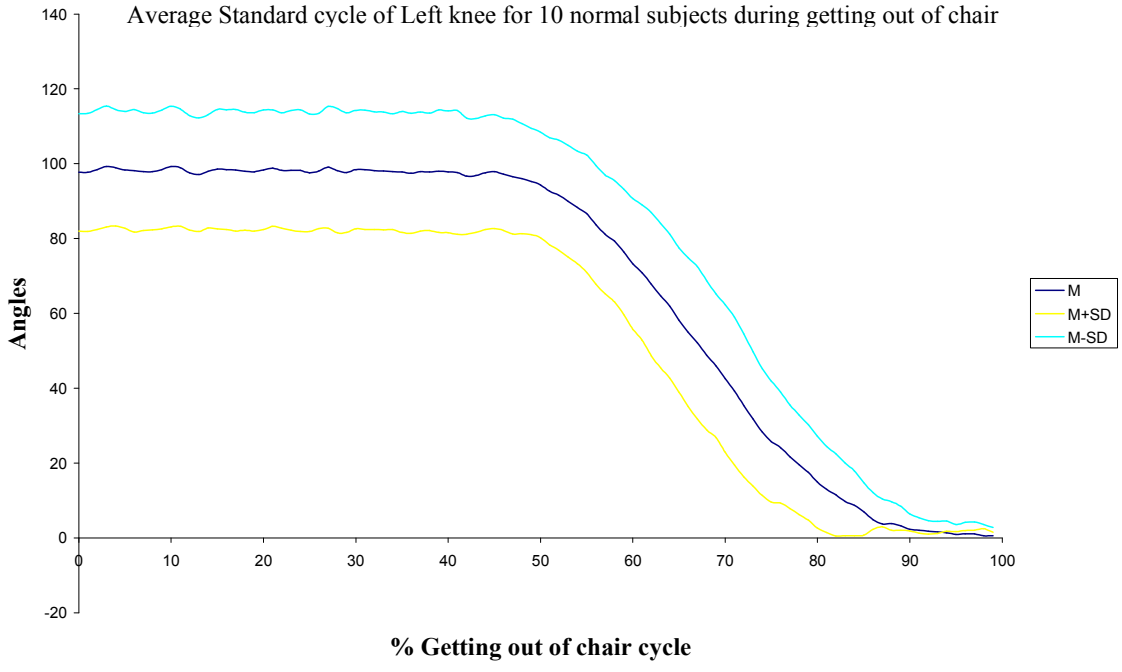


Figure 5.9

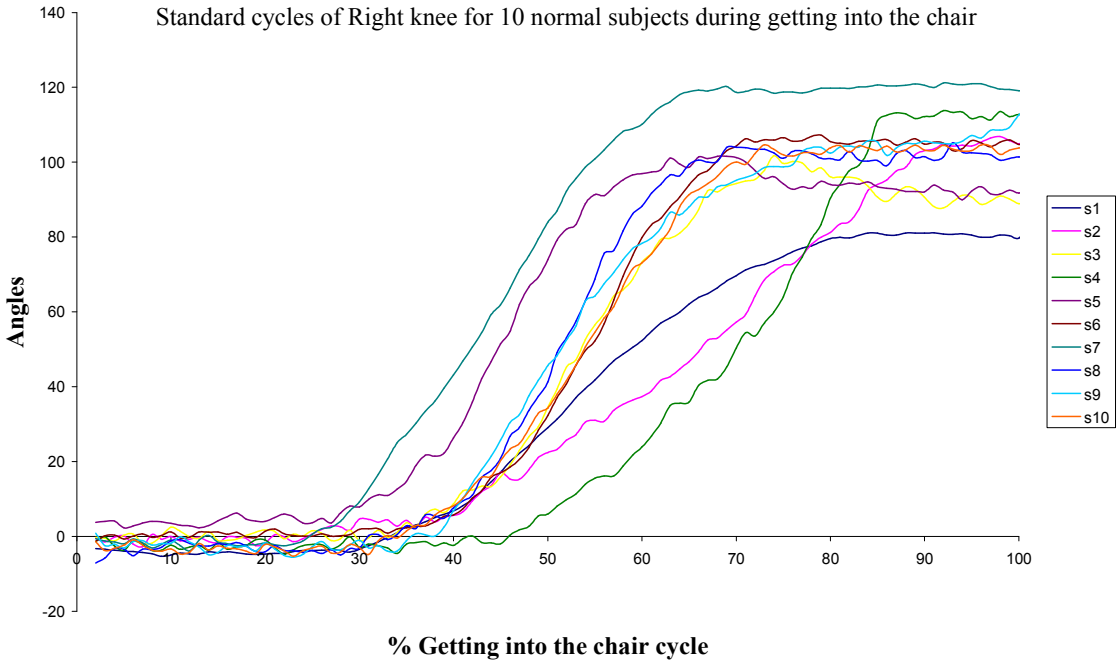


Figure 5.10

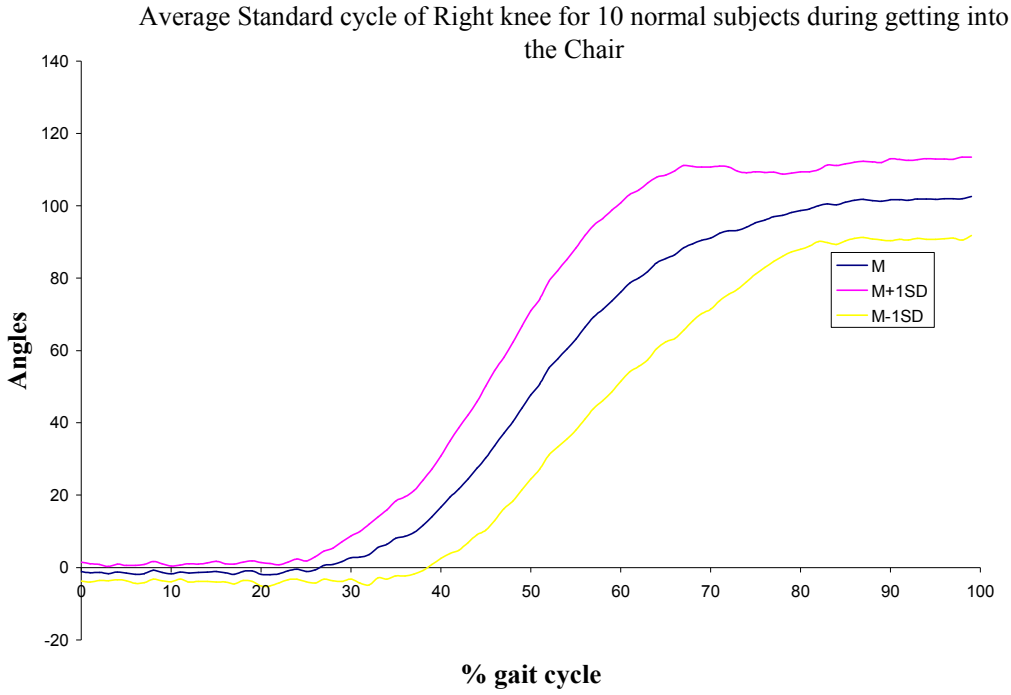


Figure 5.11

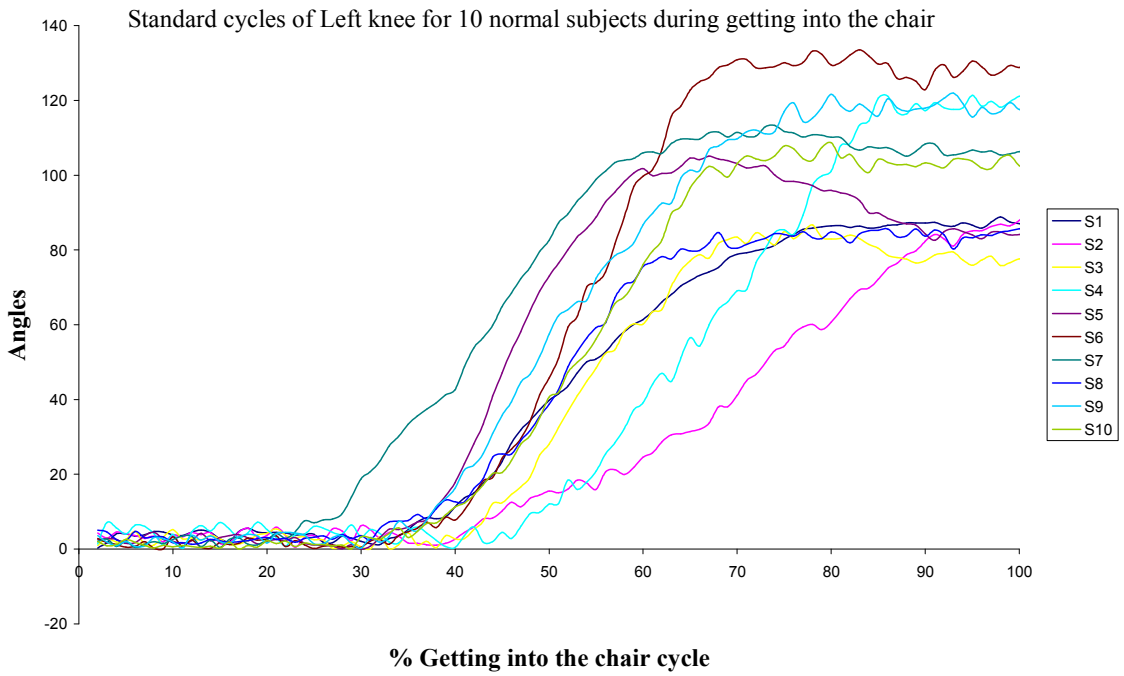


Figure 5.12

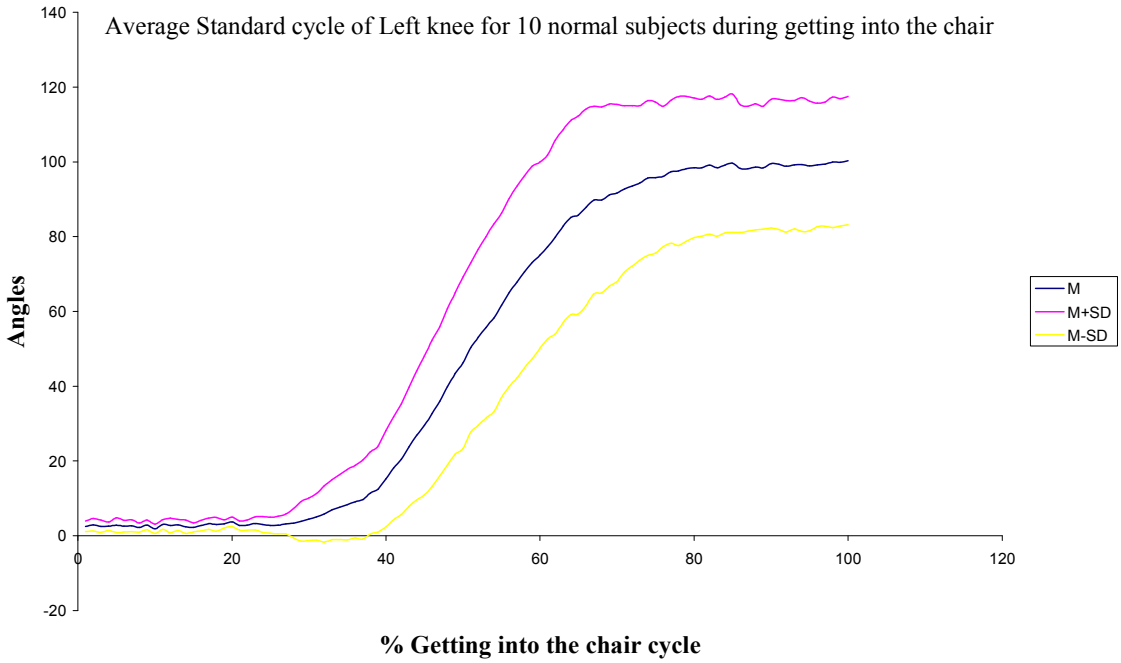


Figure 5.13

Standard cycles of Right knee for 10 normal subjects during stair ascend

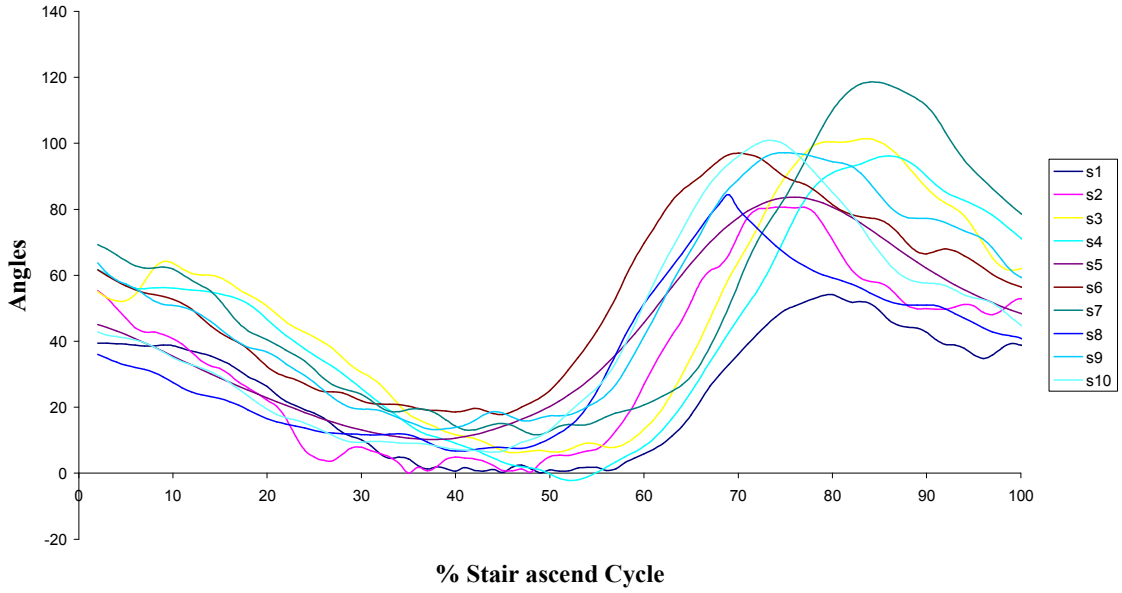


Figure 5.14

Average Standard cycle of right knee for 10 normal subjects during stair ascend

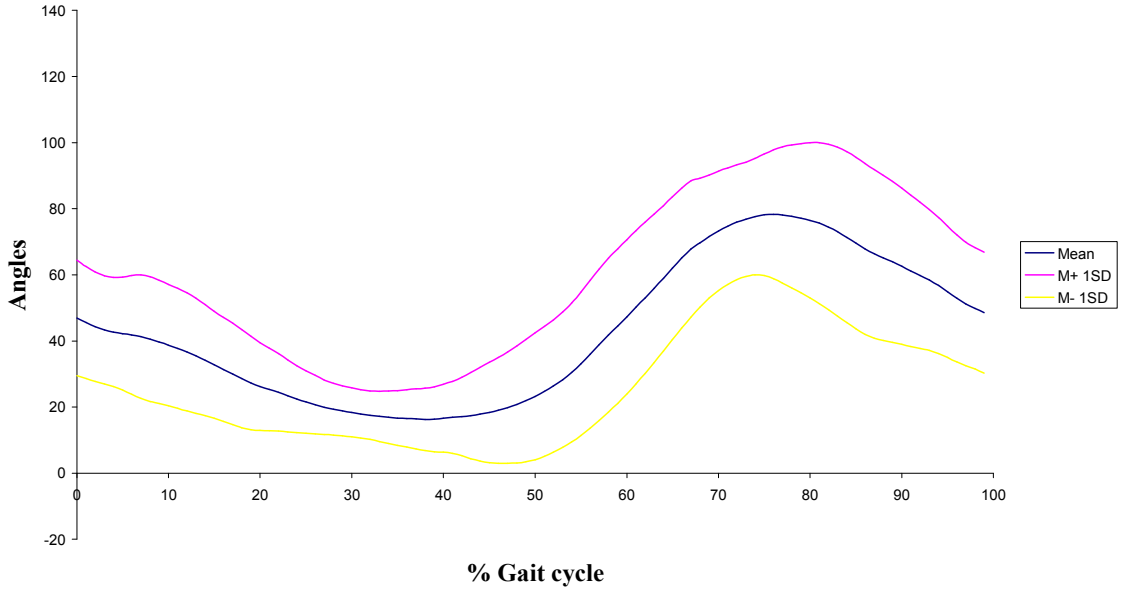


Figure 5.15

Standard cycles of Left knee for 10 normal subjects during stair ascend

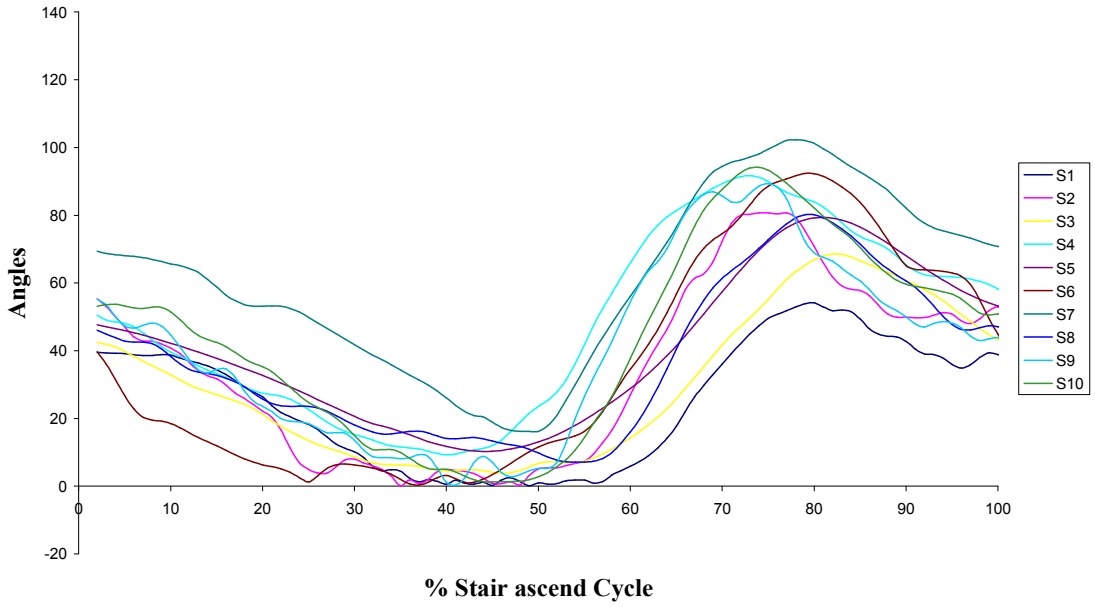


Figure 5.16

Average Standard cycle of left knee for 10 normal subjects during stair ascend

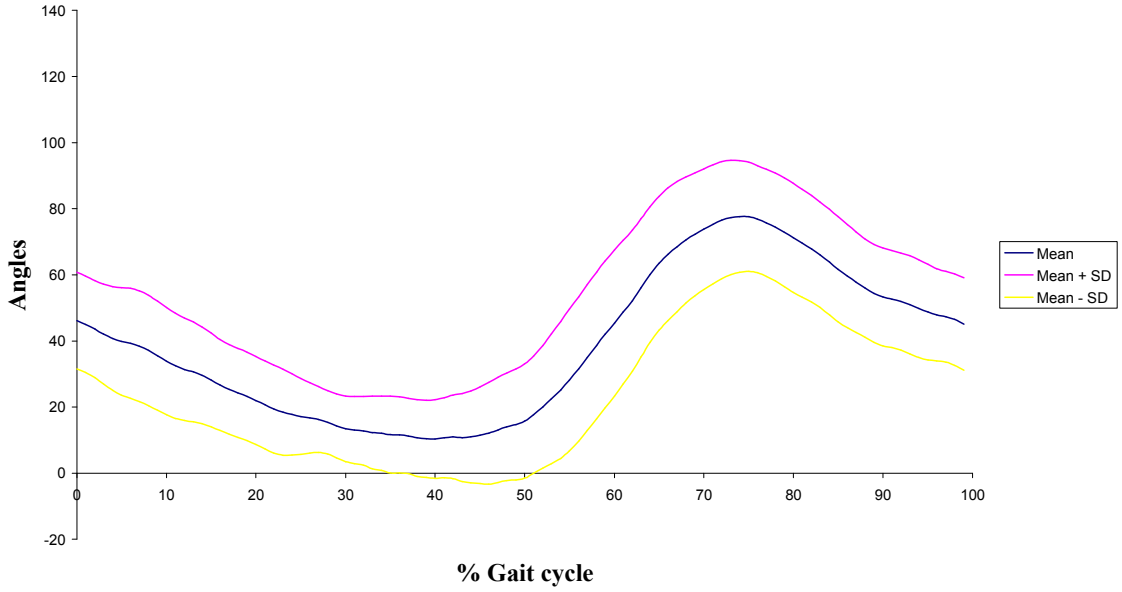
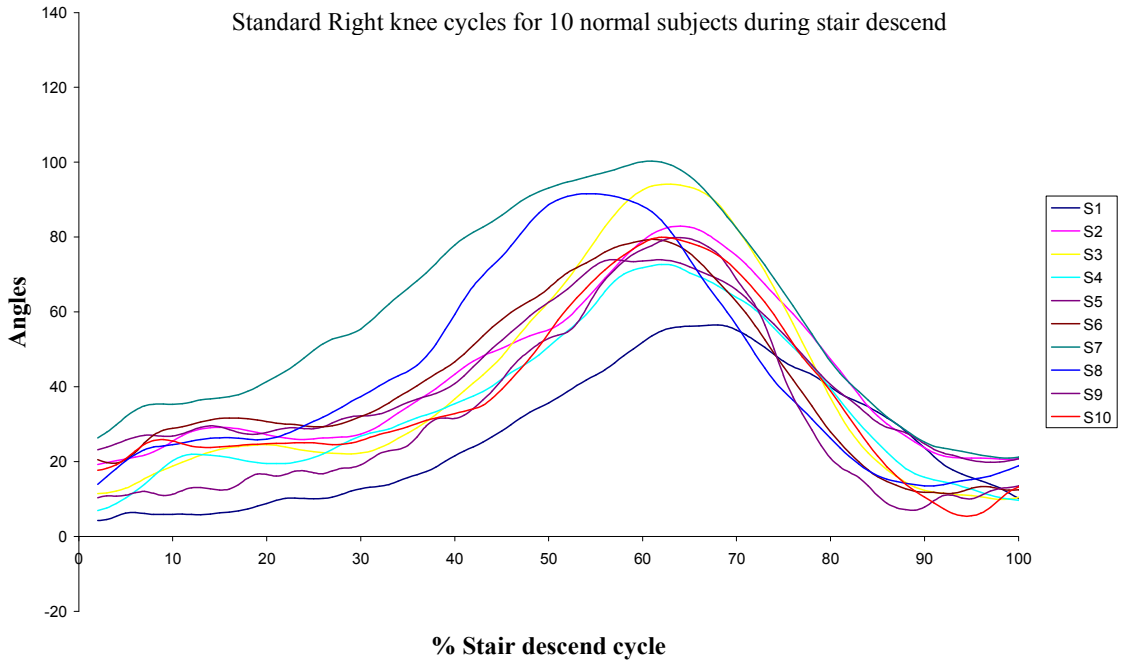


Figure 5.17



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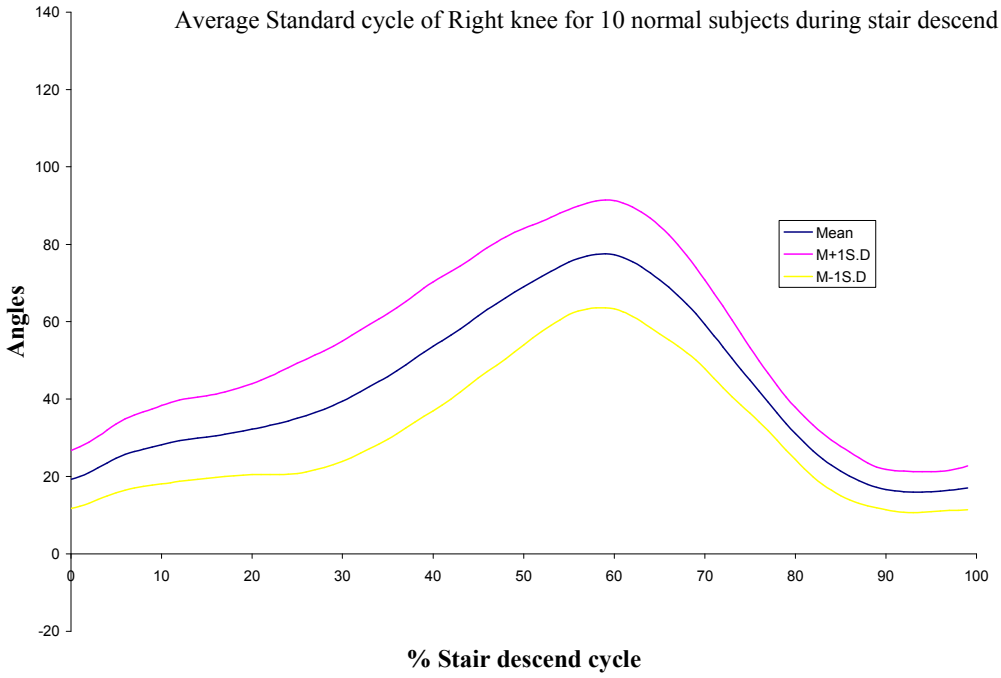


Figure 5.19

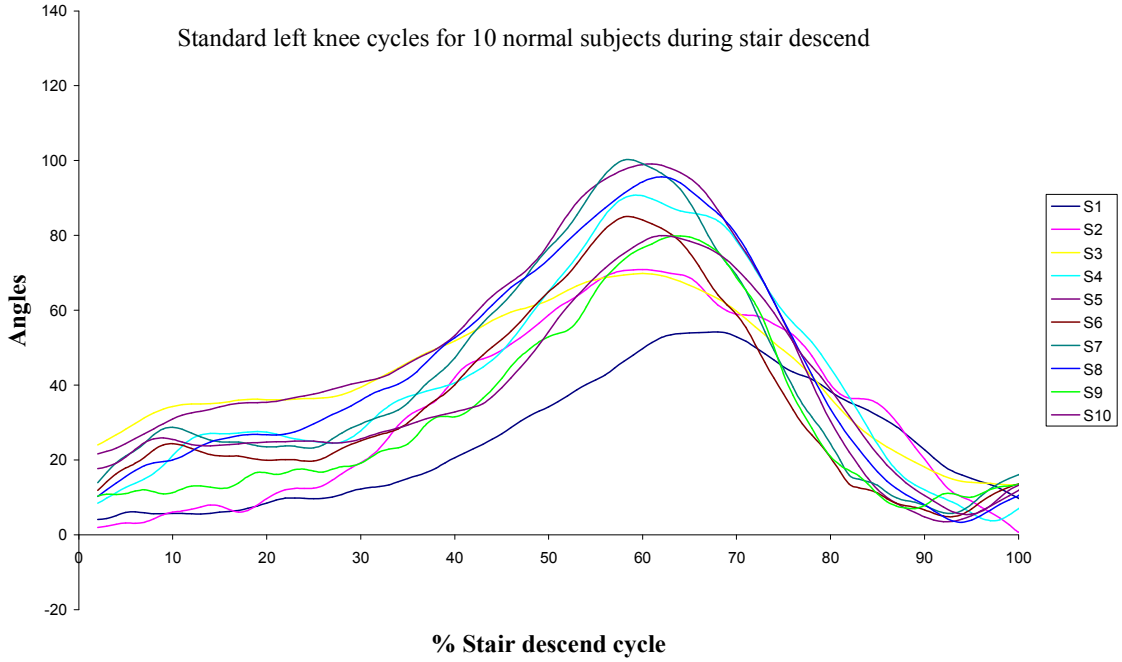


Figure 5.20

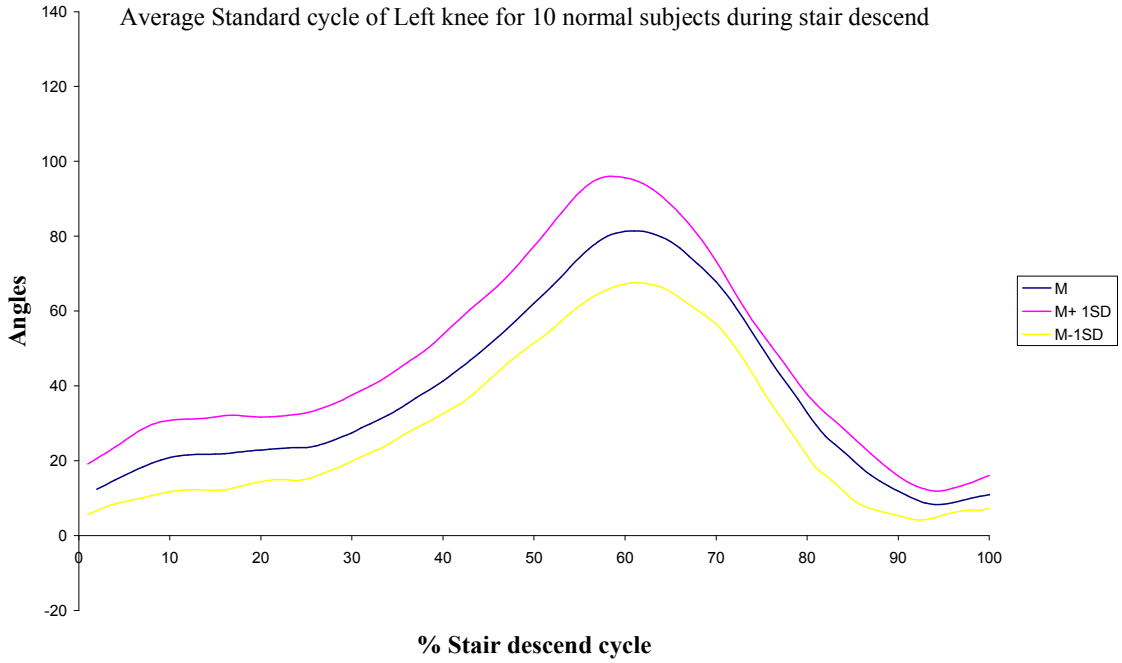
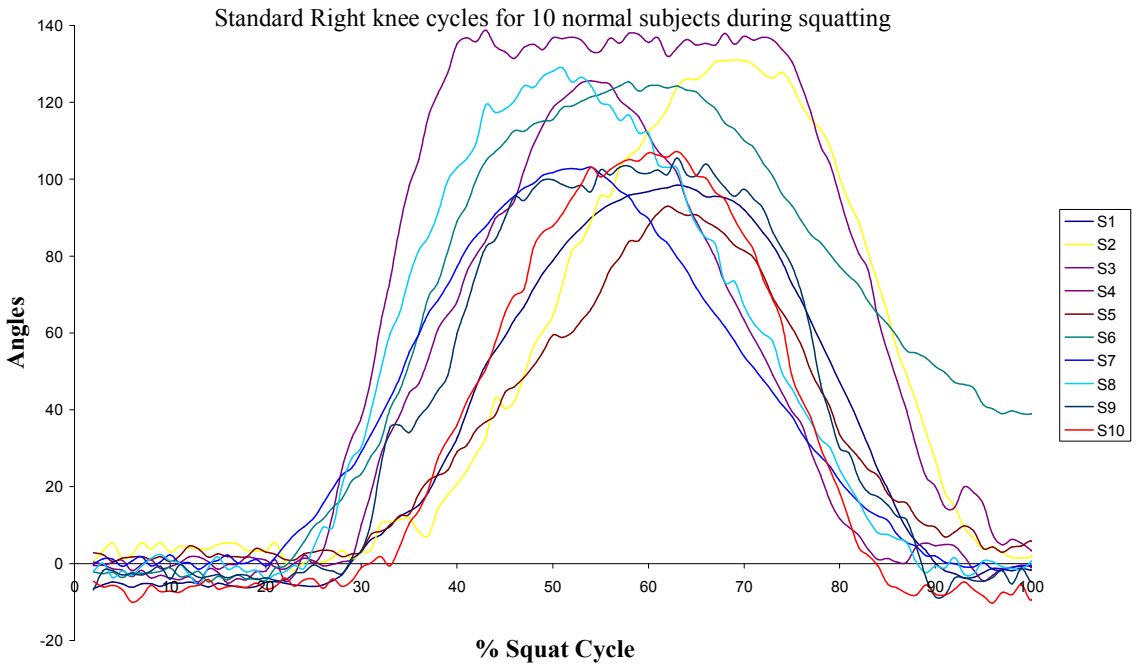


Figure 5.21



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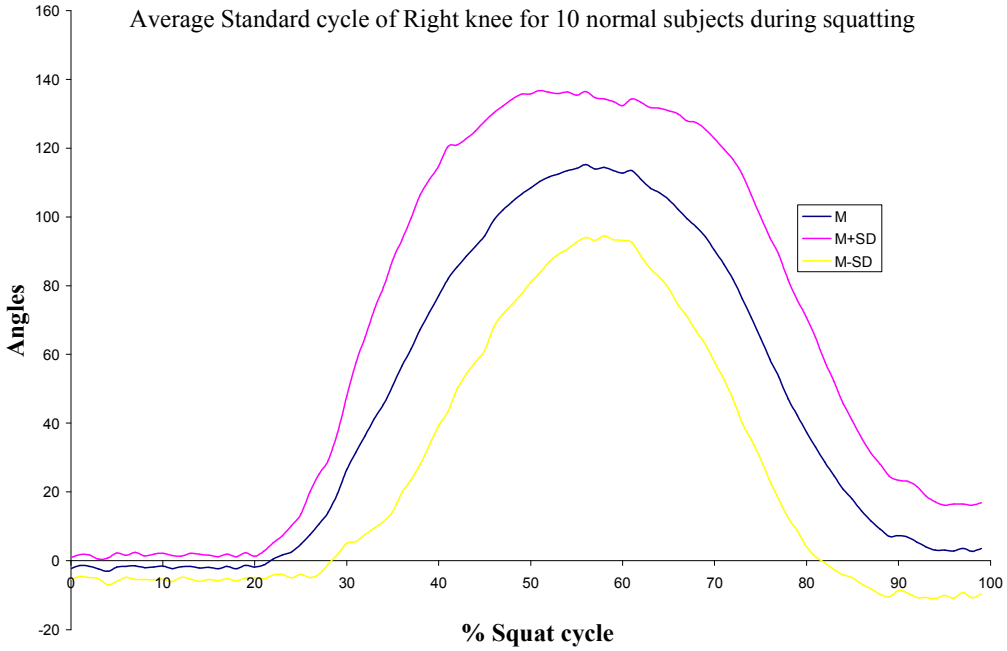
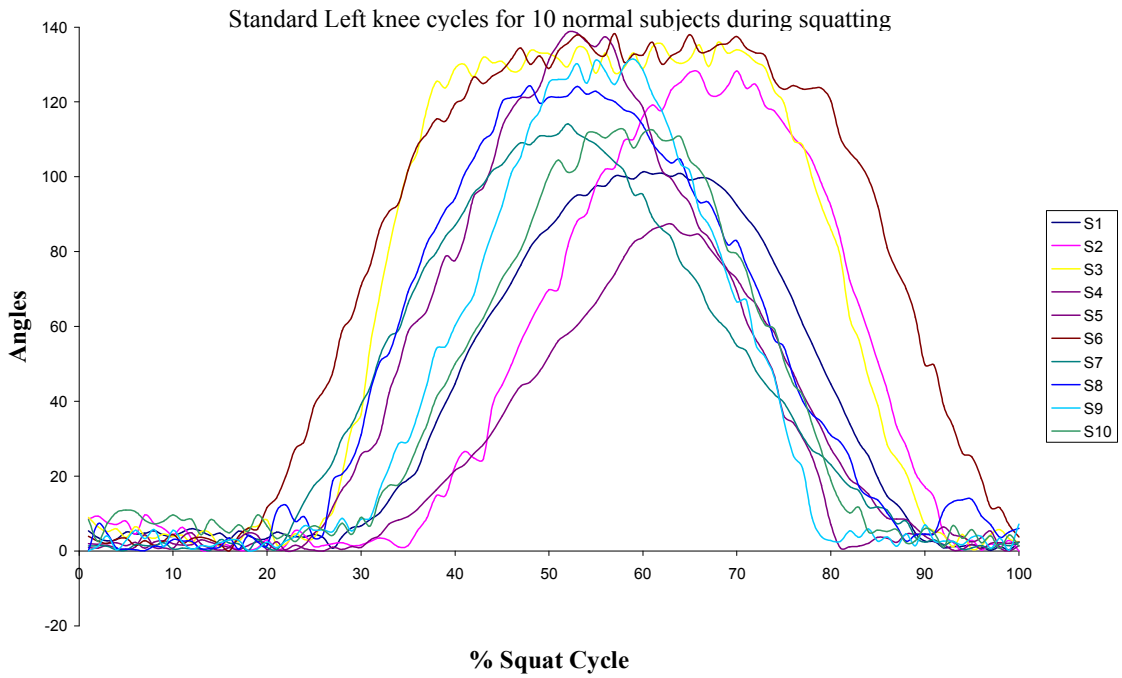


Figure 5.23



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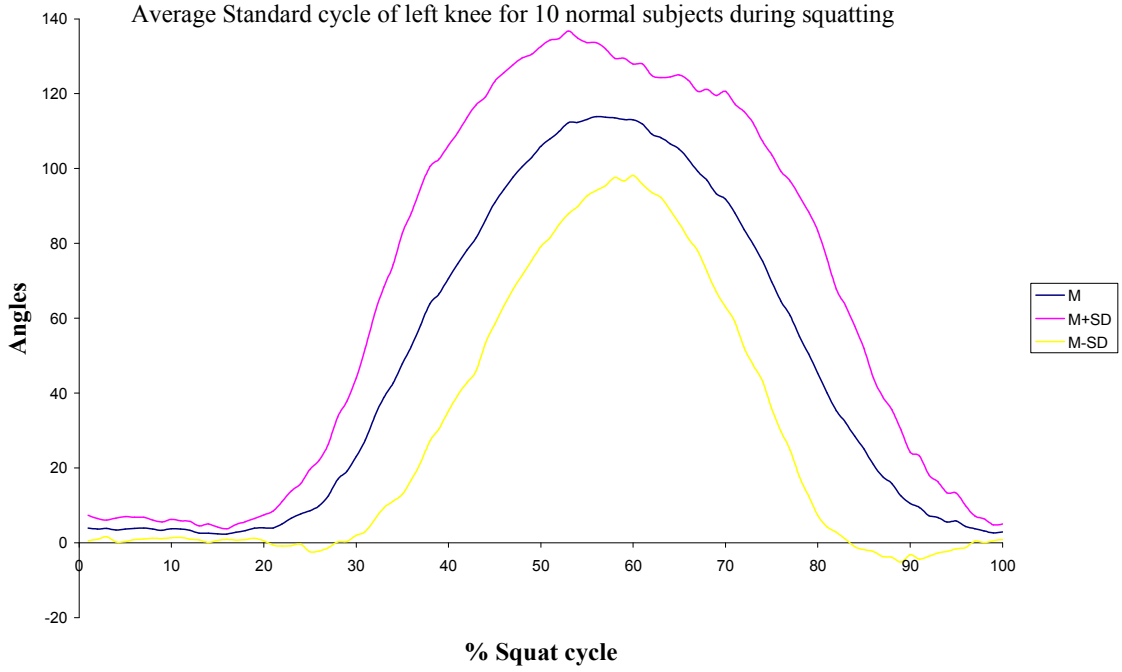


Figure 5.25

ADL	SUDALS Maximum Knee Flexion (in degrees)	
	Right Knee	Left Knee
Gait	64.9 (±12.7)	62.6 (±13.6)
Stair Up	88.8 (±20.4)	82.7(±16.2)
Stair Down	80.2(±12.4)	79.5(±16.7)
Chair In	105.8(±10.1)	105.6(±17.0)
Chair Out	112.3(±16.4)	103.5(±17.3)
Squat	115.6(±15.9)	121.2(±17.1)

Table 5.19a

ADL	SUDALS Minimum Knee Flexion (in degrees)	
	Right Knee	Left Knee
Gait	-1.5(±2.7)	-3.4(±3.7)
Stair Up	17.0(±6.9)	11.4(±12.2)
Stair Down	18.7(±5.9)	9.8(±5.3)
Chair In	4.7(±2.7)	4.1(±2.4)
Chair Out	5.2(±6.0)	1.1(±2.3)
Squat	3.9(±5.1)	4.8(±3.1)

Table 5.19b

ADL	SUDALS – excursion (in degrees)	
	Right Knee	Left Knee
Gait	66.4	66.0
Stair up	71.8	71.3
Stair Down	61.5	69.7
Chair in	100.9	101.7
Chair Out	107.1	102.4
Squat	111.7	116.4

Table 5.19c

Table 5.19a: Maximum Knee flexion values from SUDALS represented as Mean±1SD
Table 5.19b: Minimum Knee flexion values from SUDALS represented as Mean±1SD
Table 5.19c: Knee excursion values from SUDALS

	Gait	Stair Up	Stair Down	Chair In	Chair Out	Squat
Jevsevar et al. 1993	63.3° ± 8.1°	91.8° ± 10.4°	86.1°± 5.5°	-	90.0° ± 8.9°	-
Costigan et al. 2002	-	90°	-	-	-	-
Kettlekamp et al. 1970	67.4°	-	-	-	-	-
Andriacchi et al. 1980	-	73.4°	-	-	81.6°	-
Protopapadakki et al. 2007	-	93.9°± 7.4°	-	90.5°± 7.11°	-	-
Huddleston et al. 2006	-	-	-	-	120° to 160°	-
Wyss et al. 2003	-	-	-	-	-	152°
This Study (Average of maximum left and right knee flexion angles)	64°± 13.1°	86°± 18.3°	80°± 14.5°	105°± 13.5°	108°± 16.8°	114°± 16.5°

Table 5.19d: Maximum Knee flexion values reported by other researchers during various ADL's

The Figure below illustrates the concurrent validity of SUDALS with the gold standard Vicon system obtained from three normal healthy volunteers during level walking. The maximum/minimum knee flexion/extension and the knee excursion values obtained from both the systems are tabulated as shown in table 5.20.

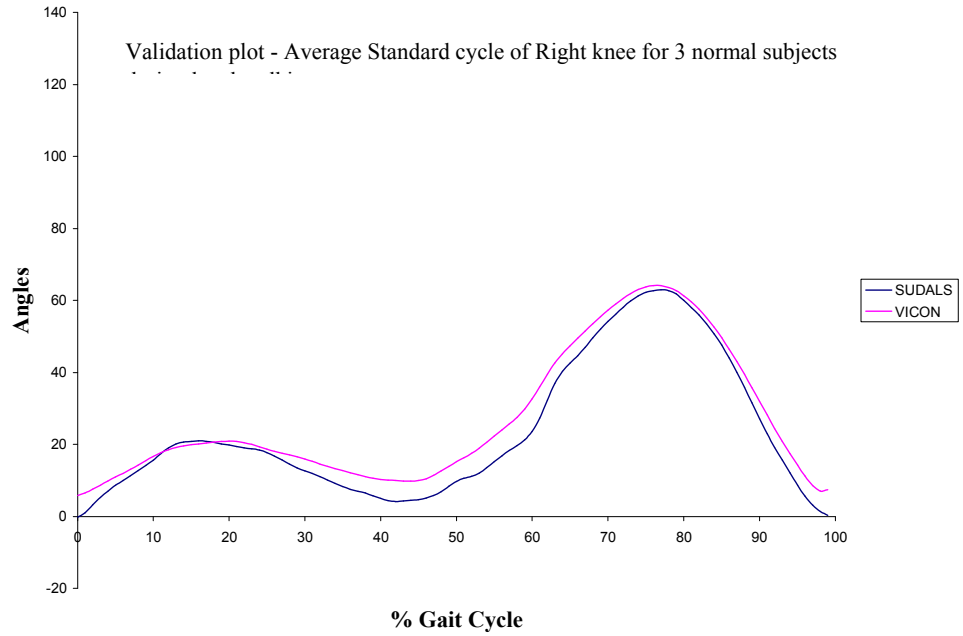


Figure 5.26

Knee flexion	SUDALS	Vicon
Maximum	63°	64°
Minimum	-0.3°	5°
Excursion	63°	59°

Table 5.20

5.3 Data analysis and Discussion

Observation of the standard knee cycles of all the participants and the average knee cycles obtained during the ADL's shows good consistency and agreement in terms of the shape of the individual participants' knee flexion/extension curves for both the knees. Considering each activity individually, each and every participant seem to have performed the activity uniformly and the system seem to have recorded the knee flexion/extension angles accurately. The system would therefore appear to perform reliably. The maximum and the minimum knee angle exhibited by each subject for each ADL are within literature values and this is evident from the standard cycle graphs plotted for all the 10 subjects for each activity. On observing the standard cycle curves for activities such as getting into the chair, getting out of the chair and squatting, the curves doesn't seem to be smooth when compared to other activities. This kind of irregularity can be seen in common for all the participants and in both the knees for these three activities. Further, on careful examination of the graphs cycles, the irregularity seems to be more prevalent in activities such as getting in and out of the chair and squatting, where the subjects are stationary and the graph patterns are much smoother in activities such as walking, stair ascend and descend where the subjects are in motion. Probably, such irregularities are due to the presence of small amount of noise or jitter in the data collected from these activities despite digital filtering. The activity of getting in and out of the chair and squatting is a low frequency activity and filtering these activities at a little lower cut-off frequency (less than 6 Hz) might eliminate these noises. Generally, a 4^{th} order zero lag Butterworth filter with a cut-off frequency of 6 Hz is used for filtering the kinematic data on walking. (Winter, 1990) Though such digital filters are used widely for such applications (Van der linden et al.., 2008), none of the researchers have reported on the use of specific activity oriented cut-off frequencies. Hence, it was not possible to use specific activity oriented cut-off frequencies for filtering the data collected in our application. Another possible reason for such noises could be due to the amplifiers used in conjunction with flexible electrogoniometers for signal conditioning purposes. Conventionally, the flexible electrogoniometers were used with strain gauge amplifiers and these amplifiers are exclusively used for amplifying the outputs of such strain gauge based transducers. However, due to their size and bulky nature, such

amplifiers are not portable and hence cannot be used in portable data acquisition applications. Hence, for this application, instrumentation amplifiers were used. Though these amplifiers are very efficient and are commonly used in signal conditioning applications (Pfister et al.., 1989), the amplifiers and other signal conditioning components are soldered on a simple strip board instead of a printed circuit board (PCB) and in turn this can also induce such jitters, noise or interference as seen in the output graph patterns. Similarly, there seems to be a slight variation and spread in the pattern of the standard cycle exhibited by subject 5 during getting out of chair. Such a variation in the curve pattern is also seen in the standard cycle exhibited by subject 3 during squatting. This may be due to some kind of other unwanted movements exhibited by the subjects – such as the movement of the legs (backwards) before standing or due to the way in which the subjects have performed these activities – some kind of pause on returning from the squatting position. Nevertheless, the maximum/minimum knee flexion/extension values of these curves don't seem to be exaggerated and the noise is eliminated in the group average cycles for these activities.

Table 5.19a and 5.19b shows the mean maximum and minimum left and right knee joint angle for the group of 10 normal healthy young subjects during various ADL such as; gait, up and down the stairs, getting in and out of a chair and deep squat and table 5.19c shows the average knee joint excursion of the group for the left and right knees during these activities. The maximum knee joint excursion exhibited by the group was during squatting - 114°. During the other activities such as the gait, up and down the stairs, their knee excursion was 66.2°, 71.5° and 65.6° respectively. Similarly, during getting in and out of the chair, the subjects seem to have used a slightly high knee range of motion of 101° and 105°. On the other hand, on analysing the average maximum flexion angles of both the knees during the 6 ADL, the results seem to lie within the values published in the literature as shown in table 5.19d. The maximum knee flexion recorded by SUDALS during gait was 64°. This is close to those values reported by Jevsevar et al.., 1993 – 63.3° ± 8.1°and Kettlekamp et al.., 1970 – 67.4°. In addition to gait, Jevsevar et al.., 1993 has also reported about the maximum knee flexion angle in young normal individuals during other ADL such as stair ascending / descending and

getting out of a chair to be 91.8°±10.4° / 86.1°±5.5° and 90.05°±8.9°, which are very close to (86° / 80° and 108°) those recorded by SUDALS. Costigan et al.., 2002 has reported the maximum knee flexion during stair climbing to be 90°, whereas Protopapadakki et al.., 2007 has reported the maximum knee flexion to be 93.92°± 7.40° for stair climbing and 90.52°± 7.11° for getting in a chair. Other than Wyss et al.., 2003 none of these authors have studied the movement of the knee during squatting. However, the maximum knee flexion (152°) reported by Wyss et al.., 2003 during squatting doesn't seem to be close to the value recorded by SUDALS. One of the possible reasons for this could be the way in which the subjects performed this activity. Though the subjects were shown what they were suppose to perform during the process of recording, certain subjects were unable to completely squat as it was a difficult task and required a lot of effort. Due to this, certain subjects performed half squat instead of a complete squat. As a result, the knee flexion angle recorded during this activity would be different from those reported by Wyss et al.., where the subjects have performed a complete squat. Other than this, the remaining values seem to be very close to those published by other researchers with little variations. The reason for these small variations could be that, none of these researchers have used flexible electrogoniometer for measuring the knee angle and none of them have reported the minimum knee flexion angles or the excursion of the knee during these ADL. Further, on examining the tables 5.1 to 5.18, shows that there is a good correlation (0.9 or greater) between the three repeat trials obtained from all the 10 subjects during all the ADL's. Also, the mean absolute errors obtained here are similar to the errors estimated during the system testing and reported in chapter 4. However, the Pearson's correlation between the repeat trials pertaining to minimum knee flexion during level walking seems to be in the range of 0.80 to 0.88, slightly less than other ADL's. The minimum knee flexion corresponds to the extension of the knee during walking and since, the subjects were asked to walk at their selected speed during these trials, small variations in their minimum knee flexion could have occurred and this in turn has reflected on the Pearson's correlation coefficient value. Nevertheless, there is a high degree of correlation between the knee flexion and knee excursion values during all ADL's and this gives us an idea of the repeatability and reproducibility of the system.

Similarly, figure 5.26 shows the comparison between the mean knee angle trace recorded via SUDALS and vicon system. There seems to be a good agreement between both the systems in terms of the knee joint excursion and maximum knee flexion angle with very little variations. The excursion of the right knee of the group, recorded by SUDALS and vicon was 63° and 58°. In addition to this, on analyzing the maximum flexion angle of the right knee of the group, recorded by SUDALS and vicon was almost same (63° and 64°). The main aim of the validation study was to compare the recorded knee joint angles through two systems. Therefore, it was important that the knee joint centre used should be as accurate as possible. However, the palpation of the medial and lateral epicondyles depends on the researchers' accuracy and is therefore subjected to human errors. Hence, if the zero degrees or neutral position of the lower limb varies, then there will be discrepancies in the neutral position determined by the vicon system and flexible goniometry system. On the other hand, it is possible that the static trials at the hip may contribute another few degrees of variation. Static trials are also used to calculate the HJC i.e. the right/left ASIS and SACR. There was also a risk that these points could be incorrect which in turn will result in an incorrect determination of the HJC. All three joint centres – ankle, knee and hip are important in determining the knee joint flexion angle. Also, the neutral axis and zero degree position should be as close as possible for both the systems or there will be a shift in the maximum and minimum knee joint angles for the activity. This in turn results in different knee excursion values collected by both the systems varying by few degrees. In addition to this, errors due to the reconstruction of the missing markers while processing the data collected from Vicon system and positioning of markers with respect to each other can contribute to such discrepancies. Though there is a difference of 4° between the knee excursion values obtained from both the systems, the pattern of the trace obtained from both the systems are identical and the maximum knee flexion angles obtained from both the systems are similar with a very little variation of 1°. Such small variations have been reported previously by Rowe et al.., 2001. A similar validation study has been carried out by Morlock et al., 2000; where the researchers validated the flexible electrogoniometers against a 6 camera motion analysis system with a single participant during various work

loading tasks and reported the accuracy of the goniometers to be higher (1.5°) than the motion analysis system.

In summary, despite some little variations SUDALS was able to zero, record and transmit the data collected during all these activities from all the 10 subjects without technical error and with accurate and reproducible data. It can be concluded that, the system is stable to measure and reproduce knee flexion/extension kinematic data accurately and reliably during various ADL's in a dynamic environment. This in turn fulfils the objectives of this pilot study. However, to further validate the SUDALS system, another experiment involving a comparison of SUDALS against the commercially available data logging system used in conjunction with flexible electrogoniometer was carried out and this is explained in the next chapter.

Chapter 6 – Testing SUDALS for reliability against a Commercial available Data logger

The Biometrics Data log (W4X8) is a multi-channel portable general purpose programmable data acquisition system that allows a user to collect both analogue and digital data from a wide range of sensors such as goniometers, torsiometers, surface EMG's, accelerometers, event markers, myometers, hand dynamometers and pinchmeters. Currently, this data logging system developed by Biometrics Ltd is being used in conjunction with flexible electrogoniometers and hence it was decided to test the newly developed system against this commercial system during various ADL's such as walking, getting in and out of a chair (as a single activity), stair ascending/descending and deep squatting. This will be useful in understanding the reliability and accuracy of SUDALS and would also help to study the usability of the developed system in different applications compared to the comparative commercial system. The methodology adopted in this experiment, together with the results and outcomes of this experiment are explained in detail in this chapter.

6.1 Methods

This experiment was carried out with 10 young normal healthy subjects (age range 24 to 30 years) who volunteered for this study. The subjects were recruited within the Bioengineering Unit of University of Strathclyde and their consent to participate in the study was obtained by personally handing over the information sheet and the consent forms (electronic Appendix 6) a week or two in advance to the actual commencement of the experiment. All the details such as the exclusion criteria, the date, time and place of testing were outlined in the information sheet given to the volunteers. A risk assessment of this protocol was carried out by the respective committee within the Bioengineering unit of University of Strathclyde and the ethical approval was granted by the University of Strathclyde Bioengineering Unit Ethics Committee. A copy of the ethical approval obtained for this study is included in the electronics appendix 8 of this thesis.

All the testing took place in the Biomechanics lab in the Bioengineering Unit of the University of Strathclyde. The data pertaining to the flexion/extension of the knee of the

subjects was collected via the body mounted transducer (flexible electrogoniometer) interfaced with SUDALS and the devices were attached to the participants as explained in the routine deployment in section 2.4 and 2.2.4. All the 10 subjects were asked to perform the following 5 activities at their selected speed –

1. 7m Level walking
2. Getting in and out of a standard Chair (410mm from floor to seat)
3. Ascending 4 step flight of stairs - 180-190mm riser, 270-300mm tread.
4. Descending 4 step flight of stairs - 180-190mm riser, 270-300mm tread.
5. Deep squatting

The procedure of zeroing the transducers and recording the data using SUDALS was as same as the procedure adopted for the pilot study in chapter 5. However, in this experiment since the activity of getting in and out of the chair was combined as a single activity, the system recorded and transmitted 6 recordings (The activity corresponding to level walking was recorded as two individual recordings similar to the pilot study explained in chapter 5). Start and stop commands were given at the beginning and completion of each task and the event marking was taken into account by the FSR's attached to the toes and heels of each subject and this information was used to select the start and end of the gait cycles of the activities recorded by the system. This procedure was repeated a further two times to examine repeatability and to make sure that there was enough data corresponding to each activity from each participant. Following this, all sensors were left in place, but the SUDALS was replaced with the Biometrics data logging system and the above procedure of zeroing the transducers and collecting data pertaining to the flexion/extension of the knee during ADL's (similar to using the SUDALS) was carried out using the commercially available system. Each and every activity was recorded individually and the recordings corresponding to each trial was saved in the memory card of the commercially available system.

Later, this data was downloaded to the PC using memory card reader and the data were automatically stored as invidual '.txt' files, which were then converted to MS-excel files for data analysis.

6.2 Results

The data collected and transmitted using SUDALS during these ADL's were then filtered at the PC end using the digital filter as explained in chapter 5 and the data were further analyzed for maximum / minimum knee flexion/extension angles and for knee excursion during all the ADL's. This procedure was carried out for both the left and right knees and was then averaged to provide the group mean. Similar to the pilot study, the data collected using SUDALS from all the subjects was time normalized using the interpolation programme, which normalized each participant's data segment for both knees for each function into 100 % points giving an angle versus percent of the movement trace. Similarly, the data collected using the Biometrics data logger were also filtered using the same filter used for the SUDALS at the PC end and were then analyzed for maximum / minimum knee flexion/extension angles and for knee excursion during all the ADL's (Figures 6.1 to 6.10) and were time normalized using the same interpolation programme and each participant's data segment for both knees for each function was plotted as an angle versus percent of the movement trace.

The standard cycles averaged over 3 (repeat trials) time normalized gait cycles of all the participants obtained by SUDALS and Biometrics during all the 5 ADL's are shown below in figure 6.11 to 6.20 and the average time normalized gait cycles of all the participants obtained by both the systems during all the 5 ADL's are shown below in figure 6.21 to 6.25. Since, the repeat trial data obtained from both the knees were similar, only the data pertaining to the maximum/minimum right knee flexion/extension angles together with the right knee excursion values of the repeat trials of all the participants during all the ADL's from both the data acquisition systems are shown in figure 6.1 to 6.10 and the absolute agreement of the results obtained from both the systems during various ADL's are represented in terms of intraclass correlation coefficient (ICC) values calculated using SPSS for windows (version 11) as shown in tables 6.1 to 6.5.

Also, the measurement error between both the systems in terms of maximum/minimum knee flexion angles and knee excursion angles for both the knees was obtained using standard error of measurement (SEM) calculated using the relation, $SEM = SD \times \sqrt{(1-r)}$ (Harvill - A Technical Note); where SD is the standard deviation of

the data obtained during a specific ADL, from both the systems from each subject and r corresponds to the reliability coefficient. The results corresponding to the SEM is shown in table 6.6a and 6.6b.

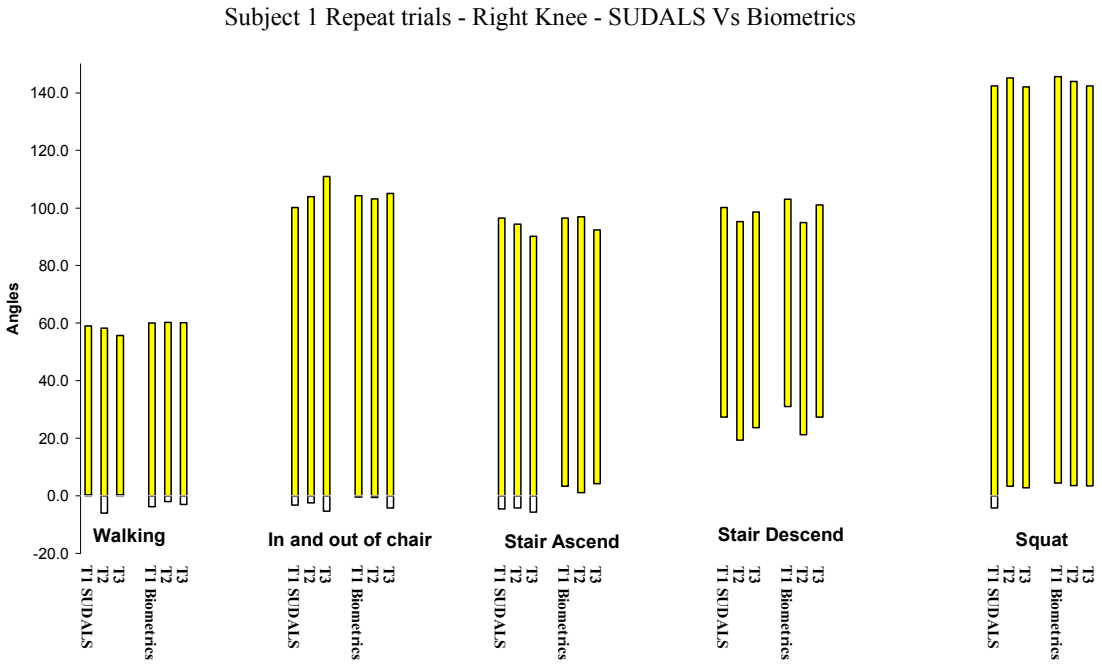


Figure 6.1: Repeat trials of Subject 1: Maximum, Minimum and Excursion of Right Knee obtained from both systems

Note: All the Y axis – Angles reported in this chapter are in Degrees.

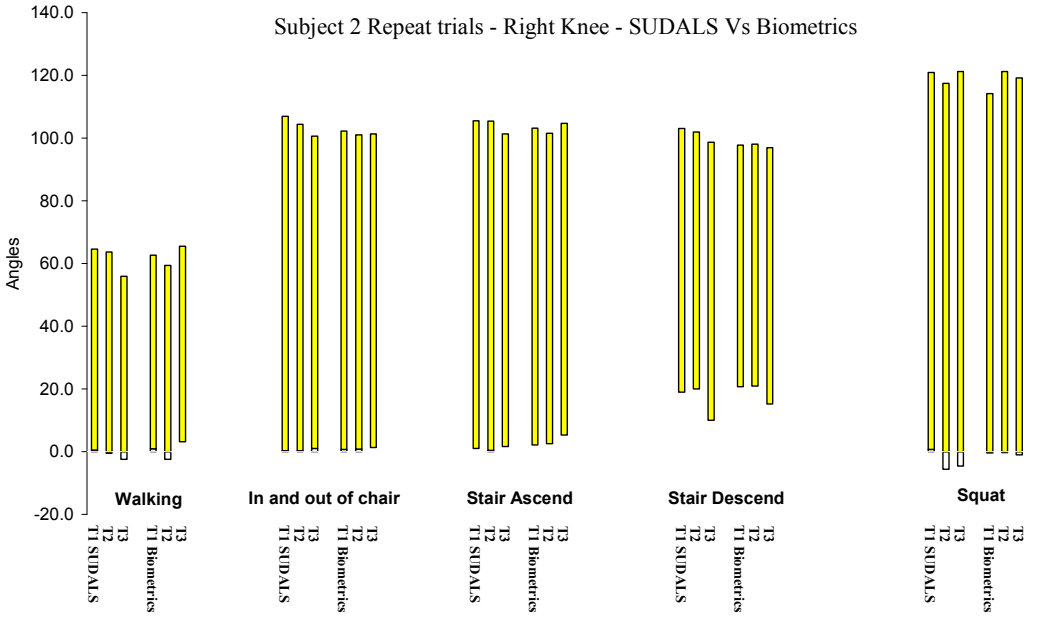


Figure 6.2: Repeat trials of Subject 2: Maximum, Minimum and Excursion of Right Knee obtained from both systems

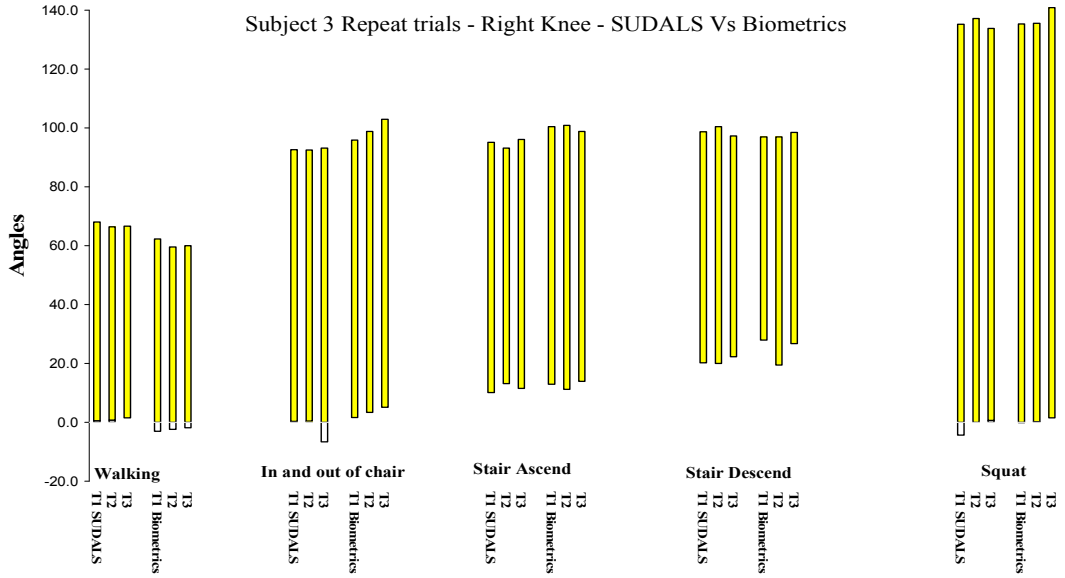


Figure 6.3: Repeat trials of Subject 3: Maximum, Minimum and Excursion of Right Knee obtained from both systems

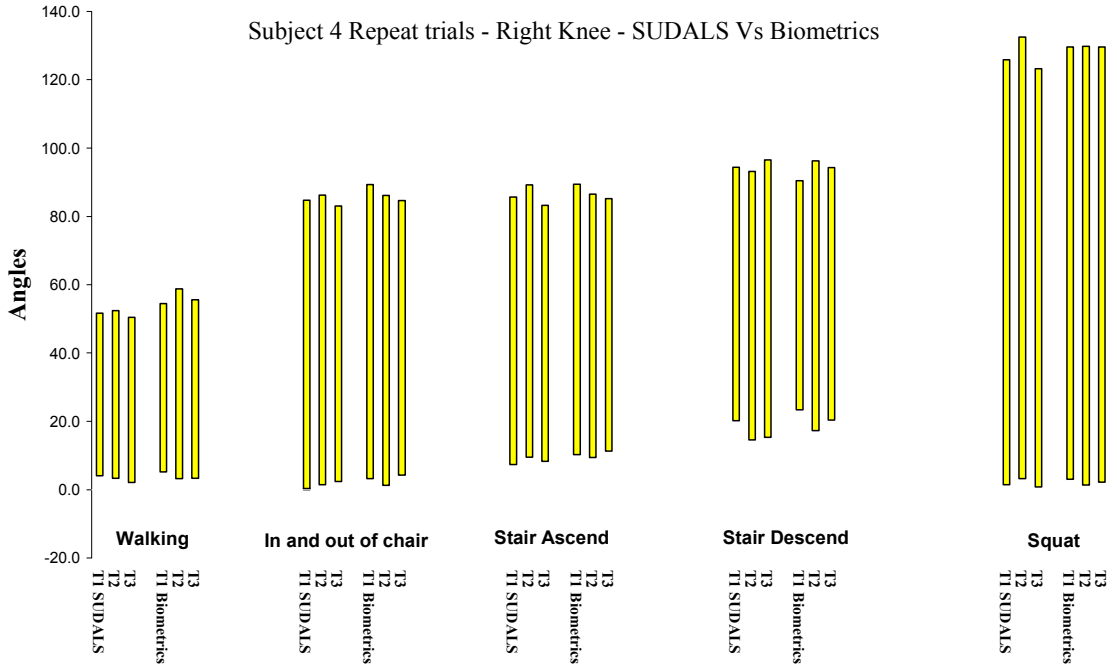


Figure 6.4: Repeat trials of Subject 4: Maximum, Minimum and Excursion of Right Knee obtained from both systems

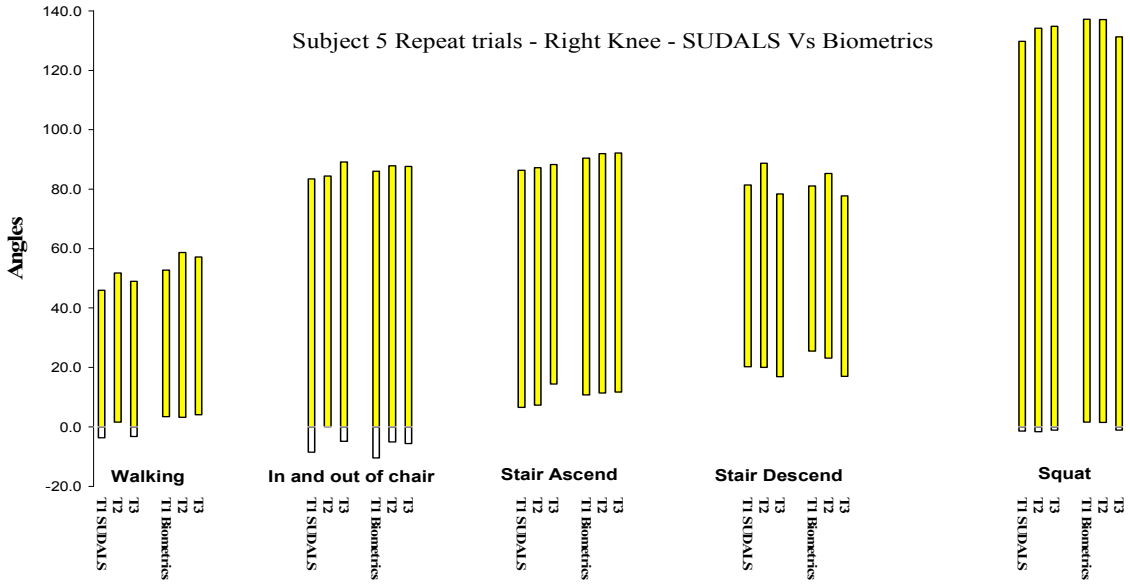


Figure 6.5: Repeat trials of Subject 5: Maximum, Minimum and Excursion of Right Knee obtained from both systems

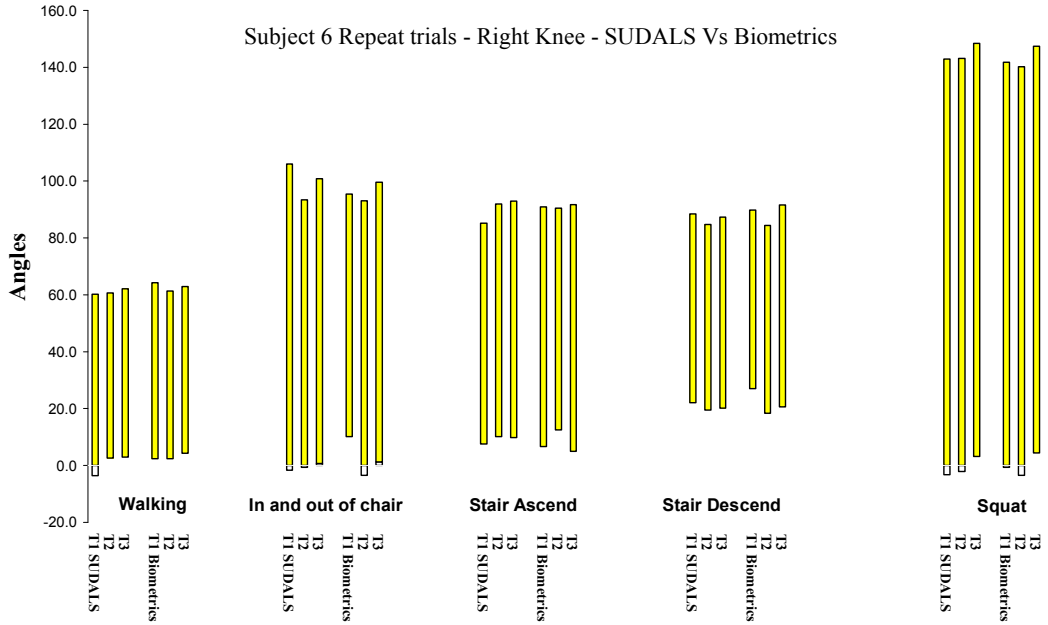


Figure 6.6: Repeat trials of Subject 7: Maximum, Minimum and Excursion of Right Knee obtained from both systems

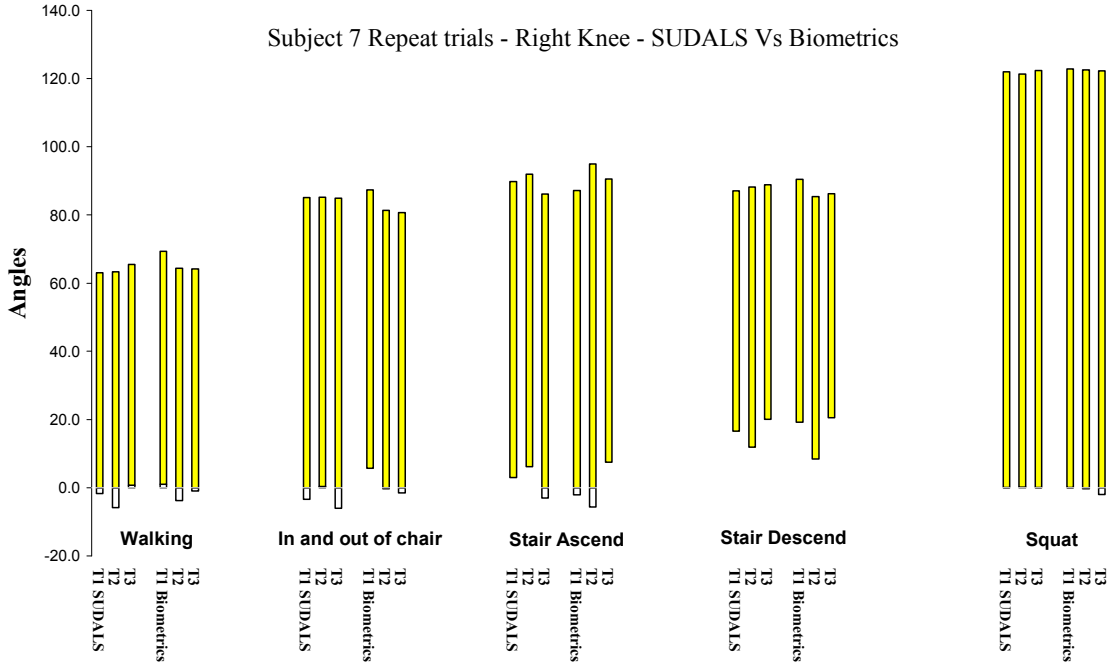


Figure 6.7: Repeat trials of Subject 7: Maximum, Minimum and Excursion of Right Knee obtained from both systems

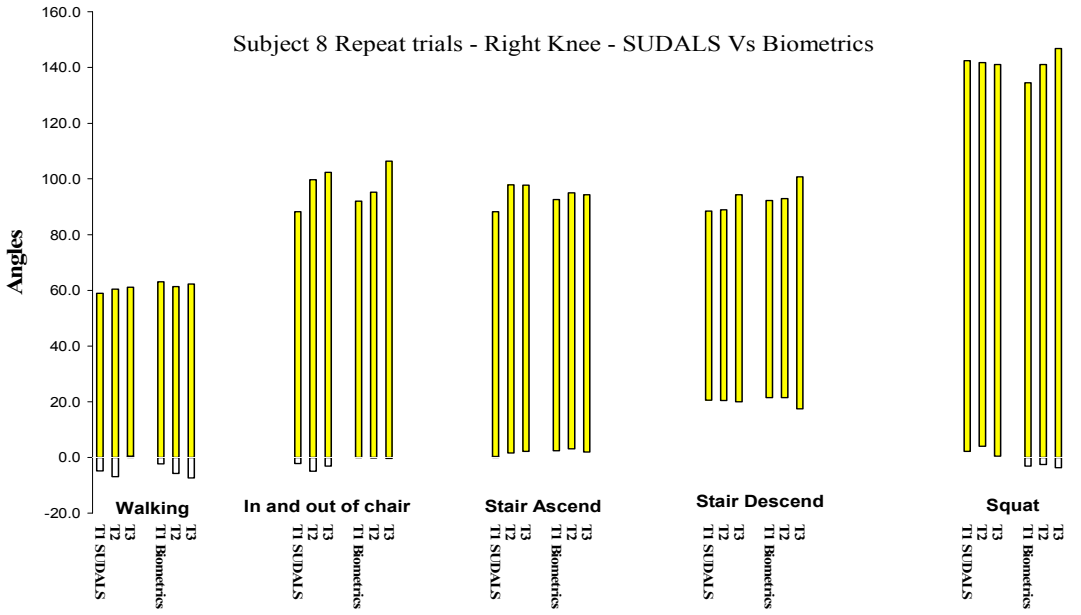


Figure 6.8: Repeat trials of Subject 8: Maximum, Minimum and Excursion of Right Knee obtained from both systems

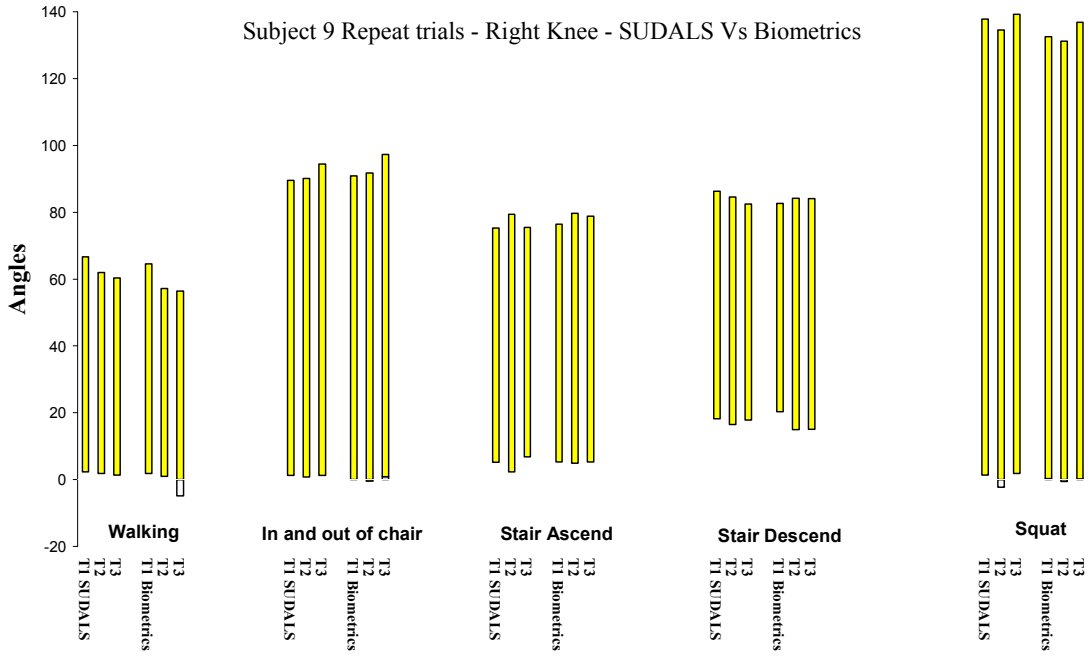


Figure 6.9: Repeat trials of Subject 9: Maximum, Minimum and Excursion of Right Knee obtained from both systems

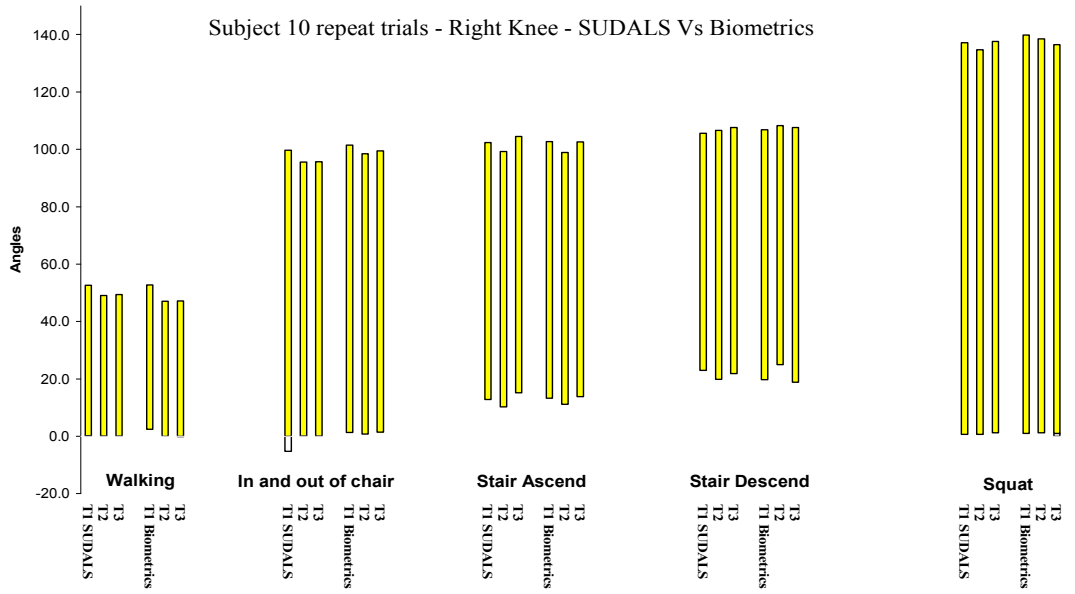


Figure 6.10: Repeat trials of Subject 10: Maximum, Minimum and Excursion of Right Knee obtained from both systems

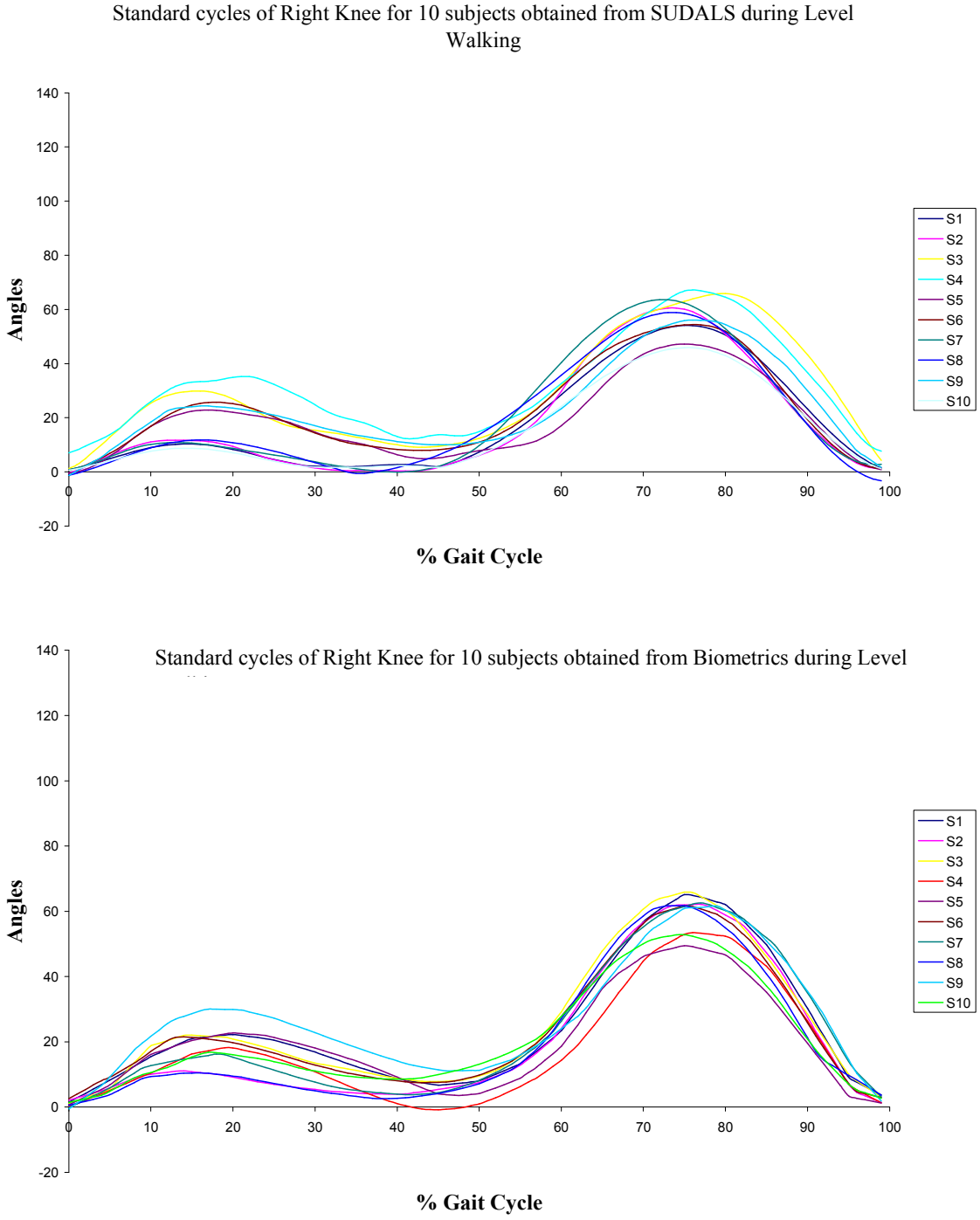
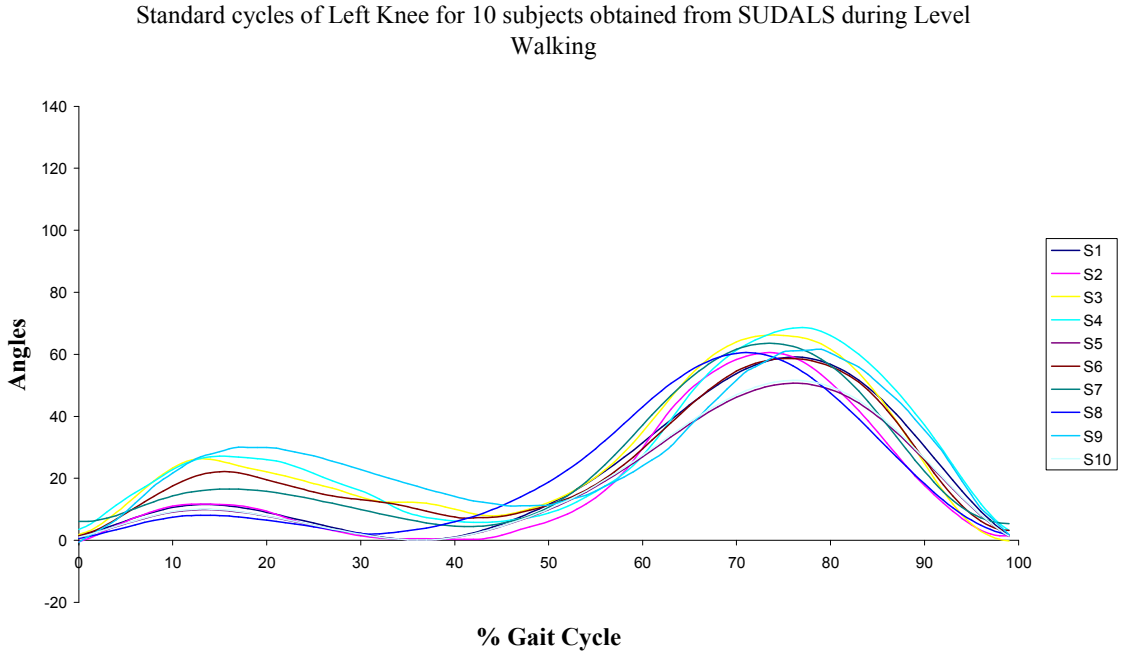


Figure 6.11 – Standard Cycles: Right Knee during level, free speed walking for 10 subjects as measured by the SUDALS and Biometrics.



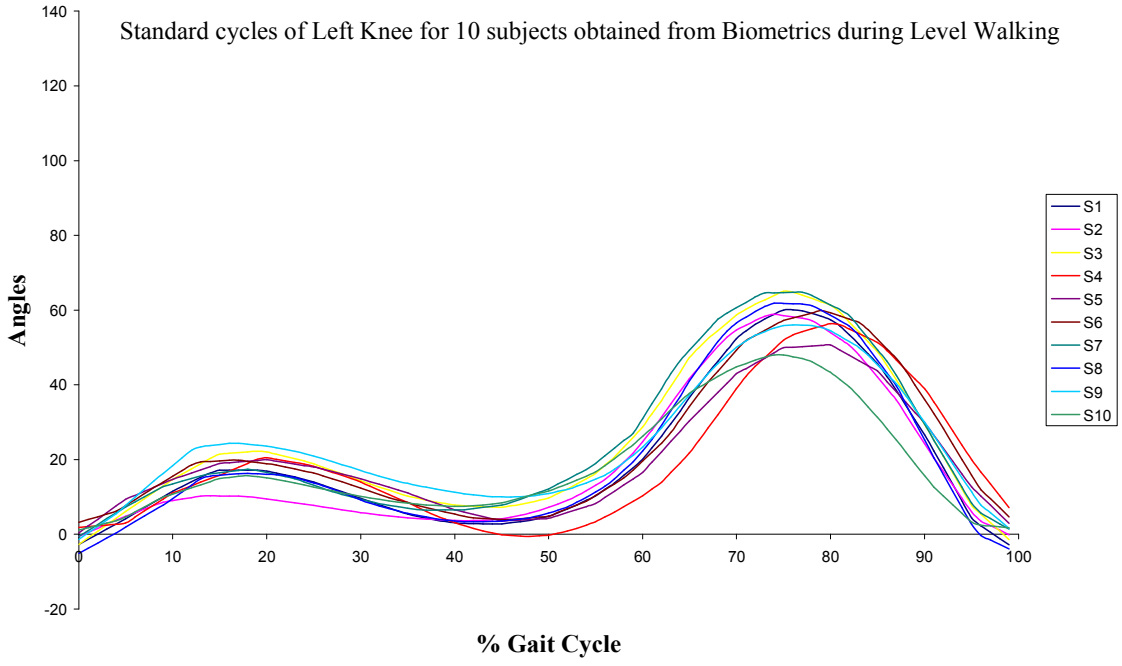


Figure 6.12 – Standard Cycles: left Knee during level, free speed walking for 10 subjects as measured by the SUDALS and Biometrics.

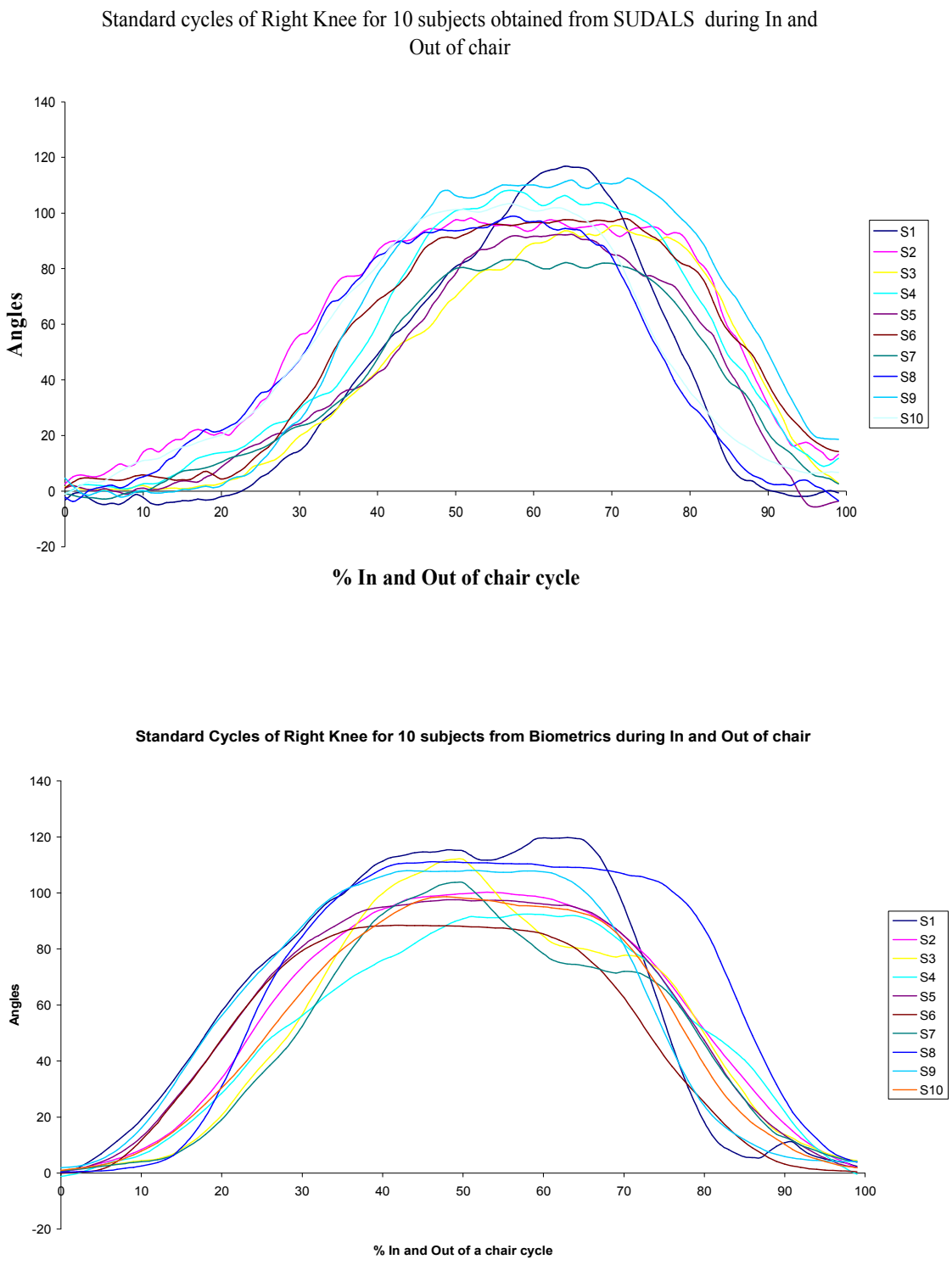


Figure 6.13 – Standard Cycles: Right Knee during getting in and out of chair for 10 subjects as measured by the SUDALS and Biometrics.

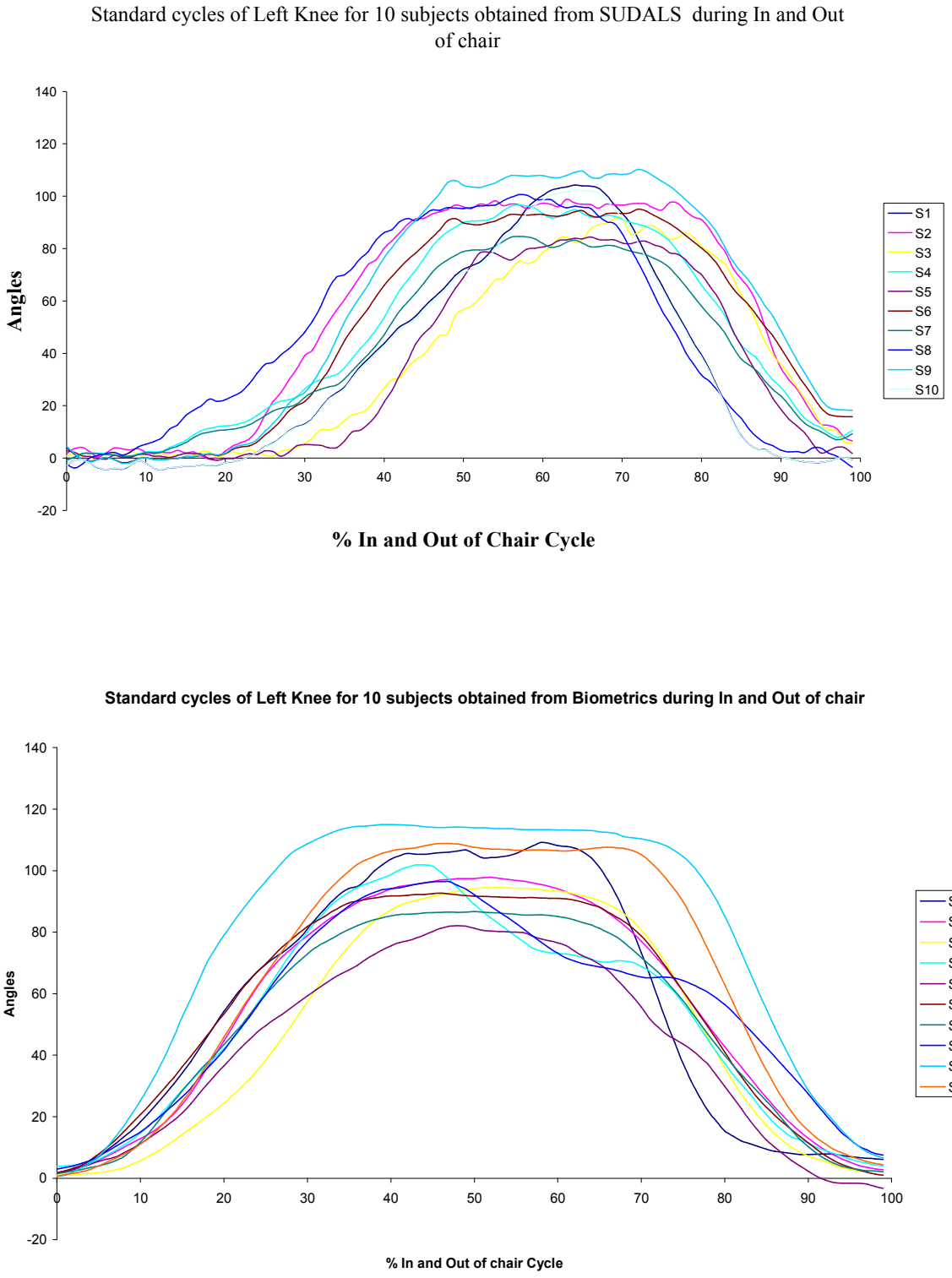


Figure 6.14 – Standard Cycles: Left Knee during getting in and out of chair for 10 subjects as measured by the SUDALS and Biometrics.

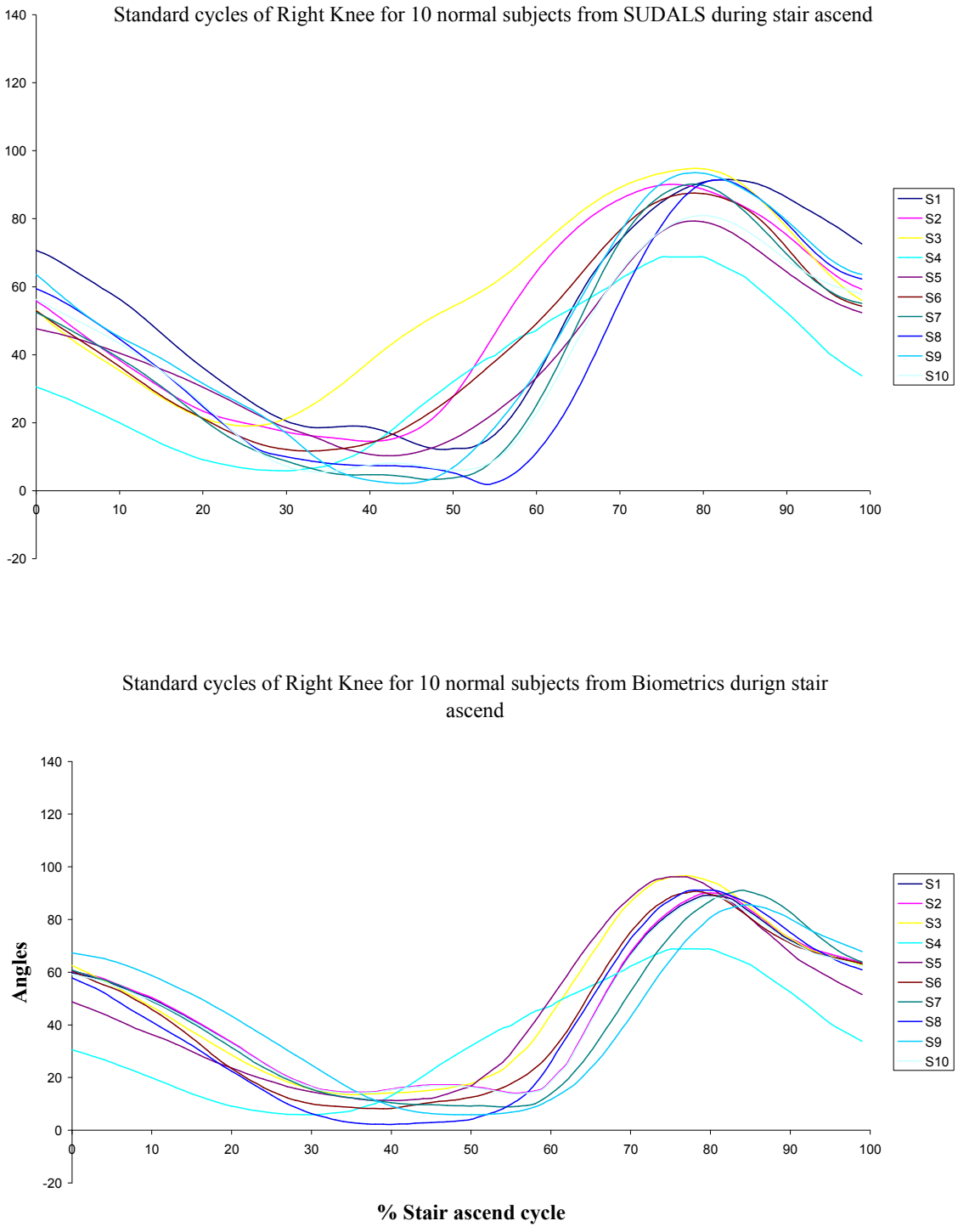
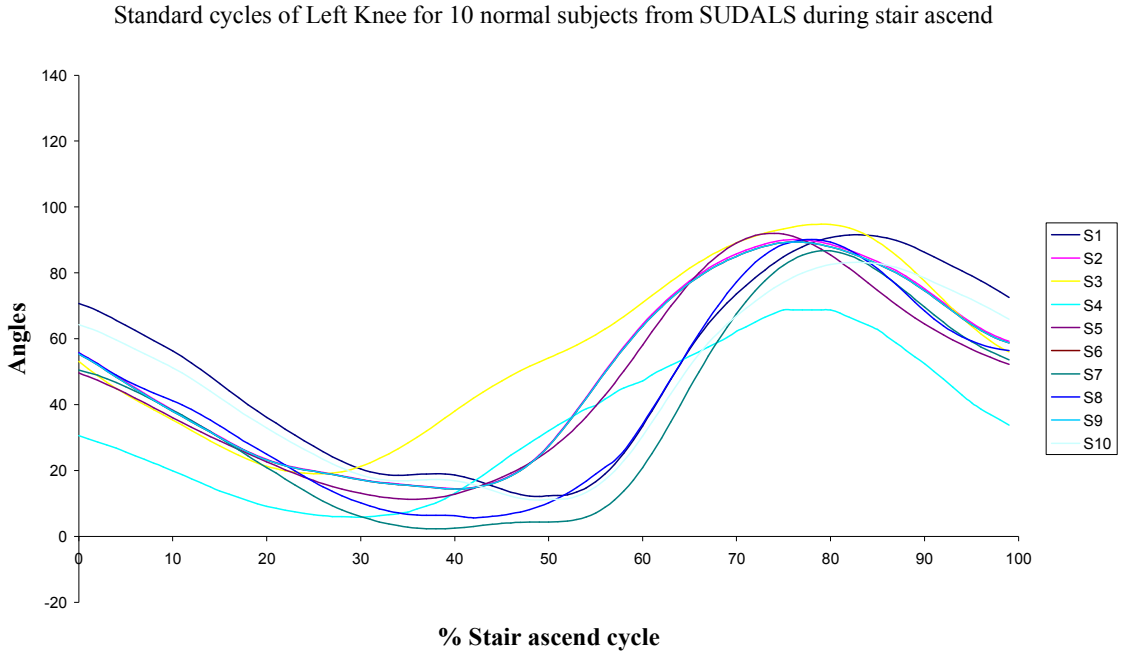


Figure 6.15 – Standard Cycles: Right Knee during Stair ascend for 10 subjects as measured by the SUDALS and Biometrics.



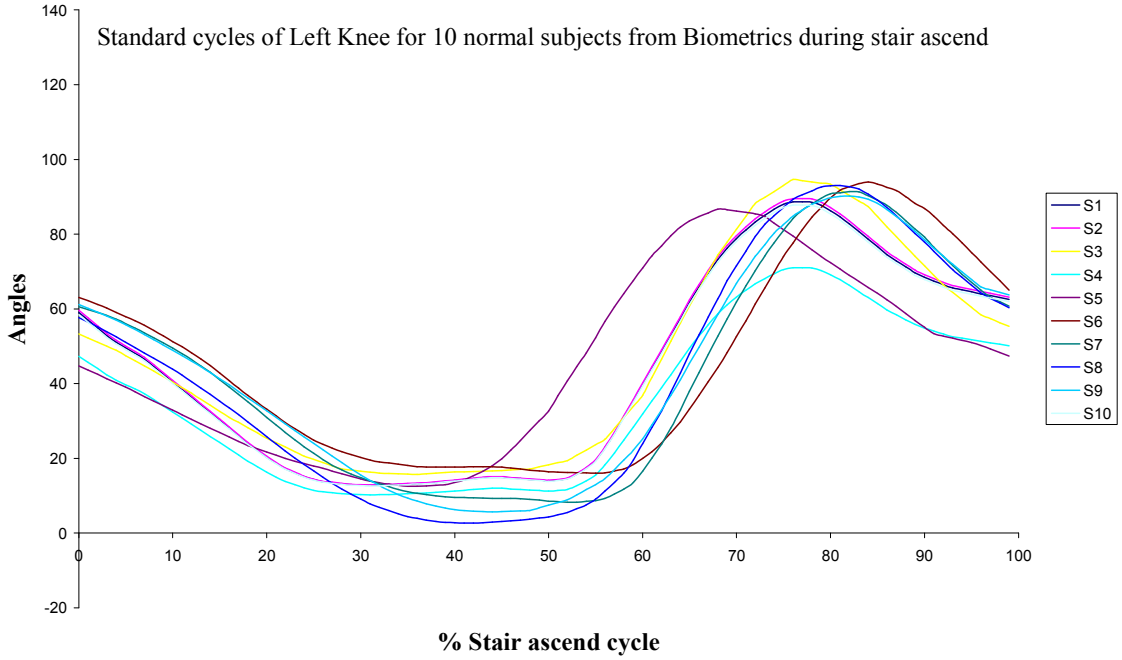


Figure 6.16 – Standard Cycles: Left Knee during Stair ascend for 10 subjects as measured by the SUDALS and Biometrics.

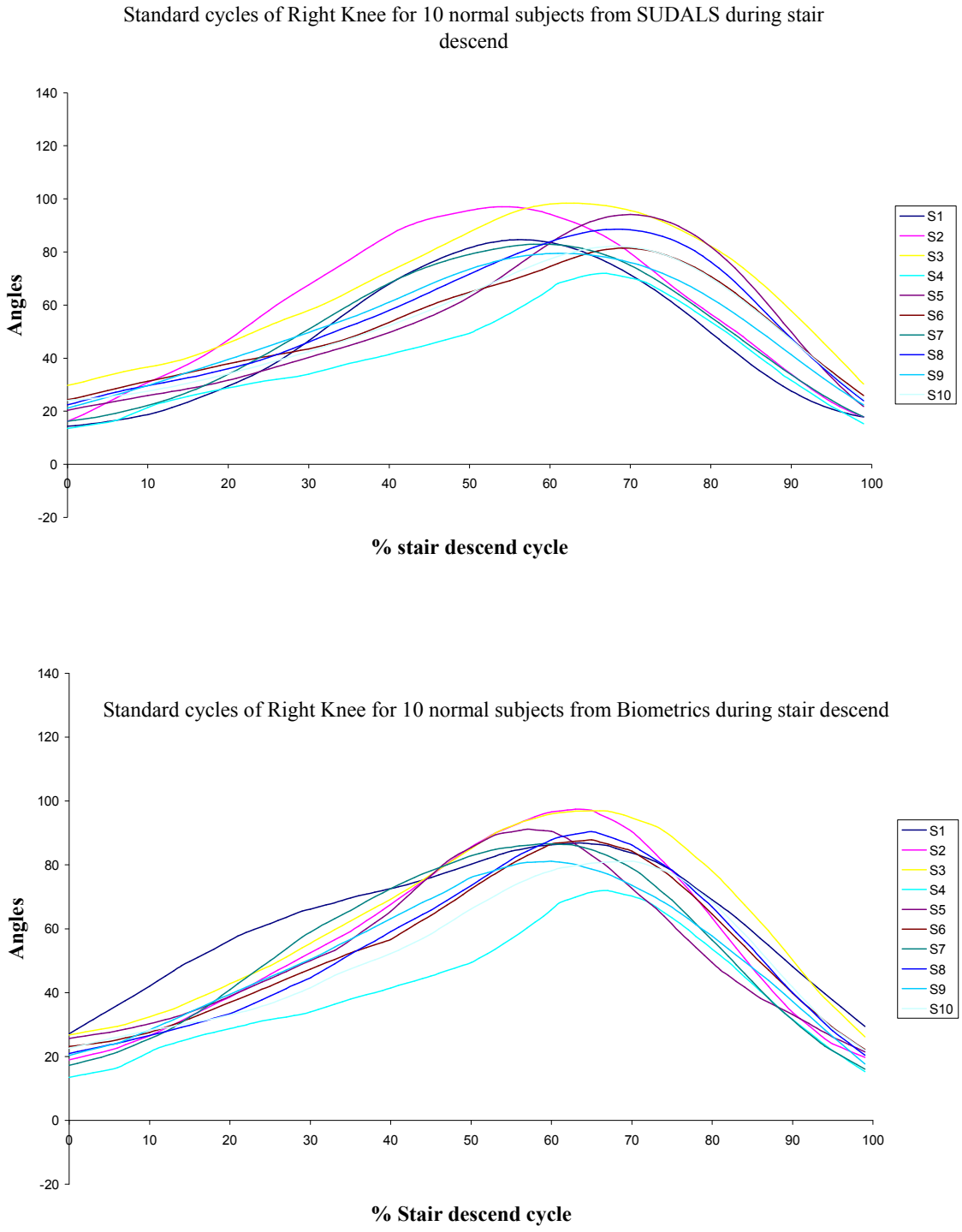


Figure 6.17 – Standard Cycles: Right Knee during Stair descend for 10 subjects as measured by the SUDALS and Biometrics.

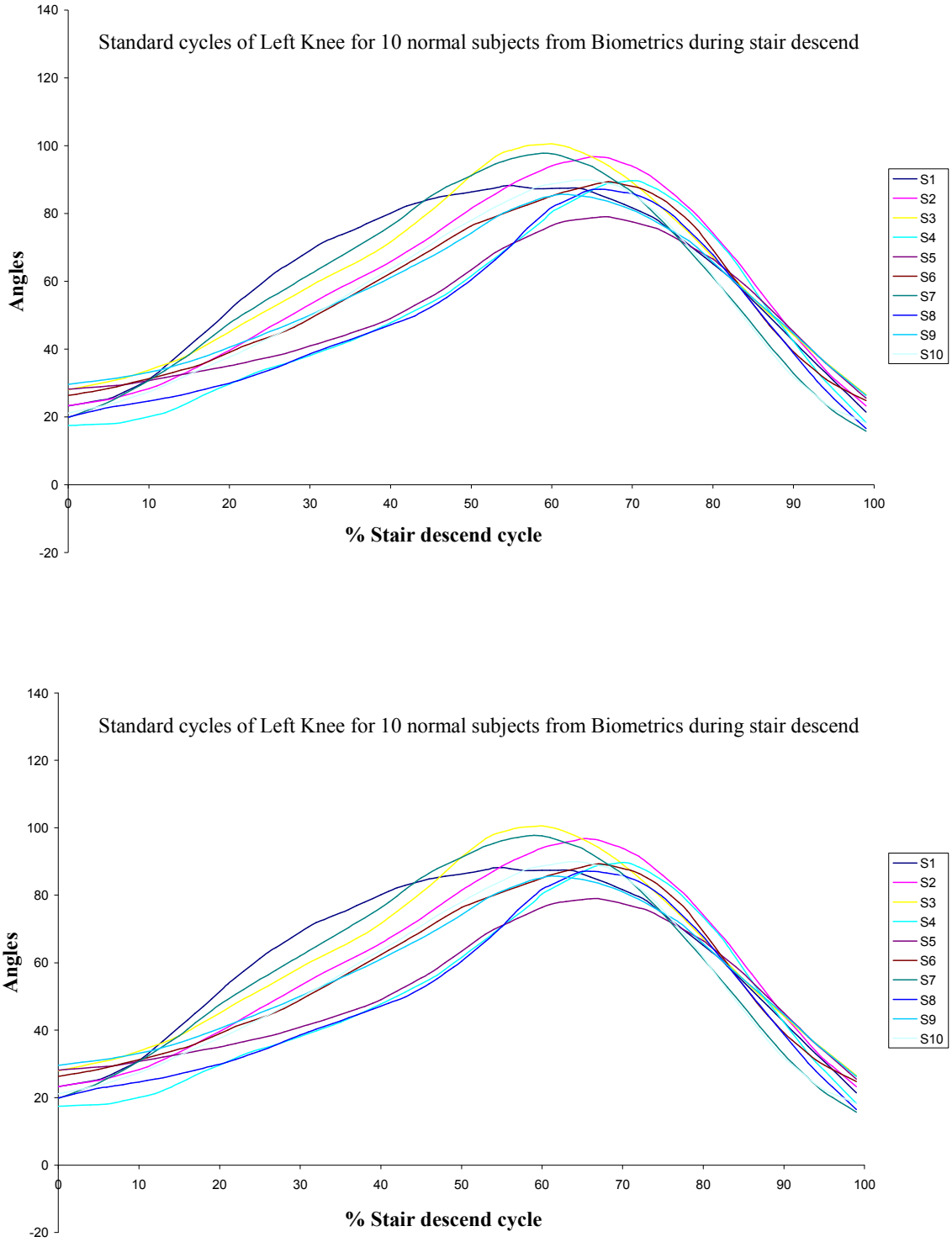
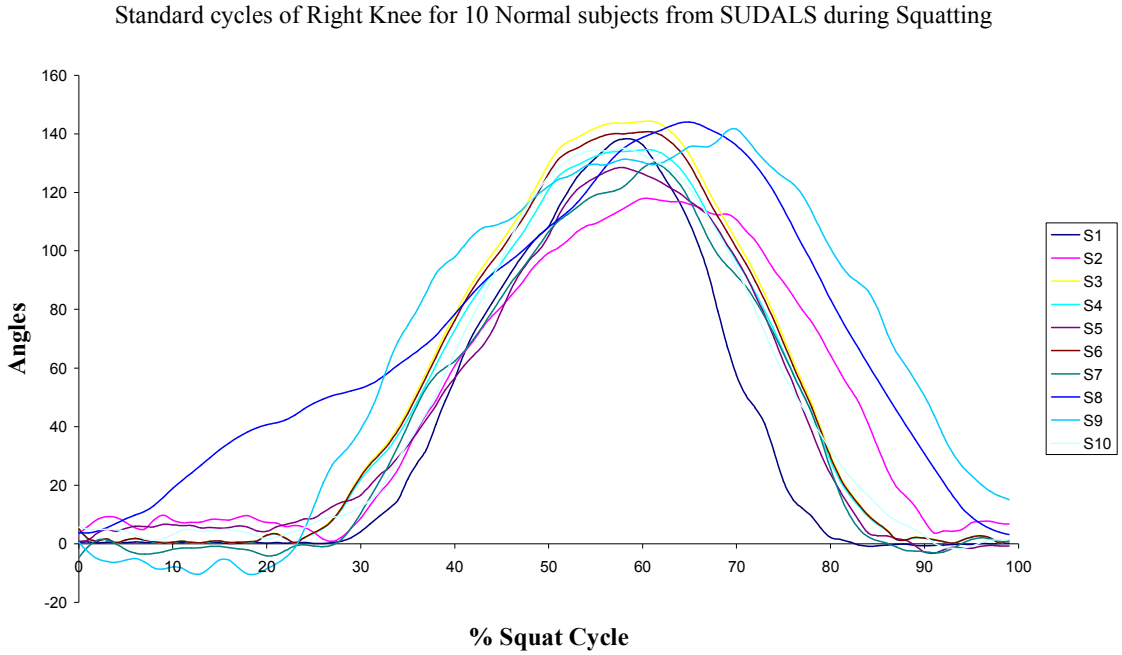


Figure 6.18 – Standard Cycles: Left Knee during Stair descend for 10 subjects as measured by the SUDALS and Biometrics.



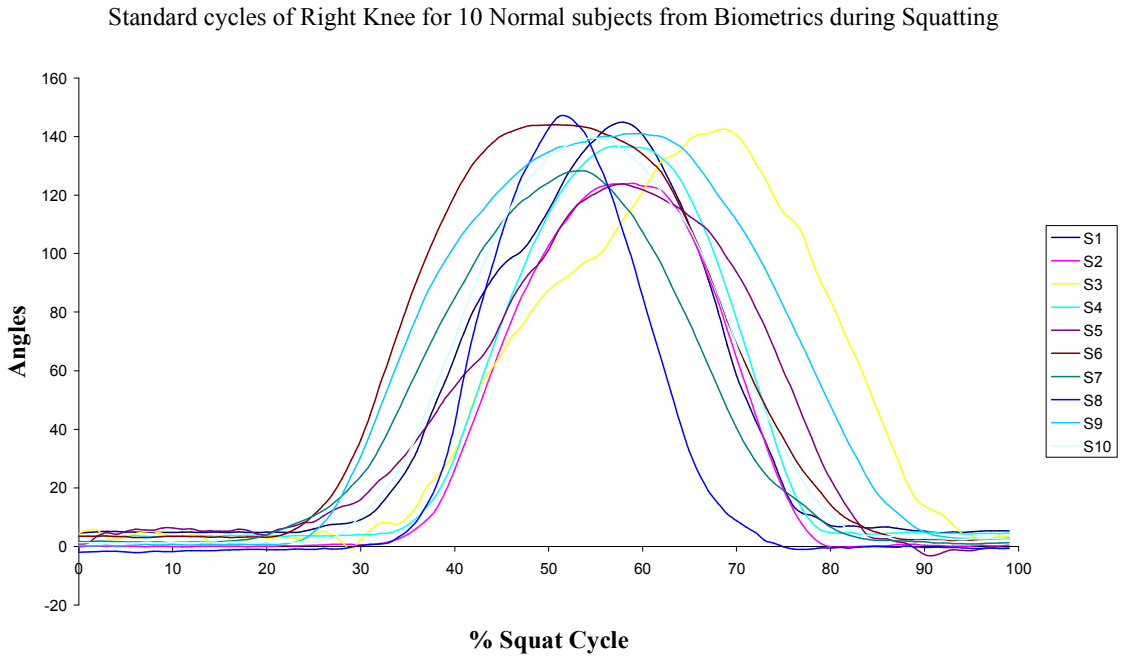
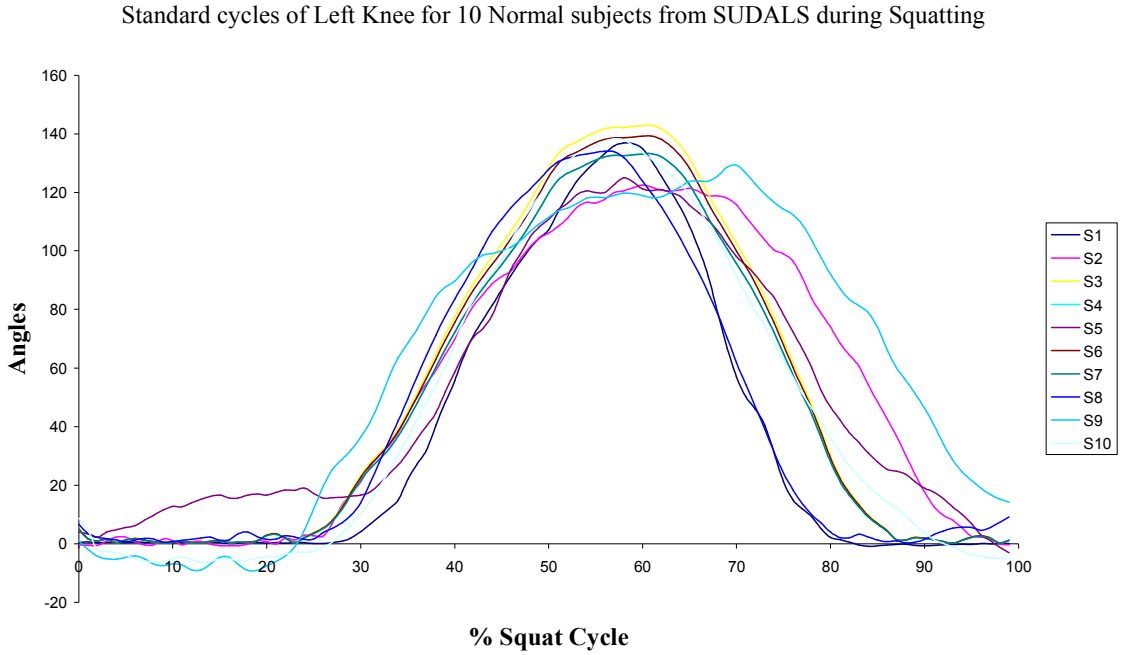


Figure 6.19 – Standard Cycles: Right Knee during squatting for 10 subjects as measured by the SUDALS and Biometrics.



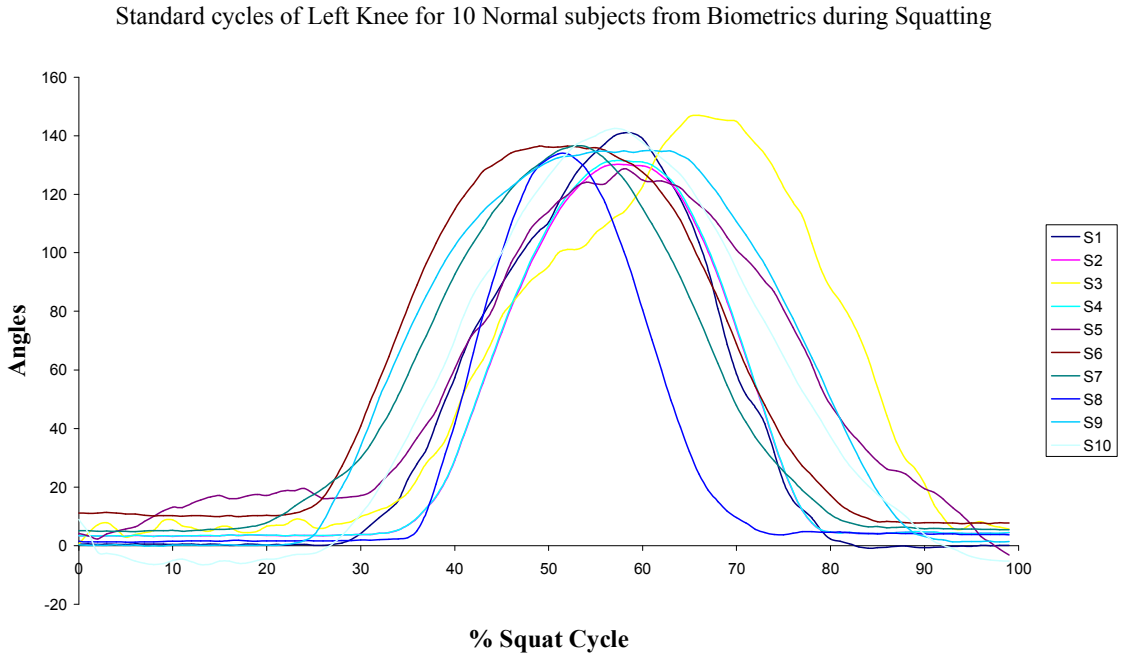
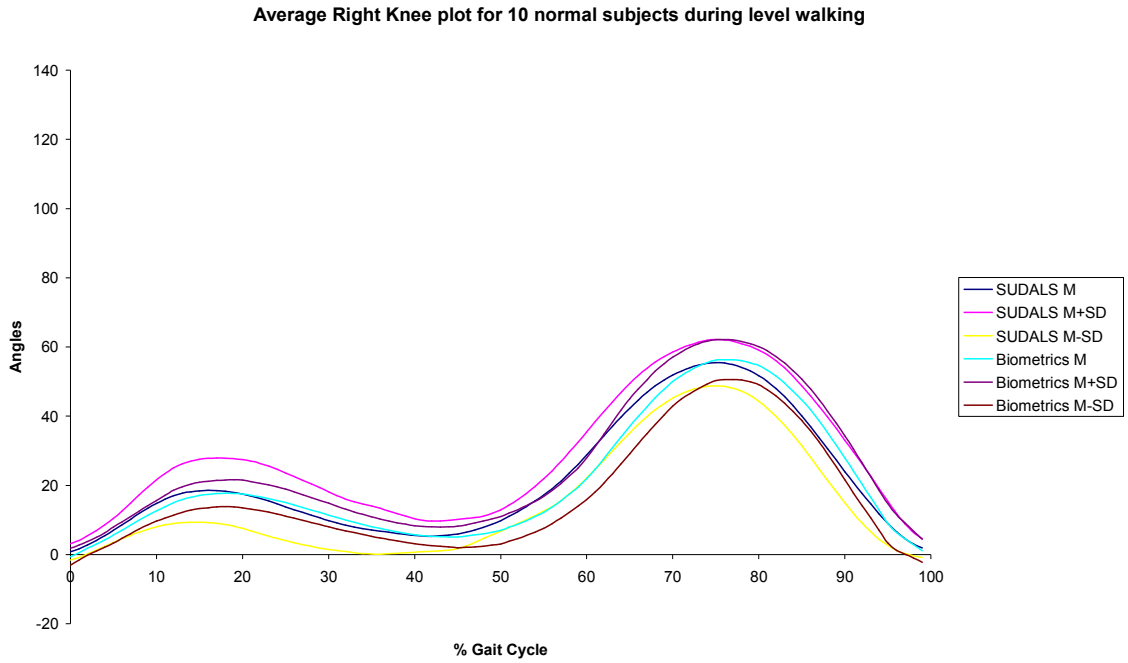


Figure 6.20 – Standard Cycles: Left Knee during squatting for 10 subjects as measured by the SUDALS and Biometrics.



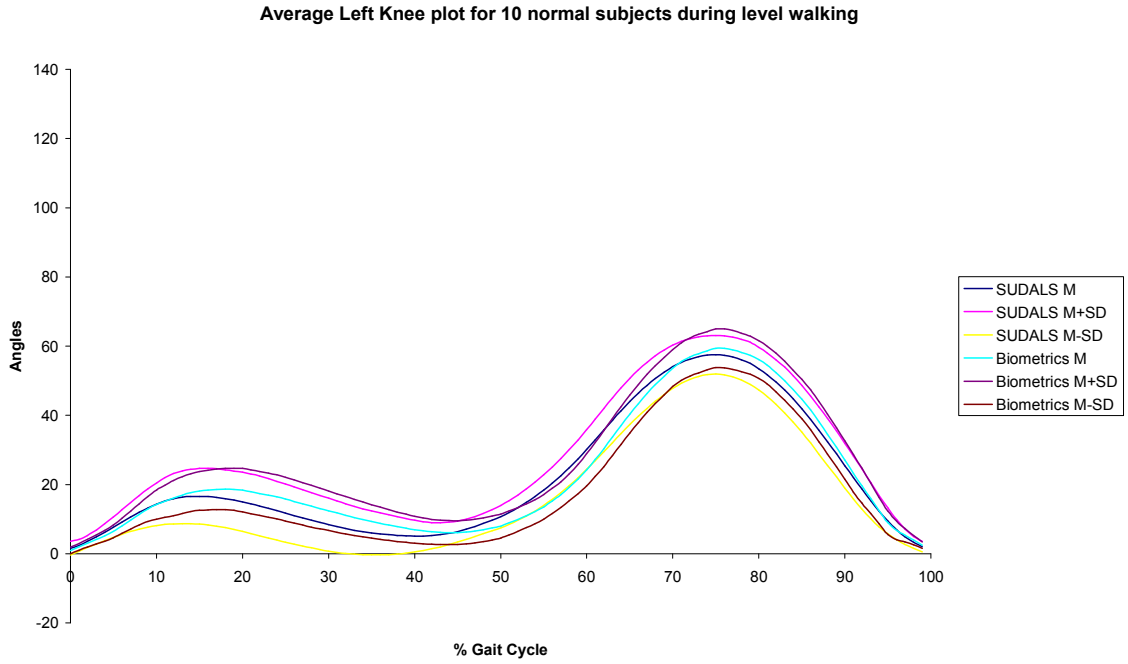


Figure 6.21 – Average Cycles: Right and left Knee during level, free speed walking for 10 subjects as measured by the SUDALS and Biometrics.

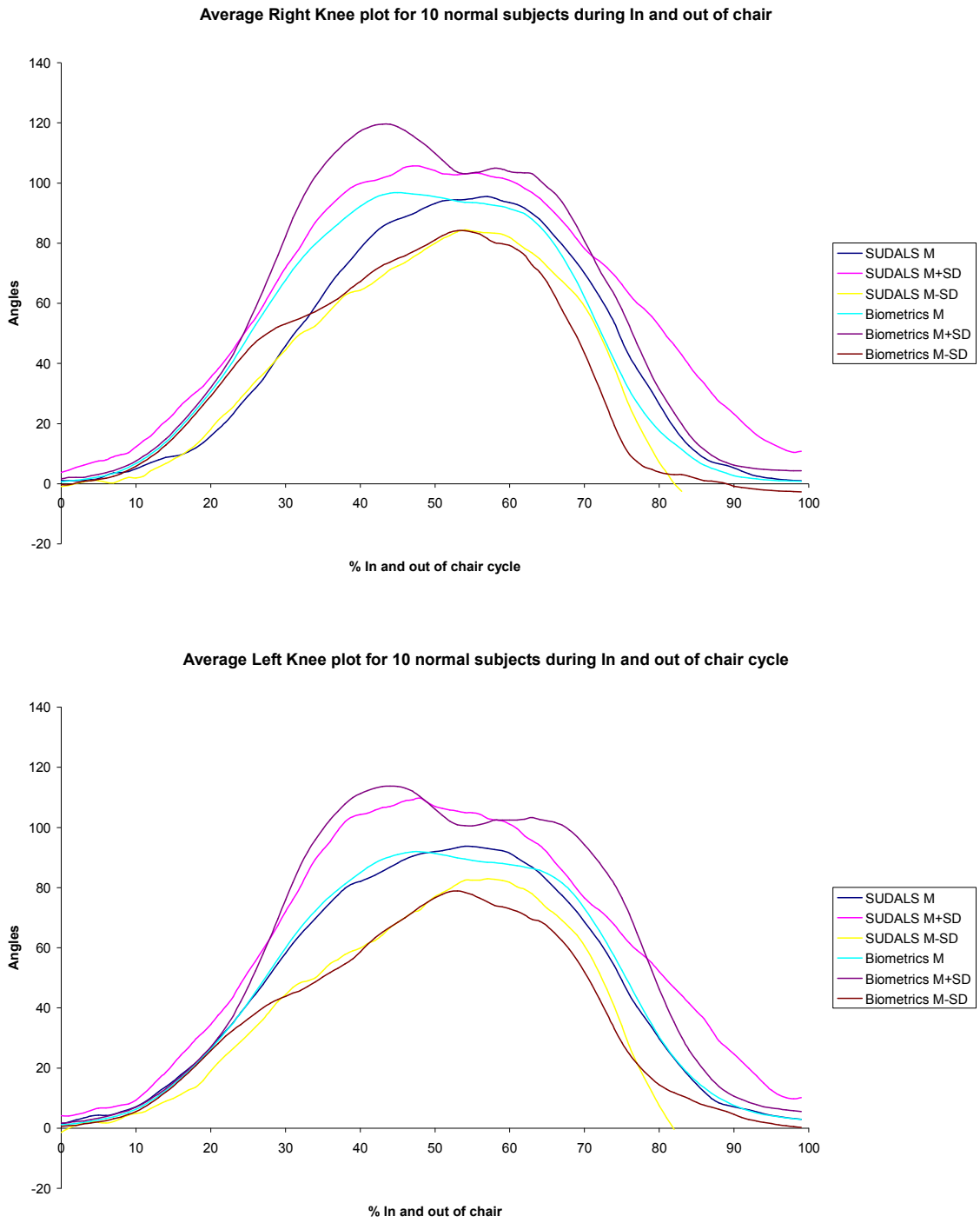


Figure 6.22 – Average Cycles: Right and left Knee during getting in and out of chair for 10 subjects as measured by the SUDALS and Biometrics.

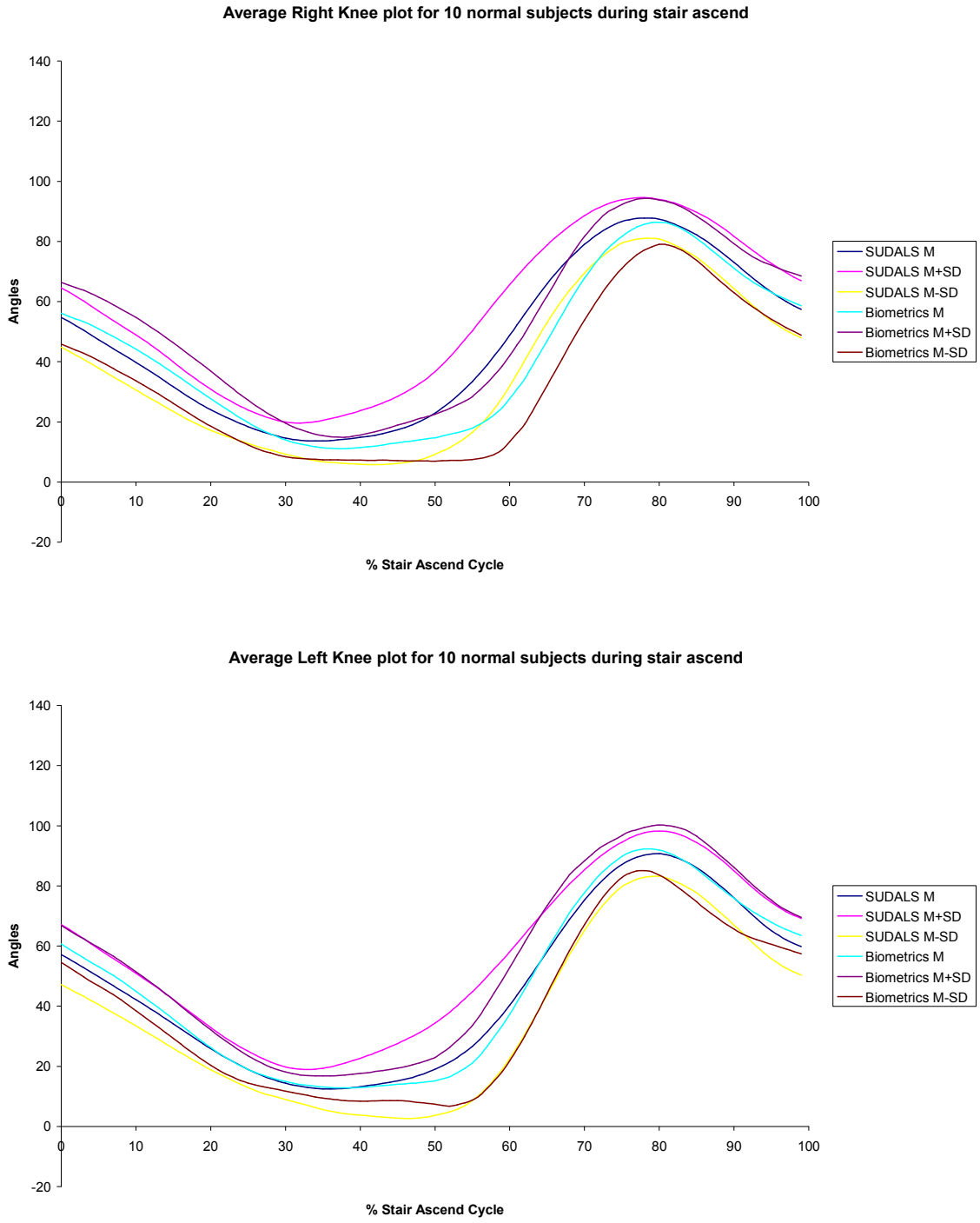


Figure 6.23 – Average Cycles: Right and left Knee during stair ascend for 10 subjects as measured by the SUDALS and Biometrics.

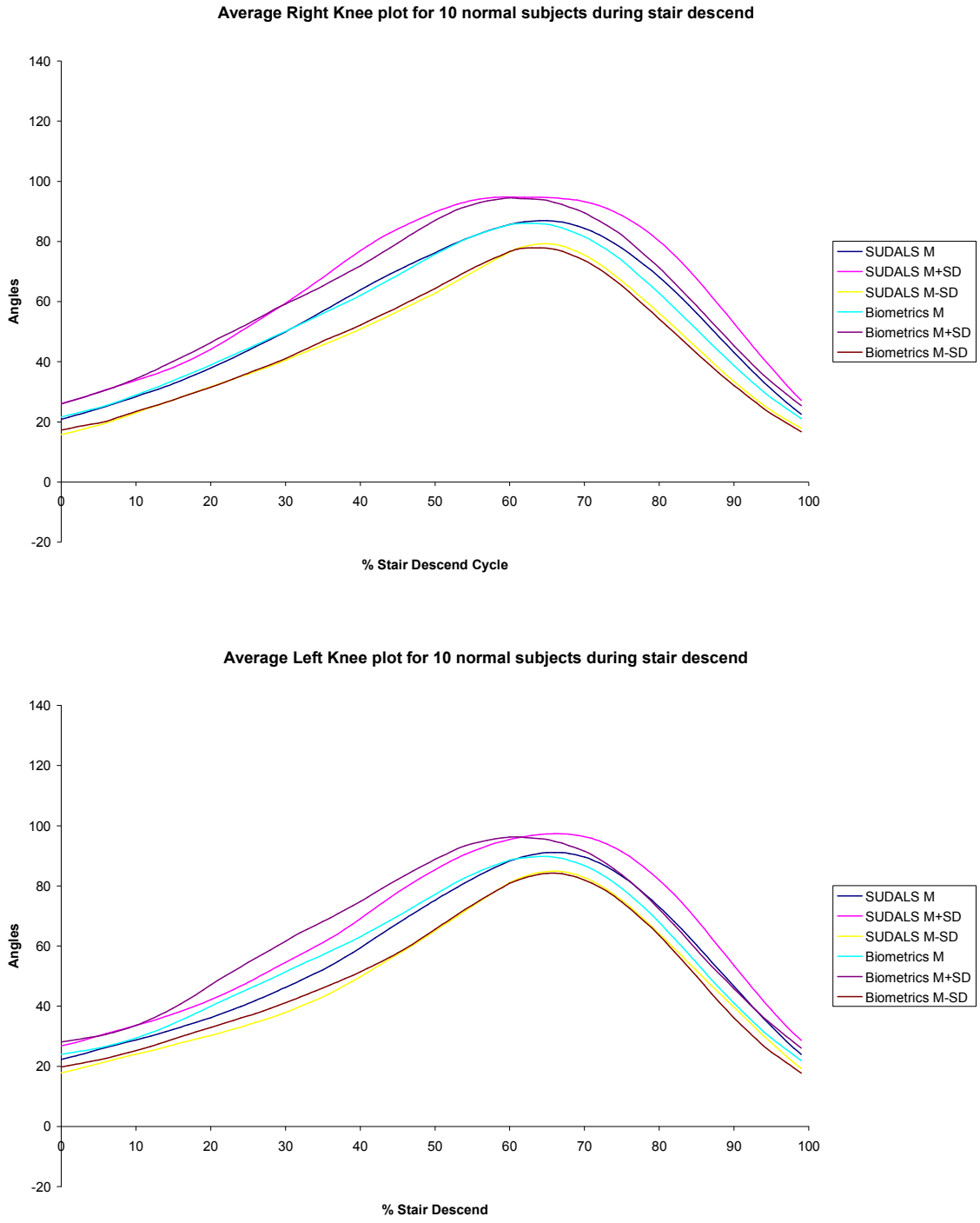


Figure 6.24 – Average Cycles: Right and left Knee during stair descend for 10 subjects as measured by the SUDALS and Biometrics.

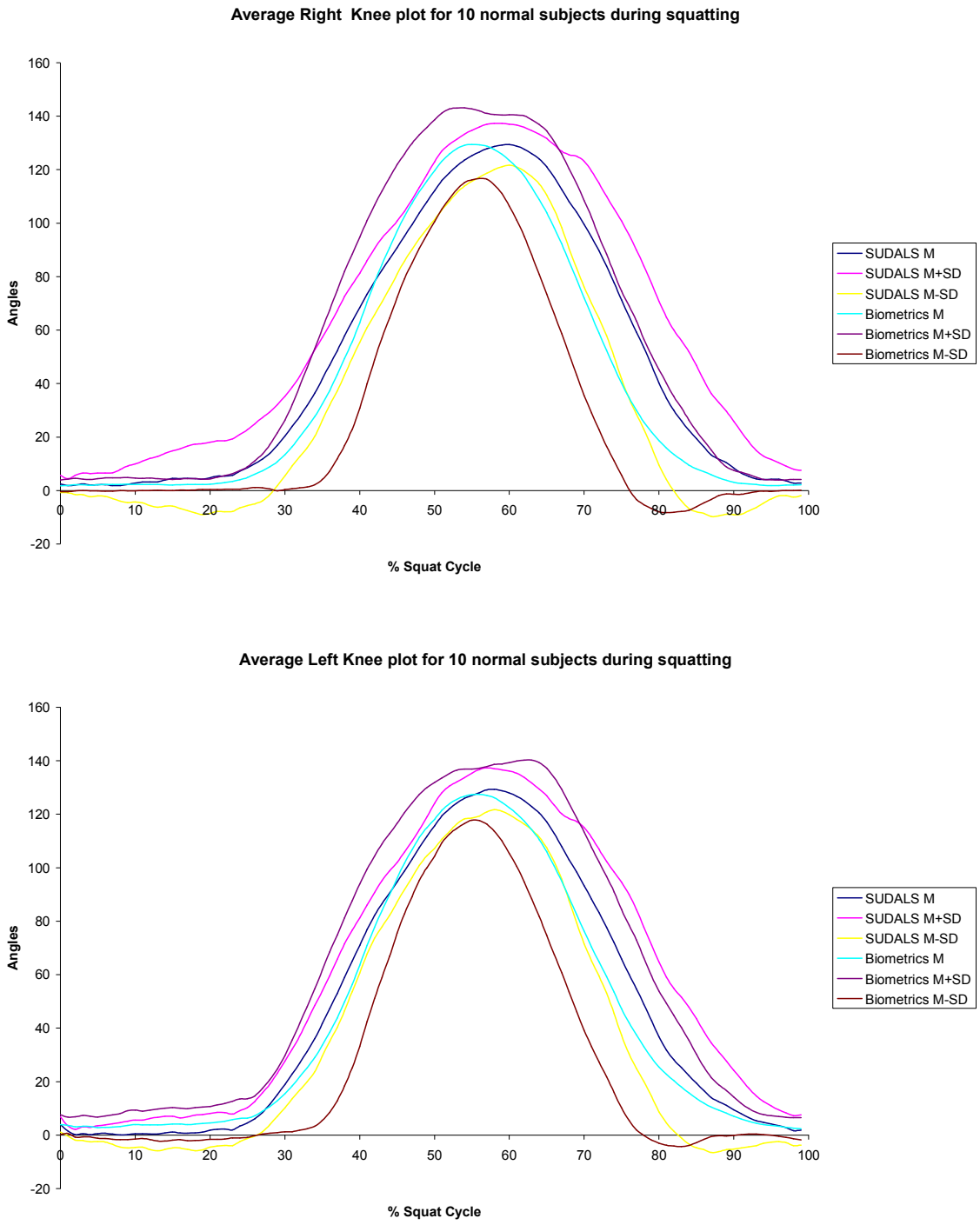


Figure 6.25 – Average Cycles: Right and left Knee during squatting for 10 subjects as measured by the SUDALS and Biometrics.

Results of Intra-rater reliability

Level Walking	ICC	Lower Bound 95% CI	Upper Bound 95% CI	Significance Value
Right Knee	.986	.979	.990	.00
Left Knee	.988	.982	.992	.00

Table 6.1: Reliability between two systems during Average Level Walking

Getting In and Out of Chair	ICC	Lower Bound 95% CI	Upper Bound 95% CI	Significance Value
Right Knee	.841	.724	.930	.00
Left Knee	.845	.764	.923	.00

Table 6.2: Reliability between two systems during Average Getting In and Out of Chair

Stair Ascend	ICC	Lower Bound 95% CI	Upper Bound 95% CI	Significance Value
Right Knee	.949	.895	.972	.00
Left Knee	.996	.994	.997	.00

Table 6.3: Reliability between two systems during Average Stair Ascend

Stair Descend	ICC	Lower Bound 95% CI	Upper Bound 95% CI	Significance Value
Right Knee	.993	.979	.997	.00
Left Knee	.987	.981	.991	.00

Table 6.4: Reliability between two systems during Average Stair Descend

Squatting	ICC	Lower Bound 95% CI	Upper Bound 95% CI	Significance Value
Right Knee	.967	.906	.984	.00
Left Knee	.987	.971	.993	.00

Table 6.5: Reliability between two systems during Average Squatting

Results of SEM

ADL's	Right knee Maximum Flexion			Left Knee Maximum Flexion			Right knee Minimum Flexion			Left Knee Minimum Flexion		
Walking	r	SD	SEM	r	SD	SEM	r	SD	SEM	r	SD	SEM
	0.88	6.3	2.1°	0.87	5.3	1.8°	0.81	2.5	1.0°	0.82	1.3	0.6°
Getting in and out of chair	0.97	9.6	1.6°	0.94	9.1	2.2°	0.85	2.4	0.9°	0.83	1.7	0.7°
Stair Ascend	0.92	7.3	1.9°	0.9	7.0	2.2°	0.80	4.4	1.9°	0.85	5.0	1.8°
Stair Descend	0.94	7.8	1.7°	0.94	6.5	1.5°	0.86	4.4	1.6°	0.86	3.9	1.5°
Squatting	0.91	8.2	2.4°	0.86	6.0	2.2°	0.84	2.3	0.9°	0.80	3.2	1.4°

Table 6.6a

ADL's	Right Knee Excursion			Left Knee Excursion		
Walking	r	SD	SEM	r	SD	SEM
	0.90	6.7	2.1°	0.86	5.1	1.9°
Getting in and out of chair	0.97	9.5	1.4°	0.91	9.3	2.7°
Stair Ascend	0.88	6.5	2.1°	0.91	8.1	2.3°
Stair Descend	0.86	6.8	2.4°	0.87	6.7	2.3°
Squatting	0.92	8.3	2.3°	0.88	7.4	2.5°

Table 6.6 b

Table 6.6a and 6.6b: Standard error of measurement between both the systems

6.3 Data analysis and Discussion

Observation of the figures 6.1 to 6.10 reveals a good similarity in the data in terms of maximum/minimum knee flexion and knee excursion collected by both the systems during all the 3 trials obtained from all the subjects during the various ADL's. Unlike the minimum knee flexion angles, which shows a little variation between the repeat trials, the maximum knee flexion angles exhibited by the individuals during the repeat trials seem to be more reproducible and this is observable in case of both the systems. In an undisturbed position, the flexible electrogoniometer is in its neutral position and the angle subtended by the end blocks of the transducer in such a position is equivalent to 0°. Similarly, in a straight knee (unbent) position, the angle subtended by the knee is equivalent to 0° approximately and this corresponds to the minimum knee flexion angle. However, the minimum knee flexion exhibited by the individuals is concerned with the way in which the subjects rest their knees following an activity every time resulting in such minor variations between the repeat trials.

Comparison of the left and right knee electrogoniometer angles recorded by SUDALS and Data log WX48 during all the ADL's, shows a good agreement in terms of the shape of the standard cycle curves and group average curves, which are evident from the figures 6.11 to 6.20 and 6.21 to 6.25. Minor variations are seen in the standard cycle curves of both the systems during level walking. However, good agreement in terms of shape, maximum/minimum knee flexion/extension and knee excursion values can be seen in the mean trace of both the knees collected by both the systems during level walking. The group average maximum/minimum knee flexion /extension and the knee excursion of both the knees obtained from SUDALS seem to be in good agreement with the Data log WX48 with very little variations (1° to 2°).

Considering the second activity – Getting in and out of chair, good agreement is found in the shape and in the electrogoniometer angles of both the knees, recorded by both the systems. However, in the data recorded by the Data log WX48, there seems to be a variation in the pattern of the standard cycles for both the knees, exhibited by three subjects especially when getting out of the chair and such variations are not observed in the data recorded by SUDALS. During this activity, all the subjects were initially asked

to get into the chair from a neutral position (standing) and then they were asked to get out of the chair back to the same neutral position. Though the subjects were asked not to move their knees and rest their feet properly while performing this activity, it wasn't possible to keep track of the resting positions of the feet of the subjects as the investigator was standing behind the subjects during the data collection process and there is an increased likelihood of the subjects resting their feet improperly, when getting in and out of the chair resulting in data variations. Given that the systems both showed precision in measurement during gait the variation in data is likely to be due to the variation in performance of this task by the subjects. Nevertheless, the average cycles for both the knees obtained from both the systems show good agreement in terms of shape and electrogoniometer angles. This is evident from the figures 6.13, 6.14 and 6.22, where the maximum/minimum knee flexion/extension values and the knee excursion values obtained from both the systems seem to vary only by a degree or two.

Considering the other activities such as stair ascend, stair descend and squatting, there seems to be good agreement in the shape and electrogoniometer knee angle data obtained from both the systems. In fact, the data pertaining to the knee flexion/extension during the stair ascend and descend, recorded by both the systems are very similar to each other. On analyzing the standard cycle curves obtained from both the systems during squatting, there seem to be a little variation in the curve patterns and also there seem to be a little amount of variation in the data recorded from both the systems similar to the chair activity. But, the average cycles of both the systems, together with the maximum/minimum and knee excursion values shows good similarity.

The commercially available data acquisition system 'Data log WX48' has been used along with the flexible electrogoniometers in different applications by various researchers as listed in table 1.5 in chapter 1. Though the researchers haven't reported on the accuracy and reliability of the data acquisition system directly, they have published the accuracy and reliability of the electrogoniometers. This in turn reflects on the characteristics and usability of the data logging system, as the transducers cannot be used without the data logging system. Hence, comparing the results obtained from SUDALS against the Data log WX48 during various ADL's has given us the overall picture of the operation and efficiency of the newly developed system. This has not only revealed the

system characteristics such as the accuracy, reliability, repeatability and reproducibility, but has also helped us in studying the response of both the systems to noise and from this experiment, it is obvious that the manner in which the participant's perform an activity, results in the majority of the data variation irrespective of the data acquisition system used. Further, reviewing the literature also reveals that the reliability of the activity of getting in and out of a chair is poor to moderate (Van der Linden et al., 2008), confirming that, the variations seen in the results pertaining to this specific activity are due to the nature of the activity and not due to the variation in the transducers or systems used for recording the activity. Though many researchers have used control groups in studying the characteristics of the flexible electrogoniometers in conjunction with the Data log WX48 (Van der Linden et al., 2008, Piriyaprasarth et al., 2008, Maupas et al., 2002), none of these researchers have actually studied the working of flexible electrogoniometers when used in conjunction with different data collecting systems. Van der Linden et al., 2008 used flexible electrogoniometers with control subjects; but the age group of the participants in her study was 38 to 70 years. As a result, the knee flexion/extension angles obtained from those subjects cannot be compared with the outcomes of this study. In another study by Piriyaprasarth et al., 2008, the authors have used the commercially available Data log WX48 in conjunction with the flexible electrogoniometers for recording the knee flexion/extension data from young healthy volunteers.

However, here the authors have used the system for acquiring knee angles from static trials and in studying the characteristics of the flexible electrogoniometer following an activity such as walking etc. Hence, comparing those results with the findings of this study would be inappropriate. Nevertheless, the findings of the study carried out by Maupas et al., 2002, seems to be close with the outcomes of this study in terms of the maximum knee flexion values measured by the commercially available flexible electrogoniometry system during various activities such as level walking, stair ascend and stair descend. The average maximum knee flexion - 50° (right knee) / 55° (left knee) during a 25 m level walking for a group of 40 participants (21 males and 19 females) reported by Maupas et al. seems to be very close to the knee flexion values obtained from this study (– 55° (right knee) / 57° (left knee) - SUDALS, 56° (right knee) / 59° (left knee) - Data log WX48). However, for the other two activities, due to the difference in the

height of the steps used in this study, the participants have exhibited a little more knee flexion when ascending the flight of stairs – 190mm high (– 88° (right knee) / 91° (left knee) – SUDALS, 86° (right knee)/ 92° (left knee) – Data log WX48 and stair descend – 87° (right knee) / 90° (left knee) – SUDALS, 86° (right knee) / 90° (left knee) – Data log WX48) when compared to the values reported by Maupas.E et al., where the height of the stairs was 160mm (stair ascend – 79.4° (right knee) / 85° (left knee) and stair descend – 81° (right knee) / 85° (left knee)). In addition to this, the results of absolute agreement between the systems obtained from the ICC values show that there is a very good reliability between both the systems. The 'Two way mixed effect model – ICC $_{[2,10]}$' used here in this study, takes into account any kind of random effects induced by the participants while performing the activities and keeps the effects induced by the user while attaching the flexible electrogoniometers fixed. The ICC values obtained for all the ADL's performed by all the subjects are in the range of 0.80 to 0.99. The calculated ICC values are similar to the results reported by Piriyaprasarth et al., 2007, 2008. Since, the information derived from ICC coefficients alone has limited utility in clinical practice, as it does not define the magnitude of the disagreement between measurements; some researchers have suggested the use of SEM to establish the actual difference between the measurements made by two different systems. The SEM was calculated using the relation SEM = SD x $\sqrt{}$ (1-r) (Harvill, A Technical Note), where r corresponds to a reliability coefficient. Previously, Pearson's correlation coefficient has been used as a reliability coefficient by researchers for testing the reliability of an instrument for assessing the post-traumatic stress disorder (Fao et al., 1993). Similarly, in this study, Pearson's correlation coefficient has been used as a reliability coefficient to represent the reliability of the measurement by two different data acquisition system and the SEM calculated for maximum/minimum knee flexion and knee excursion angles between both the systems reveals the existence of measurement error varying from 2° to 3° between both the data collecting systems.

Having compared the data obtained from SUDALS during various ADL's against those produced by the flexible electrogoniometer when used in conjunction with the commercially available Biometrics data logging system during the same ADL's. It can be

concluded that the group results are in agreement to 2 or 3 degrees. Hence the newly developed system can be used interchangeably with the commercially available system and in similar applications which require the assessment of knee kinematics during functional tasks. Following these experiments, the developed system was compared for its usability against the commercially available system, which is explained in chapter7.

Chapter 7 – Evaluation of the user friendly nature of SUDALS

ISO 9241-11 (1994), defines usability as 'the extent to which a product can be used by specific users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use' (Martin et al., 2006, Garmer et al., 2004). With an appropriate selection of application oriented tasks allowing a valid testing of a medical device, usability tests are said to involve users performing a number of such tasks and then reporting their experiences of using the device. Strictly speaking, with respect to medical devices; clinicians, allied health professionals, patients and carers are considered to be end-users and nowadays, involvement of such focus groups in medical technology development and incorporation of the assessment of user requirements has become a part of the development cycle of a medical device. Further, obtaining user feedback as part of the usability tests helps the device manufacturers to investigate the device features and characteristics required by the users and such valuable responses obtained from the users can lead to an improvement of the design over an existing product. We wished to apply this philosophy and standard to the development of the SUDALS. This necessitated the testing of SUDALS for its usability and user friendliness. The methodology adopted in carrying out this experiment, together with the discussion of the results obtained is explained in detail in the following sections.

7.1 Methods

The main objective of carrying out this study was to test the user friendly nature of the developed system against the commercially available system by giving training to 6 health professionals in the use of both the systems, allow them to collect data with the systems from two healthy volunteers during various ADL's such as level walking, getting in and out of a standard chair and deep squatting and elicit their views on the strengths and weakness of both systems. The outcomes of this study will also be useful to improve the effectiveness, safety and usability of the device based on the user feedback and in studying the inter-rater reliability of the systems. Since the end-users of this device would be AHP's and research nurses from the clinical environment, the focus group who

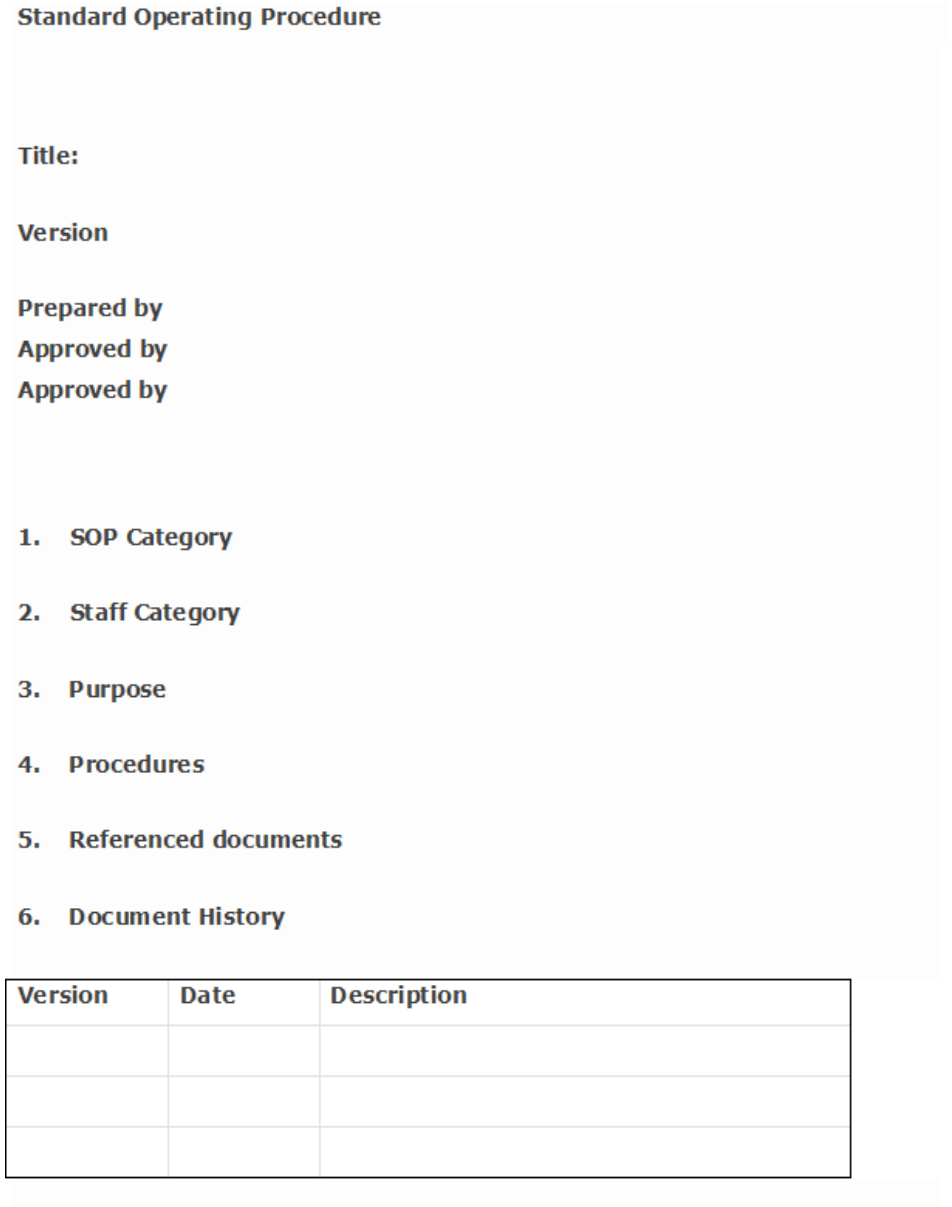
participated in this study comprised of three physiotherapists and three research nurses and to eliminate the possibility of bias, it was ensured that all the six users did not have any previous experience of using the flexible electrogoniometers. The two young normal healthy male subjects (ages 24 and 30 years) who volunteered for this study were recruited within the Bioengineering Unit of University of Strathclyde and their consent to participate in the study was obtained by personally handing over the information sheet and the consent forms (section 7.2 electronic appendix 7) a week or two in advance to the actual commencement of the experiment. All the details such as the exclusion criteria, the date, time and place of testing were outlined in the information sheet given to the volunteers. A risk assessment of this protocol was carried out by the respective committee within the Bioengineering Unit of University of Strathclyde and the ethical approval was granted by the University of Strathclyde, Bioengineering Unit Ethics Committee. A copy of the ethical approval obtained for this study is included in the electronics appendix 8 of this thesis. All the testing took place in the Biomechanics laboratory in the Bioengineering Unit of University of Strathclyde.

The users were introduced to the study, with the help of a standard operating procedure (SOP) and a training CD, the concept of the flexible electrogoniometers, their preparation and attachment, various handling precautions of the transducer and the operation of both the data acquisition systems in conjunction with the flexible electrogoniometers were explained in detail to all the users on the day of the experiment prior to the actual commencement of the trials. The SOP and training CD were used so as to standardize the training in a way familiar to research nurses working in clinical trial units and mimic the situation that would be needed to enrol multiple users to record data in multicentred RCT's and clinical audits. While more intensive to develop than personal training for the 6 users in the study, the training package approach allowed training to occur in a realistic method and for the conclusions drawn to be generalised to use of the system by research nurses in situations where in-house personal training by an experienced user was not available. The procedure involved in the preparation of the SOP and the training CD used for this study is explained below.

Preparation of SOP: A SOP is a written documentation which specifies what should be done, when, where and by whom. The SOP's for both the data collecting systems were written in a similar way to those used in the Glasgow CRF and with the help of the clinical coordinator – Bioengineering unit – University of Strathclyde. A sample of SOP's used in the Glasgow CRF was obtained from the clinical coordinator and the SOP's written for this study were prepared accordingly. The SOP used in the clinics for applications similar to this study comprised of the sections shown in figure 7.1 a. Since the end users of SUDALS would be AHP's and research nurses from the clinics, the SOP category and the staff category were designated as clinical. Further, due to the descriptive nature of a clinical SOP, the SOP's prepared for this study aimed to explain to the AHP's and research nurses (in a jargon free language) about the purpose of using flexible electrogoniometers with both the data acquisition systems, describe the initial preparation of flexible electrogoniometers, their attachment to the subjects, the protocol for connecting the data acquisition systems with the flexible electrogoniometers and using the data loggers for recording activities. The information sheets and the SOP's were handed over to the users prior to the playing of the training CD.

Preparation of Training CD: The CD prepared for training the users comprises of three parts. The basics of the transducer such as; its principle of operation, its parts, size, shape, etc. are explained in detail in the first part of the CD and this in turn gives an overall idea about the transducer to the users prior to its usage. Also, this part of the CD shows the way of preparing the equipment, subject, attaching the device to the subject and the ways and precautions involved in handling the device. The second part of the CD enables the users to know how to connect the device to the Biometrics data logger and how to operate the device for recording the data during the ADL's. The third part of the CD enables the users to understand the protocol involved in connecting the device to SUDALS, its unique features, functioning and how to operate the device for collecting the knee flexion/extension data. Prior to the actual videoing, a written consent (section 7.2 electronic appendix 7) of the volunteers (Normal Subject and Co-researcher) participating in this study was obtained and all these parts were videoed individually at the National

Centre for Prosthetics and Orthotics – University of Strathclyde with the help of a video technician. Also, prior to the videoing, a voice over script was written and a story board of the contents to be included in the training CD was prepared using the Windows Movie maker to get an idea of the actual play time of the training CD (15 - 16 minutes). The SOP's used as part of this study are shown in figure 7.1b and 7.1c and the training CD used as part of this study is included in the section 7.1 of electronic appendix 7 of this thesis.



Standard Operating Procedure

Title:

Version

Prepared by
Approved by
Approved by

1. **SOP Category**
2. **Staff Category**
3. **Purpose**
4. **Procedures**
5. **Referenced documents**
6. **Document History**

Version	Date	Description

Figure 7.1a: Format of a clinical SOP (http://www.glasgowctu.org/sop_07_002.aspx)

Standard Operating Procedure - SUDALS

1. SOP Category

Clinical

2. Staff Category

Clinical

3. Purpose

The purpose of this SOP is to instruct all unit staff on the correct procedure for obtaining the knee flexion/extension data using flexible electrogoniometer and Strathclyde University data logging system (SUDALS) from patients and volunteers participating in research trials, therefore promoting uniformity within the Glasgow clinical research facility. The flexible electrogoniometer is an instrument for measuring joint angles. This device together with SUDALS allows range of motion (ROM) and max/min knee joint angles to be recorded during range of activities of daily living (ADL) in a free living environment.

4. Procedures

Preparation of Equipment

- Attach the 2 green end plates of the flexible electrogoniometer to 2 plastic strips provided (200 mm in length) using double sided medical tape.
- Then attach the double sided medical tape to the other side of the plastic strips.

Preparation of Subject

- Give 'The subject information' sheet to the participants prior to the experiment.
- Obtain informed written consent from the participants.
- Request the participants to wear shorts or knee length skirt so that their lower limbs are accessible.
- Prior to the equipment being attached to the participants, ask the subjects to remove shoes and socks. Once the equipment is attached, shoes and socks will be replaced by staff members, so that the connections are not dislodged.

Note: No special preparation of the subjects, especially men with excess hair in the knee areas (such as shaving of the hair) is required prior to equipment attachment.

Equipment attachment

- Ask the participants to sit / lie on a bed so that the soles of their feet are visible.
- Tape 2 flat footswitches (pressure sensors) to the soles of each foot – one on the heel area and the other at the ½ metatarsal area. Then the socks are replaced to keep the cables and footswitches in place.
- Ask the participants to stand with their lower limbs as straight as possible.
- Attach the green end plates prepared to the lateral border of the individuals' lower limb using the plastic strips with double sided tape.
- Ensure that the green end plates are positioned at an equal distance from the centre of the knee joint bend.
- Then wrap Velcro strap around the green end plates; one at the thigh and one at the shin to give additional support.
- Loop the cables from the footswitches into the straps to prevent them from a trip hazard.
- Now follow the connection protocol for connecting the sensors to the SUDALS as listed below.

Connection Protocol

- The 6 channels of SUDALS are labelled as; EG CH1, EG CH2, F1H CH3, F2T CH4, F3H CH5, F4T CH6.
- Connect both the electrogoniometers to the channels; EG CH1 & EG CH2 of SUDALS hooked onto a waist belt worn by the participant via the connecting cables provided.
- Similarly connect the labelled footswitches to the channels labelled; F1H CH3, F2T CH4, F3H CH5, F4T CH6.
- Then connect the bluetooth transmitter dongle to the socket marked 'T'.
- Ensure that the sliding switch on this dongle is facing towards the antenna.
- Before commencing the test, ensure all sensors are correctly positioned and not hindering the participant from movements.
- Now switch on the SUDALS and as an indication, the LED corresponding to the Zero function is illuminated and the two LED's (blue and red) on the bluetooth transmitter dongle is also illuminated indicating that the unit is powered and is properly paired with the receiver dongle on the PC. If the dongles are not paired then the LED's on the transmitter dongle keep blinking. Report such circumstances to the staff member who will be available during the test session.

Using SUDALS for recording activities

Note: SUDALS is a two component system comprising of a data logger and a key fob.

- SUDALS has five main functions corresponding to data collection; Record, Scrap, Transmit, Zero and Reset.
- When SUDALS is switched on, the LED corresponding to the Zero function is illuminated initially and following this the LED's corresponding to the functions Zero and Record keep flashing alternatively.
- Ensure that the control area is left uncovered and the key fob is in line of sight of the control area.

- To select any of the desired functions, the key fob must be held in line of sight of control area, when corresponding LED is illuminated.
- Before every new trial / subject/ patient recording the data logger must be zeroed.
- When zeroing, make sure that the equipment is connected to the SUDALS and the participant is standing as straight as possible without bending the knees.
- When the system has been zeroed, the LED corresponding to the Record function is illuminated. This function can be selected as above.
- Once the record function is selected, wait until the LED goes out and then commence the functional test.
- Once the ADL is completed, stop the recording by pressing the switch on the key fob in line with the 'control area'. Acknowledgement of the recording process being completed, the Zero LED is illuminated. This is the same for all completed functions on the logger.
- The record LED is then illuminated. This permits the user to make a recording for the second ADL.
- Scrap, Transmit and Reset functions are only available after a single recording has been made.
- The completion of one function and the initiation of the next function in the sequence is accompanied by a 'Beep'. This corresponds to a specific function time out and helps the user to avoid clicking the key fob for unwanted functions by mistake.
- Once, an ADL is recorded and if the user is satisfied with the recordings made, the data should be transmitted to the PC.
- If the memory becomes full, all the LED's on the SUDALS will blink continuously. If the memory becomes full, the system will still transmit all the previous recordings other than the current recording. This helps in preventing the loss of data.
- When the data transmission is completed, the zero LED illuminates again. Check for the transmitted data with the staff member at the PC end (receiving end) and if all the data recorded were transmitted, then save the data in the PC and then Reset

the SUDALS (using the ‘Reset’ function) before starting the next set of data collection.

5. Reference Documents

No Reference Documents

Figure 7.1b: SOP written for SUDALS

Standard Operating Procedure - Biometrics

1. SOP Category

Clinical

2. Staff Category

Clinical

3. Purpose

To describe the procedure for obtaining flexible electrogoniometry data from patients and volunteers participating in research trials, therefore, promoting uniformity within the Glasgow Clinical Research Facility. The flexible electrogoniometers and datalog are used to collect joint angle data. The system allows range of motion (ROM) max/min joint angles of daily activities to be recorded and studied in depth in a non restricted setting.

4. Procedures (Measuring Knee Joint Angles)

Preparation of Equipment

- Using double sided medical tape the 2 green end plates of the electrogoniometer is attached to two lengths of 200mm plastic strips.
- Double sided medical tape is also attached to the other side of the plastic strips.

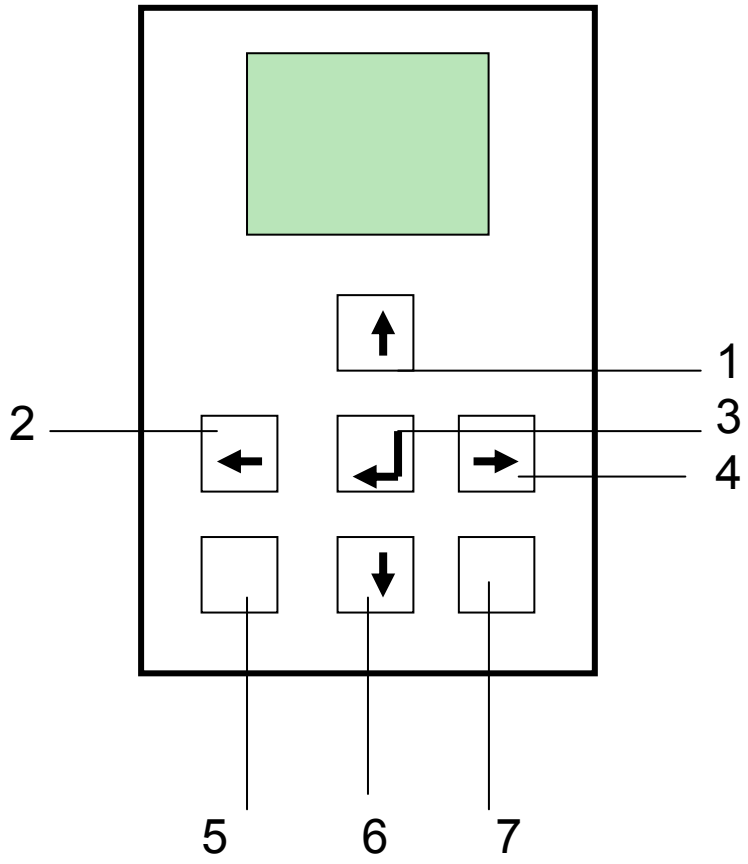
Preparation of Subject

- Inform patient/subject of the procedure – used to obtain additional functional data.
- Informed written consent is obtained.
- Individual will have to wear shorts or a knee length skirt so that their lower limbs are accessible.
- Also shoes and socks must be removed for equipment attachment but can be worn during the test session.

Attachment/Procedure

- Ask the individual now to sits/lies on a bed so that the soles of their feet are visible.
- 2 flat footswitches (pressure sensors) are taped to the soles of each foot – one on the heel area and the other at the 1/2 metatarsal area. Now the socks are put back on – helps to keep the cables in place, along with their shoes.
- Now ask the patient to stand, far enough away from the bed so that you have space to move all around them.
- Check that their lower limbs as straight as possible.
- The prepared electrogoniometer is attached to the lateral border of the individuals' lower limb. It must be positioned so that the green end plates are equal distance from the centre of the knee joint bend, therefore straddles the knee joint.
- A thigh and shin Velcro strap is then wrapped around the green end plates to give additional support.
- The cables from the footswitches are lopped in these straps to prevent them from becoming a safety issue.
- A cable connects the electrogoniometer to the data logger which is hooked onto a waist belt worn by the individual.
- The footswitch cables are also connected to the data logger.
- Finally the input channels used for each cable is recorded.

Use of Biometric Datalog/Recording



- To switch on hold down 5 for a few seconds.
- To switch off press 7, hold it and press 5.
- Key 4 is the enter key.
- 1,2,4,6 move the move in the directions they illustrate.
- Input the memory card into the slot at the bottom of the datalog, and switch on.
- Ask the individual to stand with their lower limbs straight and when the 'Zero' menu is highlighted press 3.

- Press 6 when ‘Set Zero’ is highlighted and it will display ‘Select channel: All’. Press 3.
- Press 4 so that the ‘Cancel’ menu is highlighted and press 3 taking you back to starting menus.
- Now give the instructions for the 1st task, example level walking along a corridor at the individual’s self selected pace.
- Before the individual begins the task highlight the ‘Rec’ menu. To start and stop the recording manually, hold down 7 and press 3 to start the recording. Once the individual has completed the task to stop the recording again hold down 7 and press 3. Alternatively a recording time length can be entered. Highlight the ‘Rec’ menu and press 3. Then using the arrow keys a length of time for the recording can be selected. Once this has been input press 3.
- Once the individual has completed all the tasks switch off the datalog.
- All the equipment can now be removed with care.

Note for electrogoniometer removal:

When removing this from the individual’s leg, remove the shin end block 1st then detach from the thigh. Do not allow the electrogoniometer to flop as the middle spring like section is easily damaged.

5. Referenced Documents

No Reference Documents

Figure 7.1c: SOP written for Biometrics System

Following the training session, the users were asked to prepare the flexible electrogoniometers for the experiment and were also allowed to operate both the systems (as a rehearsal prior to actual data collection). They were given an opportunity to clarify any questions that they came across during the training session. The order in which the two systems were used with the flexible electrogoniometers to collect the knee flexion/extension data during the various ADL's was randomized. The users were asked to pick one of the two cards (with one of the names of the data acquisition systems written on the back of each card) and were asked to start using the system which was picked by them. If the system happened to be SUDALS, then the devices were attached to the participants as explained in the routine deployment in section 2.4 and 2.2.4 and the subjects were asked to perform the following 3 activities at their selected speed –

1. 7m Level walking
2. Getting in and out of a standard Chair (410mm from floor to seat)
3. Deep squatting

The procedure of zeroing the transducers and recording the data using SUDALS was the same as the procedure adopted for the pilot study explained in chapter 5. The activity of getting in and out of the chair was again combined as a single activity and the system recorded and transmitted 4 recordings (The activity corresponding to level walking was recorded as two individual recordings similar to the pilot study explained in chapter 5). Unlike the previous experiments, all the activities performed by the subjects were recorded only once. Start and stop commands were given at the beginning and completion of each task. The event marking was taken into account by the FSR's attached to the toes and heels of each subject and this information was used to select the start and end of the gait cycles of the activities recorded by the system.

Following this, with all sensors still in situ, the SUDALS was replaced with the Biometrics data logging system and the above procedure of zeroing the transducers and collecting data pertaining to the flexion/extension of the knee during ADL's was repeated using the commercially available system. Each and every activity was recorded individually and the recordings corresponding to each trial were saved in the memory

card of the commercially available system. Later, this data was downloaded to the PC using the memory card reader and the data were automatically stored as invidual '.txt' files, which were then converted to MS-excel files for data analysis.

However, if the system chosen first happened to be the Biometrics system, then this was used first in collecting the data from the participants and then leaving all the sensors in situ, while the Biometrics system was replaced with SUDALS system and the whole procedure was repeated. On completion of the process of data collection using both the systems, a feedback questionnaire was given to the users and a semi-formal 'one to one' interview was carried out to know their experiences of using the systems; i.e. which system in their opinion was easy to operate, easy to learn and which was more user friendly. All the feedback questionnaires, together with the interviews given by all the users are included in section 7.2 and 7.3 of electronic appendix 7. The feedback obtained from the users in the form of the questionnaires and key statements made during the interview have been included in the results section of this chapter.

7.2 Results

The data from SUDALS collected by all the six users from both the participant's during these ADL's were filtered at the PC end using the digital filter as explained previously and the data were further analyzed for maximum / minimum knee flexion/extension angles and for knee excursion during all the ADL's and the absolute difference between both the data collecting systems in terms of maximum/minimum knee flexion angle and knee excursion was also estimated as shown in tables 7.1 to 7.3. This procedure was carried out for both the left and right knees. Similar to the pilot study, the data collected using SUDALS from both the subjects were time normalized using the interpolation programme, which normalized each participant's data segment for both knees for each function into 100 % points giving an angle versus percent of the movement trace. Similarly, the data collected using the Biometrics data logger were also filtered using the same filter used for the SUDALS at the PC end and were then analyzed for maximum / minimum knee flexion/extension angles and for knee excursion during all the ADL's and were time normalized using the same interpolation programme and each participant's data segment for both knees for each function was plotted as an angle versus percent of the movement trace. Further, the inter-rater reliability of the results obtained

by SUDALS when used by different users on same participants on different occasions during various ADL's are represented in terms of intraclass correlation coefficient (ICC) values calculated using SPSS for windows (version 11) as shown in tables 7.4 to 7.9 and the standard time normalized gait cycles of both the participants obtained by SUDALS and Biometrics data logger during all the 3 ADL's by different users are shown below in figures 7.2 to 7.25. Similar to the results reported in chapter 6, the measurement error in the same unit of measurement was obtained using SEM. The results corresponding to the SEM are shown in tables 7.10 to 7.13. Finally, the feedback on the usage of both systems, obtained from all the 6 users in the form of questionnaires and personal interview statements are summarized and are shown in table 7.14 and 7.15 and are included in full in the Appendix 7.

Walking		Right Knee Maximum Flexion (Degrees)				Left Knee Maximum Flexion (Degrees)			
User	Subject	SUDALS	Biometrics	Difference	Absolute	SUDALS	Biometrics	Difference	Absolute
1	1	63.7	60.1	3.6	3.6	64.5	61.4	3.1	3.1
2	1	44.1	45.0	-0.9	0.9	45.5	49.4	-3.9	3.9
3	1	44.7	40.6	4.1	4.1	44.2	41.6	2.6	2.6
4	2	63.2	59.8	3.4	3.4	63.2	63.2	0.0	0.0
5	2	65.1	61.1	4.0	4.0	62.9	63.9	-1.1	1.1
6	2	64.1	63.6	0.5	0.5	62.9	63.1	-0.3	0.3
			Mean Difference	2.5	2.8		Mean Difference	0.1	1.8
			Maximum Difference	4.1	4.1		Maximum Difference	-3.9	3.9

(a)

Walking		Right Knee Minimum Flexion (Degrees)				Left Knee Minimum Flexion (Degrees)			
User	Subject	SUDALS	Biometrics	Difference	Absolute	SUDALS	Biometrics	Difference	Absolute
1	1	0.5	0.4	0.0	0.0	1.0	0.9	0.1	0.1
2	1	-1.6	-2.5	0.9	0.9	-4.4	-0.8	-3.6	3.6
3	1	-7.0	-4.7	-2.3	2.3	-7.0	-7.1	0.1	0.1
4	2	0.9	1.0	-0.1	0.1	1.0	-0.5	1.5	1.5
5	2	-1.1	0.0	-1.2	1.2	-0.3	-0.5	0.3	0.3
6	2	0.0	-0.7	0.8	0.8	0.0	0.1	-0.1	0.1
			Mean Difference	-0.3	0.9		Mean Difference	-0.3	1.0
			Maximum Difference	2.3	2.3		Maximum Difference	3.6	3.6

(b)

Walking		Right Knee Excursion (Degrees)				Left Knee Excursion (Degrees)			
User	Subject	SUDALS	Biometrics	Difference	Absolute Difference	SUDALS	Biometrics	Difference	Absolute Difference
1	1	63.2	59.7	3.5	3.5	63.5	60.5	3.0	3.0
2	1	45.7	47.4	-1.8	1.8	50.0	50.2	-0.2	0.2
3	1	51.7	45.3	6.4	6.4	51.2	48.7	2.5	2.5
4	2	62.4	58.8	3.6	3.6	62.2	63.8	-1.5	1.5
5	2	66.2	61.1	5.1	5.1	63.1	64.5	-1.4	1.4
6	2	64.1	64.3	-0.2	0.2	62.8	63.0	-0.2	0.2
			Mean Difference	2.8	3.4		Mean Difference	0.4	1.5
			Maximum Difference	6.4	6.4		Maximum Difference	3.0	3.0

(c)

Table 7.1a, b, and c: Difference between both the systems in terms of Maximum/Minimum knee flexion and Knee excursion during level walking

In and out of chair		Right Knee Maximum Flexion (Degrees)				Left Knee Maximum Flexion (Degrees)			
User	Subject	SUDALS	Biometrics	Difference	Absolute Difference	SUDALS	Biometrics	Difference	Absolute Difference
1	1	106.0	95.4	10.6	10.6	101.9	101.6	0.3	0.3
2	1	94.3	96.7	-2.4	2.4	99.3	96.9	2.4	2.4
3	1	98.5	96.0	2.4	2.4	91.4	93.9	-2.5	2.5
4	2	108.2	101.5	6.7	6.7	109.1	103.3	5.8	5.8
5	2	110.2	105.0	5.1	5.1	109.1	108.0	1.1	1.1
6	2	93.4	91.1	2.4	2.4	103.0	98.1	4.9	4.9
			Mean Difference	4.1	4.9		Mean Difference	2.0	2.0
			Maximum Difference	10.6	10.6		Maximum Difference	5.8	5.8

(a)

In and out of chair		Right Knee Minimum Flexion (Degrees)				Left Knee Minimum Flexion (Degrees)			
User	Subject	SUDALS	Biometrics	Difference	Absolute Difference	SUDALS	Biometrics	Difference	Absolute Difference
1	1	-2.7	0.2	-2.9	2.9	-3.8	0.4	-4.2	4.2
2	1	0.8	1.2	-0.4	0.4	-0.1	-0.6	0.5	0.5
3	1	1.8	2.3	-0.4	0.4	2.0	-3.6	5.6	5.6
4	2	3.8	2.0	1.8	1.8	3.9	0.2	3.7	3.7
5	2	4.0	1.5	2.5	2.5	3.0	0.5	2.5	2.5
6	2	1.8	0.5	1.3	1.3	2.6	0.6	2.0	2.0
			Mean Difference	0.3	1.6		Mean Difference	1.7	3.1
			Maximum Difference	2.9	2.9		Maximum Difference	5.6	5.6

(b)

In and out of chair		Right Knee Excursion (Degrees)				Left Knee Excursion (Degrees)			
User	Subject	SUDALS	Biometrics	Difference	Absolute Difference	SUDALS	Biometrics	Difference	Absolute Difference
1	1	108.6	95.2	13.4	13.4	105.7	101.2	4.5	4.5
2	1	93.5	95.5	-2.0	2.0	99.4	97.5	1.9	1.9
3	1	96.6	93.7	2.9	2.9	89.4	97.5	-8.2	8.2
4	2	104.3	99.5	4.8	4.8	105.1	103.1	2.0	2.0
5	2	106.2	103.5	2.7	2.7	106.1	107.5	-1.4	1.4
6	2	91.6	90.6	1.0	1.0	100.4	97.5	2.9	2.9
			Mean Difference	3.8	4.5		Mean Difference	0.3	3.5
			Maximum Difference	13.4	13.4		Maximum Difference	-8.2	8.2

(c)

Table 7.2a, b, and c: Difference between both the systems in terms of Maximum/Minimum knee flexion and Knee excursion during In and out of a chair

Squatting		Right Knee Maximum Flexion (Degrees)				Left Knee Maximum Flexion (Degrees)			
User	Subject	SUDALS	Biometrics	Difference	Absolute Difference	SUDALS	Biometrics	Difference	Absolute Difference
1	1	123.2	125.0	-1.8	1.8	118.9	125.8	-6.9	6.9
2	1	124.4	125.2	-0.7	0.7	120.1	133.0	-12.9	12.9
3	1	124.3	123.2	1.1	1.1	126.6	135.1	-8.6	8.6
4	2	130.4	121.1	9.3	9.3	130.4	121.8	8.6	8.6
5	2	132.2	126.8	5.4	5.4	130.8	134.6	-3.8	3.8
6	2	126.6	119.0	7.5	7.5	127.9	131.3	-3.4	3.4
			Mean Difference	3.5	4.3		Mean Difference	-4.5	7.4
			Maximum Difference	9.3	9.3		Maximum Difference	-12.9	12.9

(a)

Squatting		Right Knee Minimum Flexion (Degrees)				Left Knee Minimum Flexion (Degrees)			
User	Subject	SUDALS	Biometrics	Difference	Absolute Difference	SUDALS	Biometrics	Difference	Absolute Difference
1	1	1.2	8.8	-7.6	7.6	-0.2	9.0	-9.2	9.2
2	1	0.5	8.7	-8.2	8.2	-0.2	8.3	-8.6	8.6
3	1	0.3	2.6	-2.2	2.2	5.9	1.9	4.0	4.0
4	2	1.0	1.8	-0.8	0.8	1.0	0.6	0.4	0.4
5	2	0.7	-1.2	1.9	1.9	0.7	0.4	0.3	0.3
6	2	1.7	-0.7	2.4	2.4	1.7	1.1	0.6	0.6
			Mean Difference	-2.4	2.4		Mean Difference	-2.1	3.8
			Maximum Difference	-8.2	8.2		Maximum Difference	-9.2	9.2

(b)

Squatting		Right Knee Excursion (Degrees)				Left Knee Excursion (Degrees)			
User	Subject	SUDALS	Biometrics	Difference	Absolute Difference	SUDALS	Biometrics	Difference	Absolute Difference
1	1	122.0	116.2	5.8	5.8	119.2	116.8	2.3	2.3
2	1	123.9	116.4	7.5	7.5	120.3	124.7	-4.3	4.3
3	1	123.9	120.6	3.3	3.3	120.7	133.2	-12.5	12.5
4	2	129.5	119.3	10.1	10.1	129.5	121.2	8.2	8.2
5	2	131.5	128.0	3.5	3.5	130.1	134.2	-4.1	4.1
6	2	124.9	119.8	5.1	5.1	126.1	130.2	-4.1	4.1
			Mean Difference	5.9	5.9		Mean Difference	-2.4	5.9
			Maximum Difference	10.1	10.1		Maximum Difference	-12.5	12.5

(c)

Table 7.3a, b, and c: Difference between both the systems in terms of Maximum/Minimum knee flexion and Knee excursion during Squatting

Results of Inter-rater reliability

Level Walking	ICC	Lower Bound 95% CI	Upper Bound 95% CI	P Value
Right Knee	.865	. 818	.902	. 00
Left Knee	.941	. 919	.958	.00

Table 7.4: Inter rater reliability of SUDALS during Level Walking - Subject1

In and Out of Chair	ICC	Lower Bound 95% CI	Upper Bound 95% CI	P Value
Right Knee	.882	.841	.915	.00
Left Knee	.922	.893	.944	.00

Table 7.5: Inter rater reliability of SUDALS during Getting in and out of chair - Subject1

Squatting	ICC	Lower Bound 95% CI	Upper Bound 95% CI	P Value
Right Knee	.976	.967	.983	.00
Left Knee	.991	.988	.994	.00

Table 7.6: Inter rater reliability of SUDALS during Squatting– Subject1

Level Walking	ICC	Lower Bound 95% CI	Upper Bound 95% CI	P Value
Right Knee	.963	.949	.974	.00
Left Knee	.952	.934	.966	.00

Table 7.7: Inter rater reliability of SUDALS during Level Walking - Subject 2

In and Out of Chair	ICC	Lower Bound 95% CI	Upper Bound 95% CI	P Value
Right Knee	.990	.986	.993	.00
Left Knee	.993	.990	.995	.00

Table 7.8: Inter rater reliability of SUDALS during Getting in and out of chair - Subject2

Squatting	ICC	Lower Bound 95% CI	Upper Bound 95% CI	P Value
Right Knee	.995	.992	.996	.00
Left Knee	.993	.991	.995	.00

Table 7.9: Inter rater reliability of SUDALS during Squatting - Subject2

Results of SEM

Activities		Reliability coefficient- r	SD	Users	SEM
Walking	Right Knee	0.95 0.92 0.96	19.6 15.5 16.2	u1*u2 u2*u3 u3*u1	4° 4° 3°
	Left Knee	0.94 0.94 0.96	19.1 16.1 18.0	u1*u2 u2*u3 u3*u1	4° 4° 3.6°
Getting In and out of chair	Right Knee	0.92 0.92 0.92	39.0 34.3 36.5	u1*u2 u2*u3 u3*u1	11° 10° 10°
	Left Knee	0.92 0.92 0.92	32.0 34.2 31.1	u1*u2 u2*u3 u3*u1	9° 10° 9°
Squatting	Right Knee	0.99 0.99 0.99	44.2 42.5 43.0	u1*u2 u2*u3 u3*u1	4° 4° 4°
	Left Knee	0.99 0.99 0.99	41.2 44.4 46.0	u1*u2 u2*u3 u3*u1	4° 4° 4°

Table 7.10 – SEM calculated for Subject 1 when tested with SUDALS

Activities		Reliability coefficient- r	SD	Users	SEM
Walking	Right Knee	0.98 0.95 0.98	17.8 13.8 14.0	u1*u2 u2*u3 u3*u1	2° 3° 2°
	Left Knee	0.98 0.96 0.91	16.0 15.8 15.0	u1*u2 u2*u3 u3*u1	2° 3° 4°
Getting In and out of chair	Right Knee	0.87 0.92 0.89	36.1 33.8 34.0	u1*u2 u2*u3 u3*u1	13° 9° 11°
	Left Knee	0.93 0.85 0.93	34.2 34.0 33.5	u1*u2 u2*u3 u3*u1	9° 13° 9°
Squatting	Right Knee	0.98 0.97 0.96	40.8 39.2 41.0	u1*u2 u2*u3 u3*u1	6° 7° 8°
	Left Knee	0.97 0.96 0.95	41.2 41.0 40.0	u1*u2 u2*u3 u3*u1	7° 8° 9°

Table 7.11 – SEM calculated for Subject 1 when tested with Biometrics

Activities		Reliability coefficient- r	SD	Users	SEM
Walking	Right Knee	0.98 0.97 0.95	21.0 20.0 22.1	u4*u5 u5*u6 u4*u6	3° 3° 5°
	Left Knee	0.96 0.99 0.95	19.1 22.0 21.0	u4*u5 u5*u6 u4*u6	4° 2° 5°
Getting In and out of chair	Right Knee	0.99 0.99 0.99	38.0 31.0 32.4	u4*u5 u5*u6 u4*u6	4° 3° 3°
	Left Knee	0.99 0.99 0.99	37.0 36.0 35.2	u4*u5 u5*u6 u4*u6	4° 4° 3°
Squatting	Right Knee	0.99 0.99 0.99	45.3 42.0 43.0	u4*u5 u5*u6 u4*u6	4° 4° 4°
	Left Knee	0.99 0.99 0.99	45.3 43.5 44.0	u4*u5 u5*u6 u4*u6	4° 4° 4°

Table 7.12 – SEM calculated for Subject 2 when tested with SUDALS

Activities		Reliability coefficient- r	SD	Users	SEM
Walking	Right Knee	0.99 0.99 0.99	19.3 19.8 19.3	u4*u5 u5*u6 u4*u6	2° 2° 2°
	Left Knee	0.97 0.96 0.95	22.0 21.3 21.4	u4*u5 u5*u6 u4*u6	4° 4° 5°
Getting In and out of chair	Right Knee	0.99 0.98 0.98	37.0 37.6 36.2	u4*u5 u5*u6 u4*u6	4° 5° 5°
	Left Knee	0.99 0.99 0.98	38.0 37.8 38.0	u4*u5 u5*u6 u4*u6	4° 4° 5°
Squatting	Right Knee	0.99 0.99 0.99	44.0 45.0 43.2	u4*u5 u5*u6 u4*u6	4° 4° 4°
	Left Knee	0.99 0.99 0.99	49.0 49.8 48.0	u4*u5 u5*u6 u4*u6	5° 5° 5°

Table 7.13 – SEM calculated for Subject 2 when tested with Biometrics

Standard cycles Obtained by different users from subject 1 and subject 2

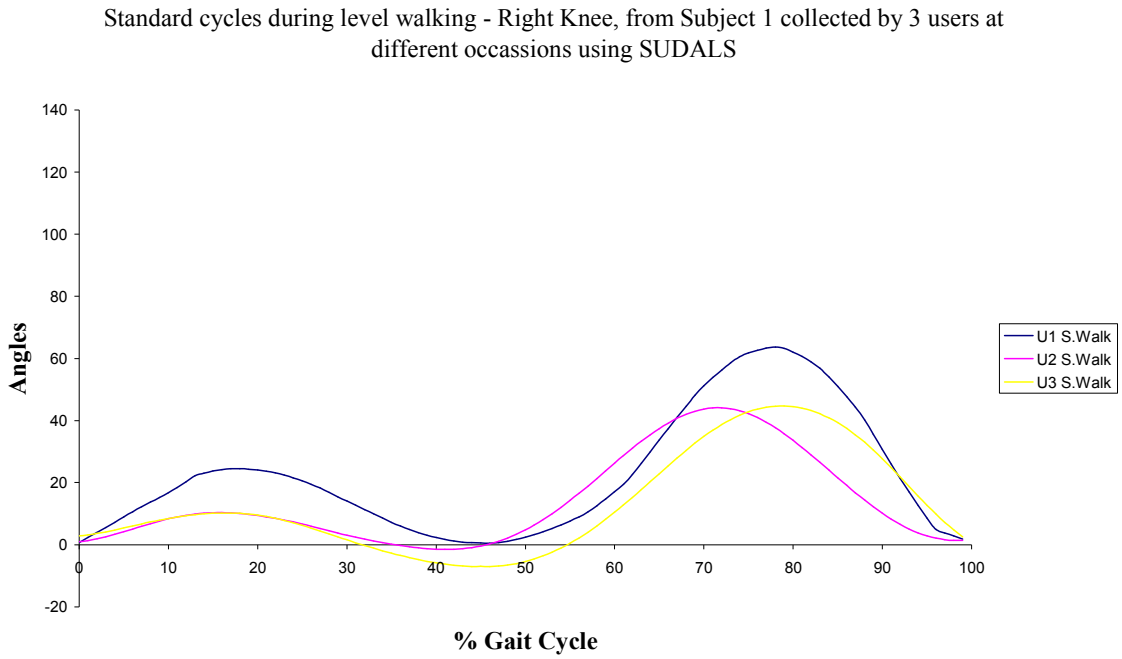


Figure 7.2 – Right Knee Angle of Subject1 during free speed level walking as measured using SUDALS by users 1, 2 and 3 in different occasions.

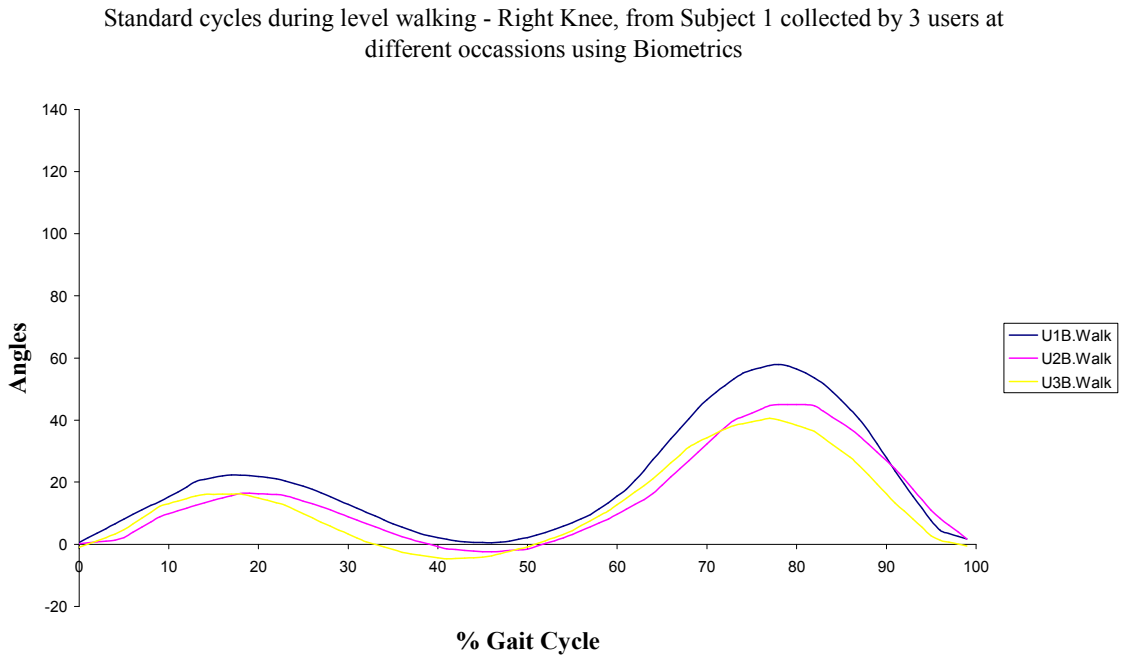


Figure 7.2a – Right Knee Angle of Subject1 during free speed level walking as measured using Biometrics system by users 1, 2 and 3 in different occasions.

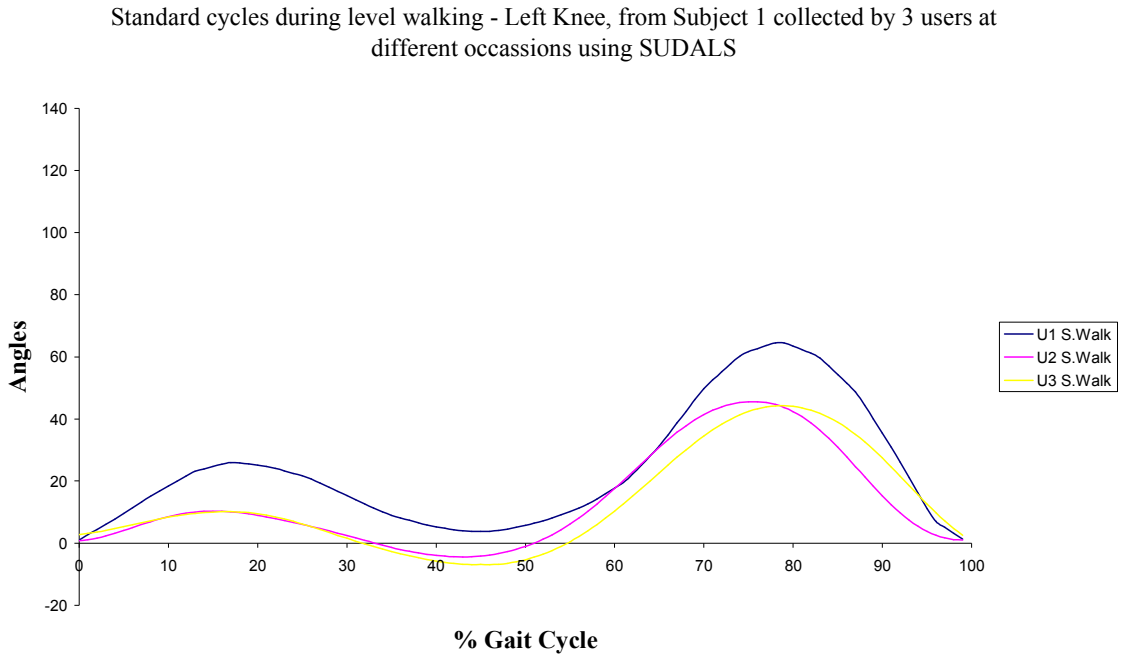


Figure 7.3 – Left Knee Angle of Subject1 during free speed level walking as measured using SUDALS by users 1, 2 and 3 in different occasions

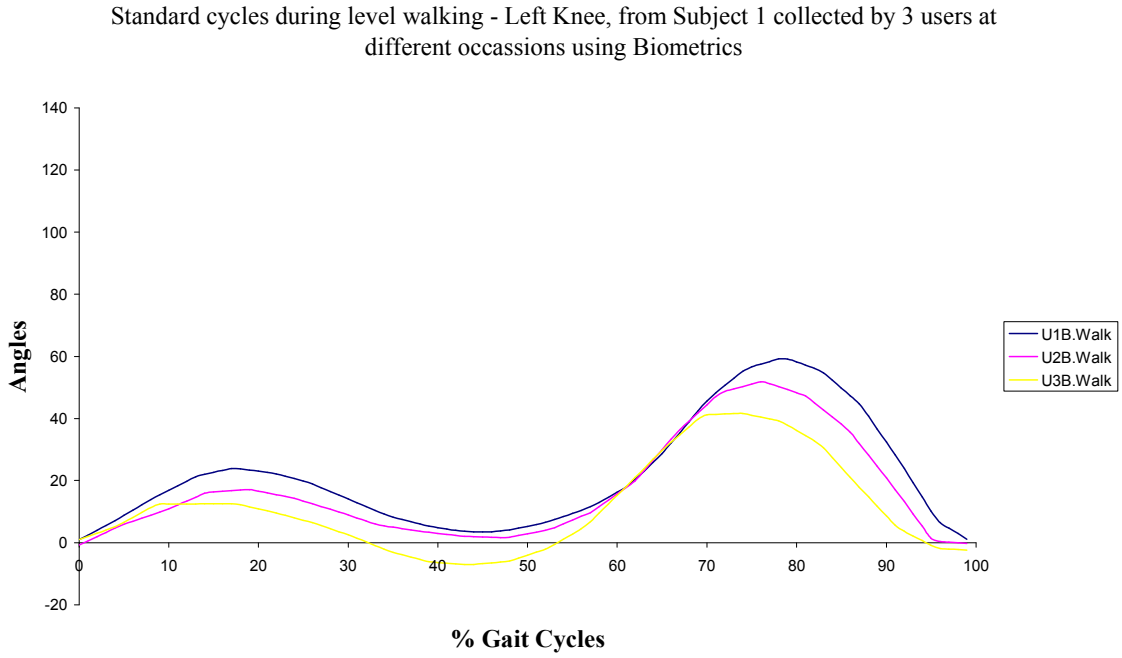


Figure 7.4 – Left Knee Angle of Subject1 during free speed level walking as measured using Biometrics system by users 1, 2 and 3 in different occasions.

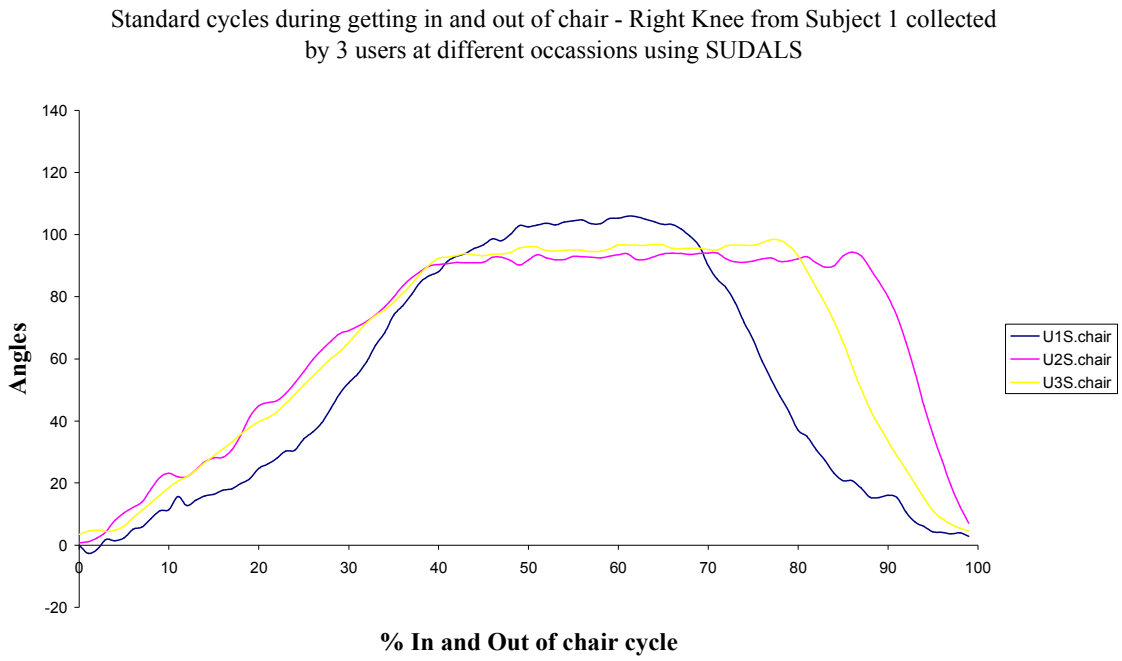


Figure 7.5 – Right Knee Angle of Subject1 during Getting in and out of chair as measured using SUDALS by users 1, 2 and 3 in different occasions.

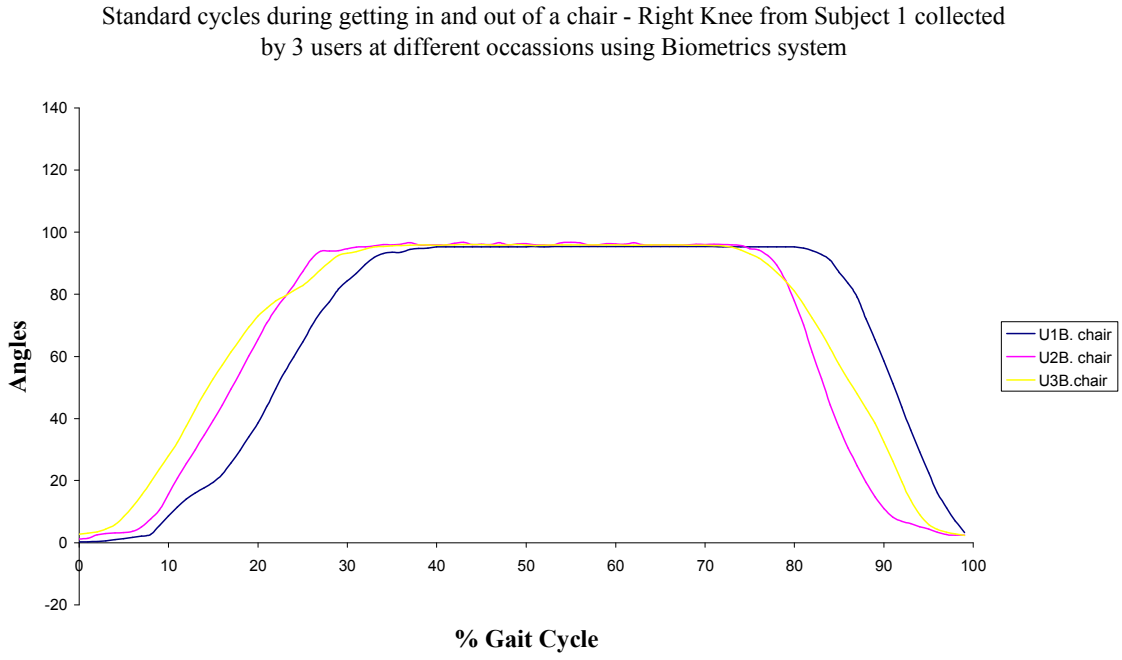


Figure 7.6 – Right Knee Angle of Subject1 during Getting in and out of chair as measured using Biometrics by users 1, 2 and 3 in different occasions.

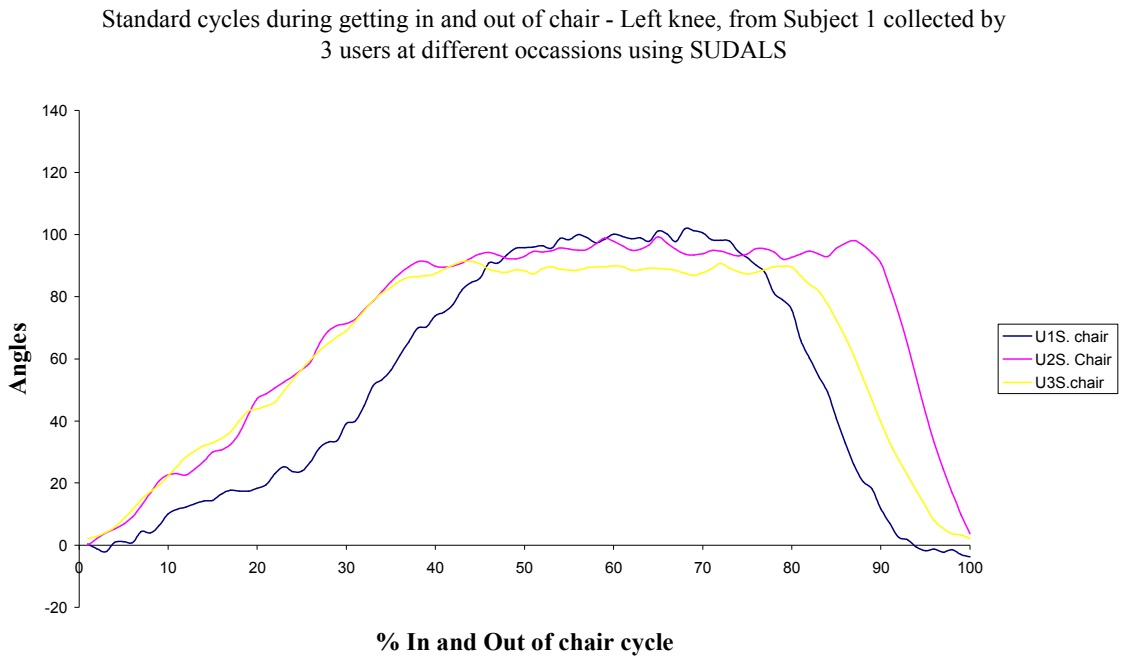


Figure 7.7 – Left Knee Angle of Subject1 during Getting in and out of chair as measured using SUDALS by users 1, 2 and 3 in different occasions.

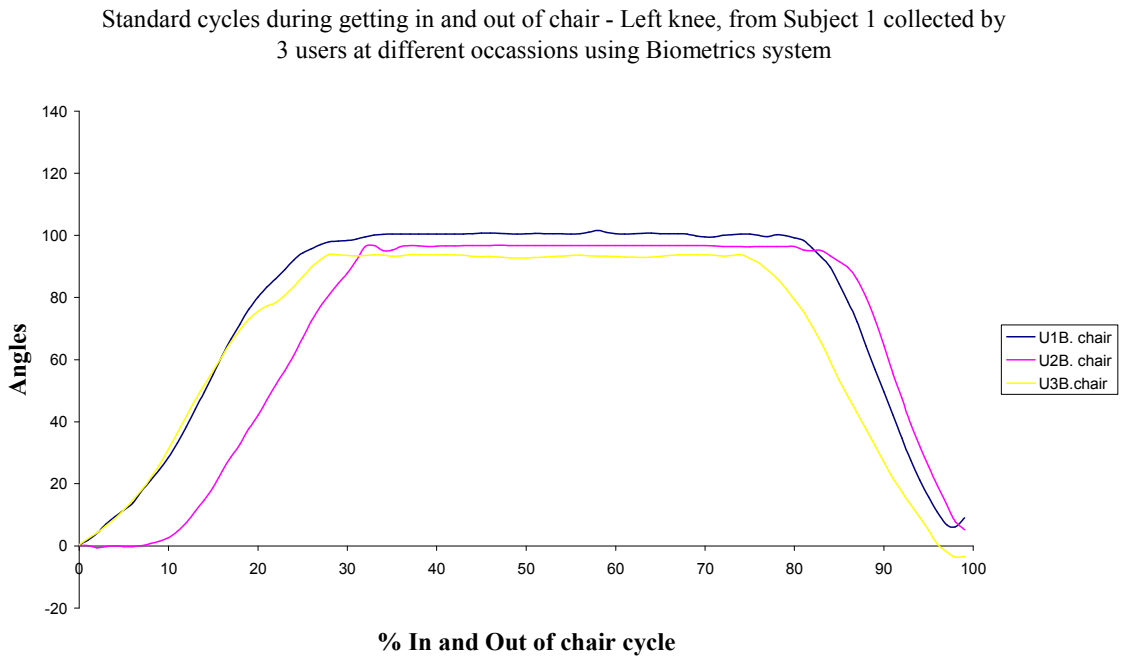


Figure 7.8 – Left Knee Angle of Subject1 during Getting in and out of chair as measured using Biometrics by users 1, 2 and 3 in different occasions.

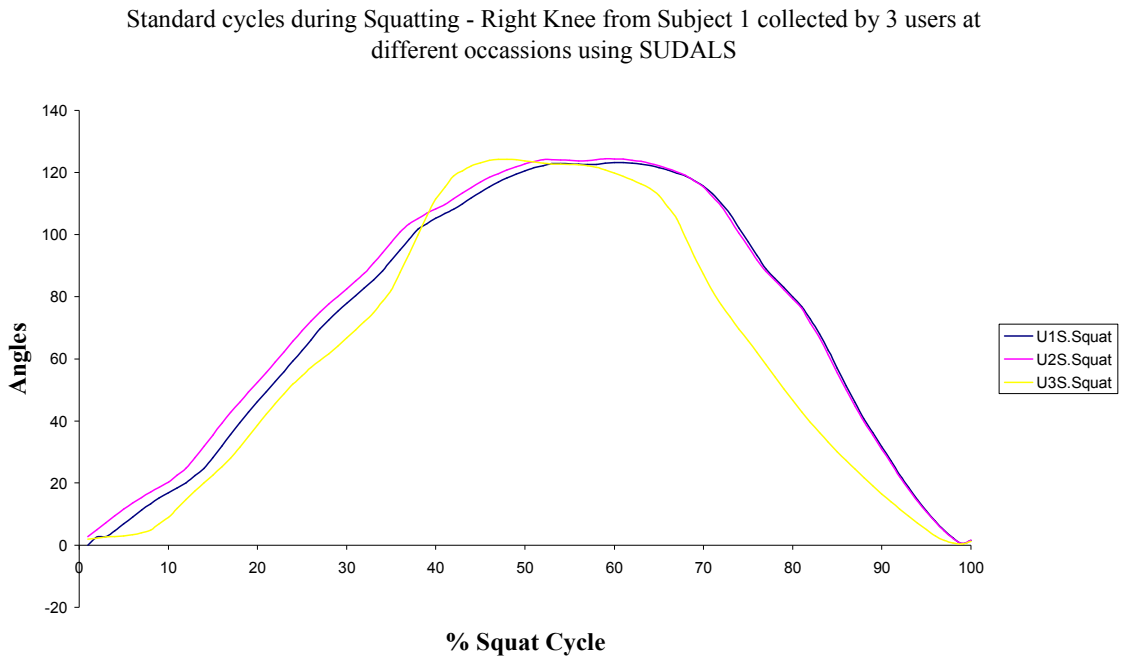


Figure 7.9 – Right Knee Angle of Subject1 during Squatting as measured using SUDALS by users 1, 2 and 3 in different occasions.

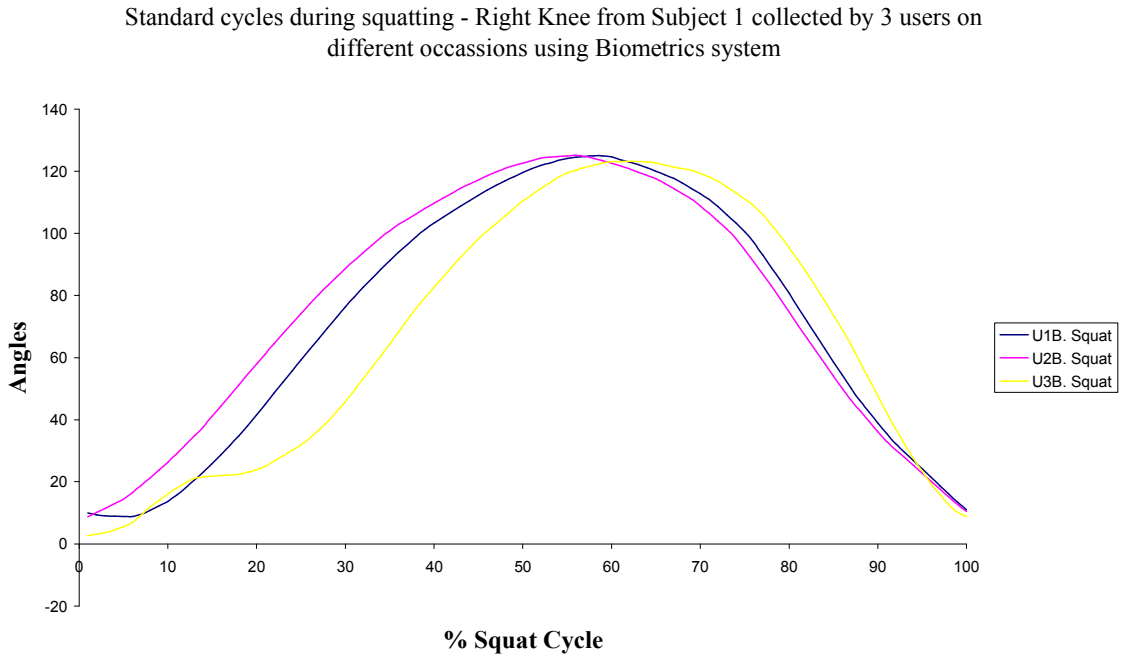


Figure 7.10 – Right Knee Angle of Subject1 during Squatting as measured using Biometrics by users 1, 2 and 3 in different occasions.

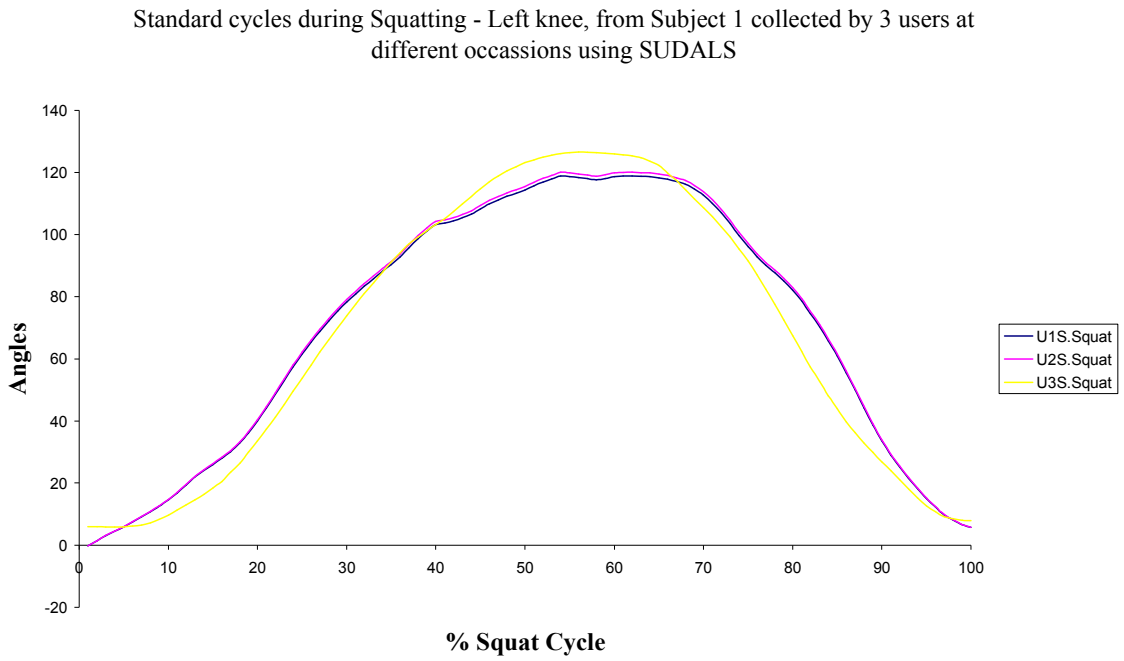


Figure 7.11 – Left Knee Angle of Subject1 during Squatting as measured using SUDALS by users 1, 2 and 3 in different occasions.

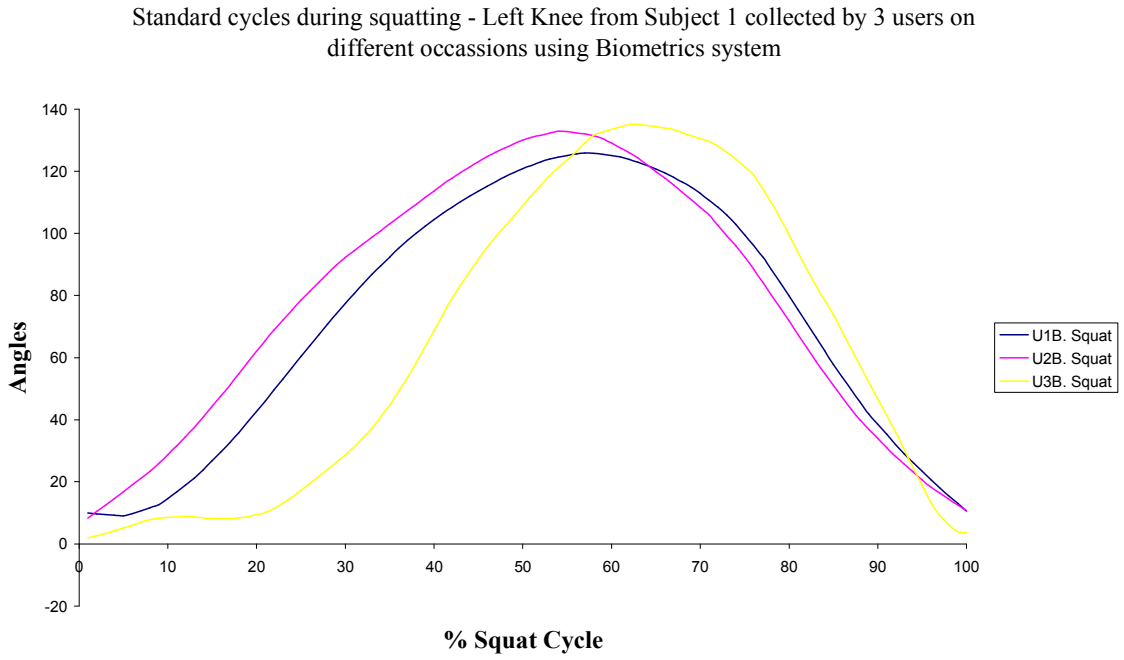


Figure 7.12 – Left Knee Angle of Subject1 during Squatting as measured using Biometrics by users 1, 2 and 3 in different occasions.

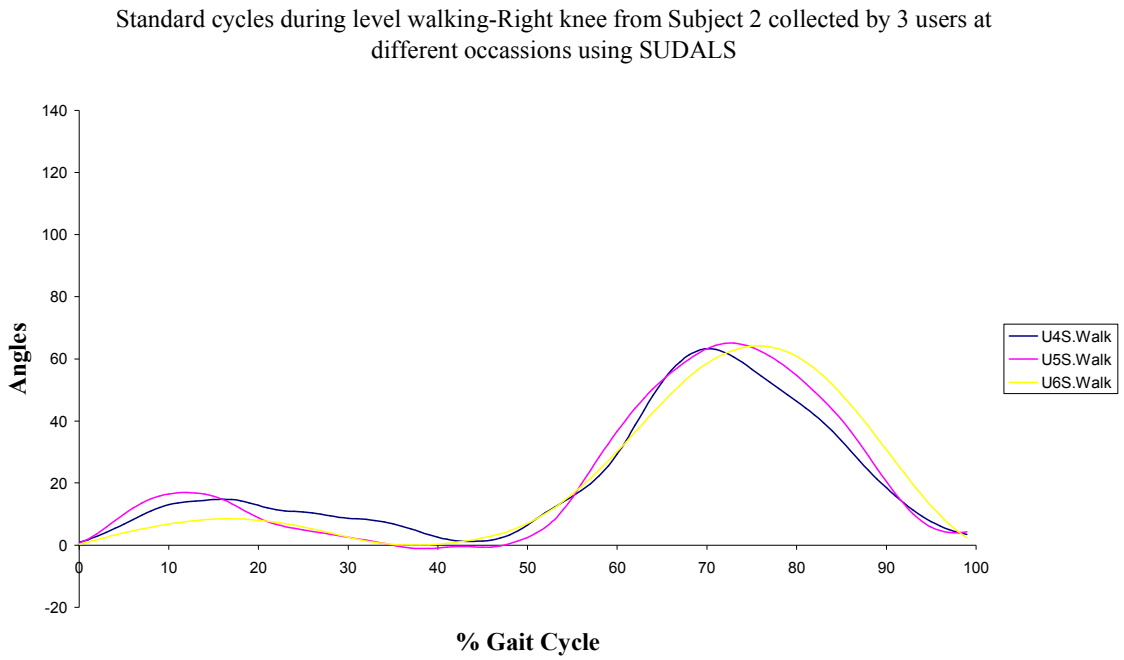


Figure 7.13 – Right Knee Angle of Subject2 during free speed level walking as measured using SUDALS by users 4, 5 and 6 in different occasions.

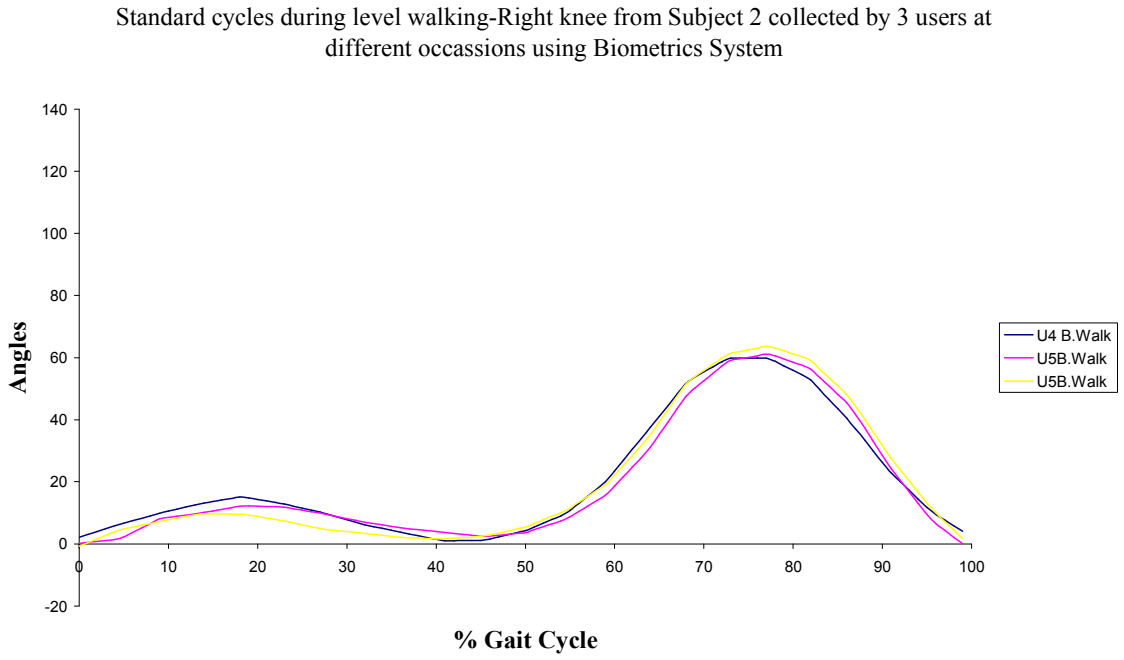


Figure 7.14 – Right Knee Angle of Subject2 during free speed level walking as measured using Biometrics by users 4, 5 and 6 in different occasions.

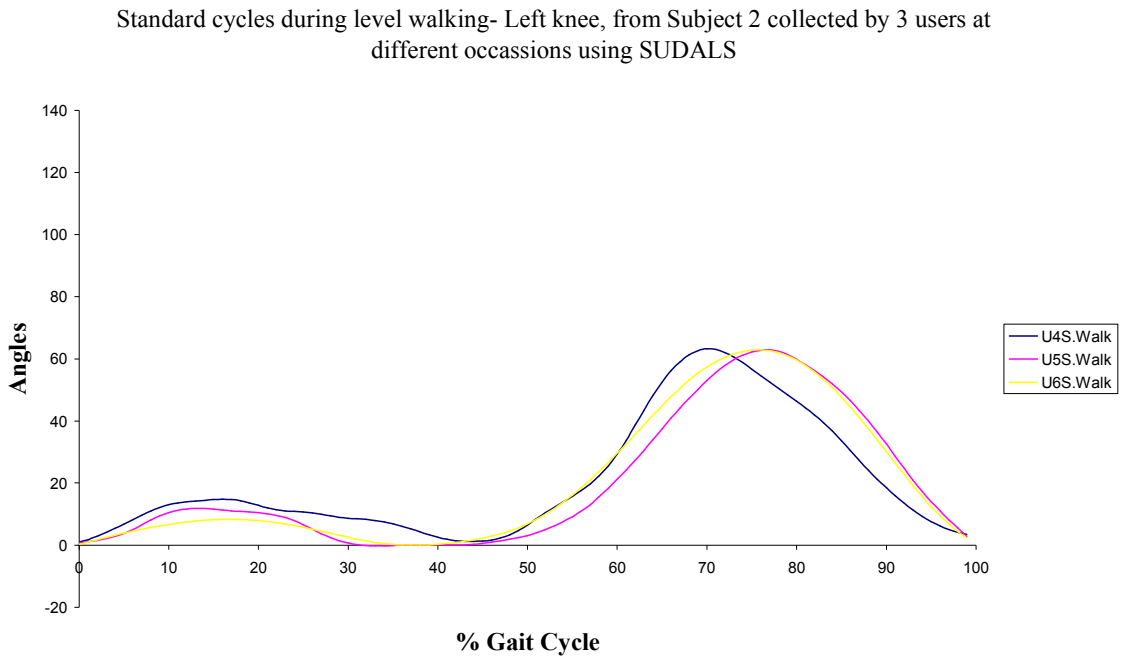


Figure 7.15 – Left Knee Angle of Subject2 during free speed level walking as measured using SUDALS by users 4, 5 and 6 in different occasions.

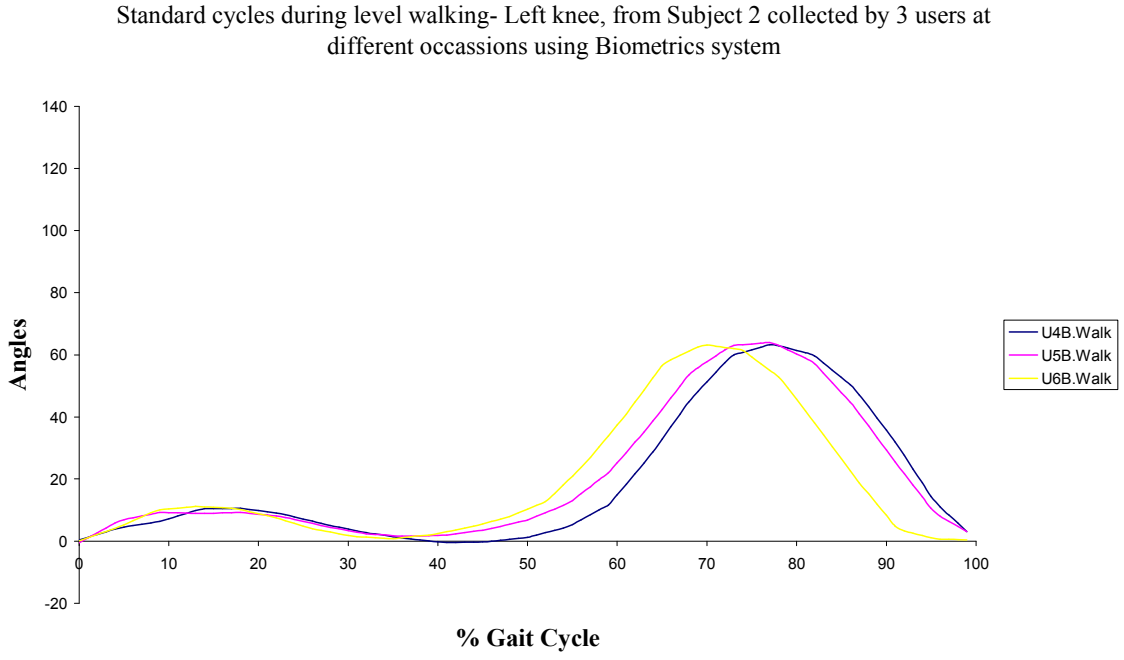


Figure 7.16 – Left Knee Angle of Subject2 during free speed level walking as measured using Biometrics by users 4, 5 and 6 in different occasions.

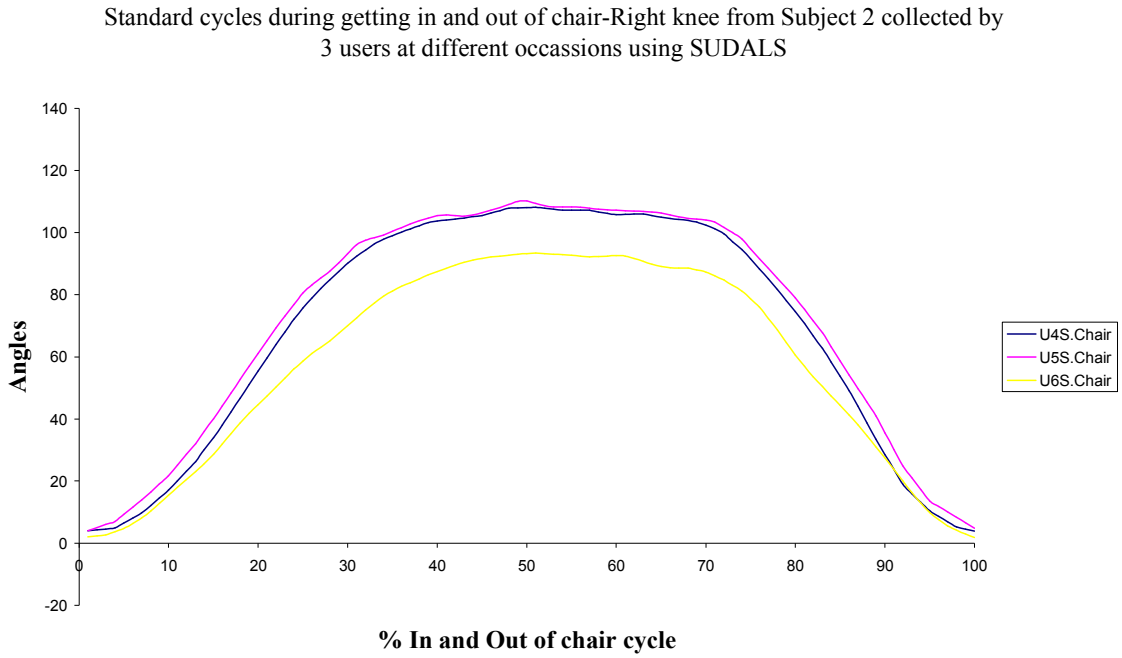


Figure 7.17 – Right Knee Angle of Subject2 during Getting in and out of chair as measured using SUDALS by users 4, 5 and 6 in different occasions.

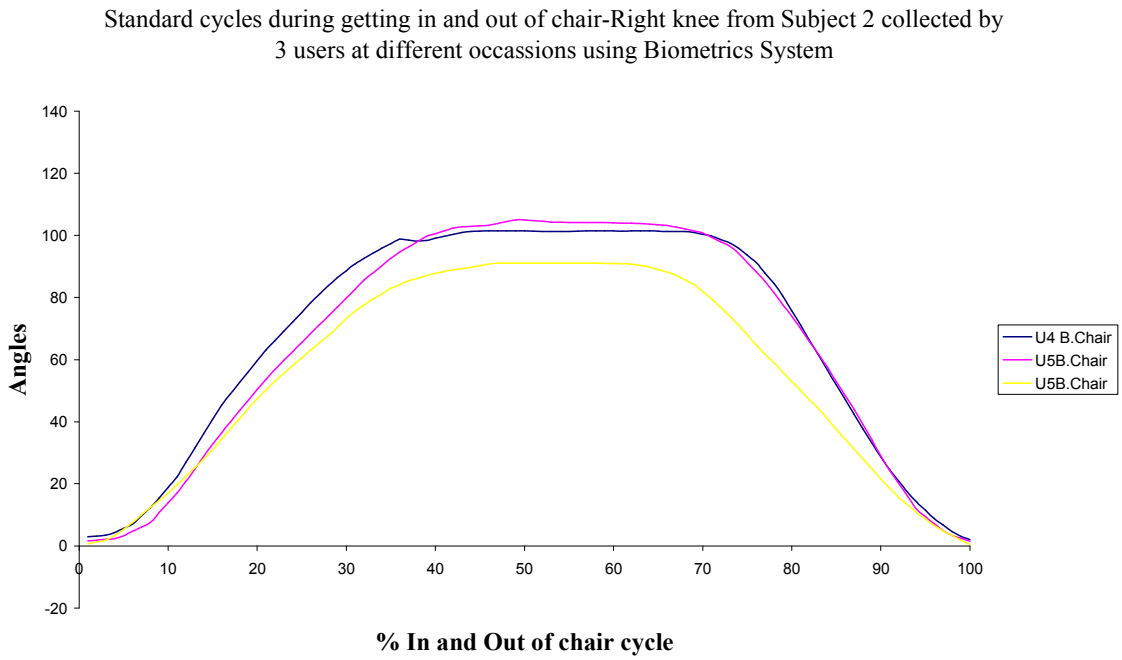


Figure 7.18 – Right Knee Angle of Subject2 during Getting in and out of chair as measured using Biometrics by users 4, 5 and 6 in different occasions.

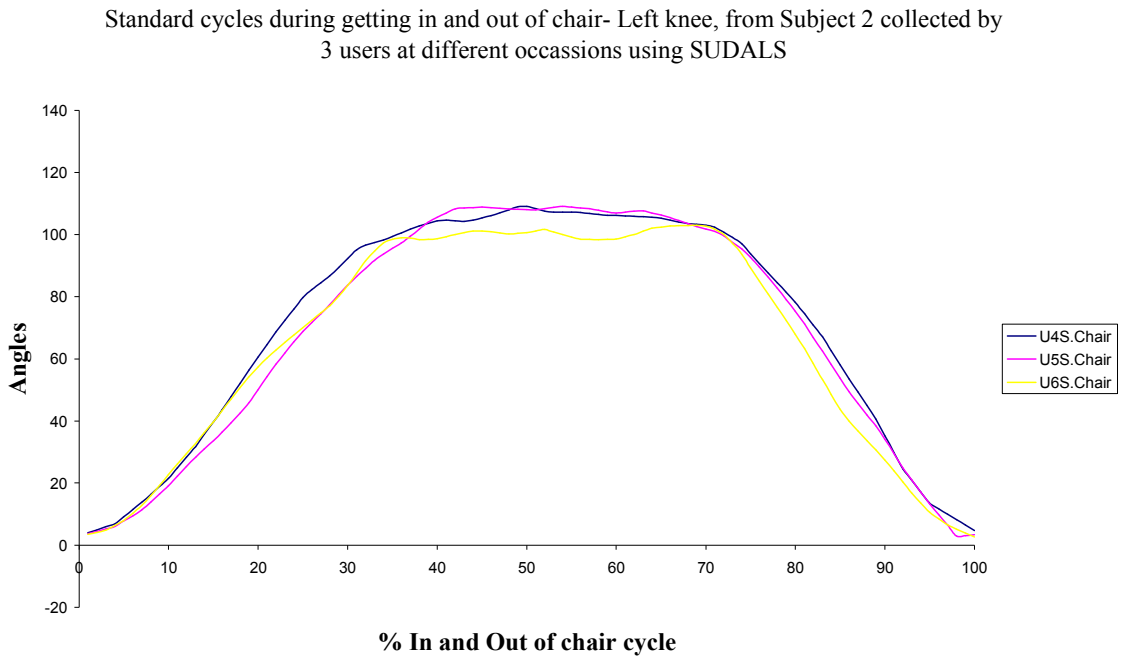


Figure 7.19 – Left Knee Angle of Subject2 during Getting in and out of chair as measured using SUDALS by users 4, 5 and 6 in different occasions.

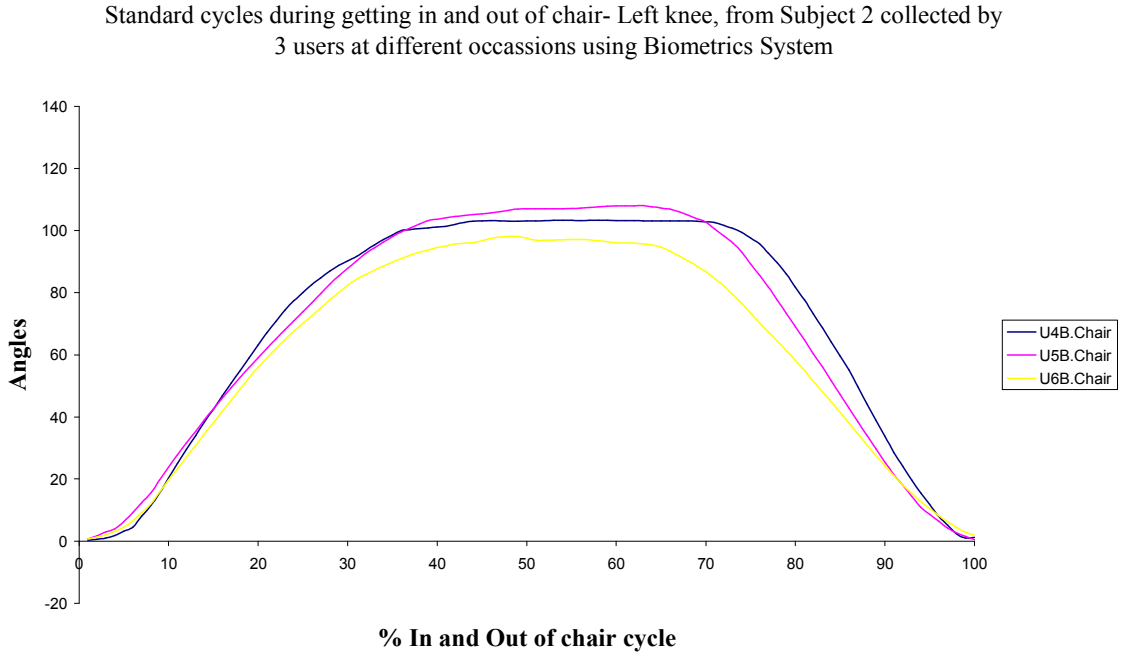


Figure 7.20 – Left Knee Angle of Subject2 during Getting in and out of chair as measured using Biometrics by users 4, 5 and 6 in different occasions.

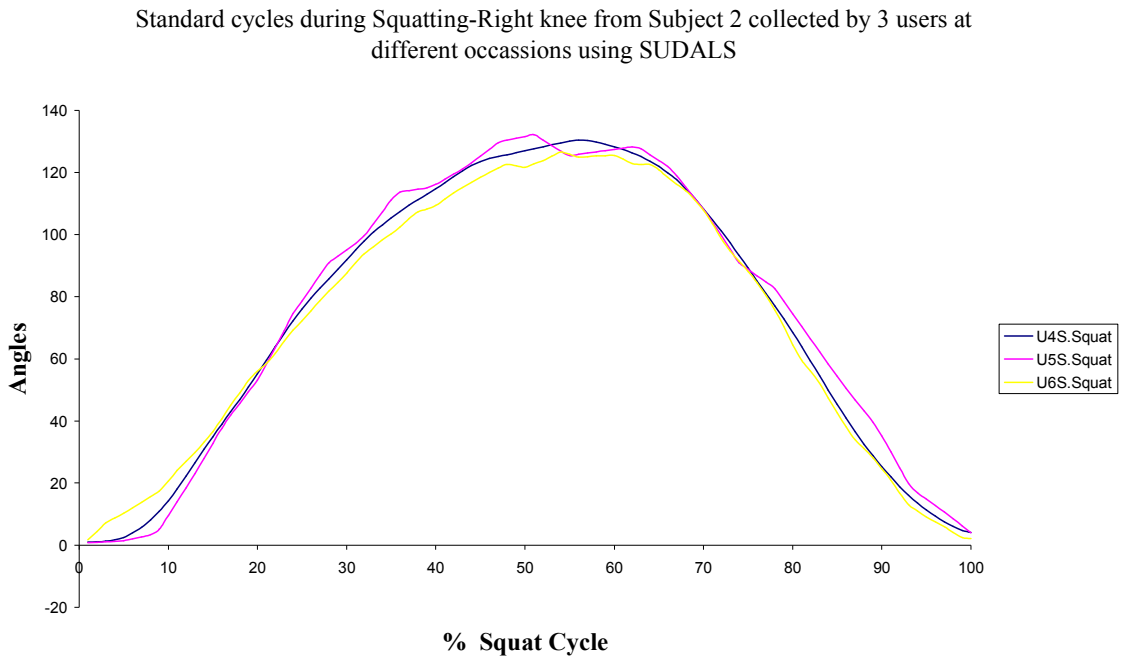


Figure 7.21 – Right Knee Angle of Subject2 during Squatting as measured using SUDALS by users 4, 5 and 6 in different occasions.

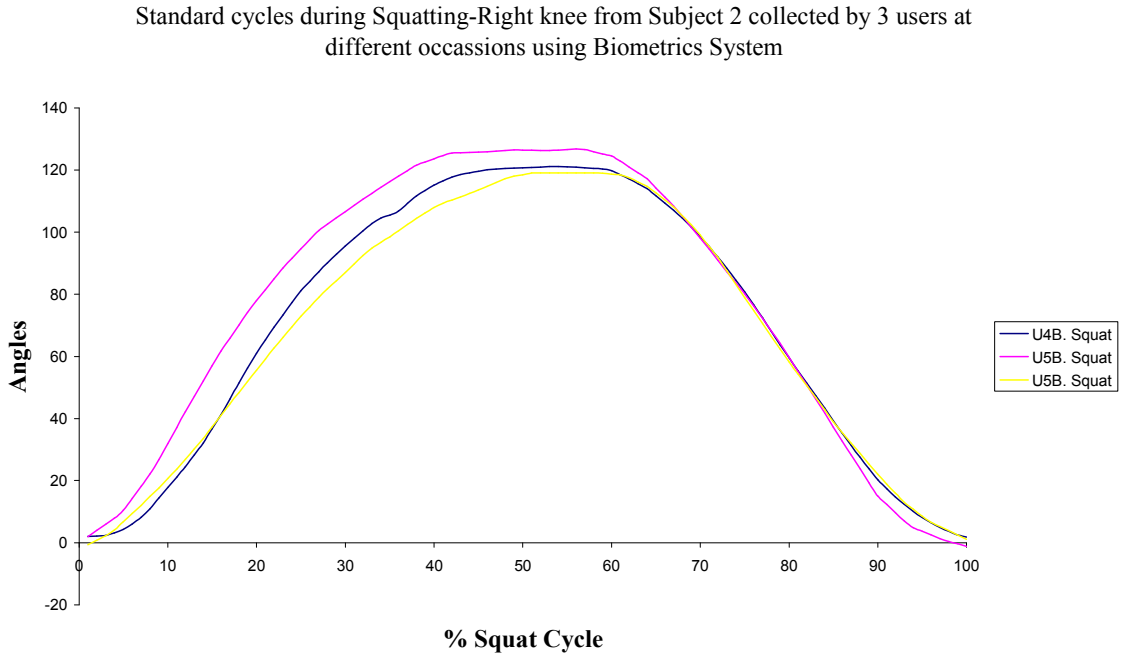


Figure 7.22 – Right Knee Angle of Subject2 during Squatting as measured using Biometrics by users 4, 5 and 6 in different occasions.

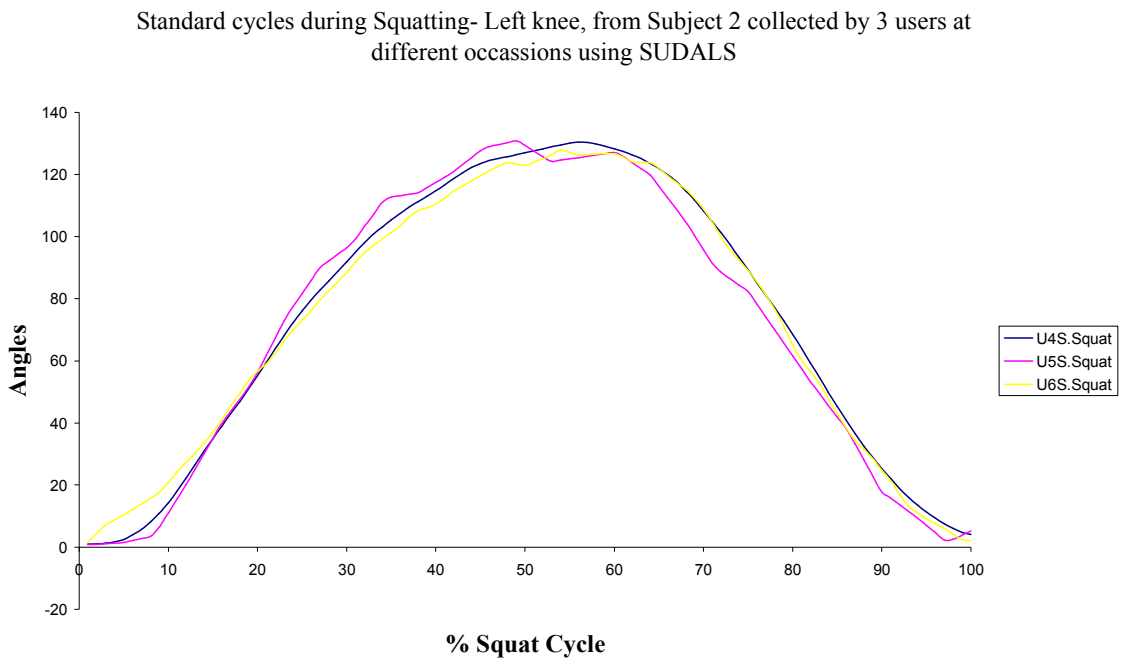


Figure 7.23 – Left Knee Angle of Subject2 during Squatting as measured using SUDALS by users 4, 5 and 6 in different occasions.

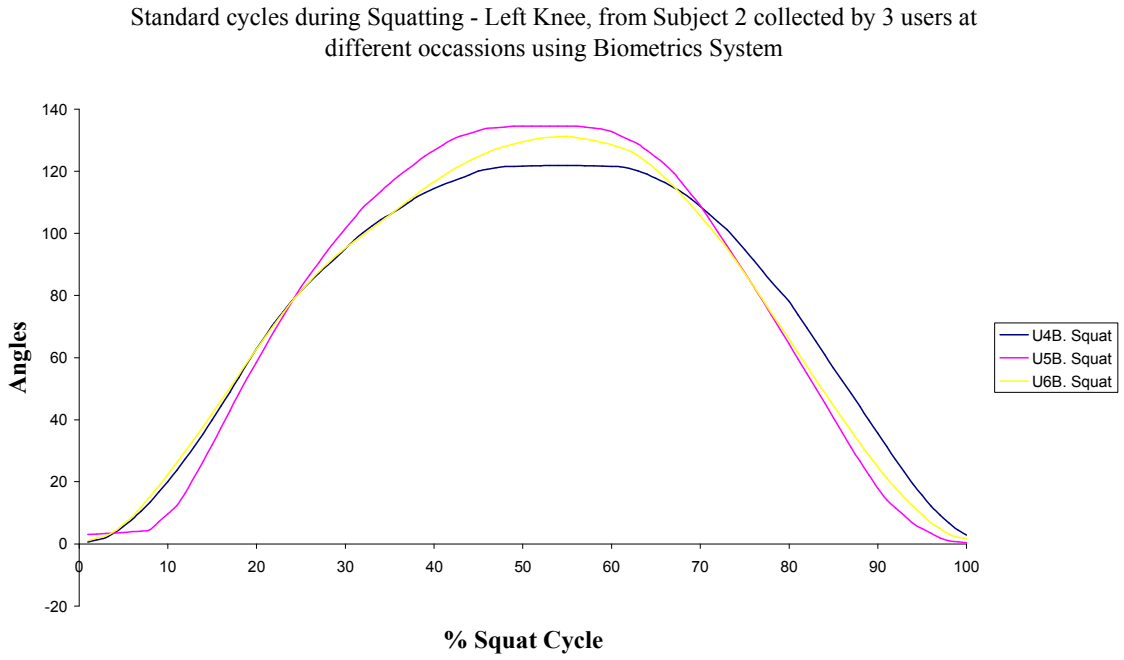


Figure 7.24 – Left Knee Angle of Subject2 during Squatting as measured using Biometrics by users 4, 5 and 6 in different occasions.

Results from user feedback Questionnaire

Feedback Questions	User 1 Feedback	User 2 Feedback	User 3 Feedback	User 4 Feedback	User 5 Feedback	User 6 Feedback
1. The training or the explanation of the system operation given prior to the usage of this system was sufficient.	Agree	Somewhat Agree	Somewhat Agree	Somewhat Agree	Somewhat Agree	Agree
2. I think we were given enough time to get to know about both the systems.	Agree	Agree	Somewhat Agree	Somewhat Agree	Agree	Somewhat Agree
3. Understanding the operation of SUDALS is much easier than the conventional system.	Somewhat Agree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Somewhat Agree
4. Operating the new system seems to be easy.	Agree	Somewhat agree	Somewhat Agree	Agree	Agree	Somewhat Agree
5. The new system doesn't involve a lot of technical issues and doesn't require a lot of technical skills.	Agree	Agree	Agree	Agree	Agree	Agree
6. I feel in minimal time useful data pertaining to knee functionality can be collected using this system.	Somewhat Disagree	Disagree	Somewhat Agree	Agree	Agree	Agree
7. Operating the system via a remote control minimises the physical contact with the subject and inconvenience to the subject during data collection.	Agree	Somewhat Agree	Somewhat Agree	Agree	Agree	Agree
8. On the whole the new system eration seems to be user friendly.	Somewhat Agree	Somewhat Disagree	Somewhat Agree	Agree	Agree	Agree

Table 7.14: Results from user feedback questionnaire

Results from Semi-formal Interview

Users	Description of SUDALS	Summarised quotes from the Users transcribed from the Interview
1	Simple objective tool	***SUDALS is a simple objective functional assessment tool for use in regular clinical practice.***
2	Highly Conceptual system	***The concept of SUDALS is much better than Biometrics system.***
3	Prompt and Instantaneous	***Gives instantaneous feedback on data recorded.***
4	Straight Forward	***Very explicit unlike Biometrics and I don't have to remember any functions.***
5	User friendly	***Its unique remote control feature makes me feel that SUDALS is user friendly.***
6	Simple and non-technical	***I think SUDALS can be used by any non-technical person like me.***

Table 7.15: Results from semi-formal interview

7.3 Data analysis and Discussion

On analysing the left and right knee angles recorded by all the assessors using SUDALS and Biometrics system during all the ADL's, there seems to be an overall good agreement in terms of the shape of the standard cycle curves of both the participants and the data is similar to those results obtained and discussed in previous chapters.

The consistency of the data collected from both the subjects by all the six users using the newly developed system (SUDALS) seems to be good and this is evident from the results displayed in the tables 7.4 to 7.9. The 'Two way random model – ICC $_{[2,6]}$' used here in this study, takes into account any kind of random effects induced by the participants while performing the activities or by the users while attaching the flexible electrogoniometers and provides an index of the mean change between two or more variables. The overall ICC values obtained for all the ADL's performed by both the

subjects are in the range of 0.8 to 0.99. This in turn shows that, the system is free from any kind of estimator effect and irrespective of newly trained assessors; the data collected on different occasions have good inter-rater reliability. The spread in the interval of the reliability data could also be due to the nature of some of the ADL as explained in previous chapter. Since, all the assessors were simply involved in data collection without influencing the performance or scoring of the participants, the possibility of the estimator interaction effect is ruled out in this study.

Though the overall agreement between the systems seems to be good, with respect to individual activities and subjects, certain discrepancies can be observed. On analysing the difference between both the data collecting systems in terms of maximum/minimum knee flexion angles and knee excursion angles, the mean absolute error for level walking and getting in and out of chair, is in the range of 1.0° to 3.4° and 2.0° to 5.0°. The maximum knee flexion recorded by both the systems from subject1 during the 1st assessment session, is slightly higher (4° to 5°) when compared to the maximum knee flexion recorded from the same subject during other two assessment sessions. Further, the subject seem to have exhibited a slight hyperextension (3° to 5°) when performing this activity during the 2nd and 3rd assessment sessions (assessed by user 2 and user 3). Since, the walking speed of an individual influences the knee flexion values and the gait pattern (Van der linden et al., 2007); this subject could have performed this activity with a different speed (higher pace) during the 1st assessment session compared to the other two assessment sessions. Similarly, considering the activity of getting in and out of the chair, in general, there seems to be a good agreement between the data recorded by both the systems when administered by different users on the subjects. However, due to the variability of the activity by itself (as discussed previously in chapter 5 and 6), there is a slight variation in the order of 4° to 5° in the maximum knee flexion recorded by both the data collecting systems.

As far as the activity of deep squatting is concerned, the data collected from both the subjects using both the data collecting systems on different occasions by all the assessors seem to show good agreement in both the graph pattern and maximum knee flexion with little variations exhibited by the subjects. The graphical pattern of the data

obtained using the Biometrics system from subject 1, by user 3 seems to vary to certain extent compared to the other graphical patterns produced by the same subject when assessed by users 1 and 2. This could be due to any kind of movement initiated by the subject during the recording process. During the recording process of this activity using the Biometrics system, the subject had to move to fetch the support and adjust his balance prior to the commencement of the activity. However, such variations are not seen in case of the data obtained from subject 2 and moreover the data from both the subjects using both the data collecting systems show less variation. The maximum knee flexion exhibited by the subjects (during squatting) here in this study is similar to those obtained from the experiments reported in the previous chapters of this thesis. However, the minimum flexion angles recorded by the Biometrics system seems to be very high compared to the SUDALS system and this in turn has increased the mean absolute error for this activity to 7.4°. In fact, the data acquisition system seems to have recorded this activity with an offset of 7° to 8°. This is evident from the figure 7.12. Further, there also seems to be a large variation (8° to 11°) in between the maximum right/left knee flexion angles recorded by the Biometrics system in case of both the subjects during the squatting. Such variations could be due to a number of reasons.

1. Due to the way in which the transducer was attached to the subjects.
2. Due to the manufacturing defects of the transducer.
3. Due to the way in which the subjects have performed this activity or
4. Due to the data logging system itself.

If such variations were due to any of the first two reasons, then the data recorded by SUDALS and the knee flexion/extension of these subjects during the other two activities should also show such large variations. However, the absence of such errors in the data recorded by SUDALS during other two activities infers that such variations could be due to some issues with the Biometrics data logging system or due to the variability of the subjects.

Further, observation of the graphs obtained from both the systems during all the ADL's from both the subjects reveal the presence of noise in the order of 2° to 3°. Possibly, this could be due to the way in which the users have attached the flexible electrogoniometers to the subjects. Though the users were given training prior to the

commencement of the assessment session and were guided during the device attachment procedures, it wasn't possible to re-check the actual positioning of the device as it would bias the results of the experiment. Hence, with a visual alignment, it was ensured that the devices were firmly attached on to the subjects' knee and the measurement was carried out. Despite the training given to the users, since they were new to the concept of flexible electrogoniometers, the users had to be assisted during the device attachment procedures to obtain acceptable outcomes similar to those reported here.

One specific incidence that took place during the second assessment session (when assessing subject 2) was the loosening of Velcro straps and attachment tapes. As explained previously in the routine deployment of the device, the double side attachment tapes are used for holding the flexible electrogoniometers firmly when attached to the subjects and the firm attachment of the flexible electrogoniometers on the subjects' knee depends on the placement of the attachment tapes on the posterior sides of the attachment strips (attached to the skin). However, if the tapes are going to be fixed at the centre of the plastic strips or at the distal end of the strip, instead of the proximal end (where one of the end plates of the flexible electrogoniometer is attached), then there are higher chances of plastic strips loosening due to the pulling weight of the goniometer. The use of Velcro straps is highly essential to compensate for such unforeseen situations and in addition to this, these straps provide an additional support to the flexible electrogoniometers and avoids the unwanted movement of the device while in use. All the users (user 4, 5 and 6) testing the second subject fixed the attachment tapes either in the centre of the plastic strips or at the distal end of the plastic strip. In addition to this, due to the unavailability of the original pair of Velcro straps, a new pair of Velcro straps for the shin area was used during these assessment sessions. These new Velcro straps weren't tight enough to hold the goniometers firmly as they weren't rubberised. As a result, during the assessment sessions, frequent loosening and slippage of these straps occurred. This inappropriate fixation of the attachment tapes and loosening of the Velcro straps could have resulted in some kind of friction rather than tension and this could have induced the additional noise observable in the data collected from this subject during the level walking. Despite such discrepancies, the results of the test for inter - rater reliability of

the data collected by both the systems during all the ADL's seem to be high to excellent similar to those reported in the literature.

Many researchers have used such statistical analysis to study the inter-rater reliability and have reported results similar to those obtained here in this study. Van der Linden et al., 2008 have used ICC coefficients to analyse the between day repeatability of knee kinematics during functional tasks recorded using flexible electrogoniometry. An ICC value of 0.75 and higher was regarded as an indication of good reliability and those below 0.75 was considered to be poor to moderately reliable by these authors. Similarly, Triolo et al., 1995, have used the ICC coefficients to study the inter-rater reliability of the functional standing test. Since, the testers involved in this study required training and practice to effectively administer the functional standing test, the researchers evaluated the inter-rater reliability with the ICC and ICC values ranging from 0.6 to 0.8 was considered to be moderately reliable and an ICC value greater than 0.8 was considered to be very reliable. In another study, Hsieh et al., 1998, have applied ICC to study the inter-rater reliability of three experienced occupational therapist in administering the 'Action Research Arm Test' on each stroke patient within a 3 day period. All these researchers have reported their reliability results based on the ICC values obtained and the use of ICC to test the inter-rater reliability seems to be a standard and common approach.

Previously, in a comparative study of clinical methods of goniometry, Goodwin et al., 1992 used Pearson's r correlation coefficient and paired T test to study the inter-rater reliability of the assessors using different clinical goniometers. Though T tests are useful in providing the degree of association between the measures and assessing the differences between the means of the measurements, it is not possible to use T test to analyse the data obtained from this study due to small sample size (2 participants). However, these researchers have concluded that, there were no significant differences between any of the testers with respect to the electrogoniometers used for measuring the flexion/extension of the elbow. Also, these researchers have suggested their preference in the use of electrogoniometers with respect to reduced inter-tester differences when compared to universal and fluid goniometers. At the same time, none of these researchers have reported about the standard error of measurement between the users when using flexible electrogoniometers together with the data collecting systems. Piriyaprasarth et

al., 2007, 2008 have suggested the use of SEM's in addition to the Pearson's correlation coefficients (r) and ICC values while reporting the inter-rater reliability of users. These researchers have highlighted the importance of SEM's when compared to other parameters such as r and ICC values. These researchers feel that, though these parameters give an idea about the degree of association between two sets of continuous data and provide an index of the mean change between two or more variables, the sole use of these parameters might not be able to fully explain the difference between the measurement tools as these coefficients do not indicate the magnitude of measurement error. Hence, to compliment the results these researchers have suggested the use of SEM. For the same reasons, SEM was calculated for the results obtained from this study. The measurement error for both the systems, irrespective of the users, varied from 2° to 5° for activities such as level walking and squatting. However, the measurement error for the activity of getting in and out of chair seems to be higher in the order of 10° to 13° irrespective of the assessors or systems used for collecting the data.

Such errors could be the resultant of the summation of errors due to the variability between the electrogoniometry measurements, which in turn can be due to the variability of the participants, instrument and the assessors attaching the electrogoniometers (Van der Linden et al., 2008; 2007) If such large errors were due to way in which the electrogoniometers were attached to the subject's, then the results of other two activities should also show such large errors. However, our results don't indicate such large errors for other two activities. Hence, the other possible reason for such large errors could be due to the way in which subjects have performed this activity. At the same time, the participants are not solely responsible for such variations, since the activity by itself is poor to moderately reliable, (Van der Linden et al., 2008; 2007.) The variability of this activity or the participants performing such an activity can be reduced to certain extent by designing a protocol similar to Boonstra et al., 2006. Whereby, the authors have marked the feet placement areas and advised the participants to place their feet at a defined distance. Though such measures could improve the reliability of the activity and reduce the error percentage by reducing the variability of the participants, the overall error percentage obtained for other activities from both the data collecting systems could certainly be due to the variability of the instrument on different days or

due to the assessors attaching the electrogoniometers as reported by Van der Linden et al., 2008.

The 6 assessors participated in this study were all allied health professionals who are considered to be the end-users of the flexible electrogoniometry systems (both SUDALS and Biometrics system) either in a clinical environment or a research area. The first group of users – User 1, 2 and 3, who assessed the subject 1, were physiotherapists with different work experiences and the second group of users – Users 4, 5 and 6, who assessed the subject 2, were research nurses. As far as the training given to the users prior to the experiment is concerned, all the users except users 1 and 6 felt that the explanation given to them regarding the system operation was sufficient to some extent. Whereas, user 1 and 6 felt that the training session was sufficient enough to operate the systems. However, unlike the users 1, 2 and 5, who considered that enough time was given to them to know about both the systems; users 3, 4 and 6 felt that the time given to them was partially adequate. Other than user 2 and user 3, all the users considered that, understanding the operation of SUDALS is easier to certain extent than the conventional system. While, user 3 suggested that, understanding the operation of SUDALS is as same as trying to understand the operation of the conventional system, user2 completely disagreed with this issue. However, the same users considered that, the operation of SUDALS is somewhat easy compared to the conventional system and this seems to be the same as the feedback given by user 6. On the other hand, user 1, 4 and 5 without any ambiguity, suggested that the operation of the newly developed system is easy compared to the conventional system.

Though the remote control operation minimises the physical contact with the subject and inconvenience to the subject during data collection, unlike users 1, 4, 5 and 6 who completely acknowledged this concept, users 2 and 3 suggested that, implementation of such an idea will benefit the patients or the subjects participating in such trials to certain extent. All the three research nurses and one of the physiotherapists (user 3) suggested that the time taken to collect useful data pertaining to knee functionality using SUDALS is minimal. However, the other two physiotherapists disagreed with this issue. Similar to other users, even though, user 3 commented that the newly developed system doesn't require a lot of technical skills and doesn't involve a lot

of technical issues, the user also suggested that the newly developed system is not that user friendly. Whereas, all the other users - the 2 physiotherapists and the 3 research nurses, considered that, SUDALS is a user friendly system to certain extent.

All the users personally suggested that 'the newly developed system is a much better concept compared to the commercially available Biometrics system'. This was revealed during the one to one personal interview with the users following the questionnaire session. However, in addition to the responses given by them via the feedback questionnaire, the users had additional feedbacks and comments regarding the operation of both the systems and the concept of flexible electrogoniometry on the whole. The user 1 (who is a physiotherapist and has also gained a PhD in Bioengineering) suggested that '***I have never used such objective measurement techniques previously in knee rehabilitation interventions and in terms of a user and a patient point of view, compared to the Biometrics system, using SUDALS is much more convenient due to the remote control feature and wireless transmission of data which provides the ability to simultaneously view the results obtained***.' With the Biometrics system, the user felt that there is a lot more of physical contact with the subject when the instrument is being worn by them and trying to select a function by using the buttons will be as if the user is trying to push the subject from his/her back. Further, the user feels that the LCD display of the system was not bright enough and visible to know whether the system is performing the required function. Similarly, with SUDALS, the user felt that there is a bit of delay in-between the selection of different functions and the user felt that both the data acquisition systems should have some form of visual or audio indication to let the user know if a specific function is selected and what the system is doing. On the whole, the user suggested that, '***Unlike questionnaire based evaluation techniques, such objective assessment tools should be used as part of the regular clinical practice to meet the requirements of evidence based approaches and with each system having its own pros and cons, SUDALS is a user-friendly system that can be used for such an application***'. The feedback obtained from user 3 (who has gained a PhD in physiotherapy) was almost similar to those given by user 1. Similar to user 1, user 3 seem to have experience in treating patients who have undergone knee surgery and in the personal interview, the user 2 reported that, '***He has never used any such assessment tools in measuring the***

functional outcomes of a patient who has undergone a knee surgery.' The user suggested that, '***It would be better if there is any kind of indication in addition to the LED switch-off to let the user know once a function is selected.***' **At the same time, the user also feels that as** ***he uses the system more frequently, he will get used to it and such an issue shouldn't be a problem***.' Towards the end of the personal interview, the user very clearly mentioned that '***Both the systems have their own pros and cons. The LCD display of the Biometrics system has been taken over by the remote control feature and the instant data feedback feature of the SUDALS. Hence, I feel comfortable to use both systems. However, the concept of flexible electrogoniometry can only be used in a research setting and not in a clinical environment due to the half an hour time slot given to us to attend each outpatient.***' This feedback is similar to one given by user 2 (who has gained a PhD in Physics). Though the user suggested that, the concept of SUDALS is much better than Biometrics system, at the same time, the assessor also thinks that, '***the idea of remote control with human beings would make them feel like a robot***.' Further, the user doesn't seem to be comfortable in using both the systems by placing the device at the back of the subjects. The users personally reported that '***I feel using both these systems will not allow me to interact with my patients face to face and I personally prefer to interact with my patients during the treatment***.' Due to the delay issue (as reported by user 1), the user 2 also feels that the time taken to collect the data using SUDALS is a bit longer than the time taken to collect data using Biometrics.

Considering the research nurses, except the user 6 – who is currently pursuing her PhD, the other two nurses are currently working for the clinical research facility in Glasgow. All the research nurses said '***SUDALS is a very straight forward system which is simple to use and user friendly***'. The user 4 found the Biometrics system a bit confusing as the user had to remember the functions of each button in the data logger. This seems to be similar to the feedback given by user 6 during the interview session. The user 5 found both the systems cumbersome and reported that, '***with respect to remote control features and instant data feedback I find SUDALS user friendly and with respect to the LCD display I find Biometrics user friendly. However, the more I practice I'll get familiarised with the systems.***' Similarly, user 6 also reported that ' ***I found SUDALS a***

bit apprehensive initially as I didn't know what is happening when I click the key fob, but later on I found it very easy with the remote control feature as I can collect the data and at the same time interact with the subject. Moreover, I think SUDALS can be used by any non technical person like me'. Though none of the research nurses had previous experience with knee rehabilitation interventions, the research nurses suggested that, '***despite the objective nature of flexible electrogoniometry systems, they can be used only in a research environment rather than in a clinical environment due to time constraint issues***'.

In conclusion, with a good agreement between the systems in terms of the reliability of the data recorded, from the feedback obtained from the users, it is very clear that the newly developed system SUDALS, has a few minor limitations which are also apparent for the commercially available system. The user feedback obtained from this study has given general recommendations on factors that should be considered when developing a device for rehabilitation application. Further, this study helped in analysing the potential advantages and disadvantages of one data acquisition system with respect to other from a user perspective, which would be useful in developing a much more efficient and a dynamic system that can be used in assessing the functional outcomes of the knee following TKA either at a research or a clinical environment. Few measurement errors occurred due to the rater, participant and instrument variability. The overall flexible electrogoniometry system in conjunction with SUDALS showed good inter-rater reliability and considerable advantages compared to the commercial system, making it a user friendly system that can be used to collect and provide meaningful data pertaining to the flexion/extension during various ADL.

Chapter 8: General Discussion

This chapter provides a general discussion of the work undertaken by reviewing the project in the light of the rationale mentioned in chapter 2. The development of a simple data acquisition system for use with flexible electrogoniometers in TKA was the main aim of this research. The result was the design, development, validation and evaluation of the SUDALS (Strathclyde University Data Logging System). The SUDALS was evaluated by assessing the flexion/extension of the knee of various normal individuals during various ADL's. Further, the developed system was validated, tested for reliability against the literature and commercially available data collecting system and also as part of the device development cycle, the system was allowed to be used by the end-users and was evaluated for its user friendly nature and inter-rater reliability. These objectives leading to the accomplishment of the final goal were successfully achieved. Specific observations, assumptions and conclusion were identified and depicted in previous chapters. This chapter deals with general discussion on the design, development, validation and evaluation of the SUDALS. In addition to this, several possibilities for further development are discussed and a strategy for further work is also outlined.

8.1 The need for a simple objective functional assessment tool

- Having studied the epidemiology and impact of OA, TKA seem to be a promising solution for such a degenerative disorder.
- However, to accomplish the goal of EBP and to promote scientific research in the filed of orthopaedics, an objective functional assessment following such an orthopaedic intervention is necessary.
- Further, such a success in the field of orthopaedic research will benefit millions of people suffering from various bone and joint conditions. Consequently, this will fulfil the preliminary objective of this '*Bone and Joint Decade*'.
- Accomplishment of such objectives, firmly relies on the ability of orthopaedic research to efficiently make use of clinically relevant, simple, objective and scientific measurement techniques that can be routinely used by research nurses

and AHP's with sufficient training in the local CRF's participating in multi centre RCT's – which will be the gold standard of EBP.

- A thorough literature review, revealed the availability of various commercially used movement analysis sensors. However, due to the simplicity, accuracy, unobtrusive nature, clinical applicability and with respect to the objective functional assessment of the knee following such an intervention, flexible electrogoniometers have gained popularity.
- At the same time, the literature shows a gap in the use of simple user friendly system of data loggers to be used in conjunction with flexible electrogoniometers for such applications, whereby clicking a single button will record and transmit data pertaining to knee flexion/extension. This in turn led to the development of SUDALS.
- The development of user friendly system of flexible electrogoniometers seem to fulfil the above needs by allowing one to study the behaviour of patients during various ADL's (walking, getting in and out of a chair, stair ascend and descend and a deep squat) and acquire sufficient information regarding the mobility or actual functioning of the knee joint following TKA, so as to allow a routine clinical appraisal of individual patients and the intervention they have received.

8.2 User friendly system of Flexible electrogoniometers

Having gained clinical popularity, the flexible electrogoniometer proved to be a simple and non-obtrusive device that can be used in the measurement of human locomotion in an unconstrained environment. However, to make use of the device efficiently and to keep the errors to a minimum, the devices have to be aligned suitably at the specific anatomical position and should be attached firmly to the subjects using the plastic strips, attachment tapes and Velcro straps as improper attachment procedures and loosening of Velcro straps can induce errors as reported in chapter 7. This issue has been highlighted by various researchers in the literature as well (Piriyaprasarth et al., 2008, Rowe et al., 2001). Though the literature reveals that the device is not sensitive to relative translation of the end plates (Nicol, 1987), researchers have suggested the use of an attachment protocol to eliminate errors due to skin movement (Rowe et al., 2001) and the attachment

protocol used here in all the experiments was similar to that suggested by Rowe et al. In addition to this, once the devices are attached to the lateral border of the knee, both visual alignment and anatomical alignment of the device should be carried out as suggested by Piriyaprasarth et al., 2008. However, with respect to the user study the users were trained to attach the devices based only on a visual alignment in such a way that the upper end-block points to the hip joint and the lower end-block points to the ankle joint. This in turn could have resulted in the errors reported in chapter 7. However, in the future the users should also be trained in the anatomical alignment procedures and it shouldn't be a problem for the end-users to perform such a check as the end-users are professionals from a medical background. As part of the user study, only the inter-rater reliability of the system was studied and it was not possible to carry out an intra-tester reliability study with the end-users due to their clinical commitments and hectic time scale. Though it would be advisable to make use of a single user to attach the devices to the participants since the intra-rater reliability of the device is better than the inter-rater reliability (Goodwin et al., 1992, Piriyaprasarth et al., 2008, Nicol, 1989), when it comes to multi centre clinical trials, such a bottle neck can be overcome by providing suitable, sufficient and frequent training to the users with the help of an economical training package similar to the one used here in this study.

The User friendly system for use with flexible electrogoniometers, namely; SUDALS, was designed to perform the 5 main functions pertaining to data collection and the system operation was kept as simple as possible (Key fob remote control) to facilitate its operation by any non-technical person. Though the primary aim of developing SUDALS was accomplished, certain compromises in the design had to be made due to the lack or limited availability of resources. The SUDALS would have been much more efficient if its design was based solely on the surface mount microcontroller IC - ADUC7026. However, the size of the system, the memory capacity and the firmware functionality has been limited due to the use of the evaluation board. The size of the SUDALS is mainly due to the size of the evaluation board used in the design of the whole system. The current size of the system - 197x145x55mm can be reduced to 38 x 37 x 18 mm by making use of the surface mount microcontroller IC of dimension 6 x 6mm. However, the cost of surface mount IC holder must be taken into account (A single

holder costs nearly £300). Further, for micro soldering and PCB mounting purposes, a suitable third party has to be identified due to lack of resources within the Bioengineering Unit of University of Strathclyde. The lack of availability of a higher capacity of an internal memory necessitated the use of an external memory. However, the capacity of the external memory was also limited by the memory footprint provided by the manufacturers. Despite such an issue, the system has proven to record and transmit data during ADL's and no technical difficulties were reported by the users from the clinics. The firmware functionality could have been made much more efficient if there were more uni-functional GPIO ports at the microcontroller end. The Limited availability of these ports has led to the firmware functionality that is currently employed in SUDALS. Such compromises have in turn reflected on some of the feedbacks given by the users as discussed in chapter 7. However, the simplicity involved in operating the system by clicking a single button has allowed non-technical professionals from the clinics to operate the system with minimal training and has enabled them to collect and transmit data in few minutes. Further, the results obtained using this system has proven to be reliable, valid and reproducible.

System Accuracy, Reliability and Validity

The SUDALS together with the flexible electrogoniometers showed good linearity with a correlation coefficient (best-fit by least squares) of r = 0.99. Further, the system was capable of quantifying angular displacements to the nearest 0.15° with a maximum inaccuracy of 3° to 5° in extreme conditions. The errors calculated for SUDALS when used with flexible electrogoniometers as reported in chapter 4 vary from ± 2° to ± 5° for all the three goniometers. These errors may be due to the flexible electrogoniometer or due to the manufacturing defects in the A/D or D/A channels of the SUDALS to which these devices were connected. However, it is difficult to come to a conclusion, since the literature reveals the existence of a measurement error due to the electrogoniometer itself. Piriyaprasarth et al., 2008 reported the measurement error from electrogoniometry to be 0.8° to 3.6°. Similarly, Shiratsu & Coury, 2003 reported the device error to be ±3°. Further, studies carried out by Rowe et al., reveal the existence of

errors due to hysteresis ranging from 1° to 1.6° for joint movements less than or equal to 100°, when these devices are subjected to repetitive angular displacements within short period of time. The errors reported in the literature are similar to those obtained from this study. On the other hand, if we assume that the error was only due to the A/D or D/A channels, then the results of the knee flexion/extension and knee excursion during various ADL's as discussed in chapters 5, 6 and 7 wouldn't be similar to those reported in the literature and there wouldn't have been any agreement between the results obtained from SUDALS and commercially available data collecting system. An important conclusion drawn from the results reported in chapter 4 is that, calibrating the bench testing the system by mimicking the conditions similar to the actual application, prior to usage of the developed device, helps one to know about the errors associated with the system and to remove any faults in the hardware, firmware and software. All the experiments; (both static and dynamic) were carried out in controlled conditions and in environments free from other electrical systems and ambient noise. Though flexible electrogoniometers are suitable for use in hospital environments (Rowe et al., 2001), it is advisable to study the effect of electrical cross contamination and the response of SUDALS in such environments prior to releasing the system for commercial use

As far as the reliability of the system is concerned, good consistency and agreement in terms of the shape of the individual participants' knee flexion/extension curves for both the knees recorded by both the systems during all the 3 trials during the various ADL's was observed and high values of correlation coefficients show that there is a good repeatability and reproducibility in the data recorded by the system. With few discrepancies in the pattern of the curves during specific ADL's such as squatting and getting in and out of chair as reported in chapter 5, the values recorded by SUDALS during the ADL's from the normal subjects seem to be within the values published in the literature. Since, all the participants who volunteered in the studies reported here in this thesis were young and slim as opposed to TKA patients who are significantly fatter. When using the electrogoniometers on fatter individuals, proper anatomical positioning and alignment of the sensors have to be taken into account to avoid errors due to misalignment of sensors. Despite the recommendation of digital filters for various applications as suggested in the literature, the use of digital filters with suitable cut off

frequency doesn't seem to smooth the curves or remove the jitters or noise present in the data completely and this is evident from the irregularities found in the graphical pattern of the activities such as getting in and out of chair and squatting. Hence, analogue filters have to be used prior to signal conditioning to eliminate the noise. In addition to this, such noises can also be eliminated by making use of dual-in-package type strain gauge type amplifiers along with instrumentation amplifiers used in this application. Yet another important factor to be borne in mind, when designing amplification circuits is that, the circuits have to be soldered on to PCB's instead of strip boards to keep the errors (due to interference) to a very minimal level. For such purposes, the laboratories should be fully equipped and provide the research students with micro soldering facilities.

Considering the system validation, despite the prevalence of offset issues due to the reasons explained in chapter 5, the data obtained from the Vicon system showed a good agreement with the data obtained from SUDALS. Similar to the validation study carried out by Rowe et al., 2001, though the validation was performed only for level walking, the system can be validated with Vicon for other ADL's such as getting in and out of the chair, stair ascend, stair descend and squatting. However, the visibility of some of the markers attached to certain joints when validating the device for all these ADL's can be limited and hence, this issue has to be taken into account during such validation trials otherwise it can lead to erroneous data.

All the activities chosen here for testing the reliability of the developed system are some of the common activities of daily living. Reviewing the literature reveals that, the activity of getting in and out of a chair is a most strenuous activity and especially getting out of a chair without an arm rest produces increased forces up to seven times the body weight at the knee joint (Boonstra et al., 2006). On the other hand, Protopapadaki et al., 2007 and Costigan et al., 2002, suggests that stair climbing activity is a common activity of daily life and the knee flexion exhibited by individuals during this activity is much larger when compared to the knee flexion during level walking and understanding the biomechanics of the knee during stair climbing from a therapeutic point of view will be useful in managing patients with lower extremity dysfunction. Further, studying the range of motion of the knee during stair descend, undertaken here in this research is similar to the work reported by Jevsevar et al., 1993. In addition to these activities, many

researchers have included the activity of getting in and out of a bath (deep knee flexion activity) in assessing the functional outcomes of the knee following TKA (Rowe et al., 2000, Van der Linden et al., 2007). It was not possible to test the developed system during this activity due to the lack of availability of a bath within the Bioengineering unit and hence, this was replicated by a similar deep knee flexion activity - squatting. However, other than Wyss et al., 2003, other researchers haven't reported anything about the range of motion of the knee during squatting. The main idea behind the inclusion of these activities in the experiments reported here in this thesis was to test the ability and reliability of the developed system in measuring deep knee flexion/extension activities, unlike all these authors, who primarily aimed to study the biomechanics of the knee during these activities. This in turn gave an understanding about the actual clinical applicability of the device and the system that can be used in the future to assess the functional outcomes of the knee following TKA during such ADL's.

All participants were asked to carry out the activities in their free speed. However, in activities such as level walking, stair ascend and descend, the impact of varying walking speed and the extent to which it affects the output of electrogoniometers when used with both the data collecting systems was not studied as part of this research. Technically speaking, variation in the walking speed shouldn't induce any errors due to the high sampling frequency (50 Hz) used in the process of recording the data. However, due to lack of evidence in the literature to support this argument, the future studies should focus on this aspect. The methodology adopted here in testing the developed system as explained in chapters 5, 6 and 7 are similar those reported in the literature. However, in chapter 6, the performance of SUDALS during various ADL's was compared to the commercially available system and good agreement and consistency of data obtained from both the systems during all the ADL's was observed. Few variations in the order of 5° were observed and this was again depended on various factors. One of the main reasons figured out for such errors are the variation in the electrogoniometric measurements which in turn could be due to the variability of the participants, instrument and the assessors attaching the electrogoniometers and the variability of activities. The variability of certain activities such as getting in and out of chair and Squatting can be overcome by standardising the protocols as suggested in chapter 7. Nevertheless, the

intra-rater reliability and inter-rater reliability of SUDLAS was found to be good. Reviewing the literature reveals the existence of very little information regarding the accuracy of the Biometrics system in assessing the functional outcomes of knee of the control groups during the above mentioned ADL's. Certain researchers have used this system with control groups in inter and intra rater reliability studies (Piriyaprasarth et al., 2008) and in comparing the functional outcomes of a control group with a treatment group (Van der Linden et al., 2007). However, the activities performed by the subjects were static trials and the age group (50 to 65 years) of the control subjects who participated in those studies does not match with those included here. Though the ICC values between both the systems seem to be good, the absolute agreement between both the systems could have been studied in detail, if there was enough evidence in the literature about the performance of the commercial system when used on younger control groups. Further, the manufacturer of the commercial system doesn't seem to have evaluated the device for its user friendly nature and no such study has been reported in the literature

Usability of the system

The experiment carried out in studying the usability of the newly developed system has helped in understanding the need for involvement of focus groups in the product development cycle. The results of the user study indicate that, training the users to handle and attach the electrogoniometers prior to the actual clinical trial measurements is mandatory. The users found the training given to them (via SOP's and CD) to be very useful to get started with the use of the concept of flexible electrogoniometry. However, from the interview it was very clear that the users will be more comfortable in using the system as they start using the devices frequently and increase their familiarity with the flexible electrogoniometry system. However, the results indicate that the research nurses and physiotherapists can be involved in obtaining sensible and objective knee functional assessment data following TKA. Such valuable information will compliment the routine assessment scales used by these professionals for such applications and would also let the orthopaedic surgeons know how far the intervention has/has not been effective on the individuals. However, the time constraint

issue of the physiotherapists can be overcome by involving the research nurses in assisting the physiotherapists to collect such information. Incorporation of such a protocol on a routine basis will fulfil the basic career goal of research nurses (as mentioned in chapter 1) and at the same time the information required can also be collected from each patient within the allocated time slot. Having shown that SUDALS is a user friendly system, inclusion of certain features as suggested by the users will make the system much better than the commercially available system.

Implementation of the user suggestions and other improvements

Some of the improvements required in terms of the overall size, the memory capacity and the functioning (firmware) of the SUDALS have already been highlighted in chapter 3. In addition to those, some of the improvements based on the user feedback (as mentioned in chapter 7) are taken into account and the ways of implementing those suggestions are summarized here in this section.

Overall Size and Memory capacity of the data acquisition system

There were no concerns regarding the size of the SUDALS as it was similar to the commercially available system. However, as mentioned in chapter 3, the overall size of the system can be reduced if the evaluation board is replaced as such by the surface mount microcontroller IC alone due to its small size as shown below in figure 8.1. Together with this IC, if all the other dual in package IC's used in the signal conditioning and power supply circuits are going to be replaced by surface mount IC's then, the size of the whole data collecting system can be miniaturized and the dimensions of the overall system will be similar to activity monitors (3.8cm x 3.7cm x 1.8cm).

Figure 8.1

As mentioned in chapter 3, the ability of the system to record and store large amounts of data for a prolonged time is limited due to the use of this specific version of the microcontroller and evaluation board. Hence, to overcome this problem, a different version of either the same microcontroller or a microcontroller belonging to a different family with a large memory capacity should be chosen for this application. An alternative approach for this issue would be, to make use of microcontrollers which have provision for interfacing high memory capacity (1 GB) flash memory cards similar to the commercial system. Further, the concept of transmitting the recorded data to a PC via wireless can be improvised to a secondary stage whereby, the data collecting system can be interfaced with a mobile phone. With an increase in the memory capacity of the device, the data recorded during the ADL's can be saved as individual excel files and all the information can be transmitted from the data acquisition system to the mobile phone. This can be accomplished by interfacing the data acquisition system with a bluetooth chip and creating a communication link between the system and mobile phone.

LCD Display

During the personal interview with the nurses, one of the nurses happened to mention that, *'She is comfortable with the commercial system with respect to*

the LCD display as she is always used to work with medical/electronic devices which had a LCD display'. To fulfil the user requirement, the concept of using LED's to indicate the status of the system can be replaced by a LCD display, which will allow the user to view the real time graph of the data being recorded and at the same time it will also let the user know the system status. This can be done by interfacing the LCD display with the GPIO ports of the microcontroller. Hence, when choosing the microcontroller, the availability of uni-functional GPIO ports should also be taken into account.

Replacing an IR remote control with RF remote control

Other than user 2 as mentioned in chapter 7, none of the users had concerns with the use of remote control. Since, the concept of this IR remote control proved to be successful among the majority of users who participated in this study, the next phase would be to improve the IR remote control to a RF remote control based system. Though the IR remote control based system seem to be useful, the current system has direct line of sight issues and also this system cannot be used in zones prone to IR radiation. Hence, this can be replaced by a RF based remote control system which would have higher operating range and can be certainly used in any environment. However, prior to selecting the frequency at which the device can be operated, its compatibility within a hospital environment should be taken into account. Further, the new remote controller can be designed with 5 buttons corresponding to 5 different functions pertaining to data collection similar to the current system. With proper labelling, the functions performed by the 5 LED's in the current system can be carried out using this remote controller and this would offer a much more sophisticated advantage compared to the current system.

Possible future applications

Improving SUDALS in all these aspects will make the system a much more efficient and a dynamic system compared to the commercially available one. Following the improvisation, the 3rd generation system developed should be tested on patients who are recovering from TKA during the above mentioned ADL's. Since, the system performance with normal subjects have been

studied and reported here, carrying out experiments with the 3rd generation system similar to those reported here, will give us information pertaining to the pros and cons of the system from a patient point of view. Though the concept of flexible electrogoniometry has been adopted by certain researchers, it's still in its infancy among the medical professionals. Hence, testing the developed system on different population (international multi centre clinical trials), will help other clinicians and researchers become aware of the availability of such a user friendly system and will also provoke them to use such an objective assessment tool as part of their routine assessment technique. However, prior to the commencement of such trials, the ethical approval ought to be sorted out. Though ethics is a mandatory framework to be adopted for good clinical practice, the time taken by ethics committees to review and sort out an ethical approval can slow down the commencement of such trials and this should be considered when designing clinical protocols. The SUDALS together with flexible electrogoniometers has been reported in this thesis with respect to its usability in assessing the functional outcomes of the knee following a TKA. However, many other conditions such as stroke, spinal cord injury (SCI) etc. where the individuals have problem in using their lower limbs to accomplish their ADL could be studied in a similar way (Bagnato et al., 2009, Amankwah et al., 2004). Further, flexible electrogoniometry can record other degrees of freedom such as abduction, adduction and other major joints. The system can also be used for studying the lower limb dysfunction by using multiple electrogoniometers and analysing the efficiency of the treatment by analysing the graph patterns or data obtained from the individuals during various ADL's.

From the research work carried out and reported here in this thesis, it is evident that all the sensors used for measuring human activities or acquiring objective information following an intervention have certain pros and cons. The issues or limitations associated with an existing system can be overcome by developing an improvised version of an existing system which can be used as an alternative to the existing one. However, due to certain human errors or materials used in the development of the system, the newly developed device will have certain limitations and hence, prior to the usage of such systems, the researchers should thoroughly investigate the

characteristics of all the available devices and study the potential strengths and weaknesses of one system over the other. With respect to the work undertaken here, the author was able to study three different systems, namely; SUDALS, Biometrics and Vicon system used in acquiring objective information following an intervention. The strengths and weaknesses of these systems are summarised in the table 8.1 given below.

In summary, though the development of SUDALS for use with flexible electrogoniometers has bridged most of the significant gaps addressed in the literature and has proven to be an efficient and user friendly system to certain extent, implementation of the user suggestions (as mentioned in this chapter) will make the system a much more dynamic one compared to the commercially available system. However, SUDALS together with flexible electrogoniometers presents an advance towards and important goal in rehabilitation science: the objective tool to assess the functional outcomes of knee following TKA.

Objective data collecting System	Strengths	Weaknesses
SUDALS	• Facilitates remote data collection via a key fob remote control. • Compact and portable. • Facilitates wireless data transfer. • Economical, simple and non-technical to use unlike the commercial one. • Can be used in clinical practice on a routine basis. • Performs five different functions pertaining to data collection. • Good resolution and accuracy similar to the commercial system. • Good inter-rater and intra-rater reliability. • Can be used in studying knee kinematics for large population in less time. • Time taken to analyse the data is less compared to conventional systems such as Vicon system.	• Increased function select time. • Lack of LCD display. • Less memory capacity. • Bulkier than the commercial system by approximately 150 grams. • Cannot be used in detailed kinematic studies involving abduction and adduction movements of the joint. • Cannot be used in zones prone to Infra Red radiation. • Accuracy of the results depends on the anatomical attachment of flexible electrogoniometers by the raters.

Biometrics/Commercial system.	• Compact and Portable. • Light weight. • No delay in selecting the desired functions • Provides an LCD display of the recordings made. • Increased memory capacity. • Can be used in any environment suitable for data collection. • Good resolution and accuracy. • Good inter-rater and intra-rater reliability. • Can be used in studying knee kinematics for large population in less time. • Time taken to analyse the data is less compared to conventional systems such as Vicon system.	• Cannot be used in detailed kinematic studies involving abduction and adduction movements of the joint. • Accuracy of the results depends on the anatomical attachment of flexible electrogoniometers by the raters. • Cannot be used for remote control data collection. • Increased likelihood of physical contact with the subjects. • Doesn't facilitate wireless transfer of data. • Due to its technical complexity, cannot be used in a clinical practice on a routine basis without extensive training. Also the system functionality doesn't include data acquisition features similar to SUDALS.

Vicon System	• Considered as Gold standard in studies involving biomechanical analysis of joints. • Can be used in detailed kinematic analysis of the joint involving abduction and adduction movements. • Can be used in any environment suitable for objective data collection. • The accuracy of Vicon system is much better compared to other systems used for objective data collection. • Doesn't involve any physical contact with the subjects during the process of data collection. • Can be used for validating any newly developed system.	• Suitable for studying smaller population. • Both experimentation and post-experiment data analysis is a very time consuming process. • Cannot be used in routine clinical practice. • Requires highly skilled professionals to operate the system. • The accuracy of the results depends upon the system calibration, position and visibility of the markers and the bodybuilder program which calculates the required knee angle with respect to the markers attached t o other joints such as ankle and hip. • Compared to the SUDALS and Biometrics system, Vicon system is a non-economical one.

Table 8.1: Strengths and Weaknesses of three different data acquisition systems used in collecting Knee Kinematics data: SUDALS, Biometrics and

Chapter 9: Conclusions

- This thesis described a novel instrument for acquiring the data pertaining to knee function of an individual during the various ADL's.
- The thesis shows initial evidence of the usability of the SUDALS together with flexible electrogoniometers for objectively measuring the knee functionality of normal subjects during various ADL's.
- The system was not only able to record the knee flexion/extension data but was also able to perform other functions such as scrap the recorded data, transmit the data to a PC via wireless, reset the system following a data collection trial and also zero the transducers interfaced with it.
- SUDALS together with flexible electrogoniometers is capable of quantifying angular displacements to the nearest of 0.15°with a maximum inaccuracy of 3° to 5° in extreme conditions.
- 95% of the measurements made by all the electrogoniometers, irrespective of the channels to which they are connected, have a standard deviation of 4° to 7°.
- The SUDALS was characterised and validated with Gold standard, commercially available system and with the literature.
- The results obtained from all the experiments were satisfactory and from the results the following conclusions were drawn:
    1. There was variability between and among the subjects when performing the activities.
    2. Also, there was variation between and among the electrogoniometers on different occasions and among the assessors using such systems.
    3. However, these variations were similar for both the data acquisition systems used for collecting the data and
    4. The reliability of the SUDALS was similar to the commercially available system.

- The systems proved to be easy to use, non obtrusive and very economical compared to the commercially available system.
- The system proved to involve less technical issues and hence it was usable by non-technical professionals.
- The wireless feature of the device allowed the users to view the data collected spontaneously and know about the reliability of the data (knee ROM) collected during various ADL's.
- Further, the concept of using a remote control was a novel idea and this proved to be much more useful than the commercial system as it eliminated the possibility of any physical contact with the subjects.

In summary, this research led to the development of an uncomplicated system to assess the functional outcome of the knee during various ADL's. The system was evaluated and its feasibility as an aid to evaluate an intervention, namely; TKA was firmly established. Thus the aim of the research was achieved satisfactorily. Benefits, limitations and possible applications of the SUDALS were identified. This encourages continued exploitation of the SUDALS by improving it and using it in other applications. Thus, the SUDALS proved to be a simple, portable, robust, unobtrusive, useful and reliable tool for assessing and evaluating the functional outcomes of the knee during various ADL's and hence the system can be used in rehabilitation studies following an intervention such as TKA.

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