A Dissertation Submitted in Fulfilment of the Requirements for the Podiatry Degree with Honours

School of Podiatry
Birmingham Metropolitan College

A Study to Investigate the Effect of Sofsole® Silicone Gel Insoles on Plantar Pressure (kPa), in Non-Pathological Participants.

Amendment: ‘Sofsole Silicone’ now known as Diaped Duosoft Flow

By
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Word Count – 8,769
Acknowledgements

I would like to thank Mrs Joycelyn Williamson, Mr John Tasker and Dr Paul Blakeman for their continuing support throughout the process of this research project. Further thanks go to my mum Bernice Williams for her support, and my husband Gareth Anthony, who spent many lonely evenings and weekends during the production of this work. Without the support of you all this project would not have been possible.
Abstract

The aim of this study was to determine the effect of Sofsole® ribbed silicone gel insoles, on maximum peak plantar pressure (kPa) and total contact area (cm²), in non-pathological patients, due to a paucity of research in this area. The Sofsole® insoles are a prototype product in the UK, which are constructed from cells of ‘solid’ silicone gel, with a polyurethane foam top cover. This experimental study used a convenience sample of ten participants, with data recorded for both the left and right feet with participants wearing standardised footwear (with and without Sofsole® insoles). A mean of three plantar pressure measurements taken during dynamic gait, was used to calculate the sum value for the maximum total foot peak plantar pressure and total contact area.

Results determined that there was a reduction in the mean maximum peak pressure across the total foot with the use of the Sofsole® insoles by 9.02%, (SD=5.43%). When a t test was applied it was found that p=<0.0001, t=6.11 and 95% Confidence Intervals were calculated to be 7.10-14.49. It was also determined that there was an increase in mean total contact area across the total foot with the use of the Sofsole® insoles, by 7.95%, (SD=3.99%). A t test found p= <0.0001, t=-8.10 and 95% Confidence Intervals were calculated to be -19.31 to -11.38. It was therefore concluded that in this study the Sofsole® insole decreased plantar pressure, and increased total contact area. These insoles may therefore have therapeutic value and be of use in a Podiatric clinical setting for patients requiring plantar pressure reduction.
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1. **Introduction**

Redistribution of plantar pressure from high pressure areas can be a vitally important Podiatric clinical treatment modality. Areas of increased plantar pressure have been indicated as a cause of pain, callus and tissue damage. (Bryant, Tinley & Singer, 1999), (Leber & Evanski, 1986), (Rogers, Otter & Birch, 2006) Plantar pressure analysis and subsequent reduction as part of treatment planning and intervention is often critical in the management of patients who are at high risk of multifactorial tissue breakdown and plantar ulceration, often involving pathologies such as diabetes mellitus. (Ibrahim et al, 2013), (McSween, Brydson & Hamilton, 1999), (Paton et al, 2012), (Raspovic, et al, 2000), (Rogers, Otter & Birch, 2006) Plantar pressure is stated to be reduced by the redistribution of pressure over a larger contact area, which is achieved by the prescription of a device worn in the patients footwear to act as an interface between the sole of the foot and the shoe. (Leber & Evanski, 1986) The amount of pressure reduction achieved can be altered by the use of specific materials in the manufacture of the device, as numerous materials with various properties have been proved to have different effects. (Duffin et al, 2003) The use of more traditional materials such as Poron®, for example, are commonly used to achieve this, (Ibrahim et al, 2013), (Leber & Evanski, 1986), (Rogers, Otter & Birch, 2006) but newer materials such as silicone gel products may be found to be more effective.

An orthotic can be defined podiatrically as either a functional or accommodative device. A functional orthotic is defined by Mooney, (2009) as a bespoke or
moulded device prescribed to improve function and misalignment by the correction of a deformity. An accommodative orthotic, commonly referred to as an insole can be defined as a device used for symptomatic relief of conditions, which is not functional, but can aid treatment by the reduction of pathology. (Mooney, 2009) Accommodative cushioning materials are used to redistribute pressure across the foot (Williams & Nester, 2010) and are ‘a simple and cost effective way to prevent ulcers developing’ (Miller, et al, 2011:81) because they can reduce forefoot pressure. (Miller et al, 2011)

Previous studies have shown materials such as Poron®, Spenco® and Plastazote® can increase contact area and decrease foot pressure. (Birke, Foto & Pfieter, 1999) It is therefore of interest to determine whether a new product to the UK Podiatry market, such as the Sofsole® ribbed silicone gel insole (SRSI), which is a prefabricated accommodative device can also achieve plantar pressure reduction and increase total contact area. Even in the 1960’s it was suggested that silicone was used to reduce forces, although in relation to shear force rather than vertical pressure. (Curryer & Lemaire, 2000) The Sofsole® investigated will be referred to as an insole throughout this study.

Plantar pressure is often measured with instrumented gait analysis systems to facilitate the objective measurement of parameters which cannot be seen by the naked eye, enabling more accurate data measurements. (Curran & Dananberg, 2005) This study uses an RS Scan footscan® pressure plate system (footscan®) to facilitate measurement of plantar pressures during the stance phase of dynamic gait, allowing for the effect of the SRSI’s to be measured accurately.
Evidence-based practice has been considered important, since the 1970’s and it was stated in a 1998 report entitled A First Class Service: Quality in the New NHS, that ‘evidence based practice must be in every-day use.’ (Curran & Dananberg, 2005:131) The Podiatry profession has adopted this practice and continued research, such as into the effects of silicone gel products. The outcome of such studies can contribute to the,

‘fundamental philosophy of all health professionals is to enhance quality of life, either by decreasing pain levels or by restoring near-optimal function.’ (Curran & Dananberg, 2005: 137)

and the use of SRSI’s may have a role in facilitation of this in clinical Podiatric practice. Should SRSI’s prove to be effective at plantar pressure reduction in this non-pathological cohort, further research into their use as a treatment modality for pathological patients in a number of clinical scenarios is indicated, such as preventing hyperkeratosis or potential risk of ulceration. (Leber & Evanski, 1986), (Paton et al, 2012), (Raspovic, et al, 2000), (Rogers, Otter & Birch, 2006), (Tsung et al, 2004)

‘Knowledge of the pressure redistribution with different insole shapes can offer guidance for the better design and construction,’

(Tsung et al, 2004:768)

which can maximise the potential Podiatric treatment success when using such products.
1.1 Aims
This research project aims to investigate the effects of SRSI’s on maximum peak plantar pressure (kPa) across the whole foot during the stance phase of dynamic gait in non-pathological patients. They are a new prototype design of insoles soon to be available to Podiatrists on the UK market. Significantly, there is a paucity of research concerning such gel insoles and their effect on plantar pressure and contact area. This is despite there being many of these products, in a wide variety of designs, available to UK Podiatrists, other healthcare professionals and also the general public.
2. Literature Review

Much Podiatically relevant previous research has focused on the use of orthotics, often cast, or bespoke devices intended to reduce plantar pressure. Most of this research has been focused on patients with systemic pathologies such as diabetes mellitus (commonly exhibiting neuropathy) and rheumatoid arthritis. (Duffin, et al, 2003), (MacSween, Brydson, & Hamilton, 1999), (Paton et al, 2012), (Raspovic, et al, 2000), (Rogers, Otter & Birch, 2006) There is less published research investigating the effect of prefabricated accommodative insoles on plantar pressure, in either non-pathological patients, or those with systemic disease, prompting research in this area. Such insoles are often prescribed in routine clinics to patients, regardless of medical conditions suffered, for offloading areas of high pressure, to decrease pain and improve skin integrity, but without the evidential clinical research to prove the effects. (MacSween, Brydson & Hamilton, 1999)

The main papers which are focused on for this literature review are, Bryant, Tinley & Singer, (1999), Kanatli et al, (2008), Kiper et al, (2012), Miller et al, (2011), Orlin & McPoil, (2000), Quesada & Sawyer, (1995), all will be discussed further below.

Traditionally custom made orthoses are made in order to reduce plantar pressure, through the method of increased total plantar contact area. The materials used in the manufacture of such are often accommodative. (Barnett, 2005), (Birke, Foto & Pifiefer, 1999), (Williams & Nester, 2010) It is suggested
that this method of plantar pressure reduction may not fully compensate for foot
dysfunction, and therefore research into new methods and in particular the
materials which are employed in such methods require research. (Paton et al,
2012) Due to previous research on Poron® and other accommodative
materials, which state the use of silicone and other such materials is of benefit
because they are said to be *essentially immune to compression set,*’ (Whittle,
1996: 5) it is justifiable to state that research into silicone gel insoles such as
the SRSI’s is required, for the continuing development of Podiatric medicine.
Further, Barnett (2005) suggests that the efficacy of simple plantar cushioning
suggests that foot orthoses are not always required to be bespoke.

Previous research is further limited by the fact that some studies have focused
on liquid silicone insoles, and others ‘solid’ silicone. Due to the focus of this
study being prefabricated, accommodative insoles and more specifically the
silicone gel which these are constructed from, the literature review will focus
exclusively on this area, including both designs.

2.1 Gait Analysis – Plantar Pressure Measurement

Gait analysis is defined as *the systemic assessment and analysis of human
locomotion,*’ (Payne & Bird as Cited in Yates, 2012: 308) and it is used in
Podiatric practice to form part of a successful diagnosis and treatment plan for
the patient, guiding decisions on therapeutic interventions, such as the use of
insoles and measuring treatment efficacy. (Payne & Bird as cited in Yates,
2012)
Scientific, quantitative methods of gait analysis are a common place feature of biomechanical assessments in the podiatric clinical setting, and in research, providing both dynamic and static objective measurements of what cannot be observed by the Podiatrist. The first scientific methods to record the magnitude of foot/heel contact with the ground were made in 19th Century France, using air reservoirs to measure the forces applied to these areas. (Sutherland, 2005) Since then technology has advanced and a variety of kinetic gait measurement systems have been produced, such as force platforms and in shoe pressure systems, with pressure plates becoming available in the 1990’s. (Curran & Dananberg, 2005) (Kiper, 2012)

2.1.1 Kinetics

Kinetics is defined as,

‘the study and measurement of forces and moments exerted on the body that influence movement.’ (Payne & Bird, as cited in Yates, 2012: 315)

Use of a pressure plate allows quantitative measurement of vertical forces (pressure), acting at the foot/floor or shoe/floor interface, on various anatomical regions of the plantar foot. (Payne & Bird, as cited in Yates, 2012) Instrumented gait analysis is stated to demonstrate both good interrater and intrarater reliability also. (Curran & Dananberg, 2005) The information can enable modification of the patient’s treatment plan, through the use of orthoses, (Birke, Foto & Pﬁefer, 1999), of various materials which provide pressure redistribution, such as Poron®. (Orlin & McPoil, 2000) Plantar pressure
measurement systems are not the focus of this research project and therefore will not be discussed further.

### 2.1.2 Pressure

Pressure can be defined as force per unit area, and is calculated as pressure equals force divided by area. Sensors in plantar pressure equipment therefore measure the force which is acting on them as the foot is in contact with the plate. Area is defined as the surface contact which occurs between the plantar foot and a sensor. (Orlin & McPoil, 2000) The International unit of pressure is the pascal. A pascal is the pressure experienced when a force of one Newton is distributed over a one metre square area. Kilopascals (kPa) are the preferred unit for the measurement of pressure, and this is therefore are the measurement used in this study. (Orlin & McPoil, 2000) Area will be measured in centimetres squared (cm²), with total contact area being defined as the total contact area between the shoe and the pressure plate, for defined areas as recorded by pressure sensors. (Tsung et al, 2004)

> ‘Mean pressure is the sum of forces, of all sensors in an area, divided by the contact area. Peak pressure shows the value of a sensor with the maximum pressure in the selected area.’ (Kanatli et al, 2008:27)

Subsequently to measure pressure the force which is applied to a given area must be quantified, and the area over which the force is applied must also be identified. Measurement enables statistical data collection, which can determine and quantify clinical effect, by providing evidence on which to base
practice, to facilitate the use of the most appropriate device to achieve the treatment goal. (Curran & Dananberg, 2005), (Raspovic, et al 2000) This is enabled with the use of pressure plate systems, such as the footscan® used in this study, as many parameters of gait are recorded by such devices. (Curran & Dananberg, 2005)

‘Peak pressures are often of interest in determining the effectiveness of a cushioned foot orthosis in decreasing pressures.’ (Orlin & McPoil, 2000:401)

The most commonly used parameters of pressure plate gait analysis are stated to be peak pressure, (Rogers, Otter & Birch, 2006), average pressure, force and area, as these can all be determinants of Podiatric clinical pathology. (Barnett, 2005), (Mori et al, 2012), (Orlin & McPoil, 2000), (Tsung et al, 2004) Peak pressure and contact area are the chosen areas of research in this study. (Hessert et al, 2005)

Pressure can be reduced at a specific location on the plantar aspect of the foot either by reducing the force applied to it, or by increasing the contact surface area of the foot, or a combination of both. Consequently in order for an accommodative insole to be effective, it must increase the contact area between the foot and the device/shoe, to reduce peak pressure. (Williams & Nester, 2010) The properties of an insole can alter the pressure exerted on the plantar aspect of the foot. It is suggested thick, deformable cushioning materials which gives to the shape of the foot when weight bearing reduces the rate of loading and the amount of load which is exerted on the foot. Materials
which achieve this and increase contact area should maximise pressure reduction, no previous studies were found where this was disputed. (Paton et al, 2012), (Raspovic et al, 2000), (Williams & Nester, 2010)

2.2 Plantar Pressure (Normal and Abnormal and as a Determinant of Injury)

A number of papers consider that there is no previously quantified level of plantar pressure which can be determined as putting the foot at risk. (Armstrong et al, as cited by Raspovic et al, 2000), (Paton et al, 2012), (Rogers, Otter & Birch, 2006) However studies have found that ‘high’ plantar pressure can be a causative factor in the development of pain, and integumentary lesions such as callosities. (Orlin & McPoil, 2000) Miller et al, (2011) stated that they achieved a reduction in peak pressure to the target required to prevent re-ulceration found by a 2009 study. (Owings et al, 2009 as cited by Miller et al, 2011) The validity and reliability of the 2009 study were not commented on by Miller et al, and the target peak pressure was not quantified, suggesting that it was inappropriate for assumptions to be drawn from Miller et al’s study, as external validity may have been compromised.

In a study undertaken by Kanatli et al, (2008) investigating pressure distribution under the metatarsal heads, (with the aim of improving the treatment of metatarsalgia), it was found that the greatest plantar pressures occurred in the middle column of foot. It was a study of 106 non-pathological participants, which increased the probability of the result being scientifically proven rather
than occurring by chance, but the researchers did not specify the type of sample used. As gender bias occurs and all participants were young university students, it can be presumed that the most scientifically rigorous sampling procedure, a simple random sample was not used. Interestingly, Quesada & Sawyer, (1995) used silicone gel-filled insoles in their research, also suggesting their possible role in metatarsalgia treatment, through the method of plantar pressure reduction. Exclusion criteria in the Kanatli et al, study was by physical examination for disease and deformity, which was not an accurate measure to conclude the existence of disease due to external validity being compromised. Subsequently data could not be generalised to a wider population, however, the results of the study may still have implications for metatarsalgia treatment. (Leber & Evanski, 1986)

Plantar pressure distribution was investigated by Bryant, Tinley & Singer (1999), in normal, hallux valgus and hallux limitus feet, with foot type determined according to the researchers, with classification of a deformity large enough to warrant surgical correction, internal validity was maintained by the fact that all participants were assessed by the same researchers, although this may have affected inter-rater reliability. Mean peak pressure values were found to be significantly different (across different locations) in both pathological foot types compared to the ‘normal’ control group. Although certain forefoot areas were found to have significant differential in pressure according to biomechanical dysfunction pressure in other areas of the foot such as the heel were found to be of similar reading.
2.3 The Effect of Silicone Gel on Plantar Pressures

Miller et al, (2011) found that use of compartmentalised liquid gel-filled insoles (LiquaCare®) reduced forefoot pressure in individuals with diabetes mellitus and peripheral vascular insufficiency. A mean peak forefoot pressure reduction of 21.5% (kPa) was made. The finding of a pressure reduction was confirmed in an article by Kiper, (2012) who stated that silicone fluid dynamic orthotics have beneficial effects in managing high plantar pressures, as they are able to redistribute pressure, by reducing it in certain areas and increasing it in other areas.

It should be noted in the study by Miller et al, (2011) only a small number of participants were used, compromising external validity. All subjects were pathological, however the article is contradictory in stating that type 1 and type 2 diabetics are included, but it later states that all were type 2. This may have been due to a convenience sample being drawn, and only type 2 diabetic patients attending clinic at the time of data collection, but this can only be presumed as no actual sampling criteria other than a state of vascular insufficiency is stated. This means that the generalizability of the study to a larger population is limited. Due to a mix of patients being utilized, some with a degree of neuropathy and some not, the results may have been skewed as there was a variable unaccounted for, questioning internal validity of the study also. It was not stated by Miller et al, that the insoles were standardised, by being filled with the same amount of fluid gel, if they were not then the study is not repeatable and ultimate reliability and validity are compromised. Conversely all data was included in the report for the reader to evaluate, and the statistical
tests which were used were appropriate for the raw data collected. Importantly, it can be concluded that there is controversy, and hence a gap in evidence based research in this area, which may be addressed by this research project.

Kiper (2012) states that during stance phase the fluid in the orthotic is in constant loading or unloading, which increases contact area and reduces pressure. The main difference compared to the article by Miller et al, (2011) was that Kiper (2012) customised the insoles to each patient by altering the weight of fluid in their orthotic, and subsequently the orthoses used were not standardised. The study does not include any quantitative measurement of pressure reduction which has been achieved by these devices, and it is extremely biased, being written by someone who sells dynamic silicone insoles. However it was published in a peer reviewed journal.

Miller et al,’s (2011) results are contradicted by Quesada & Sawyer (1995), who also assessed efficacy of silicone gel-filled insoles for plantar pressure relief. Data was collected using the Pedar system of shoe inserts, which were taped to participants’ feet, rather than being used in shoe. The researchers chose this methodology believing it gave more accurate data, than if a pressure platform was used. The reliability of the results may have been affected, as the instrument was not used as intended. It is understandable that the researcher required total plantar foot contact with the insoles, but this flawed the methodology, so extrapolation of this data is comprised.

Internal validity may have been compromised, due to taping of the foot possibly limiting normal soft tissue spread at ground contact. Data was collected at slow
and fast cadence, with participants not walking at their normal speed, interrupting their gait pattern thus the internal validity of the study, as is confirmed by Duffin et al, (2003). All insoles used the same amounts of gel, and hence were standardised. The report of the study was not published in its entirety, but presented verbally. However, peak plantar pressures were not affected significantly by insole use.

A study of three healthy participants undertaken by Ibrahim et al, (2013) investigating the effect of orthotics on plantar soft tissue strain, also considered plantar pressure at a specific location of the foot. The study was biased as only male participants were included, bringing internal validity into question, however it was only intended as a pilot study. A full length prefabricated silicone insole was compared to a simple custom made orthotic, both with and without a metatarsal pad, and only static measurements were taken. The custom insoles were found to be more effective than the prefabricated ones. The products are not directly comparable, as the prefabricated insoles were full length and the others not. Accurate limitations were suggested by the researchers. It is questionable whether the silicone was used because of its potential properties of reducing plantar pressure, or whether it simply allowed the researchers to ultrasound the plantar foot with the insole in situ for soft tissue strain measurement. Of interest was that the functional custom device were more effective than the accommodative device.

It is difficult to compare the findings of much previous research due to the variance in the specifications of various materials used, anatomical locations at which results are recorded, and differences in the parameters which are chosen
for analysis. (Curran & Dananberg, 2005) It can be concluded from this literature review that further research with the use of silicone insoles will add to the evidence base already in existence which suggests a role of plantar pressure reduction in the field of podiatric medicine.
3. Hypotheses

Hypothesis - 1

The study hypothesises that peak plantar pressures across the total foot during the stance phase of dynamic gait will be reduced with the use of the SRSI insoles.

Null Hypothesis - 1

Peak Plantar Pressure across the total foot, during the stance phase of dynamic gait will not be reduced by the use of SRSI insoles.

Hypothesis – 2

Total contact area across the total foot, during the stance phase of dynamic gait will be increased by the use of SRSI insoles.

Null Hypothesis – 2

Total contact area across the total foot, during the stance phase of dynamic gait will not be increased by the use of SRSI insoles.
4. **Methodology / Research Methods**

The chosen methodology was an experimental, quantitative study, using a deductive approach, taking into consideration the positivist paradigm. Reductionism can be applied allowing for the complexities of the gait cycle to be reduced to simple units which can be measured. The study is deterministic, as it believes in cause and effect. As in all quantitative research, the aim here is to quantify by measuring, and to use predetermined standardised methods, which are benefits of using a quantitative study. (Parahoo, 1997) The methodology used was done so because it allowed measurement of the potential mechanism by which such insoles can relieve plantar pressure. (Quesada & Sawyer, 1995)

This method was chosen in order to allow comparison of the use of no insoles versus the SRSI insoles, through the use of a study which was repeatable and enabled statistical tests to determine the probability of the results, and allowed accurate measurements which were appropriate to the research project title. (Parahoo, 1997)

4.1 **Pilot Study**

A pilot study was performed to identify that this study was viable. Data was collected using the footscan®, and three participants, selected at random according to availability, who wore standardised Safety First footwear, to walk across the plate with the SRSI’s in, and with no insoles. The following table shows the peak plantar pressure measurements which were obtained.
Table 1 – Pilot Study Results

<table>
<thead>
<tr>
<th>Participant</th>
<th>No Insole – Mean Value, Sum Total Foot</th>
<th>Sofsole® Insole – Mean Value , Sum Total Foot</th>
<th>Difference (kPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A – Left Foot</td>
<td>88.80</td>
<td>83.70</td>
<td>-5.10</td>
</tr>
<tr>
<td>A – Right Foot</td>
<td>125.93</td>
<td>117.50</td>
<td>-8.43</td>
</tr>
<tr>
<td>B – Left Foot</td>
<td>284.13</td>
<td>255.33</td>
<td>-28.80</td>
</tr>
<tr>
<td>B – Right Foot</td>
<td>154.50</td>
<td>144.48</td>
<td>-10.03</td>
</tr>
<tr>
<td>C – Left Foot</td>
<td>89.80</td>
<td>81.90</td>
<td>-7.90</td>
</tr>
<tr>
<td>C – Right Foot</td>
<td>79.90</td>
<td>71.00</td>
<td>-8.90</td>
</tr>
<tr>
<td>Total</td>
<td>823.06</td>
<td>753.91</td>
<td>-69.16</td>
</tr>
</tbody>
</table>

Table 1 – Showing the results of mean maximum peak plantar pressure difference in the Pilot study.

The pilot study showed that the SRSI’s had an effect on maximum peak plantar pressure, and confirmed the procedure for the study. It also ensured that any potential problems with the research were identified, addressed, and study modifications where required, were undertaken prior to the main study being carried out. One consideration was that an in-shoe pressure system may have been beneficial in order to obtain a more accurate result, however it was not possible to test this as the in shoe system was not available for use at the time of data collection. It was determined that the use of the footscan® scan had produced effective results, and during pre-pilot tests it was identified that the use of certain footwear, with thick soles was not possible, as the data with them was not accurate enough. A number of different types of footwear were trialled.
before locating and ordering the Safety First slippers. These were then also trialled and identified as producing the best repeatable results.

4.2 Subject Population

The ‘population’ for the study were undergraduate students enrolled on the BSc (Hons) Podiatry course at Birmingham Metropolitan College, Matthew Boulton Campus. This was chosen due to their proximity to the location of the equipment required for the study, and due to ethical constraints. Access to participants was not difficult as the population were also readily available to contact by the researcher.

A sample population was drawn from the study population outlined above, of ten participants. All participants were chosen at random, determined by those who were ‘free’ at the time which data collection occurred, therefore a convenience or incidence sample was used. Participant numbers were limited by the time available to undertake the study. Convenience sampling was chosen in order to eliminate any bias, such as age or gender, although should more time have been available for the project a simple random sample would have been used as this is determined to be the most rigorous sampling procedure. (Parahoo, 1997) See the table below for demographics of participants.

Table 2 – Participant Details

<table>
<thead>
<tr>
<th>No. of Participants</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>4</td>
</tr>
</tbody>
</table>
Female | 6
---|---
Mean Age (SD) | 34 (8.87)
Age Range | 21-45
Mean Shoe Size (SD) | 6 (1.40)
Shoe Size Range | 4.5-8
Mean BMI (SD) | 26.25 (7.26)
BMI Range | 18.29-42.52

Table 2 – Showing participant biometrics

### 4.3 Ethical Considerations

Participation in the study was voluntary. Participants were given a standardised verbal and written explanation of the purpose of the study, and an information sheet detailing the research process. Following this, participants were asked to read, complete and sign a questionnaire detailing their eligibility and informed consent to participate, with some data collection also included. It was explained that all data provided would only be used in the study as described to them, that any personal information provided would be confidential, and that all data would be anonymous, with identification of participants not being possible in the final written report.

The following were considered in relation to ethics, beneficence, although individuals did not benefit, the findings of the research may in future benefit patients. Non-maleficence, no harm would be caused to participants. Fidelity, the researcher safeguarded participants. Justice, all participants were treated equally, with no one and no method favoured over another. Veracity, participants were told the truth, and were not deceived in any way.
Confidentiality was upheld in regards to all details provided, and no participant would be identifiable from any part of the write up. (Parahoo, 1997)

It was also made clear that all participants were under no obligation to take part in the research, and that should they decide not to do so that they would not be affected by this decision, and that they were free to withdraw at any point during the study without being affected in anyway by this decision.

Anonymity was achieved by assigning each participant a number, under which their data was collected. The only persons with access to raw data was the researcher and her personal tutors. Analysed secondary data, and the full research document will be available for all participants to access in the college library following marking.

4.4 Economic Considerations

There were no cost implications of the study. This is due to the footscan®, weighing scales and tape measure being available for use of students at the Matthew Boulton College. The Safety First Shoes were kindly supplied by TalarMade Ltd in a variety of sizes, and the SRSI’s by A Algeo Ltd. All printing for consent forms and information sheets was done in college using the yearly balance allocated to the researcher.
4.5 Inclusion & Exclusion Criteria

Inclusion criteria stipulated that the participant was able to give informed consent to participate in the study, and was aged between eighteen and sixty. Participants were excluded if any of the following applied:

- Had suffered major trauma to the foot, leg or lower back within a year prior to the study. (Curryer & Lemaire, 2000)
- Had a sensory, motor or gait disorder. (Curryer & Lemaire, 2000)
- Were unable to walk unaided. (Barnett, 2005)
- Had active foot ulceration, infection, or severely oedematous feet. (Barnett, 2005)
- Had a history of diabetes mellitus (type I or type II).
- Had no systemic, inflammatory condition which may affect the lower limb, including, but not limited to rheumatoid arthritis, systemic lupus erythematos.

The list was limited to these constraints to ensure a cohort of suitable participants were available, and non-pathological as required to eliminate a possible variable.

4.6 Apparatus & Instruments

The following instruments, apparatus and written documents were used to perform the study.
4.6.1 Rs Scan Footscan® System

Plate 1 - The Rs Scan System

Plate 1 - An Image of the Rs Scan Footscan® System – Courtesy of Rs Scan Lab Ltd

The footscan® system is manufactured by RS Scan Lab Ltd, 14 Pegasus, Orion Avenue, Addison Way, Great Blakenham, Ipswich, IP6 0LW. The model available for use at Matthew Boulton College has a plate with the dimensions 100cm x 40cm, with 8192 small sensors sized 5mm x 7mm. (RS Scan Lab Ltd, 2006) It uses a 175Hz sampling rate, allowing for in depth pressure analysis. (Rs Scan International, undated) It has been determined that between 45Hz and 100Hz are required for normal walking gait pressure assessment, therefore the footscan® was determined the better apparatus for this research. (Orlin & McPoil, 2000) The measurement method used by footscan® is force-sensing resistors. (Rs Scan International Catalogue, 2007) Resolution is the number and the size of sensors in a system, and the higher the number of sensors, the higher the resolution. Size of sensors is important because they can alter the pressure reading due to pressure being calculated according to force and area. (Orlin & McPoil, 2000) In order to avoid any potential deviation of results, the same footscan® system was used for all measurements taken in this study.
The advantages of using the footscan® system are that it has a large number of sensors, producing a higher resolution, enabling a true vertical force measurement to be obtained, as the plantar foot is always parallel to the sensors. (Orlin & McPoil, 2000)

4.6.2 Bodymedics Safety First Shoe

Plate 2 - Safety First Shoes

Plate 2 - The Bodymedics Safety First Shoe – Image courtesy of TalarMade

The Bodymedics Safety First Shoe is manufactured and supplied by TalarMade Ltd, Springwood House, Foxwood Way, Foxwood Industrial Park, Chesterfield, Derbyshire, S41 9RN. It is a product designed to be used as a supportive, adjustable, durable, non-slip product primarily for use in hospitals as a superior, safer, option to disposable slippers. (TalarMade Ltd, 2012) They are available in shoe sizes UK3 to UK12, with sizes 4 to 8 available for this study. They were used as a means of standardising footwear for the study, due to suitability for both genders.
Further reasons for use of the Safety First Slippers included having a substantial fastening, being available in a large range of sizes enabling a good fit in all participants, which allowed the feet to be held in place in the footwear while the study took place. The insole supplied with the Safety First Shoe, was removable which allowed for data collection with no insole and which facilitated the fitting of the SRSI’s with adequate room still available, so that the feet were not constricted, enabling a comparison to be drawn. The relatively thin EVA base of the shoe allowed a good reading to be obtained from the footscan®.

4.6.3 **Sofsole® Ribbed Gel Insole (SRSI)**

**Plate 3 - The Sofsole® Insole Ribbed Gel**

Plate 3 – Image of Sofsole® Ribbed Silicone Gel insole base, with plantar surface upwards.

**Plate 4 - The Sofsole® Insole (Top & Bottom)**
Plate 4 - Image showing the Sofsole® Ribbed Silicone Gel Insoles, with the upper surface on the left, and the plantar surface on the right.

The SRSI insole is a prototype insole supplied by A. Algeo Ltd (UK), Sheridan House, Bridge Industrial Estate, Speke Hall Road, Liverpool, L24 9HB. It consists of 3mm soft polyurethane foam top cover, which lies on a 7mm ribbed silicone gel base, and is therefore a multi-density device. (SofSole®, undated) It is a full length insole, which was used in the Safety First Shoes (both left and right) with the foam top cover uppermost. For the study, the insoles were cut precisely to fit each size of Safety First Shoe used, a pair of UK 4, UK 5, UK 6, UK 7 and UK 8 were therefore created, and used for the relevant size for each participant. Due to the durability and rebound of the materials it was not deemed necessary to use a new pair of insoles for each participant. The SRSI’s were the independent variable in this study.
4.6.4 Weighing Scales
A standard mechanical weighing scale was used to weigh participants in kilograms prior to data collection. Calibration of the scale occurred before each participant was weighed, which was entered into the footscan® system to aid accurate measurement.

4.6.5 Height Measurement
A standard tape measure was used to measure the height of participants unshod in centimetres.

4.6.6 Computer Collection and Analysis
A computer attached to the footscan® recorded the results which were generated from data collection. These were then exported and processed using Microsoft Excel 2010, and GraphPad.com (2013), which is a free statistical software programme available on the internet.

4.6.7 Written Documents
All written documents used in this study are listed below and can be found in the appendices.

- Consent Letter
- Participant Eligibility & Details Questionnaire
- Information Sheet
4.7 Procedures

All data was collected in the musculoskeletal room, at the Birmingham School of Podiatry, Matthew Boulton Campus, Birmingham Metropolitan College. This is an air-conditioned room, which is regulated at a constant temperature. Before data collection took place the footscan® was set up on a hard, level floor, so that the plate did not bend during measurements and cause a false result. (Rs Scan International, undated) It was then calibrated by the researcher according to the weight calibration instructions for the footscan®. (Rs Scan International, undated)

Participants were invited to take part in the study, with those interested being given a copy of the consent letter and information sheet. They were given ample opportunity to read through all the documentation, before being given the same standardised information verbally as that on the information sheet. Following this, verbal confirmation of their understanding was gained, and they were asked if they had any questions, which were answered by the researcher.

The participant was then asked to read and complete the Participant Eligibility and Data Questionnaire, and if all criteria were met both the researcher and the participant signed the consent form, indicating inclusion in the study. As part of the data collection on this questionnaire, the participant’s weight was measured and recorded as was their height, after removing their shoes. Next the participants’ hosiery was removed, as this potentially could have affected the results obtained, and they were sized for the most appropriate Safety First
Shoes. These had no insoles in, they were put on and fastened so they felt comfortable and secure on the participants feet.

The participant was then required to walk back and forwards over the pressure plate three times in order to get used to the footwear and to try and stop the participant focusing on ‘stepping up’ on to the footscan® plate and adjusting their gait in order to ‘target’ the plate, so that their normal gait pattern would be recorded.

Next the participant stood at least two steps back from the pressure plate, to allow for acceleration prior to stepping on the plate, and then walked across the pressure plate under the instruction of the researcher when the plate was switched on for data collection, there was room for at least two steps following the plate for deceleration. This was repeated until three accurate recordings with both feet on the pressure plate were obtained. Reliability of measurements is necessary for accuracy of data findings. It is stated by Hughes *et al* (1991), (as cited by Orlin & McPoil, 2000) that taking a mean value of three to five steps enhances the reliability of the measurements obtained.

Next the Safety First Shoes were removed and the SRSI’s were placed in the shoes, before they were put back on by the participant. Data collection again took place as described previously.

All data for each participant was collected in the same session. Once the raw data had been collected each participant was given a number, under which their data would be processed, to maintain their confidentiality. Three sets of data for no insole and the SRSI insole was collected per participant to allow a mean
value to be calculated. Data was collected in order to accept or reject the null hypothesis. (Parahoo, 1997)

Parametric, continuous data was collected. The mean value, sum value, standard deviation, 95% confidence intervals and paired t test were used to analyse the results, to determine if the results had statistical significance. (Bowers, House & Owens, 2001)
5. Results & Data Analysis

Data was recorded from both the left and right feet of all participants (n=20). Raw data from three steps was analysed, initially by selecting the relevant information, which was maximum peak plantar pressure (kPa) and total contact area (cm²). The Rs Scan computer programme formulated raw data tables for each footstep, which were extracted into Microsoft Excel spreadsheets for analysis. Further statistical analysis was carried out at GraphPad.com (2013). The data tables provided a means of making the data both clearer and more concise.

Data from the pressure plate was recorded over ten masks of the foot, which were predetermined by the footscan®, these being Toe 1, Toes 2-5, Metatarsal 1, Metatarsal 2, Metatarsal 3, Metatarsal 4, Metatarsal 5, Midfoot, Medial Heel and Lateral Heel. A mean value was calculated for each area over the three footsteps which were recorded, for both the left and right feet individually. Following this the sum total of mean values for each area was calculated to give the mean maximum peak pressure across the total foot. The results are detailed in the table 3 below for each foot of each participant. The same method was used for data from both, no insole in the shoe and for the Sofsole® insole in the shoe. This process was repeated in the same manner using the data for total contact area.

Table 3 - Participant Data Table, Maximum Peak Pressure

<table>
<thead>
<tr>
<th>Participant Number and Foot</th>
<th>Total Pressure Whole Foot,</th>
<th>Total Pressure Whole Foot,</th>
<th>Difference</th>
<th>Percentage Difference</th>
<th>Both Sets of Data</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No Insole (kPa)</td>
<td>Sofsole® (kPa)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----</td>
<td>----------------</td>
<td>---------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Left</td>
<td>119.18</td>
<td>106.87</td>
<td>12.32</td>
<td>10.33%</td>
<td></td>
</tr>
<tr>
<td>1 Right</td>
<td>139.10</td>
<td>107.47</td>
<td>31.63</td>
<td>22.74%</td>
<td></td>
</tr>
<tr>
<td>2 Left</td>
<td>95.37</td>
<td>88.67</td>
<td>6.70</td>
<td>7.03%</td>
<td></td>
</tr>
<tr>
<td>2 Right</td>
<td>85.20</td>
<td>79.23</td>
<td>5.97</td>
<td>7.00%</td>
<td></td>
</tr>
<tr>
<td>3 Left</td>
<td>147.53</td>
<td>129.12</td>
<td>18.42</td>
<td>12.48%</td>
<td></td>
</tr>
<tr>
<td>3 Right</td>
<td>136.30</td>
<td>118.37</td>
<td>17.93</td>
<td>13.16%</td>
<td></td>
</tr>
<tr>
<td>4 Left</td>
<td>80.37</td>
<td>71.43</td>
<td>8.93</td>
<td>11.12%</td>
<td></td>
</tr>
<tr>
<td>4 Right</td>
<td>94.63</td>
<td>87.13</td>
<td>7.50</td>
<td>7.93%</td>
<td></td>
</tr>
<tr>
<td>5 Left</td>
<td>111.58</td>
<td>103.42</td>
<td>8.17</td>
<td>7.32%</td>
<td></td>
</tr>
<tr>
<td>5 Right</td>
<td>103.40</td>
<td>93.18</td>
<td>10.22</td>
<td>9.88%</td>
<td></td>
</tr>
<tr>
<td>6 Left</td>
<td>125.30</td>
<td>127.20</td>
<td>-1.90</td>
<td>-1.52%</td>
<td></td>
</tr>
<tr>
<td>6 Right</td>
<td>137.57</td>
<td>141.03</td>
<td>-3.47</td>
<td>-2.52%</td>
<td></td>
</tr>
<tr>
<td>7 Left</td>
<td>127.90</td>
<td>115.30</td>
<td>12.60</td>
<td>9.85%</td>
<td></td>
</tr>
<tr>
<td>7 Right</td>
<td>104.80</td>
<td>92.20</td>
<td>12.60</td>
<td>12.02%</td>
<td></td>
</tr>
<tr>
<td>8 Left</td>
<td>101.27</td>
<td>85.72</td>
<td>15.55</td>
<td>15.36%</td>
<td></td>
</tr>
<tr>
<td>8 Right</td>
<td>104.80</td>
<td>99.33</td>
<td>5.47</td>
<td>5.22%</td>
<td></td>
</tr>
<tr>
<td>9 Left</td>
<td>88.50</td>
<td>82.90</td>
<td>5.60</td>
<td>6.33%</td>
<td></td>
</tr>
<tr>
<td>9 Right</td>
<td>86.40</td>
<td>80.57</td>
<td>5.83</td>
<td>6.75%</td>
<td></td>
</tr>
<tr>
<td>10 Left</td>
<td>171.67</td>
<td>155.07</td>
<td>16.60</td>
<td>9.67%</td>
<td></td>
</tr>
<tr>
<td>10 Right</td>
<td>185.67</td>
<td>166.47</td>
<td>19.20</td>
<td>10.34%</td>
<td></td>
</tr>
<tr>
<td>Sum</td>
<td>2346.53</td>
<td>2130.67</td>
<td>215.87</td>
<td>180.49%</td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>117.33</td>
<td>106.53</td>
<td>10.79</td>
<td>9.02%</td>
<td></td>
</tr>
<tr>
<td>Standard Deviation (SD)</td>
<td>28.96</td>
<td>26.23</td>
<td>7.90</td>
<td>5.43%</td>
<td></td>
</tr>
<tr>
<td>Standard Error Margin (SEM)</td>
<td>6.48</td>
<td>5.87</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 3 – Showing mean data collected and statistical test results for maximum peak pressure (kPa).
The sum of the mean maximum peak pressure for the total foot, for both without an insole and with the SRSI’s, for the left and right foot of each participant were then used to create a bar chart, using Excel which is shown below in Figure 1.

**Figure 1 - Peak Pressure Change Bar Chart**

![Bar Chart Showing Peak Plantar Pressure (Total Foot) with No Insole and Sofsole®](chart.png)

**Figure 1 - Showing Mean Maximum Peak Plantar Pressure decrease with use of the SRSI’s.**

The graph shows the decrease in mean maximum peak plantar pressure across the total foot, for each foot of each participant, except in the case of participant six, where the peak pressure for both the left and right foot increased with the use of the SRSI insole, the cause of this result was determined as a variable and will be discussed later.
The SRSI insole showed a mean drop in maximum peak pressure, across the total foot for all participants to be 9.02% (SD=5.43%). A paired t test was performed through GraphPad.com which yielded the following values, t=6.11, and p=<0.0001, which is considered to be extremely statistically significant. 95% Confidence Intervals were also calculated (10.79) and were found to have a range of 7.10-14.49.

Table 4, below, shows a summary of the results obtained and the results of statistical tests found for the measurements taken for total contact area during the study.

Table 4 - Participant Data Table, Total Contact Area

<table>
<thead>
<tr>
<th>Participant Number and Foot</th>
<th>Mean Total Contact Area (cm²), No Insole</th>
<th>Mean Total Contact Area (cm²), Sofsole®</th>
<th>Difference</th>
<th>Percentage Difference</th>
<th>Both Sets of Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Left</td>
<td>188.98</td>
<td>208.87</td>
<td>19.88</td>
<td>9.52%</td>
<td></td>
</tr>
<tr>
<td>1 Right</td>
<td>164.70</td>
<td>187.77</td>
<td>23.07</td>
<td>12.28%</td>
<td></td>
</tr>
<tr>
<td>2 Left</td>
<td>175.60</td>
<td>189.87</td>
<td>14.27</td>
<td>7.51%</td>
<td></td>
</tr>
<tr>
<td>2 Right</td>
<td>178.20</td>
<td>190.13</td>
<td>11.93</td>
<td>6.28%</td>
<td></td>
</tr>
<tr>
<td>3 Left</td>
<td>163.97</td>
<td>176.05</td>
<td>12.08</td>
<td>6.86%</td>
<td></td>
</tr>
<tr>
<td>3 Right</td>
<td>176.05</td>
<td>194.92</td>
<td>18.87</td>
<td>9.68%</td>
<td></td>
</tr>
<tr>
<td>4 Left</td>
<td>161.90</td>
<td>166.80</td>
<td>4.90</td>
<td>2.94%</td>
<td></td>
</tr>
<tr>
<td>4 Right</td>
<td>158.83</td>
<td>163.10</td>
<td>4.27</td>
<td>2.62%</td>
<td></td>
</tr>
<tr>
<td>5 Left</td>
<td>167.22</td>
<td>207.88</td>
<td>40.67</td>
<td>19.56%</td>
<td></td>
</tr>
<tr>
<td>5 Right</td>
<td>184.92</td>
<td>190.70</td>
<td>5.78</td>
<td>3.03%</td>
<td></td>
</tr>
<tr>
<td>6 Left</td>
<td>182.50</td>
<td>200.28</td>
<td>17.78</td>
<td>8.88%</td>
<td></td>
</tr>
<tr>
<td>6 Right</td>
<td>177.67</td>
<td>198.10</td>
<td>20.43</td>
<td>10.31%</td>
<td></td>
</tr>
<tr>
<td>7 Left</td>
<td>167.93</td>
<td>175.13</td>
<td>7.20</td>
<td>4.11%</td>
<td></td>
</tr>
<tr>
<td>7 Right</td>
<td>167.87</td>
<td>181.80</td>
<td>13.93</td>
<td>7.66%</td>
<td></td>
</tr>
<tr>
<td>8 Left</td>
<td>181.10</td>
<td>190.87</td>
<td>9.77</td>
<td>5.12%</td>
<td></td>
</tr>
<tr>
<td>8 Right</td>
<td>174.43</td>
<td>199.87</td>
<td>25.43</td>
<td>12.73%</td>
<td></td>
</tr>
<tr>
<td>9 Left</td>
<td>156.57</td>
<td>166.72</td>
<td>10.15</td>
<td>6.09%</td>
<td></td>
</tr>
<tr>
<td>9 Right</td>
<td>162.97</td>
<td>178.48</td>
<td>15.52</td>
<td>8.69%</td>
<td></td>
</tr>
<tr>
<td>10 Left</td>
<td>190.23</td>
<td>202.20</td>
<td>11.97</td>
<td>5.92%</td>
<td></td>
</tr>
<tr>
<td>10 Right</td>
<td>186.57</td>
<td>205.53</td>
<td>18.97</td>
<td>9.23%</td>
<td></td>
</tr>
<tr>
<td>Sum</td>
<td>3468.20</td>
<td>3775.07</td>
<td>306.87</td>
<td>159.03%</td>
<td></td>
</tr>
</tbody>
</table>
Table 4 – Showing mean data collected and statistical test results for total contact area (cm²).

<table>
<thead>
<tr>
<th></th>
<th>173.41</th>
<th>188.75</th>
<th>15.34</th>
<th>7.95%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Standard Deviation (SD)</strong></td>
<td>10.33</td>
<td>14.06</td>
<td>8.48</td>
<td>3.99%</td>
</tr>
<tr>
<td><strong>Standard Error Margin (SEM)</strong></td>
<td>2.31</td>
<td>3.14</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>95% Confidence Interval</strong></td>
<td></td>
<td></td>
<td></td>
<td>-15.34</td>
</tr>
<tr>
<td><strong>95% Confidence Interval Range</strong></td>
<td></td>
<td></td>
<td></td>
<td>[-19.31 to -11.38]</td>
</tr>
<tr>
<td><strong>t test p=</strong></td>
<td></td>
<td></td>
<td></td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>t=</strong></td>
<td></td>
<td></td>
<td></td>
<td>-8.10</td>
</tr>
</tbody>
</table>

The sum of the total contact area for the total foot for both without an insole and with the SRSI's, for each foot of each participant were then used to create a bar chart using Excel which is shown below in Figure 2.

**Figure 2 - Total Contact Area Change Bar Chart**
Figure 2 - Showing Total Contact Area increase with use of the SRSI's.

The graph shows the increase in mean total contact area, across the total foot, for each foot of the participant, in all cases.

The SRSI insole showed a mean increase in total contact area, across the total foot to be 7.95% (SD=3.99%). A paired t test was performed through GraphPad.com which yielded the following values, $t=-8.10$, and $p<0.0001$, which is considered to be extremely statistically significant. 95% Confidence Intervals were also calculated (-15.34) and were found to have a range of -19.31 to -11.38.

The mean (a measure of central tendency) was used because it takes into consideration all of the data collected, representing a central value of the three
results, unlike the median, and it is also suggested as the best for metric data with symmetrical distribution. (Bowers, House & Owens, 2001), (Parahoo, 1997) Ten participants, each generating results with, no insole and the SRSI’s, repeated three times to allow a mean value to be calculated, giving far greater accuracy, than if only one set of measurements had been taken for each participant.

Statistical tests such as those described below were carried out as they enable decisions to be made concerning the statistical significance of the data, (Polgar & Thomas, 1991) this is called descriptive statistics. (Parahoo, 1997) Standard Deviation (SD) was calculated as this is suggested to be the most appropriate measure of spread with metric data. (Bowers, House & Owens, 2001) The 95% confidence interval (95% CI) ‘represents a plausible range of values for the true (population) value’ (Bowers, House & Owens, 2001:101) and subsequently this was used as it provided a means of understanding what range of data is likely to have been measured should the whole of the population been used.

Matched paired t tests were performed because it is a test which is appropriate for making a statistical decision about sample means between two groups, in order to address the hypotheses of the study, as it produces a p value. (Bowers, House & Owens, 2001), (Polgar & Thomas, 1991)
6. Discussion

6.1 Results
The aim of this study was to investigate the effects of the SRSI’s on peak plantar pressure, and total contact area in a non-pathological cohort. One statistical test used in determining the results of this study was the p value, which can be used as a means of testing the statistical significance of the results against the null hypotheses. As the p value determined in the results for both mean maximum plantar pressure and mean total contact area changes with the use of the SRSI’s being <0.0001, the null hypothesis can be rejected, and it can be stated that in the case of this study that both hypothesis 1 and 2 were evidenced to have occurred. (Bowers, House & Owens, 2001) This also determined that the aims of the study had been met.

Confidence intervals of 95% such as those used to statistically evaluate the mean figures for recorded data in this study do not include zero, for either maximum peak plantar pressure, or total contact area. Therefore it can be said that there is likely to be a difference in the values obtained with insoles in situ in the shoes compared to without and therefore, it can be determined that the SRSI’s have had an effect. The effect which they are likely to have exerted in both cases, is likely to be within the stated range of values for the 95% confidence interval. (Bowers, House & Owens, 2001) Although Confidence intervals may have statistical significance, they can still have limited value, as they may be too wide to give a clear indication of the application to the population. (Bowers, House & Owens, 2001)
The strict methodological process followed throughout this experimental study, and the tight rigour which was implemented allowed for the collection of data which was determined to be as unbiased as plausibly possible. This meant that the statistical analysis which was undertaken helped to achieve the aims set out, with a process which was scientifically just. Due to the only variable between the measurements taken for no insole and with the SRSI's, being the insertion of the Sofsole® insoles into the shoes, it can be determined that it is these which caused the decrease in maximum peak pressure, and the increase in total contact area. Descriptive and analytical data were included as part of the study in order to get as much relevant information from the participants as possible in order to identify anything which may have potentially affected the reliability or validity of the study.

The results obtained for maximum peak plantar pressure suggested that participant 6 was a variable, as they were the only participant who showed a mean total foot increase in peak pressure values. The most plausible suggestion for this is that the participant had a gross biomechanical deformity, which had not been determined for by the data collection and eligibility form, prior to data collection.

The results described in the section above show that the SRSI's decreased maximum peak plantar pressure, similar to findings by Miller et al, (2011). Mean planter forefoot pressure was reduced in their study by 20.5% (kPa), comparable results were found here, although looking at total foot, where a 9.02% (kPa) mean maximum peak pressure reduction occurred. It was also found that total contact area (cm²) increased with the use of the SRSI’s as
suggested by Williams & Nester, (2010). The result of this study confirms the suggestion by Duffin et al, (2003) that the use of cushioning insoles may prevent plantar ulceration in certain patients when used appropriately. Further, prescription of such insoles may offer much needed relief to patients suffering pain and/or pressure-induced lesions of the plantar feet. (Leber & Evanski, 1986) This highlights the Podiatric clinical application of the SRSI’s, and adds evidence to the following quote,

‘Viscoelastic materials are effective in redistributing the pressure beneath the foot, thereby reducing local pressures and stresses on foot structures.’ (Whittle, 1996: 1)

Orlin & McPoil (2000) as discussed in the literature review stated that peak plantar pressure is reduced by increasing total contact area. Subsequently, in all participants except number 6, total contact area increased, and peak plantar pressure decreased, which was enabled by the properties of the SRSI’s due to the force being spread out over a larger contact area.

The statistical data, although useful as a means of quantifying the result does not give any qualitative, or subjective information regards the effectiveness of the insoles. Therefore, although it can be stated that in the case of the participants in this study maximum peak plantar pressure decreased, (excluding participant 6) and total contact area increased not all clinical relevance of the SRSI’s can be determined. It is stated that orthotics are primarily intended to have a successful clinical outcome, rather than just a biomechanical one, and
therefore not all outcomes of orthotic intervention can be quantitatively measured. (Williams & Nester, 2010)

Measurements taken by the pressure plate were objective, and suitable for this quantitative study. However, with hindsight the perceived comfort level of the SRSI’s should have been considered, as no matter how beneficial the insole at pressure reduction was, if they were considered uncomfortable and could not be tolerated by participants the measurements may have been questionable as would the whole study, as if the patient would not wear them, no pressure reduction would occur.

Objective plantar pressure measurements such as those obtained from this research can only be a guide, (Curran & Dananberg, 2005) which forms part of a thorough assessment, and treatment plan formation for a patient, as gait analysis is very complex and requires various means of assessment. The results which have been found with the use of the SRSI’s, although, potentially a very effective treatment modality, this study does not offer a full picture as to their effects on all aspects of gait.

Results from research such as this may be of use in determining the specific effects of silicone gel insoles particular materials in plantar pressure reduction, leading to cost effective treatment methods for patients with a wide variety of conditions who require plantar pressure reduction. (Barnett, 2005), (Orlin & Mc Poil, 2000)
6.2 Limitations

Although this study aimed to employ scientific rigour throughout, which included the use of a repeatable methodology for all participants, limitations did occur which are discussed below.

It is possible that inaccurate convenience sampling due to the small sample size used in this study meant that the calculated p value was in fact a false negative, which has occurred due to chance, rather than due to the effects of the SRSI’s. (Bowers, House & Owens, 2001) If the study was repeated this can be avoided by, a sample size calculation being performed, in order to indicate the required sample size which will generate a minimum size needed to detect the effect of the SRSI’s. (Bowers, House & Owens, 2001), (Raspovic et al, 2000)

One limitation of the study was the footscan® being calibrated only once prior to data collection, by means of someone of a known weight walking over the plate. Although this is determined by Rs Scan international to be an appropriate means of calibration (Rs Scan International, undated) it is suggested by Orlin & McPoil, (2000) that having a patient stand on the platform may not be sufficient as each sensor is not uniformly loaded, therefore not adequately calibrating all sensors which may have compromised the validity of the study.

Biomechanical assessments were not done on participants, this is a major limitation as, it may have been advisable to do such in order to identify any gross pathologic features which may potentially have affected the data. It was considered that as participants were only compared against themself rather than against the sample that this was not necessary, however in order to gain a
more insightful knowledge of the SRSI’s this may be necessary in future studies, particularly as Bryant, Tinley & Singer (1999) determined pressure differences between normal, hallux valgus and hallux limitus foot types, as discussed in the literature review. (Paton et al, 2012)

A consideration which must be given to data recorded is that stride length may have been altered by the length of the pressure plate, and adjustments which were subconsciously made by participants in order to get both the left and right feet on to the plate during the same walk across. The length of the approach to the footscan®, which was dictated in this study by the size of the room which the apparatus is housed in may also have had a similar effect on the participants gait.

The changes in both peak pressure and total contact associated with the insole use cannot be stated to have been caused by either the silicone gel, or the top cover, as neither were tested individually. Currently they are not available on the market as individual products. In order to determine whether the results were due to the multi-density insoles and the effects of the materials overlying one another, rather than the ribbed gel or the top cover material, further studies would have to be undertaken utilising the materials individually and in combination, with the necessary controls in place. Whittle, (1996) states that insoles which are composed of a base of a polyurethane elastomer, offers both shock attenuation and pressure redistribution across the foot, and a top cover of polyurethane foam which gives some shock attenuation, pressure redistribution and is relatively resistant to compression set, offers the best of both materials in
one insole and give optimal results. The SRSI’s used in this study was of a similar construction.

In this study a new pair of SRSI’s were not used for each participant, as there was only one set of SRSI’s per shoe size. This should not have affected the results due to the properties of the insole materials, and the small number of steps taken when used by each participant, however, due to the lack of previous research in this area it is not possible to speculate the exact affect. It would have been more scientifically rigorous therefore to use a new set of SRSI’s for each participant so that any detrimental effects of usage did not affect the individual results in any way.

BMI was not taken into consideration as part of this study and therefore all BMI categories were included. This potentially could have skewed the data. A further study would be necessary which considered participants BMI. Further, not all UK shoe sizes could be used in this study, which meant that results were limited in their generalizability to a wider population as external validity was compromised.

6.3 Modifications for Further Studies

Potential modifications for the future if the study was repeated, are discussed below.

Due to the fact that the resolution of the system used can affect the pressure measurements which are collected, (Orlin & McPoil, 2000) it would be necessary to undertake the study again, using a wider variety of pressure
measurement systems, in order to determine if similar peak pressure reduction and total contact area increase occurs.

The footscan® plate was set up on the floor for data collection to occur. Participants gait may have been affected, causing inaccurate measurement collection due to the plate not being inset into the walkway, so that the participants did not ‘target’ the plate. (Orlin & McPoil, 2000) An in shoe pressure measurement system may be considered, or using a facility which has a pressure plate inset into the floor, in order to eliminate artificial measurement in future studies. (Curran & Dananberg, 2005)

Footwear was standardised for this research in order to reduce variables and identify the effect of the SRSI’s. In reality men and women do not wear the same style of shoes, and insoles would be used predominately in outdoor footwear rather than slippers, which limit the extrapolation possibilities of the data. (Paton et al, 2012) Further research is indicated into the effect of the insoles in a variety of shoe types, also in patients own footwear, which would bring more Podiatric clinical relevance to the data. (Raspovic et al, 2000), (Quesada & Sawyer, 1995)

Natural cadence was used during data collection due to the fact that if a participants mass remains the same, then the only factor which potentially could have influenced pressure measurements other than the intervention used, i.e. the SRSI’s, should have been gait speed. (Duffin et al, 2003) Plantar pressure and force are stated to vary at different gait speeds. (Cavanagh, et al, 1997, as cited by Hessert et al, 2005), (Quesada & Sawyer, 1995) In future research
cadence speed should be monitored in order to increase the internal validity of the results.

Other studies indicate that by using a pressure platform, it is only possible to measure the vertical forces, i.e. those which were perpendicular to the sensor surface of the platform. Therefore shear forces were not measured or considered in this study, but measurement of these would be necessary in order to determine the full effects of the SRSI's. (Orlin & McPoil, 2000)
7. Conclusion

High plantar pressure is evidenced as having a role in the development of pain, callus and in certain cases as a factor in development of ulceration in high risk patients. Although previous research has failed to conclude the level of increased plantar pressure which is a determinant of such problems, the role of plantar pressure reduction is documented. Further to this, it was highlighted that previous research into the use of accommodative devices is limited, particularly in patients who are not categorised as high risk, or are non-neuropathic. It is however noted in previous studies that the use of accommodative devices can be a successful treatment option.

This study identified that the SRSI’s caused a statistically significant decrease in mean maximum peak plantar pressure, and an increase in total contact area, when used in standardised footwear, during the stance phase of dynamic gait. This suggested, as stated by Orlin & McPoil, (2000) that an increase in total contact area is related to a decrease in peak plantar pressure, as all participants, other than number 6 demonstrated this with use of the SRSI’s. As the contact area increased the peak plantar pressure decreased because the force was spread over a larger surface area.

This indicates that the SRSI’s have a role in Podiatric clinical practice, however, given that all participants in this study were non-pathological, this research data cannot be extrapolated to include patients with systemic conditions such as diabetes mellitus. The study has indicated though that further research is warranted in order to determine the possible therapeutic effects of the SRSI’s in
high risk podiatric patients. Should further research indicate a role for silicone gel insoles such as the SRSI’s, this would strengthen the rationale for their implementation in treatment plans, not only for their podiatric clinical benefits, but also as a cost effective and time efficient treatment modality, when compared with time and money spent on prescribing accommodative devices in traditional materials.

A quantitative study was undertaken in this project, however qualitative research is required in order to determine the perceived effect of the SRSI’s on patient comfort, and possible pain reduction, with investigation surrounding their possible function as a placebo. This would further strengthen the evidence base for indication of use of such a product in podiatric practice.
8. **Declared Interests**

The support of two companies enabled this research project. The Sofsole Silicone Gel insoles were provided at nil cost by A. Algeo Ltd, Sheridan House, Bridge Industrial Estate, Speke Hall Road, Liverpool. The Safety First Shoes were also provided at nil cost by TalarMade Ltd, Springwood House, Foxwood Way, Foxwood Industrial Park, Chesterfield, Derbyshire. There was no further involvement from either company, and therefore the methodological rigour and the statistical analysis and evaluation of all data were not compromised in any way by such interest. All support was sanctioned by the Podiatry Department at Matthew Boulton College, Birmingham. A copy of this research project will be supplied to both A. Algeo Ltd, and TalarMade.
9. References


http://www.japmaonline.org/content/93/3/214.full?sid=176a8282-b622-4cbf-bbf7-e3aa750829c8 [Accessed 19/04/13]


Appendices

Appendix 1 - Consent Letter

Birmingham School of Podiatry

March 2013

Dear Participant

Re: Investigating the Effect of Sofsole® Ribbed Silicone Gel Insoles on Plantar Pressure – Research Project – Serena Anthony

I am a student Podiatrist under the direction of Mrs J Williamson in the School of Podiatry at Birmingham Metropolitan College. I am conducting a study to investigate the effect of Sofsole® silicone gel insoles on plantar pressures during normal walking.

I require your participation to enable data to be collected and for the research project to be completed. Your participation in the study will involve providing some personal data and then wearing a pair of slippers to walk over a pressure plate a number of times. It is expected that this will take no more than fifteen minutes of your time.

Your participation in this study is voluntary. You are free to refuse to participate in the study, or to withdraw at any time during the proceedings. Should you choose not to participate, or to withdraw from the study at any time, this will not affect you in any way in terms of your time at the Birmingham School of Podiatry.

Although there may be no direct benefit to you by participating in the study, the possible benefits of your participation are knowledge about the use of the pressure plate system, and the participation within a research project (of use if you are an undergraduate).

If you have any questions concerning the research or your participation in this study, please contact me Serena Anthony or Mrs J Williamson at the Birmingham Metropolitan College, on 0121 446 4545.

Yours sincerely,

Mrs Serena Anthony
Final Year Podiatry Student
Birmingham School of Podiatry

Consent Form

Your participation in this study is voluntary. You are free to refuse to participation in the study, or to withdraw at any time during the proceedings. Should you choose not to participate, or to withdraw from the study at any time, this will not affect you in any way in terms of your time at the Birmingham School of Podiatry. The results of the research study may be published, and a copy of the full written report of the study will be available in the Birmingham Metropolitan College, Matthew Boulton College Library, but no individual identifying information will be used within the write up.

I have read the above informed consent letter, and the document entitled Information Sheet, and consent to my inclusion in this study. The nature, demands, risks and benefits of the study have been explained to me, and I have been given the opportunity to ask any further questions. I understand that I may withdraw my consent and discontinue participation at any time without penalty or loss of benefit to myself. I also understand that my assistance in this study, and all information which I provide in relation to this is voluntary, anonymous and confidential.

Signed ………………………………………………………………………
Printed……………………………………………………………………..
Date………………………………………………………………………..

If you have any questions about your rights as a participant in this research study, or if you feel you have been placed at risk, you may contact the Ethics Chair, through the Head of the Birmingham School of Podiatry, Mr M Ratcliffe.

I certify that I have explained to the above individual the nature, purpose, known potential benefits and known possible risks associated with participation in this research study. I have answered any questions that have been raised, and have witnessed the above signature.

Researcher's Signature…………………………………………………
Appendix 2 - Participant Eligibility

Participant Eligibility and Data Questionnaire

Data Capture

Please fill in the following details about yourself;

Name

Date of Birth

Age

Gender

Shoe Size (UK)

Height

Weight

Eligibility

Please answer the following questions by circling either YES or NO according to your answer. Please note that your answers may affect your ability to participate in the study as certain eligibility criteria apply.
1. Are aged 18 to 60? YES NO
2. Have you suffered any major trauma to your foot/feet, leg/legs within the last year? YES NO
3. Do you have a sensory, motor or gait disorder? YES NO
4. Do you require an aid to walk? E.g. Walking Stick YES NO
5. Do you suffer from diabetes mellitus? YES NO
6. Do you have any current foot ulcers, foot infection, or severely swollen feet? YES NO
7. Do you have a systemic inflammatory condition? E.g. rheumatoid arthritis or systemic lupus erythematos YES NO
8. Do you have an allergy to silicone gel products? YES NO
9. Have you had a hip or knee joint replacement? YES NO
10. Have you ever been diagnosed with osteoarthritis in any lower limb joints? YES NO

……………………………………………………………………………………………
………………….For the use of the researcher

Participant Number ………………….Date of Data Collection…………………..

Appendix 3 - Participant Information Sheet

Information Sheet

Thank you for participating in this study. It is important that you understand what your participation involves, and that you have the opportunity to ask any questions which you might have before agreeing and confirming your consent. This document provides you with a summary of your involvement.

The study aims to investigate the effect of Sofsole® silicone gel insoles on plantar pressures during walking, measured by walking across a pressure plate, at the Matthew Boulton College.

You are not required to do anything prior to your participation. You will be asked to wear an appropriately sized pair of slipper type shoes, first with no insoles in, and then with the Sofsole® insole in. You should walk normally with the slippers on, and must inform the researcher if they are uncomfortable at any time. You will have the opportunity of walking about in the shoes in order to become used to the feel of walking in them before data collection begins.

You will be asked to step across the pressure plate, with the whole of both the left and right foot making contact with the plate, during the same walk across it.
This will be repeated until three accurate recordings of both feet walking across the plate are captured.

Following data collection you will be free to leave. Your participation should take no longer than fifteen minutes, and this will be over a single session only, when you are already in college.

Once all data collection has been undertaken the research project will be written up, and data will be included within this. Once the project has been marked, a copy will be available in the Matthew Boulton College Library should you wish to read it. Unfortunately the researcher is unable to provide you personally with your individual results, or with any explanation of their meaning.

There are no known risks involved with your participation in this research project. All data that you provide, both written and measured will be used solely for the purpose of this study, and you will remain anonymous (other than to the researcher) throughout the process, including in the written report. You have the right to withdraw from the study at any time without reason, with no detrimental effect to yourself. You are also free to ask any questions which you may have in relation to this research project at any time.