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Efficacy of Diabetic Off-Loading Devices Measuring Peak Plantar Pressure

Von M. Homer

BARRY UNIVERSITY

SCHOOL OF HUMAN PERFORMANCE AND LEISURE SCIENCES

EFFICACY OF DIABETIC OFF-LOADING DEVICES MEASURING PEAK PLANTAR PRESSURE

BY

VON M. HOMER

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Abstract

Decreasing forefoot plantar pressure is an important factor in the prevention and treatment of diabetic ulcerations. Although offloading devices have been shown to mitigate plantar pressure, there is currently little research comparing the directly comparing the efficacy of these offloading devices. The purpose of this study was to compare the forefoot plantar pressure between four of the most commonly used off-loading devices (TCC EZ, Medi-Kast, BSN Cutimed cast systems, Extra-depth Diabetic Shoe [DS]).

Twenty healthy participants' forefoot plantar pressure was measured while walking in each device. One podiatrist applied the device around the Tekscan f-scan Versa Tek Wireless mapping plantar pressure sensor. Data collection was randomized between each device as plantar pressure was collected during a 3 minute walk on a treadmill at a pace of 1.8 mph. A Repeated Measures ANOVA was conducted to compare the peak pressures between each device.

In this direct comparison of popular off-loading methods, all TCC devices significantly lowered peak forefoot plantar pressure as compared to the DS. Additionally, the peak plantar pressure in the TCCEZ and Cutimed casts was significantly lower than that of the Medicast , however, there was no difference in peak forefoot plantar pressure between the TCCEZ and Cutimed. Therefore since there is a greater correlation in the reduction of peak forefoot pressure in these TCC devices compared to DS as well as the TCC devices compared to one another, we can begin to draw positive trends for best practice in the treatment of Diabetic Foot Ulcers.

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CHAPTER 1

INTRODUCTION

In 2014 diabetes remains the 7th leading cause of death in the United States with 69,071 death certificates listing diabetes as the underlying cause of death (Prevention, 2011). The total estimated costs of diagnosed diabetes have increased 41%, from $174 billion in 2007 to $245 billion in 2012. Certain complications and co-morbid conditions are associated with diabetes, among many listed conditions ulcerations and amputations are the focal point (Prevention, 2011). Ulcers are open sores or wounds that will occur in 15% of patients with diabetes and of those who develop a foot ulcer, 6% will be hospitalized due to infection or other ulcer-related complications (Cavanagh & Bus 2010). Ulcers form due to a combination of factors, such as lack of feeling in the foot, poor circulation, foot deformities, irritation (such as friction or pressure), and trauma, as well as duration of diabetes. Patients who have diabetes for many years can develop neuropathy, a reduced or complete lack of ability to feel pain in the feet due to nerve damage caused by elevated blood glucose levels over time.

Statement of Problem

In the treatment of diabetic foot ulcers, pressure modulation, commonly referred to as “offloading,” is most successful when pressure is mitigated at an area of high vertical or shear stress (Bus et al. 2008). During weight-bearing activities, the feet are exposed to large forces, particularly when the activity is dynamic, such as walking (Groner 2013). The pressure under the plantar surface during walking varies per foot area because of a number of factors related to the normal rollover during the stance phase of gait. Diabetes mellitus often results in loss of protective sensation and in structural changes that make the feet more susceptible to injury. Increased plantar pressure is an important factor in the development and maintenance of diabetic foot ulceration (Groner 2013). Increased plantar pressures and associated ulcers need to be treated by off-loading of the plantar surface. Useful off-loading mechanisms include reduction of walking speed, alteration of (Dinh, Veves, & Tecilazich 2013) foot rollover during gait, and transfer of load from affected areas to other areas of the foot or the lower leg. These plantar off-loading mechanisms could result in an optimization of treatment (Bus et al. 2008), but clinical effectiveness must be demonstrated. Common methods to offload the foot include bed rest, wheel chair, crutch assisted gait, total contact casts, half shoes, therapeutic shoes, and removable cast walkers (Dinh et al., 2013). Although it is well known that pressure mitigation through offloading devices is crucial for the healing of plantar diabetic foot ulcers, in our knowledge there are currently no reports in the literature that describe the characteristics and considerations associated with the use of pressure mitigation devices in a broad geographically diverse sample of specialists.

Purpose of Study

There is no consensus in the literature concerning the role of off-loading through footwear in primary or secondary prevention of ulcers. This is likely due to the wide diversity of intervention and control conditions tested, the lack of information about off-loading efficacy of the footwear used, and the absence of a target pressure threshold for off-loading. Uncomplicated plantar ulcers should heal in 6 to 8 weeks with adequate off-loading (Gurney, Kersting, & Rosenbaum 2008). The total contact cast and other non-removable devices are most effective because they eliminate the problem of non-adherence to recommendations for using a removable device. Conventional or standard therapeutic footwear is not effective in ulcer healing (Wu, Jensen, Weber, Robinson, & Armstrong 2008). Recent United States and European surveys show a large discrepancy between guidelines and clinical practice in off-loading diabetic foot ulcers (Deschamps et al., 2013). Many professionals continue to use methods that are known to be ineffective or have not been proven effective, while ignoring methods that have been demonstrated to be successful (Deschamps et al., 2013). The central goal of any treatment program designed to heal neuropathic foot ulcers is effective reduction in pressure or off-loading. Several off-loading devices are available such as walkers, half shoes, orthotics, felted foam and Total Contact Cast (TCC). TCC is considered as the gold standard of ulcer treatment by many experts in this field. TCC involves a molded and minimally padded cast that maintains contact with entire plantar aspect of foot and lower leg and keeps the weight off the foot when the patient is standing (Myerson, Papa, Eaton, & Wilson, 1992). TCC have been shown to reduce the pressure at the ulcer site by 84-92% (Hartsell, Fellner, Frantz, & Saltzman, 2001). Besides off-loading pressure, there is also reduction in shearing forces and edema of the foot. It optimizes the healing environment and prevents further wound injury. Healing rates of up to 90% are achieved with TCC in diabetic patients with neuropathic foot ulcers (Bus et al. 2008). The main objective of this research is to analyze average and peak pressures under the plantar surface of the foot while walking inside 4 different diabetic ulcer offloading devices. Including 3of the most commonly used total contact cast systems and a extra depth diabetic shoe. Pressure distribution in each offloading device will be measured by a pressure sensor applied directly to the plantar surface of the foot. TCC EZ, Medi-Cast, and BSN cutimed cast systems along with an extra depth diabetic shoe will be used in this study. Using a /within Repeated Measures MANOVA test design volunteers will have each device applied to one leg at a time, and then instructed to walk the same distance for the same amount of time.

Research Hypothesis

Patients who develop neuropathic plantar ulcers in the forefoot region, may benefit from a reduction in plantar pressures. By using a Total Contact Cast rather than extra depth shoes and inserts with modifications or other pneumonic devices pressure, will be equally distributed through the plantar surface of the foot. Off-loading includes two elements, reduction of pressure (ground reaction forces) and reduction of shearing (frictional forces). The principle involved here is that the cast is molded directly to the contours of the foot. Therefore the pressure which has been concentrated on the bony prominence or ulcers is distributed over the entire plantar aspect of the foot, allowing reversal of the mechanism that will cause the ulcer to heal. Additionally shear forces are mitigated through the limiting of ankle range of motion. Total contact cast usually captures the patient's tibial talar joint in a 90 degree angle, restricting sagittal and frontal plane movements and limiting tangential forces (Wu etl al. 2008).

Operational Definitions

1. Kinetics – the study of forces and moments of force and their characteristics, such as work, energy, impulse, momentum, power, and so on.
2. Ground Reaction Forces (GRF) – A single equivalent force equal to the sum of a distribution of forces applied to a surface.

3. Plantar Peak Pressure – Highest level of pressure applied to the plantar surface of the foot.

4. Peripheral Neuropathy – A result of nerve damage, often causes weakness, numbness and pain, usually in your hands and feet, but it may also occur in other areas of your body. People generally describe the pain of peripheral neuropathy as tingling or burning, while they may compare the loss of sensation to the feeling of wearing a thin stocking or glove. Peripheral neuropathy can result from problems such as traumatic injuries, infections, metabolic problems and exposure to toxins. One of the most common causes is diabetes. In many cases, peripheral neuropathy symptoms improve with time, especially if the condition is caused by an underlying condition that can be treated. A number of medications are used to reduce the painful symptoms of peripheral neuropathy.

5. Diabetic Foot Ulcer – Diabetic foot ulcer is a major complication of diabetes mellitus, and probably the major component of the diabetic foot. It occurs in 15% of all patients with diabetes and precedes 84% of all diabetes-related lower-leg amputations. The major increase in mortality among diabetic patients observed over the past 20 years is considered to be due to the development of macro and micro vascular complications, including failure of the wound healing process.

6. Diabetic Shoes – Diabetic shoes, sometimes referred to as extra depth, therapeutic shoes or Sugar Shoes, are specially designed shoes, or shoe inserts, intended to reduce the risk of skin breakdown in diabetics with co-existing foot disease. People with diabetic neuropathy in their feet may have a false sense of security as to how much at risk their feet actually are. An ulcer under the foot can develop in

a couple of hours. The primary goal of therapeutic footwear is to prevent complications, which can include strain, ulcers, calluses, or even amputations for patients with diabetes and poor circulation. Neuropathy can also change the shape of a person's feet, which limits the range of shoes that can be worn comfortably. In addition to meeting strict guidelines, diabetic shoes must be prescribed by a physician and fit by a qualified individual, such as an orthotist, podiatrist or pedorthist.

7. Total Contact Cast – A total contact cast is a cast used to treat ulcers (serious, deep sores) on a person's foot. It consists of a fiberglass shell that fits around your leg and foot very closely and has a bar on the bottom.

8. Ankle Dorsiflexion – Movement at the ankle joint that points the foot up towards the leg, or movement of the toes that lifts them away from the sole of the foot.

9. Ankle Plantarflexion – Movement at the ankle joint that points the foot downwards away from the leg, or movement of the toes that curls them down towards the sole.

10. Foot Pronation – Sequence during normal gait after the heel hits the ground, the ankle tends to angle inwards, the foot is supported briefly on its inner side, the arch tends to flatten whilst weight is transferred progressively forwards towards the toes.

11. Foot Supination – Movements resulting in raising of the medial margin of the foot, hence of the longitudinal arch.

12. Heel Strike – The stage in gait at which the heel of the foot or shoe first makes contact with the walking surface. The beginning of stance phase, at the point of heel strike there is zero reaction. Immediately after contact there is an increase in ground reaction, known as heel strike transient, which pre-empts the major increase in ground reaction forces which complete the first of the double peaks in normal stance phase.

13. Stance Phase – The gait phase that lasts from heel strike to toe off, which accounts for 60% of a single gait cycle. During the stance phase, the foot is on the ground acting as a shock absorber, mobile adapter, rigid lever and pedestal, and the body passes over its top. Stance phase can be subdivided into contact phase and support phase.

14. Gait – The manner or style of walking.

15. Single Support – Only one foot in contact with the floor

16. Double Support – Both feet in contact with the floor

17. Total Contact Cast -- Snug-fitting, below-knee casts that protect insensitive limbs from repetitive trauma, promote ulcer healing, and allow the patient to remain ambulatory.

18. Extra Depth Diabetic Shoe -- sometimes referred to as therapeutic shoes are specially designed shoes, or shoe inserts, intended to reduce the risk of skin breakdown in diabetics with co-existing foot disease.

19. Diabetic Insert -- A device that provides total foot contact to disperse weight as evenly as possible throughout the plantar aspect of the foot and to reduce pressure from pre-ulcerative or ulcerative areas.

Assumptions

The efficacy of total contact casts was examined to assume that there is still some validity in how diabetic footwear such as extra depth shoes, diabetic Plastazote inserts reduce plantar pressure and heal plantar foot ulcers. The research performed in this study was controlled by the investigator to preserve reliability and validity. In order for the testing to be considered the most reliable and valid, certain assumptions were made:

1. The participants in this study were prepared and motivated ot perform the testing procedures that was required of them to the best of their ability.

2. The participants in this study fully understood the directions for the task given before testing began.

3. The participants in this study were truthful with their responses to the medical history questionnaire.

4. The participants in this study had minimal previous knowledge of the procedures involved in performing this study.

5. All equipment and procedures listed in the methods section are both reliable and valid.

Delimitations

1. Total contact casts were applied to every subject by the same clinician, throughout the entire study.

2. Participants were asked to perform the same task in the same sequence throughout the entire study.

3. The subjects were healthy male and female students between the ages of 18- 25

4. Trials were eliminated if they were not compliant with the instructions listed in the methods section.

5. The study was performed in a lab setting.

Limitations

Aspects within this study that are harder to control but may have influenced the data include:

1. Subjects were tested without the cast being allowed to dry properly according to the manufacturer's instructions.

2. There was a leg length difference on the leg where the cast was applied compared to the contra lateral leg without the cast.

3. Subjects were healthy without neuropathy.

Therefore delimitations for this study will have to be creating and testing the efficacy of total contact cast in patients without neuropathy. Healthy participants will have to have flexible foot deformities that could easily be positioned and manipulated without any variance in order to fabricate and test the efficacy of total contact cast and its role in diabetic wound care off-loading during dynamic activity.

Significance

The research will show how effect ground reaction forces are equally distributed along the plantar surface of the human foot when it is forced to remain in one position inside of a total contact cast along with other off-loading medical devices. The significance of this study will generate new knowledge in dynamic gait analysis as it relates to plantar pressure analysis. Examining plantar pressure inside of most commonly used off-loading devices could provide better standard care protocols for clinicians who care for diabetic wounds. Additionally medical device companies will develop new ways of constructing the mechanical devices that are commonly used in clinic. Should this research support my hypothesis technicians and scientist will have the information to develop an accurate design of a mechanical device to fit the best practice for an ulcerated foot.

CHAPTER 2

LITERATURE REVIEW

There are two main purposes for this study: First, to quantify how much plantar pressure is off-loaded under the fore-foot inside four of the most commonly used off-loading devices within the standard care protocol of wound care (Bus et al., 2008). Those devices are total contact cast, cast shoes, pneumonic walking boots and diabetic shoes. The second objective is to examine kinematic values of the tibia and ankle joint relative to plantar pressure values. This literature review is broken down by topic headings and subheadings, which include:

Effects of Forces on Plantar Foot tissue

During weight-bearing activities, such as standing and walking, the plantar surface of the foot is exposed to ground reaction forces. Such forces lead to tissue deformation. The relationship between force and deformation is expressed as the stress-strain relation. Stress is equal to normalized force (force per unit area to which the force is applied), otherwise known as pressure. Strain is equal to normalized deformation (percentage change from the original tissue dimensions) (Healy et al., 2012). A stress perpendicular to the tissue surface will lead to a compressive strain. A stress parallel to the tissue surface (shear stress) will lead to a shear strain, depending on the presence of friction.

Without sufficient friction, the surfaces slide over each other. The amount of strain in response to a particular stress depends on the characteristics of the tissue, expressed by a stress-strain curve. When a person is standing, the magnitude of the GRF is equal to body weight. Each foot experiences 50% of body weight distributed over the whole plantar weight-bearing surface. This is predominantly a vertically directed force, with negligible forces in the horizontal (shear) directions. As a result, moderate peak plantar pressures occur, with higher pressures at the heel than at the forefoot (Healy et al., 2012). Although moderate, these pressures are sufficient to occlude capillary blood flow. Quiet standing involves a certain amount of body sway, so there are variations in the amount of pressure that each part of the foot will experience, but this effect may be too small to be beneficial for capillary blood flow. When a person is walking, the stresses applied to the feet are much higher than when standing, for a number of reasons. First, weight is borne on one foot for a substantial amount of time, because both feet are in contact with the floor for only 22% of the gait cycle (Gurney et al., 2008). Secondly the stance phase of gait is characterized by a rollover of the foot. Normally, the foot first rotates around the heel (heel rocker), followed by the ankle joint (ankle rocker) and the metatarsal heads and hallux (forefoot rocker) (Healy et al., 2012) (See figure 1).

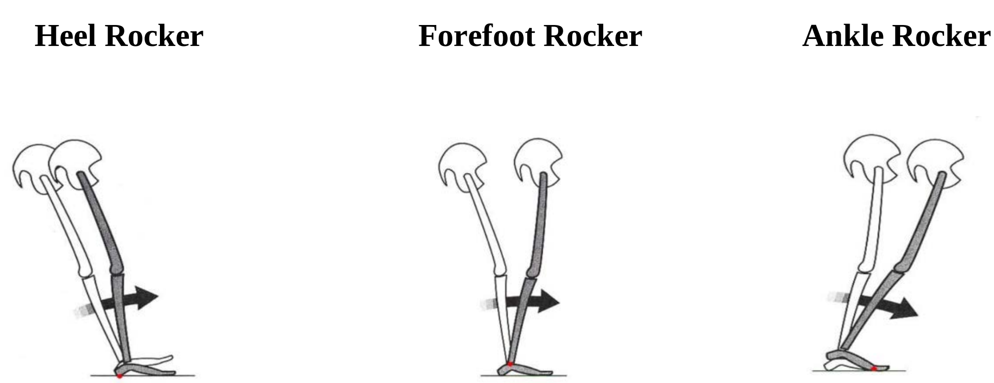


Figure 1: 3 Rocker Gait Cycle

Stance Phase of Gait

Different parts of the foot make contact with the floor during the different phases of stance. As a result, the plantar support surface changes in size and location while the GRFs progress anteriorly from heel to hallux (Harradine et al., 2006).

The heel is in contact with the floor during the first 64% of the stance phase. The forefoot and toes are in contact with the floor for the last 59% of the stance phase. Therefore, the period that both the heel and the forefoot are in contact with the floor (foot flat) occurs only during the middle 23% of the stance phase (Healy et al., 2012). Third, the GRFs vary in magnitude (Bus et al., 2008). The vertical force component is characterized by a double-hump curve. The first peak is related to landing on the heel, and the second peak is related to pushing off with the forefoot at the end of stance (See Figure 2).

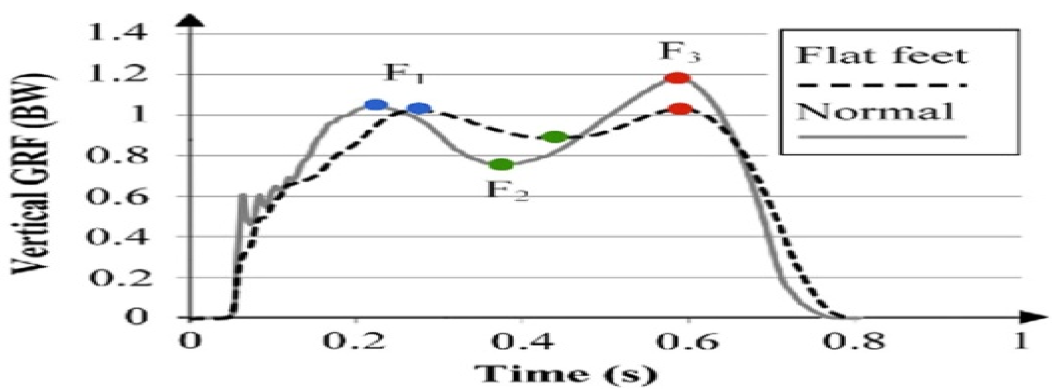


Fig 2: Normalized Plantar Pressure Curve during Gait

At a self-selected walking speed, these vertical peaks are 1.2 times the body weight, but this increases with fast walking to 1.5 times body weight. The heel and the forefoot therefore experience much higher peak pressures than the midfoot. The highest peak pressures normally occur over the medial metatarsophalangeal region and over the great toe. Besides the double-hump pattern of the vertical force, there are also horizontal (shear) forces at work during gait (Bus et al., 2008; Femery et al., 2004). The magnitude of the anteriorly or posteriorly directed force can be 25% of body weight. This shear force is directed posteriorly at the heel and anteriorly at the forefoot. It appears that these shear stresses are also distributed unequally over the support surface, so that localized peaks occur. Adults walking at a self-selected speed occurs at 1.4 m/s and at a cadence of 113 steps/min (Healy et al., 2012). The foot is therefore exposed very frequently to the stresses described for a single step. The mechanical loading of the feet is therefore substantial.

Diabetic Foot Ulcers

Diabetes causes different physiological changes such as retinopathy, disease, hearing issues, cardiovasucal, nephropathy, and foot ulcers (Benbow, 2012). Diabetic foot ulcer are wounds that develops when high blood sugar levels damage the blood vessels and nerves, leading to breakdown of the tissue and skin (see Figure 3).

Figure 3: Diabetic Foot Ulcer

Foot ulcers occur from vascular, neurological, and musculoskeletal alterations that cause high forces and pressure on the foot (Roberts & Newton, 2011). Neuropathic ulcers are found on the plantar surface of the foot. Ischaemic ulcers are commonly found on the margins of the foot, over the phalangeal joints, the tips of the phalanges, and under the toenails. Ulcers occurring from neuropathy are characterized by loss of sensation that helps protect the feet and biomechanical abnormalities (Vuorisalo, Venermo, & Lepantalo, 2009). The lack of protective sensation allows ulceration in areas of high pressure. Autonomic neuropathy causes decreased sweating resulting in dryness of the skin and therefore making the skin vulnerable to break down. Ischemia ulcers are caused by peripheral arterial disease (Vuorisalo et al., 2009). Signs of diabetic foot ulcers may be a red mark from a shoe rubbing leading to a blister which develops into a shallow ulcer with pale granulation tissue or filled with yellow (Benbow, 2012). Diabetic foot ulcers can be difficult to manage, slow healing, prone to infection, tissue destruction, amputation, and disability and impaired quality of life. Sixty percent of ulcers occur from neuropathy, with other risk factors being peripheral vascular disease, previous foot disease, foot deformity, visual impairment, poor glycaemic control, and cigarette smoking (Benbow, 2012). Wearing inappropriate footwear and walking barefoot will also influence ulcer development. Prevention of ulcers can be poor due to patient's reduced peripheral sensory function. Reduced function can make patients unaware of pain and tissue damage, making it difficult to notice an ulcer until the patient goes to a foot care appointment. Essential elements for assessing diabetes foot include: palpating the dorsalis pedis pulse and the posterior tibial arteries to determine the presence of vascular disease, assessing neuropathy to ascertain whether intact pain sensations are, and visually examine to identify any inappropriate footwear, as these can cause excessive high pressure on the foot and increase the risk of ulceration (Roberts & Newton, 2011).

Contributors to Increased Plantar Pressure

In diabetes, several factors can affect the stresses applied to the feet. Loss of protective sensation can be dramatic, with the effect that patients cannot feel pain or discomfort when the plantar surface is injured or overloaded (Owings et al., 2008). Ulcers and lesions can remain undetected for some time, providing opportunities for an initial injury to become worse. Additional problems of diabetic vascular pathology and dryness of the skin make the plantar surface even more vulnerable to the imposed stresses and strains (Femery et al., 2004). Generalized limitations in joint mobility have been demonstrated in diabetes. Reduced mobility at the ankle and first metatarsophalangeal joints interferes with normal rollover of the foot during gait. This can lead to higher plantar pressures and a higher risk of ulceration. Limited dorsiflexion of the ankle results in an earlier heel rise in the gait cycle and an earlier loading of the forefoot. Limited dorsiflexion of the great toe results in an earlier loading of this toe during the push-off phase. Structural foot changes related to motor neuropathy include intrinsic muscle wasting, associated with narrowing of the foot, and hammer and claw toes. Other deformities, such as hallux valgus, lesser toe joint dislocations, and alterations in arch height, also seem to be more prevalent in diabetes (Owings et al., 2008).

Such changes contribute to an increase in plantar pressure by reducing the support surface or by increasing the prominence of bony points (metatarsal heads and bunions). Midfoot fractures (Charcot) and partial foot amputations have similar effects and therefore result in higher plantar pressures. The plantar soft tissues were found to be stiffer and thinner in elderly subjects with diabetes than in healthy young subjects. The increase in stiffness seems particularly to occur in the soft tissue under the first metatarsal head (Bus et al., 2008). The reduced shock absorption characteristics of these tissues results in increased peak pressures under dynamic conditions, such as the heel strike and push-off phases of gait (Harradine et al., 2006). Decreased plantar tissue thickness has been shown to relate to increased peak plantar pressure. The buildup of callus under the forefoot has also been associated with increased plantar pressures and increased risk of ulceration (Boulton et al., 2008). Balance in standing and walking are affected by diabetic neuropathy. During quiet standing, patients with diabetic neuropathy demonstrate substantially increased body sway. During walking, a “conservative” gait pattern seems to be adopted, with slower walking speed and cadence and with increased double support time.

Obesity and the Diabetic Foot

Subjective observations of physical limitations and movement difficulties are often made about the obese population. Common problems include discomfort and difficulty with simple activities of daily living. In normal weighted individuals during locomotion, the lower extremities major joints are exposed to reaction forces of approximately three to six times body weight (Hill, Hennig, Mcdlonald, & Bar-Or, 2001). It may be reasonable to hypothesize that obese individuals experience greater loads than normal weight individuals (Hill et al., 2001). Because overweight affects the magnitude of the GRFs during gait and standing, an increase in mechanical loading of the foot can be expected (Healy et al., 2012). Increased plantar pressures in obese adults have been reported, in particular on the forefoot, but increased areas of contact between foot and ground have also been reported. Apparently the feet become wider in the presence of obesity. These changes in plantar support area might explain why peak plantar pressure and body mass were only mildly related to each other in patients with diabetes (Hartsell et al., 2001).The constant loads on the musculoskeletal system of the obese population have been implicated to predisposition of pathological gait patterns, disability and loss of mobility, orthopedic conditions, and diabetic foot pathology. A worldwide increase in diabetes mellitus and the severe complications have become a larger socioeconomic and medical issue (Skopljak et al., 2014). Diabetes being a worldwide problem and having such undesirable consequences, has created a strong interest in the scientific community. The pathological changes on diabetic patient's feet are the most frequent cause of hospitalization in the western world and the number one problem in consumption of the healthcare resources worldwide (Skopljak et al., 2014). Mechanical loading of the diabetic foot is clearly part of the etiology of foot ulceration and is subsequently a major factor in delaying wound healing. Therefore, off-loading the affected plantar areas is an important component of prevention and treatment.

Ulcer Reoccurrence, Amputation, and Death Rate

Diabetic foot ulcers are considered a major health problem and complications of foot ulcers being the leading cause of hospitalization and amputation in diabetic patients. Approximately 15-25% of diabetics will develop a foot ulcer during their lifetime (Vuorisalo et al., 2009). And 10% of diabetic patients end up with an amputation with fifty percent of the cause for amputation being the diabetic foot (Skopljak et al., 2014). Diabetic foot disease due to neuropathy and arterial disease with infections has risen. Poor arterial flow decreases blood flow to the ulcer area reducing oxygenation, nutrition, and slowing down the healing process (Vuorisalo et al., 2009). Infection is seldom the initial cause of ulcers, but often complicates existing ulcers. In a study done by Vuorisalo et al. (200) reports that five independent statistically significant risk factors of infection includes ulcer, depth to bone, ulcer duration greater than 30 days, reoccurring ulcers, traumatic etiology for ulcer, and arterial disease. There is a lack of growth and impaired defense against infection with necrotic tissue that’s laden with bacteria. The cause behind ulceration and healing problems in the diabetic foot are multifactorial, but a very important factor causing ulcers and the recurrence of ulcers is neuropathy. Often making the basic factor of healing prevention inadequate circulation. Revascularation is important when the blood supply is compromised. Relieving pressure on the ulcer area is a necessity to the healing process. More than a million amputations will be performed in people with diabetes per year and more than half of them could be prevented (Vuorisalo et al., 2009). Patients with previous ulcers are at higher risk for new ulcers because every second patients with primary ulcers develop new ulcers. Lower extremity amputation can be a result of reulceration and infection. In a multivariate analysis done on risk variables for amputation occurrence complication count, two or fewer of four foot pulses, and previous foot ulcers showed a statistical significance (Martins-Mendes et al., 2014). The most frequent causes of death were infections, oncologic disease, and heart failure (Martins-Mendes et al., 2014). The most important treatment of the ulcer is prevention. Procedures to medically manage diabetic foot ulcers include offloading, treatment on infection, debridement, wound bed preparation and dressings.

A Comparison of Commonly Used Off-Loading Devices

Ulcers caused by increased external pressure due to foot deformity, limited joint mobility, and neuropathy are commonly prevented and treated by using footwear and offloading techniques. Offloading the area of high pressure has been the main factor to prevent ulcer problems. Offloading reduces the continual injury to the tissue and allows the physiology of wound healing to occur. Evidence available on offloading ulcers is mainly related to treating non-complicated plantar neuropathic ulcers and very scared when it comes to complicated and non-plantar foot ulcers (Bus, 2012). Dorsal foot ulcers can be caused from biomechanical issues such as ill-fitting shoes. Offloading dorsal wounds may be relatively easy by providing enough room inside the footwear. Treatments of ischaemic/infected neuropathic ulcers can be more difficult than pure neuropathic ulcers. Bus (2012) reported a study that showed that neuropathic ulcers and mildly infected/ischaemic ulcers can be treated effectively with casting and have a 69-90% healing rate but infected ulcers have poor healing rate of 36%.

A number of different off-loading mechanisms are available, but not all of them are evidently practical. Two common off-loading interventions include wearing of a total contact cast or therapeutic shoe (See figure 4-5). It's unrealistic to tell a patient immobilize the foot for the time required for the ulcer to heal. Immobilization also carries the risk of thrombosis, wasting of muscle, depression, and secondary ulceration. Custom-made orthotic devices and plaster or fiberglass casts are used to off-load the wound and greatly lower plantar pressure while still allowing patients to be partially active.

Figure 4: Total Contact Cast (Dinh et al., 2013)

Figure 5: Therapeutic Shoe (Dinh et al., 2013).

Studies on the use of crutches, canes, bed rest, wheelchairs, offloading dressings, and plugs on ulcer healing were not found in the literature research (Bus et al., 2008). Complete bed rest and confinement to a wheelchair would work in specific cases but will be too restrictive for most patients. In the case of obesity, reduction of body weight would be appropriate, but since this takes time, it can only realistically be used for prevention and not to treat ulcers in the acute stage (Femery, Moretto, Hespel, Thevenon, & Lensel, 2004). The effects of walking aids to reduce the GRFs applied to the feet have not been thoroughly researched. It is conceivable that there would be an effect, but walking with a cane does not seem to reduce plantar pressures (Wu et al., 2008). Patients might benefit from crutches but would need sufficient upper-body strength to manage them and would have to put up with the inconvenience that these walking aids impose.

A change in walking style as a therapeutic intervention has been proposed. It has been demonstrated in previous research that plantar pressures, in particular in the forefoot, are considerably reduced during a shuffling gait or a “step to” gait, but this requires tremendous discipline from the patient. Research has shown that normally the ankle push-off can generate up to 80% of the power required for walking (Hartsell et al., 2001). “Therapeutic walking” has the effect of limiting ankle push-off and dramatically reducing walking speed to 0.5 m/s. At this walking speed, the double-hump pattern of the vertical GRF will be much flatter and the vertical peaks will be equal to body weight, rather than higher. Demonstrated that when walking speed is reduced from an average of 1.19 m/s (normal) to 0.83 m/s (slow), peak plantar pressures are reduced at the heel (5%–18%), at the medial forefoot (9%–11%), and at the hallux (11%) (Bus et al., 2008). Down gait, resulting in reduced peak plantar pressures, footwear can be used in multiple ways for transferring load from plantar areas at risk of ulceration to other areas. Load transfer means that the total amount of loading by the GRF is not reduced but is distributed differently than it would be normally. Useful mechanisms include alteration of foot rollover during gait, transfer of forefoot load to midfoot and/or heel, transfer of plantar load to the normally non–weight-bearing parts of the foot, and transfer of plantar load to the lower leg.

A rigid rocker sole limits dorsiflexion of the hallux and toes and, therefore, the involvement of the forefoot rocker mechanism. In a study published by Healy et al. (2012), plantar peak pressures in the medial forefoot and hallux were reduced by 30% with the use of rocker bottom shoes. This reduction was independent of the effect of walking speed, which was kept constant in this study (Healy, Dunning, & Chockalingam, 2012). However, the average walking speed was 0.83 m/s, which has a general reducing effect on plantar pressures (Harradine, Bevan, & Carter, 2006). Insoles can influence plantar pressures on the basis of their material properties and their design. Pliable materials will help to reduce instantaneous peak pressures under dynamic conditions and can be expected to make increased contact with the foot (increasing the support surface) compared with hard materials. However, under static conditions, these effects may be limited as soon as the material is fully compressed. Custom molded insoles can further help transfer load. The medial arch and the area around the heel are normally non–weight-bearing areas of the foot. With a molded support surface, these areas can be involved in weight bearing. This effect is rather small with custom-molded insoles but can be larger in molded-cast shoes. Load transfer to the lower leg is achieved by making use of the conical shape of the leg (Owings et al., 2008).

Accommodative and functional are two specific types of orthoses. Any type of patient can use orthoses and braces. The devices are utilized to prevent ulceration or reulceration by reducing plantar pressures while bracing or accommodating the collapsed foot. Rigid orthoses are typically used to functionally correct a flexible, biomechanical abnormality. The soft orthoses are used to accommodate a misshaped or painful rigid foot. No matter if they are using a orthotic or cast treatment the concept of total contact helps spread out pressure evenly off the prominent areas and helps maintain current joint position.

Total Contact Cast

A close-fitting cast or brace can provide support, thereby reducing the plantar load. Although there is new technology that is promoted for the offloading of the diabetic foot, the total contact cast (TCC) continues to be the gold standard with which all other offloading techniques are compared to. Treatment using TCC supports the joints of the foot and ankle and keeping them in a well-immobilized and locked position. Eliminating the ankle joint motion in the sagittal plane helps to decrease the propulsive phase of gait (Hartsell, Brand, & Saltzman, 2002). The casted foot pressure distribution, stride length, loading times, cadence, and velocity are also altered and reduce the vertical forces on the foot (Hartsell et al. 2002). The total contact cast has been shown to achieve 31% load transfer to the cast wall (see figure 6).

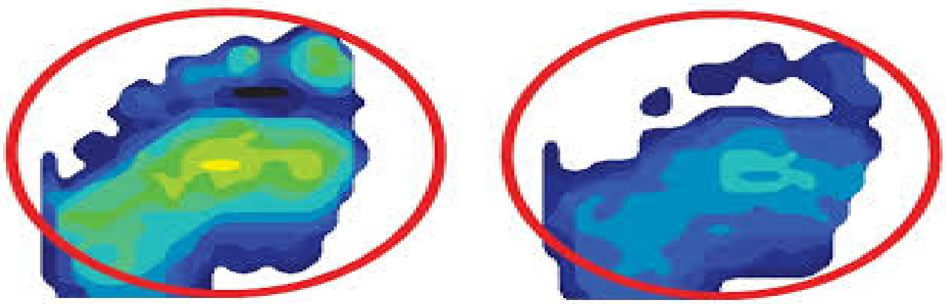


Figure 6: Forefoot Plantar Pressure (Hartsell, 2001)

The cast acts by distributing pressure evenly off the affected area of the foot (Guyton, 2004). Shaw et al. (1997) reported that the total contact cast highly reduced forefoot pressures and has capability of bypassing the foot and transferring up to 30% of the pressure directly to the leg. Hartsell et al. (2001) reported that loading of the heel increased 37% in the TCC, nevertheless, ulcers in this location is usually considered a contraindication to using the total contact cast technique. The TCC is useful in the relief of direct pressure on the bottom of the foot but may also relieve pressure in the shear or sliding forces (Guyton, 2004). To improve the patient's ability to bear weight and alter offloading characteristics of the cast terminal devices may be added to the total contact cast. At the heel of the cast rubber wedge or rocker-bottom soles can be added to offload the forefoot even further (Hartsell et al., 2002). In a randomized clinical trial done by Armstrong et al. (2001) results reported a significantly higher proportion of healed ulcers at a faster rate of healing with the total contact cast when compared with the wedge shoes and diabetic walker boots. Approximately 85% of diabetic patients with planter ulcers heel with the total contact cast within an average of five weeks (Hartsell et al., 2002).

Guyton (2004) found that the chance of a new ulcer developing on some portion of the foot covered by the cast was roughly 6% per cast. Most patients had multiple cast during their treatment course, with the average risk of complications during a patient's treatment course being 30% (Guyton, 2004). Most complications being superficial and responding to local measures only. New cast-induced ulcer can occur, but it is rare for the original ulcer to worsen as a result of the cast. It is clear that different mechanisms are used to achieve the desired effect of off-loading the ulcerated area.

Lower Extremity Kinematics related to Plantar Pressure:

Biomechanical alterations in the foot rollover process during gait and its relationship with plantar ulcerations have been discussed in the literature, especially using plantar pressure distribution as an important predictor parameter mainly under the forefoot. This mechanical parameter also has been broadly used for footwear and insole prescriptions (Healy et al., 2012). However, there are several other important biomechanical alterations in the gait of diabetic neuropathic patients that may lead to ulcer formation.

These include less ankle range of motion; alterations in spatial-temporal patterns (velocity, step length, stride length, and time of double support) differences in kinetic patterns with modified ground reaction forces and net joint moments and delayed leg and thigh muscle activation. Although these changes in gait have been identified in the diabetic population, it is still unclear if any available therapeutic interventions (pharmacological, physiotherapy, and use of orthotic devices and insoles) are efficient in restoring the biomechanical parameters to a more physiological pattern, thus reducing ulcer formation and risk of amputation (Boulton et al., 2008). The most common intervention for healing and minimizing plantar ulceration risk is the prescription of some type of orthotic device (special footwear, casting, or insoles) to reduce plantar pressure in specific foot areas (Gurney et al., 2008). However, a recent systematic review reported that those devices are only effective in the healing process; there is still not enough evidence that they are efficient in preventing plantar ulcer formation (Gurney et al., 2008). The prescription of this treatment is mostly based on clinical practice, but not on clear scientific evidence. To my knowledge there are no studies available regarding prevention of a first ulcer incidence. The above mentioned systematic review reported that not all studies showed a lower ulcer recurrence in patients who used those devices; therefore, the results are still inconclusive.

It is important to emphasize that this type of intervention only focuses on relieving the effects brought on by DPM that overload some plantar areas (Gurney et al., 2008). The other impairments that are associated with these overloads, and which also may be the causes of plantar alterations (limited joint movement, muscle weakness, and sensory loss), are not the focus of prescribing orthotic devices or special shoes. Foot rigidity is associated with increasing local loads and predisposes to plantar ulcerations. The increase in range of motion of these segments could contribute to restoring foot rollover during gait (Healy et al., 2012). The weakness of the intrinsic foot muscles and ankle flexors and extensors represents an independent risk factor for the development of plantar ulcers, leading to a less effective plantar load distribution. The strengthening and recovery of their function also could be reflected in foot rollover during gait. There is evidence that shows that patient with DPM can improve gait and confidence, suggesting a possible recovery of motor control functions at some level.

The overall purpose of this study is to examine the average and peak pressures under the plantar surface of the foot while walking inside 4 most commonly used diabetic ulcer offloading devices. Quantifying the magnitude and duration of forces generated at the plantar surface of a foot will provide substantial evidence that will support the author's belief that the onset of tissue damage is deeply correlated to the prolonged direct ground & shear forces applied to the plantar surface of feet during ambulation. The retrospective research included in my literature review supports the idea of relating prolonged forces with tissue breakdown and supports the cause for further research on this topic.

CHAPTER 3

METHODS

In this study Plantar foot wounds require offloading devices to allow for proper healing to occur. This study will analyze average peak pressures under the plantar surface of the foot while walking inside four different diabetic ulcer-offloading devices. TCC EZ, Medi-Cast, and BSN cutimed cast systems along with extra depth diabetic shoes will be used in this study (See Figure 7). The specific aim of the study is to determine which of the offloading device provides the most efficient means of offloading plantar foot wounds.


TCC EZ


Medi-Cast & Cutimed Cast


Diabetic Shoes

Figure 7: Off-loading Devices Used in the Study

The study will use the following cohorts: (1) one pedorthist ("caster") to properly fit, apply and remove devices; 25 participants ("castees"), including alternates, to walk in the devices; (4) research personnel to assist with the equipment and collection of kinetic data; (5) project coordinator. Using a Repeated Measures test design volunteers will have each device applied to one leg at a time, and then instructed to walk the same distance for the same amount of time.

Participants:

Only the castees will be recruited. Barry University Under-graduate and Graduate students currently enrolled at the University. Podiatric and Pedorthic professional will facilitate proper fit of Extra depth shoes and apply each total contact cast along with f-scan sensor to the castees. A research project coordinator would be present to aid and oversee the entire process of the day's events to closely ensure that participants and personnel operate in total compliance to the research protocol guidelines and answer any questions for volunteers.

Caster:

A Pedorthist is a clinical professional with experience in application of total contact casts who will be fitting each volunteer in extra depth diabetic shoes and total contact cast along with f-scan sensor.

Castees:

Recruitment flyers for castees will be distributed around the university's main campus in common student meeting and gathering spaces and throughout the School of Podiatric Medicine Potential castees will be encouraged to take recruitment flyers home so they have ample time to review and to contact the investigators with any questions or concerns. It will be made clear to potential participants that their participation is voluntary and that refusal to participate will involve no penalty. Prospective castees interested in taking part in the project will contact the investigators and will make appointments for screening at a time convenient for them. Screening will take place in room POD-Med 105 on the podiatry campus. During the screening, the investigators will explain the study and answer questions. There will be samples of all cast kits used in the study for the prospective participants to peruse. The investigators will work through the inclusion/exclusion checklist to identify the pool of eligible castees. Those deemed eligible for the study and willing to participate will be asked to sign the Informed Consent Form. The investigators will enroll up to 25 castees from among those eligible for the study. The castees will be chosen on a first come, first served basis.

Instrumentation:

The Tekscan in-shoe pressure mapping sensors will be used in the identification of gait cycle events. These instruments will be used to record and measure plantar surface peak pressure, center of pressure, timing stance and sway. Pressure sensors will be calibrated to each participant’s weight to give an accurate and relative value for statistical analysis.

Procedures:

Their height and weight will be taken and recorded for calibration of sensors. Tekscan F-Scan Versa Tek Wireless System sensors will be applied to one foot of the castees and placed in an appropriate sized pneumatic walking boot. The castees will then be asked to walk on F60 Sole treadmill at a pace of 2mph for a period of 3 minutes. Kinetic data collection will only take place during the last 2 minutes allowing the 1-minute to the participant to gain comfort on the treadmill while walking in the device. Participants will be prepared for application of the Total Contact Casts (TCC). Calibrated sensors will first be applied to the plantar aspect of the participants' foot and held in place with tape. The caster will then apply the first cast to the participant directly over the sensors. The cast will be given 5 minutes to dry, as the patient remains seated. Once dry, castees will stand and receive ambulation instructions by the caster for 5 minutes before performing the walking trial on the treadmill for 2 minutes at 2 mph. The process will repeat until all three TCC kits are applied to the same participant; thus, each participant will be fitted with 4 casts.

Kinetic Data

The kinetic variables that were analyzed were peak plantar pressure and impulse beneath the forefoot. A collective average of plantar peak pressure was calculated and normalized for body weight and then compared amongst all of the participants. Impulse was determined by finding the area under the force curve of first impact of the forefoot through toe off. The starting point of the first contact in the forefoot was made qualitatively using saggital 2D kinematic analysis and quantitatively using the (STAM) Stance Timing Analysis Module in F-scan. Qualitatively the trace of force points were defined numerically using the Trapezoid method, approximating the region under the graph of the function as a trapezoid and calculating its area.

Kinematic Data

The Kinematic variables of ankle flexion and tibial position were analyzed from two points of view, saggital and posterior frontal plane. Vertical alignment of the calcaneas and tibia was observed in the posterior frontal plane. The importance of vertical alignment of these two parts indicates total pronatory control in the hind-foot and mid-foot as well as stability. Most foot and ankle clinicians believe that if you can limit motion in the frontal plane and maintain a vertical alignment of the calcaneas this will cause limited mobility but more stability, which is indicated in the application of a total contact cast and considered ideal when off loading a plantar wound. In the saggital plane we were able to analyze ankle flexion by relating tibial position relative to the foot shank. We observed three points on the cast as reference points for ankle flexion. As shown in figure 8. (1) Apex of the gastrocnemeus, (2) Center of the medial malleolus (3) Center of the first metatarsal phalangeal joint.

Fig 8 Ankle Flexion TCC versus Diabetic Shoe

Flexion angles were defined as negative degree amounts less than 90 degrees, with neutral being defined at 90 degrees.

Statistical Analysis:

A Repeated Measures ANOVA was conducted using SPSS 17.0 software (SPSS Inc. Chicago,IL). to compare the peak pressures between each device. Statistical means and standard deviations for each dependent variable were calculated. The data was inspected and tested to ensure that the assumptions for data normality and sphericity of the analysis of variance were not violated.

In the first part of the study a Pearson's correlation and a Repeated Measures ANOVA was run to show a direct relationship between most commonly used off-loading methods and diabetic shoes. It showed that all TCC devices significantly lowered peak forefoot plantar pressure as compared to the DS. Additionally, the peak plantar pressure in the TCCEZ and Cutimed casts was significantly lower than that of the Medicast however; there was no significant difference in peak forefoot plantar pressure between the TCCEZ and Cutimed. Therefore since there is a greater correlation in the reduction of peak forefoot pressure in these TCC devices compared to DS as well as the TCC devices compared to one another, we can begin to draw positive trends for best practice in the treatment of Diabetic Foot Ulcers.

For the second part of the study, a repeated measures MANOVA found a strong positive correlation in differences relating tibial position to peak plantar pressure between the casts and the Diabetic Shoe. A Paired – samples t-tests revealed that all 3 casting techniques significantly reduced peak plantar pressure (PPP) as compared to the Diabetic shoe. There were no significant differences in PPP between casts, however the second repeated measures ANOVA found significant differences between casts and Diabetic Shoes. Paired – samples t-tests revealed that the TCCEZ and BSN Cutimed had significantly lower tibial angles at PPP than the Diabetic Shoe. There were no significant differences in Tibial Angle at PPP between the MediKast and Diabetic Shoe.

For the third part of the study, a repeated measures MANOVA was run to determine a strong positive correlation between tibial position, PPP and impulse. Between dependent grouping effects tests and multivariate tests were conducted and revealed that impulse significantly affected both PPP and tibial position variables in both diabetic shoe trials and total contact cast trials. There was a significant increase in peak plantar pressure as well as a decrease in tibial angle when impulse was quantified in high amounts,

Results

Descriptive data for the dependent variable for all of the participants are presented in Tables 1 and 2.

Table 1.

Case processing summary, information about the data used. There were 20 participants total and 10 were included in the full data analysis.

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
TCCEZ	10	50.0%	10	50.0%	20	100.0%
Cutimed	10	50.0%	10	50.0%	20	100.0%
MediKast	10	50.0%	10	50.0%	20	100.0%
D_Shoes	10	50.0%	10	50.0%	20	100.0%

Table 2.

Descriptive report lists the name of the dependent variable along with every level of the independent variable.

Descriptive Statistics

	Mean	Std. Deviation	N
SMEAN(TCCEZ)	26.8667	6.34837	20
SMEAN(Cutimed)	26.4286	6.74119	20
SMEAN(MediKast)	35.7500	11.43920	20
SMEAN(D_Shoes)	59.1250	21.03099	20

Table 3.

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	TCCEZ & Cutimed	13	.218	.475
Pair 2	TCCEZ & MediKast	11	.337	.311
Pair 3	TCCEZ & D_Shoes	14	.486	.078
Pair 4	Cutimed & MediKast	10	.389	.267
Pair 5	Cutimed & D_Shoes	14	.356	.212
Pair 6	MediKast & D_Shoes	12	.909	.000

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	TCCEZ	25.9231	13	6.95775	1.92973
	Cutimed	25.9231	13	8.25087	2.28838
Pair 2	TCCEZ	27.3636	11	8.58222	2.58764
	MediKast	37.2727	11	14.76544	4.45195
Pair 3	TCCEZ	26.9286	14	7.67077	2.05010
	D_Shoes	58.0714	14	23.16982	6.19240
Pair 4	Cutimed	23.8000	10	5.32917	1.68523
	MediKast	34.5000	10	12.17694	3.85069
Pair 5	Cutimed	26.4286	14	8.14970	2.17810
	D_Shoes	57.1429	14	21.33202	5.70122
Pair 6	MediKast	35.7500	12	15.03405	4.33996
	D_Shoes	57.0833	12	25.61412	7.39416

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
					95% Confidence Interval of the Difference				
		Mean	Std. Deviation	Std. Error Mean	Lower	Upper			
Pair 1	TCCEZ - Cutimed	.00000	9.56556	2.65301	-5.78041	5.78041	.000	12	1.000
Pair 2	TCCEZ - MediKast	-9.90909	14.36283	4.33056	-19.55817	-.26001	-2.288	10	.045
Pair 3	TCCEZ - D_Shoes	-31.14286	20.56456	5.49611	-43.01648	-19.26923	-5.666	13	.000
Pair 4	Cutimed - MediKast	-10.70000	11.23536	3.55293	-18.73729	-2.66271	-3.012	9	.015
Pair 5	Cutimed - D_Shoes	-30.71429	19.94388	5.33023	-42.22954	-19.19903	-5.762	13	.000
Pair 6	MediKast - D_Shoes	-21.33333	13.49972	3.89703	-29.91065	-12.75602	-5.474	11	.000

Multiple paired-samples t test was calculated to compare the mean of total plantar pressure between each cast and the diabetic shoes. The lowest mean plantar pressure comparison was 23.8(sd=5.32), and the highest mean total plantar pressure was 58.07(sd=23.1). A significance increase was found in each comparison with the highest showing ($t(12)=.000, p<.001$).

Table 4.

Tests of Between-Subjects Effects

Measure: PlanPressure

Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[a]
Intercept	47817.225	1	47817.225	124.740	.000	.933	124.740	1.000
Error	3450.025	9	383.336					

a. Computed using alpha = .05

Table 5.

Tests of Within-Subjects Contrasts

Measure: PlanPressure

Source	Cast	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[a]
Cast	Linear	4427.405	1	4427.405	16.357	.003	.645	16.357	.948
	Quadratic	1177.225	1	1177.225	17.006	.003	.654	17.006	.955
	Cubic	9.245	1	9.245	.410	.538	.044	.410	.089
Error(Cast)	Linear	2436.045	9	270.672					
	Quadratic	623.025	9	69.225					
	Cubic	202.805	9	22.534					

a. Computed using alpha = .05

Tests of Within-Subjects Effects

Measure: PlanPressure

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[a]
Cast	Sphericity Assumed	5613.875	3	1871.292	15.490	.000	.632	46.469	1.000
	Greenhouse-Geisser	5613.875	1.497	3750.384	15.490	.001	.632	23.186	.986
	Huynh-Feldt	5613.875	1.728	3247.916	15.490	.000	.632	26.773	.993
	Lower-bound	5613.875	1.000	5613.875	15.490	.003	.632	15.490	.937
Error(Cast)	Sphericity Assumed	3261.875	27	120.810					
	Greenhouse-Geisser	3261.875	13.472	242.124					
	Huynh-Feldt	3261.875	15.556	209.685					
	Lower-bound	3261.875	9.000	362.431					

a. Computed using alpha = .05

In table 5 it shows that a one-way repeated measures ANOVA was calculated comparing the result of plantar pressure values of subjects in three different casts. Significant effects were found ($F(1,9) = 124.74$, $p<.005$)

Histograms in figure 9 show significant interactions between the average peak pressure for each cast during each trial.

Figure 9

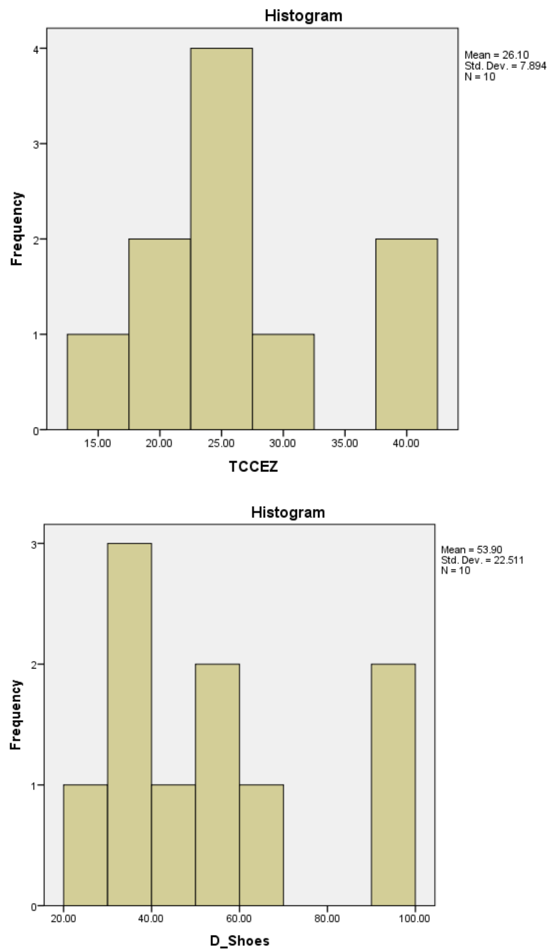
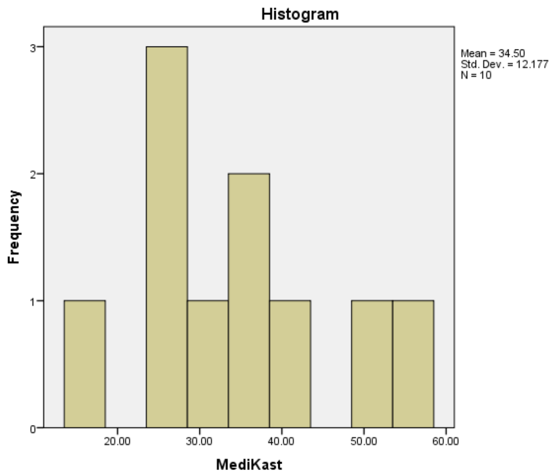


Figure 9 cont.



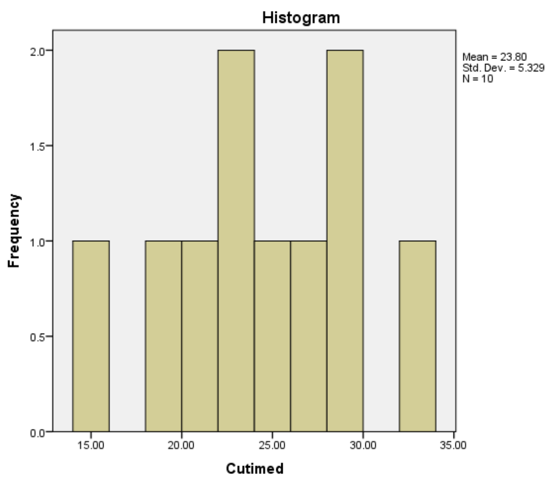


Table 6.

Peak Forefoot Plantar Pressure and Tibial Angle in 3 casting techniques

	PPP (N/cm3) Mean (SD)	Tibial Angle (degrees) Mean (SD)
Diabetic Shoe	589.89 (317.15)*	110.17 (9.03)[1,2]
TCCEZ	385.07 (161.91)	93.63 (5.56)[1]
Medi-Kast	359.93 (276.47)	105.31 (10.65)
BSN Cutimad	299.03 (173.85)	98.90 (9.09)[2]

Note: PPP = Peak Forefoot Plantar Pressure, Tibial angle as measured in the sagittal plane
* significantly different from all 3 casting techniques ($p < 0.05$)
[1] = significantly different ($p < 0.05$), [2] significantly different ($p < 0.05$)

Table 6 shows that all cast significantly lowered peak planter pressure related to Diabetic shoe control. Additionally the TCC-EZ cast restricted ankle joint dorsiflexion to limit tibial position closest to 90 degrees. Clinically the goal in wound care is to maximize offloading of wounds. We found that each casting method reduces peak forefoot plantar pressure. We also found that there was great variability in Tibial Angle at PPP, which could be associated with issues in cast application and cast design . As a result of these limitations we would propose future research that would focus on the influence of duration of peak pressure due to differences in Cast design and application.

Discussion

In this study a Repeated Measures ANOVA was conducted to compare the peak pressures between each device. In this direct comparison of popular off-loading methods, all TCC devices significantly lowered peak forefoot plantar pressure as compared to the DS (Diabetic Shoes). Additionally, the peak plantar pressure in the TCCEZ and Cutimed casts was significantly lower than that of the Medicast. However, there was no difference in peak forefoot plantar pressure between the TCCEZ and Cutimed.

Therefore since there is a greater correlation of the reduction of peak forefoot pressure in these TCC devices compared to DS as well as a significant difference in the reduction of peak plantar pressure in the TCCEZ and Cutimed cast as compared to the Medikast we can begin to draw positive trends for best case practice in the treatment of Diabetic Foot Ulcers. The first repeated measures ANOVA found significant differences between the casts and the Diabetic Shoe. Paired – samples t-tests revealed that all 3 casting techniques significantly reduced PPP (peak plantar pressure) as compared to the Diabetic shoe. There were no significant differences in PPP between casts.

The first hypothesis states that patients who develop neuropathic plantar ulcers in the forefoot region, may benefit from a reduction in plantar pressures. By using a Total Contact Cast rather than extra depth shoes and inserts with modifications or other pneumonic devices, pressure will be equally distributed throughout the plantar surface of the foot. Off-loading includes two elements, reduction of pressure (ground reaction forces) and reduction of shearing (frictional forces). The principle involved here is that the cast is molded directly to the contours of the foot. Therefore the pressure which has been concentrated on the bony prominence or ulcers is distributed over the entire plantar aspect of the foot, allowing reversal of the mechanism that will cause the ulcer to heal.

The second repeated measures ANOVA found significant differences between casts and Diabetic Shoe. Paired – samples t-tests revealed that the TCCEZ and BSN Cutimed had significantly lower Tibial Angle at PPP than the Diabetic Shoe. Athlough there were no significant differences in Tibial Angle at PPP between the MediKast and Diabetic

Shoe. We can begin to draw positive trends that suggest best case practice for the application of total contact cast are related to casting positioning, limiting range of motion at the ankle and possibly cast material and drying time. These variables were found to also have an effect on plantar pressure.

The second hypothesis states that direct pressure and shear forces are mitigated through the limiting of ankle range of motion. Total contact cast usually captures the patient's tibial talar joint in a 90 degree angle, restricting sagittal and frontal plane movements and limiting tangential forces (Wu etl al. 2008).

Limiting ROM at the ankle promotes benefits at the plantar surface. This is beneficial for offloading the forefoot. Direct pressure is reduced because the forefoot spends less time on the ground during the propulsion phase which would result in lower PPP. Impulse is also effect because of this chain of events.

To strengthen this study I would consider that the positive effect on impulse, which may be the key difference in the efficacy of pressure modulation and off loading between popular off loading methods. The less time insensate patients are allow to spend in contact with the ground the better. In the treatment of a diabetic foot ulcer, pressure modulation, commonly referred to as "off-loading," is most successful when pressure is mitigated in areas of high vertical and shear stress. During weight-bearing activities, the feet are exposed to these significant forces, particularly when the activity is dynamic, such as walking.

Common methods to off-load the foot include bed rest, wheelchair, crutch assisted gait, total contact casts, half shoes, therapeutic shoes, and removable cast walkers. Off-loading data for vertical forces, or "ground reactive forces", are well established for varying off-loading modalities and has been present in the literature for over 20 years. In the past scientists have primarily focused on the dermis and subcutaneous layers of tissue. Retrospective histology studies have a vast amount of information on physical and mechanical properties, but neglect to draw conclusions about each layer and its interaction with medical devices and their micro environment.

The main objective of this research was to analyze average and peak pressures under the plantar surface of the foot while walking inside 4 different diabetic ulcer off-loading devices. This included three different total contact cast systems and an extra depth diabetic shoe. Pressure distribution in each off-loading device was measured by a pressure sensor applied directly to the plantar surface of the foot. This data will be used in formulating the data necessary to assess “shear” forces and micro environment in a prospective study.

The goal of the prospective research would be to quantify the magnitude and duration of forces generated at the plantar surface of a foot where tissue breakdown mainly occurs. The core component of this research would be to develop a quantitative measurement for “shearing” or “frictional” forces. Until we can quantify the vertical and shearing forces, we do not fully understand the pathogenesis of diabetic foot ulcers, pressure ulcers and other aspects of wound healing. A unit of measurement would provides a quantitative, reproducible number could become the standard measurement of shear that completes the “off-loading picture” that encompasses the “healing chamber” afforded by the total contact cast.

Our team believes that the onset of tissue damage is deeply correlated to the prolonged shear forces applied to the plantar surface of feet during ambulation.

Mitigating these forces is also a requirement to enable wounds to heal and is believed to be a major reason the total contact casts enjoys “gold standard” status as an off-loading modality. The quantitative and reproducible measure of shear for in-shoe plantar shear force through a single device has not been previously accomplished. The creation of such a device could potentially provide us with data to understand effective off-loading for Diabetic Foot Ulcers.

Conclusion

The onset of tissue damage is correlated to the prolonged ground reactive forces (vertical forces), in combination with shear forces (horizontal forces) applied to the plantar surface of feet during ambulation. The outermost layer of the plantar surface of the foot will continue to produce more skin cells as a result of pressure and overall forces applied to its surface. This is a defense mechanism the body naturally employs to protect itself from breakdown.

As a result of this defense mechanism, callusing will occur. However in most insensate diabetics this defense mechanism is impaired and leads to tissue breakdown. This is why proper diabetic foot ulcers should be properly off loaded using the best available options. Therefore the results of this research are far reaching and should mightily impact the medical community. The results of this study show that all of the off loading devices used in this study reduce the amount of total pressure in the fore foot during ambulation. This is important to relate to clinicians who may use other popular off loading devices such as extra depth shoes and inserts.

The comparison of extra depth diabetic shoes and total contact cast plantar pressure reduction are intuitive and paint a clear picture that one method/device is clearly superior over the other. However, the results of the comparisons between total contact cast are not as intuitive and suggest more research. The results of this research suggest that although the designs are different, functionality remains the same. Generally the concept of a total contact cast offers functional mobility for non compliant or severely wounded patients, and given the results of the research that concept can be reaffirmed with confidence. With proper application total contact cast should be considered the gold standard and best option for off loading diabetic foot ulcers along with two key recommendations, 1) Be sure to cast the wearer at 90 degree saggital plane alignment. 2) Recommend a removable pneumatic walking device for more efficient ambulation. As mentioned in the discussion section these two recommendations significantly separate the most efficient devices from the others. As a result patients will heal faster, walk more efficiently and ambulate in an ideal and safe environment conducive to pressure modulation and off loading.

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Appendix A: IRB Form

Barry University

Research with Human Participants

Protocol Form

PROJECT INFORMATION

1. **Title of Project:** Plantar Pressure Study

2. **Principal Investigator** (please type or print)

Faculty Number: 1713210

Name: Claire Egret, PhD

School: Human Performance and Leisure Sciences

Mailing Address: 11300 NE 2nd Avenue, Miami Shores, FL 33161

Telephone Number: 305-899-3064

E-Mail Address: cegret@barry.edu

Faculty Number: 1032453

Name: Kathryn Ludwig, PhD

School: Human Performance and Leisure Sciences

Mailing Address: 11300 NE 2nd Avenue, Miami Shores, FL 33161

Telephone Number: 305-899-4077

E-Mail Address: kludwig@barry.edu

Faculty Number: 2867435

Name: Von Homer, BOCPD

School: School of Podiatric Medicine

Mailing Address: 11300 NE 2nd Avenue, Miami Shores, FL 33161

Telephone Number: 305-899-3283

E-Mail Address: vhomer@barry.edu

*NOTE: You **WILL NOT** receive any notification regarding the status of your proposal unless accurate and complete contact information is provided at the time the proposal is submitted.*

3. **Faculty Sponsor** (If Applicable)

Name:

School – Department:

Mailing Address:

Telephone Number:

E-Mail Address:

Faculty Sponsor Signature: _________________________________ Date: _____________

4. **Is an IRB Member on your Dissertation Committee? Yes _____ No: ___X_____**

5. **Funding Agency or Research Sponsor**

Derma Sciences

214 Carnegie Center, Suite 300

Princeton, NJ 08540

6. **Proposed Project Dates**
Start _ December 15, 2014______
End _December14, 2105_______

Please Provide the Information Requested Below

A. Project activity STATUS is: (check one of the following three as appropriate)

_X_ NEW PROJECT

___ PERIODIC REVIEW ON CONTINUING PROJECT

___ PROCEDURAL REVISION TO PREVIOUSLY APPROVED PROJECT

(Please indicate in the PROTOCOL section the way in which the project has been revised)

B. This project involves the use of an **INVESTIGATIONAL NEW DRUG (IND) OR AN APPROVED DRUG FOR AN UNAPPROVED USE** in or on human participants

___ YES _X_ NO

Drug name, IND number and company: ___________________________________

C. This project involves the use of an **INVESTIGATIONAL MEDICAL DEVICE (IMD) or an APPROVED MEDICAL DEVICE FOR AN UNAPPROVED USE.**

___ YES _X_ NO

D. This project involves the use of RADIATION or RADIOISOTOPES in or on human participants.

__ YES _X_ NO

E. This project involves the use of Barry University students as participants. (If any students are minors, please indicate this as well.)

_X_ YES Barry Students will be participants (Will minors be included? ___ YES _X_ NO)

___ NO Barry Students will participate

F. HUMAN PARTICIPANTS from the following population(s) would be involved in this study

___ Minors (under age 18)

___ Fetuses

___ Abortuses

___ Pregnant Women

___ Prisoners

___ Mentally Retarded

___ Mentally Disabled

___ Other institutionalized persons (specify)

_X_ Other (specify) ________________see above__________________________________

G. Total Number of Participants to be studied: 25

Description of Project

1. Abstract *(200 words or less)*

This study is funded by DermaSciences, a medical device company focused on wound care.

Plantar foot wounds require offloading devices to allow for proper healing. This study will analyze average peak pressures exerted on the foot's plantar surface while walking on a treadmill, wearing four different offloading devices: TCC-EZ, MedE-Kast, BSN Cutimed cast and a diabetic shoe. An F-scan sensor placed inside each device will measure pressure. A 3D Motion Analysis System Vicon® will also be used to collect kinematic data during gait analysis. The specific aims of the study are to determine which offloading device provides the most effective relief from plantar pressure and the various gaits used in each case.

The study will use the following cohorts: (1) one pedorthist ("caster") to properly fit, apply and remove devices; (2) up to 25 participants ("castees"), including alternates, to walk in the devices; (4) research personnel to assist with the equipment and collection of kinetic data; (5) project coordinator.

Castees will have F-scan sensors and each of the offloading devices applied to one leg only, and reflective markers will be placed on their lower extremities. They will then be instructed to walk at 2.8 mph on a treadmill for three minutes. Plantar pressures will be measured and recorded.

2. Recruitment Procedures

*Describe the selection of participants and methods of recruitment, including recruitment letter if applicable. (**NOTE**: If the investigator has access to participants by virtue of his or her position within the study setting, please provide a brief description of such access.*

Only the castees will be recruited.

<u>Castees</u>:

Recruitment flyers for castees will be distributed around the university's main campus in common student meeting and gathering spaces and throughout the School of Podiatric Medicine (see Attachment #1 – Recruitment Flyer.) Potential castees will be encouraged to take recruitment flyers home so they have ample time to review and to contact the investigators with any questions or concerns. It will be made clear to potential participants that their participation is voluntary and that refusal to participate will involve no penalty.

Prospective castees interested in taking part in the project will contact the investigators and will make appointments for screening at a time convenient for them. Screening will take place in the

Motion Analysis Center (MAC) Lab. During the screening, the investigators will explain the study and answer questions. There will be samples of all offloading devices (casts and diabetic shoe) used in the study for the prospective participants to peruse. The investigators will work through the inclusion/exclusion checklist to identify the pool of eligible castees (see Attachment #2 – Inclusion/Exclusion Checklist.) Those deemed eligible for the study and willing to participate will be asked to sign the Informed Consent Form (Attachment #3 – Informed Consent Form.) The investigators will enroll up to 25 castees from among those eligible for the study. The castees will be chosen on a first-come, first-served basis. The total time commitment for each castee is two and a half hours.

The screening data collected from subjects deemed ineligible for the study will be destroyed.

A convenient time will be set for data collection.

3. Methods

Describe procedures to which humans will be subjected. Include a description of deceptive techniques, if used, and debriefing procedures to be used on completion of the study. Use additional pages, if necessary.

Data collection will take place within one year of IRB approval, in the MAC-Lab, located in the Health and Sports Center on the main campus of Barry University.

Castees will check in at the laboratory at their agreed upon time. Castees will change into appropriate attire for data collection, i.e. close-fitting athletic wear to allow the placement of reflective markers on the lower limbs. Their height and weight will be taken and recorded for calibration of sensors. Leg length, knee width and ankle width will also be measured.

The castees will then be fitted for the F-scan sensor, which will be affixed to the plantar aspect of one foot with gauze tape.

The castee will then be instructed to put on the diabetic shoe (already sized for each castee). The sensor will then be calibrated. This calibration requires the castee to stand still on one foot for 10 seconds while the sensor calibrates.

After the calibration, the castee will be given one minute to walk around the lab to become familiar wearing the sensor and shoe. The castee will then be asked to ambulate on an F60 Sole treadmill at a pace of 2.8 mph for three minutes. Kinetic data collection will take place during a randomly chosen 30 seconds within the last two minutes of walking; the first minute will be devoted to the castee becoming comfortable while walking on the treadmill with the device.

Kinematic data will be also recorded with 3D Motion Analysis System (Vicon MX system, Oxford Metrics Ltd, Oxford, England) with 7 MX3 cameras (operating at a sampling frequency of 240 Hz). Sixteen reflective markers will be placed on the participants' lower extremities according to the Vicon Plug-in-gait marker protocol. The marker placement, which includes right and left anterior superior iliac spines, right and left posterior superior iliac spines, each thigh, knee, shank, lateral malleoli, heel, and distal ends of both second metatarsals, will remain constant throughout all experimental conditions.

After completion of the diabetic shoe data collection, the castee will remove the shoe and one of the three casts will be applied. See below for application and removal procedures for each cast. The order of the casts will be randomized.

After data collection of each device, the device will be removed and the castee's leg prepared for the next cast. The process will repeat until all casts have been applied to the leg of the same castee and that castee has walked and data recorded on the treadmill for three minutes each.

The total time for data collection is approximately two and a half hours for each castee.

All collected data will be kept for a minimum of 5 years from the completion of the study.

Below, please find methods of application and removal for all four devices used in the study.

Castees will participate in all four cycles of data collection and will be given a $50 gift card Alternates who did not participate, but who did make themselves available for use in the study, will be given a $25 gift card.

TCC-EZ cast

Application:

The castees will be prepped for application of each cast. Castees will sit on treatment tables with legs stretched out before them, flexed at ankle, while stockinette, protective felt padding, foam dressing pad, and tape are applied to one leg at a time, over the entire foot extended to the knee.

Castee will then be in prone position with leg flexed at knee while application continues with cast sock, which will be saturated in water (tap water at 70° F – 85° F). Cast sock will be rubbed to conform to the leg, with foot in neutral position and ankle as close to 90-degree angle as possible, for five minutes until cast is dry. The castee will sit upright for additional 15 minutes while cast cools and hardens.

The application process for this cast, not including drying time, takes approximately 10 minutes.

Removal:

Castee will sit on the treatment table with legs stretched out before them, flexed at ankle, while top of cast, stockinette and felt padding are cut with bandage scissors and a cast saw is used to cut the hardened cast. Cast spreaders will be used to remove the opened cast safely from the lower leg.

The removal process for this cast takes approximately 5 minutes.

MedE-Kast

Application:

Castees will sit on treatment tables with legs stretched out before them, flexed at ankle, while stockinette, protective felt padding, foam dressing pad, and tape are applied to one leg at a time, over the entire foot extended to the knee.

Castee will then be in prone position with leg flexed at knee, and foot as close to a 90-degree angle as possible, while application continues with strips of cotton cast padding and then rolls of plaster, which will be saturated in water (tap water at 70° F – 85° F). Cast and applied plaster rolls will be smoothed and patted to conform to the leg. A three-inch roll of fiberglass will be moistened with tap water and wrapped around already-padded foot, ankle and lower leg. Two fiberglass splints will be applied (with castee still in prone position and ankle flexed at 90 degrees), followed by the last roll of moistened fiberglass tape. The castee will sit upright for an additional 15 minutes while cast cools and hardens.

The application process for this cast, not including drying time, takes approximately 10 minutes.

Removal:
Castee will sit on patient bench with legs stretched out before them, flexed at ankle, while top of cast, stockinette and felt padding are cut with bandage scissors and cast saw is used to cut hardened cast. Cast spreaders will be used to remove the opened cast safely from the lower leg.

The removal process for this cast takes approximately 5 minutes.

<u>BSN Cutimed Cast</u>
Application:
Castees will sit on treatment tables with legs stretched out before them, flexed at ankle, while stockinette, protective felt padding, foam dressing pad, and tape are applied to one leg at a time, over the entire foot extended to the knee.

A three-inch roll of fiberglass tape will be moistened with tap water and wrapped around already-padded foot, ankle and lower leg. A four-inch roll of fiberglass tape will then be applied. A flat surface board will be pressed against the plantar surface of the foot to ensure complete contact, and then removed, followed by another four-inch roll of fiberglass tape. Castee will be asked to stand on board with knee flexed for up to 30 seconds to ensure complete contact. The castee will sit upright for additional 15 minutes while cast cools and hardens.

The application process for this cast, not including drying time, takes approximately 10 minutes.

Removal:
Castee will sit on patient bench with legs stretched out before them, flexed at ankle, while top of cast, stockinette and felt padding are cut with bandage scissors and cast saw is used to cut hardened cast. Cast spreaders will be used to remove the opened cast safely from the lower leg.

The removal process for this cast takes approximately 5 minutes.

(See attachments #4, #5, and #6 for package instructions for the TCC-EZ, MedE-Kast, and BSN Cutimed Cast, respectively.)

4. Alternative Procedures

Describe alternatives available to participants. One alternative may be for the individual to withhold participation.

The alternatives are to choose not to participate. Castees may withdraw at any time without adverse consequences.

5. Benefits

Describe benefits to the individual and/or society.

There are no direct benefits to the castees or alternates, The study will benefit society by advancing the body of evidence in total contact casting and to provide insight into the various offloading modalities currently available and their effectiveness in offloading plantar ulcers.

6. Risks

Describe risks to the participant and precautions that will be taken to minimize them. Include physical, psychological, and social risks.

There is minimal risk the castees will experience irritation on the plantar aspects of their feet from the application and removal of the gauze tape used to adhere the F-scan sensor. In order to minimize the risk, hypoallergenic tape will be used.

There is minimal risk the castees will experience irritation on their legs from the cast components during the cast application process. To minimize the risk, the caster will apply a stockinet – a sock-like material that covers the skin – to the legs of the castees before the other materials are applied. The stockinet provides a cushioned edge for the cast.

There is minimal risk the castees will experience discomfort or a burning sensation from the exothermic reaction of the cast materials as they dry. The risk can be mitigated by applying the correct amount of padding, and monitoring the dip water temperatures.

There is also the risk of the participants tripping and/or falling while walking on the treadmill. This risk will be minimized by providing the participants ample time to get familiar with walking in the various casts. Spotters will also be on hand to prevent falls and an automatic stop mechanism will be used to stop the treadmill in the event the castee moves away from “normal distance” from the front of the treadmill.

The caster and castees will wear surgical mask and goggles during the removal process to prevent any irritation from fiberglass cast dust.

7. Anonymity/Confidentiality

Describe methods to be used to ensure the confidentiality of data obtained.

The identification of the castees in the study will be kept confidential. Names of all participants will be replaced with a numerical coding system. All participants will sign consent forms, which will be kept in a locked file cabinet and stored separately from the working records regarding data collection during data collection electronic data will be collected and stored on a secured internal hard drive entitled "Derma Science Plantar Pressure Data." After study completion electronic data will be transferred and stored on an external hard drive and kept in a locked file cabinet along with other related paper documents and consent forms for five years and then destroyed.

8. Consent

Attach a copy of the consent form(s) to be signed by the participant and/or any statements to be read to the participant or informational letter to be directed to the participant. ***(A copy of the consent form should be offered to each participant.)*** *If this is an anonymous study, attach a cover letter in place of a consent form.*

Consent forms for the castees (Attachment #3) are included with this submission.

9. Certification

I certify that the protocol and method of obtaining informed consent as approved by the Institutional Review Board (IRB) will be followed during the period covered by this research project. Any future changes will be submitted to IRB review and approval prior to implementation. I will prepare a summary of the project results annually, to include identification of adverse effects occurring to human participants in this study. I have consulted with faculty/administrators of any department or program, which is to be the subject of research.

____________________________ ______________________

Principal Investigator Date

____________________________ ______________________

Principal Investigator Date

____________________________ ______________________

Principal Investigator Date

Reminder: Be sure to submit sixteen (16) individual collated and bound (i.e. stapled or paper clipped) copies of this form with your application.

*NOTE: Your proposal **WILL NOT** be reviewed until the completed packet is received in its entirety.*

Appendix B: Thesis Journal Manuscript

Abstract

Decreasing forefoot plantar pressure is an important factor in the prevention and treatment of diabetic ulcerations. Although offloading devices have been shown to mitigate plantar pressure, there is currently little research comparing the directly comparing the efficacy of these offloading devices. The purpose of this study was to compare the forefoot plantar pressure between four of the most commonly used off-loading devices (TCC EZ, Medi-Kast, BSN Cutimed cast systems, Extra-depth Diabetic Shoe [DS]).

Twenty healthy participants' forefoot plantar pressure was measured while walking in each device. One podiatrist applied the device around the Tekscan f-scan Versa Tek Wireless mapping plantar pressure sensor. Data collection was randomized between each device as plantar pressure was collected during a 3 minute walk on a treadmill at a pace of 1.8 mph. A Repeated Measures ANOVA was conducted to compare the peak pressures between each device.

In this direct comparison of popular off-loading methods, all TCC devices significantly lowered peak forefoot plantar pressure as compared to the DS. Additionally, the peak plantar pressure in the TCCEZ and Cutimed casts was significantly lower than that of the Medicast , however, there was no difference in peak forefoot plantar pressure between the TCCEZ and Cutimed.

Therefore since there is a greater correlation in the reduction of peak forefoot pressure in these TCC devices compared to DS as well as the TCC devices compared to one another, we can begin to draw positive trends for best practice in the treatment of Diabetic Foot Ulcers.

Introduction

In 2014 diabetes remains the 7th leading cause of death in the United States with 69,071 death certificates listing diabetes as the underlying cause of death (Prevention, 2011). The total estimated costs of diagnosed diabetes have increased 41%, from $174 billion in 2007 to $245 billion in 2012. Certain complications and co-morbid conditions are associated with diabetes, among many listed conditions ulcerations and amputations are the focal point (Prevention, 2011). Ulcers are open sores or wounds that will occur in 15% of patients with diabetes and of those who develop a foot ulcer, 6% will be hospitalized due to infection or other ulcer-related complications (Cavanagh & Bus 2010). Ulcers form due to a combination of factors, such as lack of feeling in the foot, poor circulation, foot deformities, irritation (such as friction or pressure), and trauma, as well as duration of diabetes. Patients who have diabetes for many years can develop neuropathy, a reduced or complete lack of ability to feel pain in the feet due to nerve damage caused by elevated blood glucose levels over time.

In the treatment of diabetic foot ulcers, pressure modulation, commonly referred to as “offloading,” is most successful when pressure is mitigated at an area of high vertical or shear stress (Bus et al. 2008). During weight-bearing activities, the feet are exposed to large forces, particularly when the activity is dynamic, such as walking (Groner 2013). The pressure under the plantar surface during walking varies per foot area because of a number of factors related to the normal rollover during the stance phase of gait. Diabetes mellitus often results in loss of protective sensation and in structural changes that make the feet more susceptible to injury. Increased plantar pressure is an important factor in the development and maintenance of diabetic foot ulceration (Groner 2013). Increased plantar pressures and associated ulcers need to be treated by off-loading of the plantar surface. Useful off-loading mechanisms include reduction of walking speed, alteration of (Dinh, Veves, & Tecilazich 2013) foot rollover during gait, and transfer of load from affected areas to other areas of the foot or the lower leg. These plantar off-loading mechanisms could result in an optimization of treatment (Bus et al. 2008), but clinical effectiveness must be demonstrated. Common methods to offload the foot include bed rest, wheel chair, crutch assisted gait, total contact casts, half shoes, therapeutic shoes, and removable cast walkers (Dinh et al., 2013). Although it is well known that pressure mitigation through offloading devices is crucial for the healing of plantar diabetic foot ulcers, in our knowledge there are currently no reports in the literature that describe the characteristics and considerations associated with the use of pressure mitigation devices in a broad geographically diverse sample of specialists.

There is no consensus in the literature concerning the role of off-loading through footwear in primary or secondary prevention of ulcers. This is likely due to the wide diversity of intervention and control conditions tested, the lack of information about off-loading efficacy of the footwear used, and the absence of a target pressure threshold for off-loading. Uncomplicated plantar ulcers should heal in 6 to 8 weeks with adequate off-loading (Gurney, Kersting, & Rosenbaum 2008). The total contact cast and other non-removable devices are most effective because they eliminate the problem of non-adherence to recommendations for using a removable device. Conventional or standard therapeutic footwear is not effective in ulcer healing (Wu, Jensen, Weber, Robinson, & Armstrong 2008). Recent United States and European surveys show a large discrepancy between guidelines and clinical practice in off-loading diabetic foot ulcers (Deschamps et al., 2013). Many professionals continue to use methods that are known to be ineffective or have not been proven effective, while ignoring methods that have been demonstrated to be successful (Deschamps et al., 2013).

The central goal of any treatment program designed to heal neuropathic foot ulcers is effective reduction in pressure or off-loading. Several off-loading devices are available such as walkers, half shoes, orthotics, felted foam and Total Contact Cast (TCC). TCC is considered as the gold standard of ulcer treatment by many experts in this field. TCC involves a molded and minimally padded cast that maintains contact with entire plantar aspect of foot and lower leg and keeps the weight off the foot when the patient is standing (Myerson, Papa, Eaton, & Wilson, 1992). TCC have been shown to reduce the pressure at the ulcer site by 84-92% (Hartsell, Fellner, Frantz, & Saltzman, 2001). Besides off-loading pressure, there is also reduction in shearing forces and edema of the foot. It optimizes the healing environment and prevents further wound injury. Healing rates of up to 90% are achieved with TCC in diabetic patients with neuropathic foot ulcers (Bus et al. 2008). The main objective of this research is to analyze average and peak pressures under the plantar surface of the foot while walking inside 4 different diabetic ulcer offloading devices. Including 3of the most commonly used total contact cast systems and a extra depth diabetic shoe. Pressure distribution in each offloading device will be measured by a pressure sensor applied directly to the plantar surface of the foot. TCC EZ, Medi-Cast, and BSN cutimed cast systems along with an extra depth diabetic shoe will be used in this study. Using a /within Repeated Measures MANOVA test design volunteers will have each device applied to one leg at a time, and then instructed to walk the same distance for the same amount of time.

Patients who develop neuropathic plantar ulcers in the forefoot region, may benefit from a reduction in plantar pressures. By using a Total Contact Cast rather than extra depth shoes and inserts with modifications or other pneumonic devices pressure, will be equally distributed through the plantar surface of the foot. Off-loading includes two elements, reduction of pressure (ground reaction forces) and reduction of shearing (frictional forces). The principle involved here is that the cast is molded directly to the contours of the foot. Therefore the pressure which has been concentrated on the bony prominence or ulcers is distributed over the entire plantar aspect of the foot, allowing reversal of the mechanism that will cause the ulcer to heal. Additionally shear forces are mitigated through the limiting of ankle range of motion. Total contact cast usually captures the patient’s tibial talar joint in a 90 degree angle, restricting sagittal and frontal plane movements and limiting tangential forces (Wu etl al. 2008).

The research will show how effect ground reaction forces are equally distributed along the plantar surface of the human foot when it is forced to remain in one position inside of a total contact cast along with other off-loading medical devices. The significance of this study will generate new knowledge in dynamic gait analysis as it relates to plantar pressure analysis. Examining plantar pressure inside of most commonly used off-loading devices could provide better standard care protocols for clinicians who care for diabetic wounds. Additionally medical device companies will develop new ways of constructing the mechanical devices that are commonly used in clinic. Should this research support my hypothesis technicians and scientist will have the information to develop an accurate design of a mechanical device to fit the best practice for an ulcerated foot.

Methods

In this study Plantar foot wounds require offloading devices to allow for proper healing to occur. This study will analyze average peak pressures under the plantar surface of the foot while walking inside four different diabetic ulcer-offloading devices. TCC EZ, Medi-Cast, and BSN cutimed cast systems along with extra depth diabetic shoes will be used in this study (See Figure 7). The specific aim of the study is to determine which of the offloading device provides the most efficient means of offloading plantar foot wounds.


TCC EZ


Medi-Cast & Cutimed Cast


Diabetic Shoes Figure 7: Off-loading Devices Used in the Study

The study will use the following cohorts: (1) one pedorthist (“caster”) to properly fit, apply and remove devices; 25 participants (“castees”), including alternates, to walk in the devices; (4) research personnel to assist with the equipment and collection of kinetic data; (5) project coordinator. Using a Repeated Measures test design volunteers will have each device applied to one leg at a time, and then instructed to walk the same distance for the same amount of time.

Participants:

Only the castees will be recruited. Barry University Under-graduate and Graduate students currently enrolled at the University. Podiatric and Pedorthic professional will facilitate proper fit of Extra depth shoes and apply each total contact cast along with f-scan sensor to the castees. A research project coordinator would be present to aid and oversee the entire process of the day’s events to closely ensure that participants and personnel operate in total compliance to the research protocol guidelines and answer any questions for volunteers.

Caster:

A Pedorthist is a clinical professional with experience in application of total contact casts who will be fitting each volunteer in extra depth diabetic shoes and total contact cast along with f-scan sensor.

Castees:

Recruitment flyers for castees will be distributed around the university's main campus in common student meeting and gathering spaces and throughout the School of Podiatric Medicine Potential castees will be encouraged to take recruitment flyers home so they have ample time to review and to contact the investigators with any questions or concerns. It will be made clear to potential participants that their participation is voluntary and that refusal to participate will involve no penalty. Prospective castees interested in taking part in the project will contact the investigators and will make appointments for screening at a time convenient for them. Screening will take place in room POD-Med 105 on the podiatry campus. During the screening, the investigators will explain the study and answer questions. There will be samples of all cast kits used in the study for the prospective participants to peruse. The investigators will work through the inclusion/exclusion checklist to identify the pool of eligible castees. Those deemed eligible for the study and willing to participate will be asked to sign the Informed Consent Form. The investigators will enroll up to 25 castees from among those eligible for the study. The castees will be chosen on a first come, first served basis.

Instrumentation:

The Tekscan in-shoe pressure mapping sensors will be used in the identification of gait cycle events. These instruments will be used to record and measure plantar surface peak pressure, center of pressure, timing stance and sway. Pressure sensors will be calibrated to each participant's weight to give an accurate and relative value for statistical analysis.

Procedures:

Their height and weight will be taken and recorded for calibration of sensors. Tekscan F-Scan Versa Tek Wireless System sensors will be applied to one foot of the castees and placed in an appropriate sized pneumatic walking boot. The castees will then be asked to walk on F60 Sole treadmill at a pace of 2mph for a period of 3 minutes. Kinetic data collection will only take place during the last 2 minutes allowing the 1-minute to the participant to gain comfort on the treadmill while walking in the device. Participants will be prepared for application of the Total Contact Casts (TCC). Calibrated sensors will first be applied to the plantar aspect of the participants' foot and held in place with tape. The caster will then apply the first cast to the participant directly over the sensors. The cast will be given 5 minutes to dry, as the patient remains seated. Once dry, castees will stand and receive ambulation instructions by the caster for 5 minutes before performing the walking trial on the treadmill for 2 minutes at 2 mph. The process will repeat until all three TCC kits are applied to the same participant; thus, each participant will be fitted with 4 casts.

Kinetic Data

The kinetic variables that were analyzed were peak plantar pressure and impulse beneath the forefoot. A collective average of plantar peak pressure was calculated and normalized for body weight and then compared amongst all of the participants. Impulse was determined by finding the area under the force curve of first impact of the forefoot through toe off. The starting point of the first contact in the forefoot was made qualitatively using saggital 2D kinematic analysis and quantitatively using the (STAM) Stance Timing Analysis Module in F-scan. Qualitatively the trace of force points were defined numerically using the Trapezoid method, approximating the region under the graph of the function as a trapezoid and calculating its area.

Kinematic Data

The Kinematic variables of ankle flexion and tibial position were analyzed from two points of view, saggital and posterior frontal plane. Vertical alignment of the calcaneas and tibia was observed in the posterior frontal plane. The importance of vertical alignment of these two parts indicates total pronatory control in the hind-foot and mid-foot as well as stability. Most foot and ankle clinicians believe that if you can limit motion in the frontal plane and maintain a vertical alignment of the calcaneas this will cause limited mobility but more stability, which is indicated in the application of a total contact cast and considered ideal when off loading a plantar wound. In the saggital plane we were able to analyze ankle flexion by relating tibial position relative to the foot shank. We observed three points on the cast as reference points for ankle flexion. As shown in figure 8. (1) Apex of the gastrocnemeus, (2) Center of the medial malleolus (3) Center of the first metatarsal phalangeal joint.

Fig 8 Ankle Flexion TCC versus Diabetic Shoe

Flexion angles were defined as negative degree amounts less than 90 degrees, with neutral being defined at 90 degrees.

Statistical Analysis:

A Repeated Measures ANOVA was conducted using SPSS 17.0 software (SPSS Inc. Chicago,IL). to compare the peak pressures between each device. Statistical means and standard deviations for each dependent variable were calculated. The data was inspected and tested to ensure that the assumptions for data normality and sphericity of the analysis of variance were not violated.

In the first part of the study a Pearson's correlation and a Repeated Measures ANOVA was run to show a direct relationship between most commonly used off-loading methods and diabetic shoes. It showed that all TCC devices significantly lowered peak forefoot plantar pressure as compared to the DS. Additionally, the peak plantar pressure in the TCCEZ and Cutimed casts was significantly lower than that of the Medicast however; there was no significant difference in peak forefoot plantar pressure between the TCCEZ and Cutimed. Therefore since there is a greater correlation in the reduction of peak forefoot pressure in these TCC devices compared to DS as well as the TCC devices compared to one another, we can begin to draw positive trends for best practice in the treatment of Diabetic Foot Ulcers.

For the second part of the study, a repeated measures MANOVA found a strong positive correlation in differences relating tibial position to peak plantar pressure between the casts and the Diabetic Shoe. A Paired – samples t-tests revealed that all 3 casting techniques significantly reduced peak plantar pressure (PPP) as compared to the Diabetic shoe. There were no significant differences in PPP between casts, however the second repeated measures ANOVA found significant differences between casts and Diabetic Shoes. Paired – samples t-tests revealed that the TCCEZ and BSN Cutimed had significantly lower tibial angles at PPP than the Diabetic Shoe. There were no significant differences in Tibial Angle at PPP between the MediKast and Diabetic Shoe.

For the third part of the study, a repeated measures MANOVA was run to determine a strong positive correlation between tibial position, PPP and impulse. Between dependent grouping effects tests and multivariate tests were conducted and revealed that impulse significantly affected both PPP and tibial position variables in both diabetic shoe trials and total contact cast trials. There was a significant increase in peak plantar pressure as well as a decrease in tibial angle when impulse was quantified in high amounts,

Result

Descriptive data for the dependent variable for all of the participants are presented in Tables 1 and 2.

Table 1.

Case processing summary, information about the data used. There were 20 participants total and 10 were included in the full data analysis.

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
TCCEZ	10	50.0%	10	50.0%	20	100.0%
Cutimed	10	50.0%	10	50.0%	20	100.0%
MediKast	10	50.0%	10	50.0%	20	100.0%
D_Shoes	10	50.0%	10	50.0%	20	100.0%

Table 2.

Descriptive report lists the name of the dependent variable along with every level of the independent variable.

Descriptive Statistics

	Mean	Std. Deviation	N
SMEAN(TCCEZ)	26.8667	6.34837	20
SMEAN(Cutimed)	26.4286	6.74119	20
SMEAN(MediKast)	35.7500	11.43920	20
SMEAN(D_Shoes)	59.1250	21.03099	20

Table 3.

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	TCCEZ & Cutimed	13	.218	.475
Pair 2	TCCEZ & MediKast	11	.337	.311
Pair 3	TCCEZ & D_Shoes	14	.486	.078
Pair 4	Cutimed & MediKast	10	.389	.267
Pair 5	Cutimed & D_Shoes	14	.356	.212
Pair 6	MediKast & D_Shoes	12	.909	.000

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	TCCEZ	25.9231	13	6.95775	1.92973
	Cutimed	25.9231	13	8.25087	2.28838
Pair 2	TCCEZ	27.3636	11	8.58222	2.58764
	MediKast	37.2727	11	14.76544	4.45195
Pair 3	TCCEZ	26.9286	14	7.67077	2.05010
	D_Shoes	58.0714	14	23.16982	6.19240
Pair 4	Cutimed	23.8000	10	5.32917	1.68523
	MediKast	34.5000	10	12.17694	3.85069
Pair 5	Cutimed	26.4286	14	8.14970	2.17810
	D_Shoes	57.1429	14	21.33202	5.70122
Pair 6	MediKast	35.7500	12	15.03405	4.33996
	D_Shoes	57.0833	12	25.61412	7.39416

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
					95% Confidence Interval of the Difference				
		Mean	Std. Deviation	Std. Error Mean	Lower	Upper			
Pair 1	TCCEZ - Cutimed	.00000	9.56556	2.65301	-5.78041	5.78041	.000	12	1.000
Pair 2	TCCEZ - MediKast	-9.90909	14.36283	4.33056	-19.55817	-.26001	-2.288	10	.045
Pair 3	TCCEZ - D_Shoes	-31.14286	20.56456	5.49611	-43.01648	-19.26923	-5.666	13	.000
Pair 4	Cutimed - MediKast	-10.70000	11.23536	3.55293	-18.73729	-2.66271	-3.012	9	.015
Pair 5	Cutimed - D_Shoes	-30.71429	19.94388	5.33023	-42.22954	-19.19903	-5.762	13	.000
Pair 6	MediKast - D_Shoes	-21.33333	13.49972	3.89703	-29.91065	-12.75602	-5.474	11	.000

Multiple paired-samples t test was calculated to compare the mean of total plantar pressure between each cast and the diabetic shoes. The lowest mean plantar pressure comparison was 23.8(sd=5.32), and the highest mean total plantar pressure was 58.07(sd=23.1). A significance increase was found in each comparison with the highest showing (t(12)=.000,p<.001).

Table 4.

Tests of Between-Subjects Effects

Measure: PlanPressure

Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[a]
Intercept	47817.225	1	47817.225	124.740	.000	.933	124.740	1.000
Error	3450.025	9	383.336					

a. Computed using alpha = .05

Table 5.

Tests of Within-Subjects Contrasts

Measure: PlanPressure

Source	Cast	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[a]
Cast	Linear	4427.405	1	4427.405	16.357	.003	.645	16.357	.948
	Quadratic	1177.225	1	1177.225	17.006	.003	.654	17.006	.955
	Cubic	9.245	1	9.245	.410	.538	.044	.410	.089
Error(Cast)	Linear	2436.045	9	270.672					
	Quadratic	623.025	9	69.225					
	Cubic	202.805	9	22.534					

a. Computed using alpha = .05

Tests of Within-Subjects Effects

Measure: PlanPressure

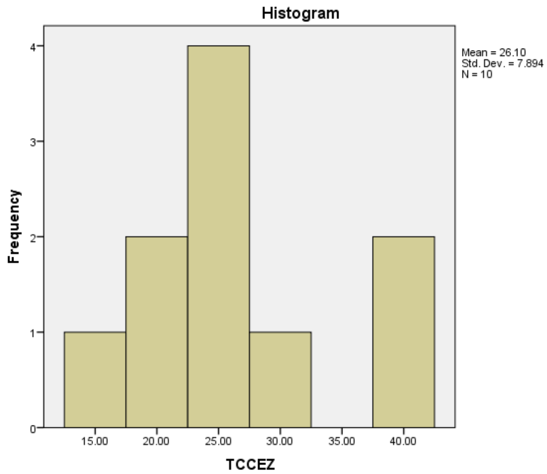
Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[a]
Cast	Sphericity Assumed	5613.875	3	1871.292	15.490	.000	.632	46.469	1.000
	Greenhouse-Geisser	5613.875	1.497	3750.384	15.490	.001	.632	23.186	.986
	Huynh-Feldt	5613.875	1.728	3247.916	15.490	.000	.632	26.773	.993
	Lower-bound	5613.875	1.000	5613.875	15.490	.003	.632	15.490	.937
Error(Cast)	Sphericity Assumed	3261.875	27	120.810					
	Greenhouse-Geisser	3261.875	13.472	242.124					
	Huynh-Feldt	3261.875	15.556	209.685					
	Lower-bound	3261.875	9.000	362.431					

a. Computed using alpha = .05

In table 5 it shows that a one-way repeated measures ANOVA was calculated comparing the result of plantar pressure values of subjects in three different casts. Significant effects were found ($F(1,9) = 124.74$, $p<.005$)

Histograms in figure 9 show significant interactions between the average peak pressure for each cast during each trial.

Figure 9



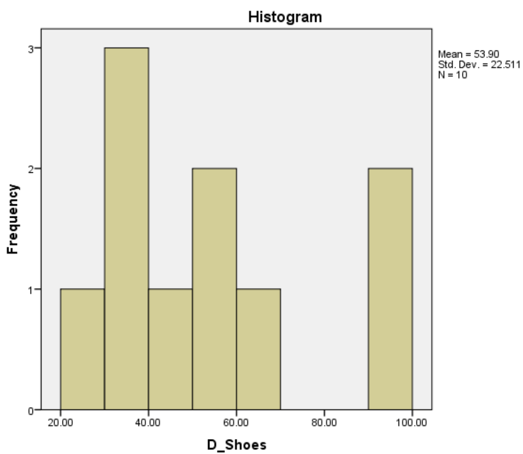
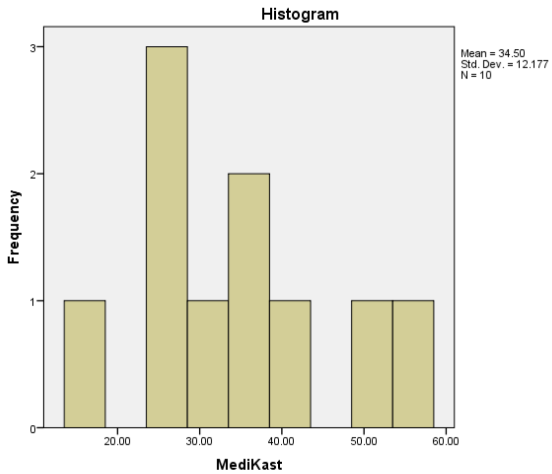


Figure 9 cont.



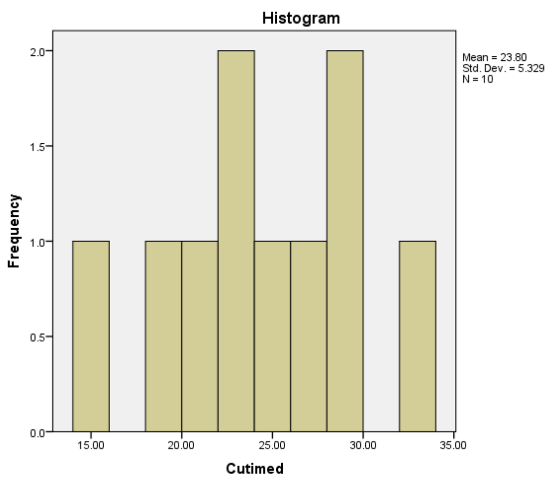


Table 6.

Peak Forefoot Plantar Pressure and Tibial Angle in 3 casting techniques

	PPP (N/cm3) Mean (SD)	Tibial Angle (degrees) Mean (SD)
Diabetic Shoe	589.89 (317.15)*	110.17 (9.03)[1,2]
TCCEZ	385.07 (161.91)	93.63 (5.56)[1]
Medi-Kast	359.93 (276.47)	105.31 (10.65)
BSN Cutimad	299.03 (173.85)	98.90 (9.09)[2]

Note: PPP = Peak Forefoot Plantar Pressure, Tibial angle as measured in the sagittal plane

* significantly different from all 3 casting techniques ($p< 0.05$)

[1] = significantly different ($p< 0.05$), [2] significantly different ($p< 0.05$)

Table 6 shows that all cast significantly lowered peak planter pressure related to Diabetic shoe control. Additionally the TCC-EZ cast restricted ankle joint dorsiflexion to limit tibial position closest to 90 degrees. Clinically the goal in wound care is to maximize offloading of wounds. We found that each casting method reduces peak forefoot plantar pressure. We also found that there was great variability in Tibial Angle at PPP, which could be associated with issues in cast application and cast design . As a result of these limitations we would propose future research that would focus on the influence of duration of peak pressure due to differences in Cast design and application.

Discussion

In this study a Repeated Measures ANOVA was conducted to compare the peak pressures between each device. In this direct comparison of popular off-loading methods, all TCC devices significantly lowered peak forefoot plantar pressure as compared to the DS (Diabetic Shoes). Additionally, the peak plantar pressure in the TCCEZ and Cutimed casts was significantly lower than that of the Medicast. However, there was no difference in peak forefoot plantar pressure between the TCCEZ and Cutimed.

Therefore since there is a greater correlation of the reduction of peak forefoot pressure in these TCC devices compared to DS as well as a significant difference in the reduction of peak plantar pressure in the TCCEZ and Cutimed cast as compared to the Medikast we can begin to draw positive trends for best case practice in the treatment of Diabetic Foot Ulcers. The first repeated measures ANOVA found significant differences between the casts and the Diabetic Shoe. Paired – samples t-tests revealed that all 3 casting techniques significantly reduced PPP (peak plantar pressure) as compared to the Diabetic shoe. There were no significant differences in PPP between casts.

The first hypothesis states that patients who develop neuropathic plantar ulcers in the forefoot region, may benefit from a reduction in plantar pressures. By using a Total Contact Cast rather than extra depth shoes and inserts with modifications or other pneumonic devices, pressure will be equally distributed throughout the plantar surface of the foot. Off-loading includes two elements, reduction of pressure (ground reaction forces) and reduction of shearing (frictional forces). The principle involved here is that the cast is molded directly to the contours of the foot. Therefore the pressure which has been concentrated on the bony prominence or ulcers is distributed over the entire plantar aspect of the foot, allowing reversal of the mechanism that will cause the ulcer to heal.

The second repeated measures ANOVA found significant differences between casts and Diabetic Shoe. Paired – samples t-tests revealed that the TCCEZ and BSN Cutimed had significantly lower Tibial Angle at PPP than the Diabetic Shoe. Athlough there were no significant differences in Tibial Angle at PPP between the MediKast and Diabetic Shoe. We can begin to draw positive trends that suggest best case practice for the application of total contact cast are related to casting positioning, limiting range of motion at the ankle and possibly cast material and drying time. These variables were found to also have an effect on plantar pressure.

The second hypothesis states that direct pressure and shear forces are mitigated through the limiting of ankle range of motion. Total contact cast usually captures the patient's tibial talar joint in a 90 degree angle, restricting sagittal and frontal plane movements and limiting tangential forces (Wu etl al. 2008).

Limiting ROM at the ankle promotes benefits at the plantar surface. This is beneficial for offloading the forefoot. Direct pressure is reduced because the forefoot spends less time on the ground during the propulsion phase which would result in lower PPP. Impulse is also effect because of this chain of events.

To strengthen this study I would consider that the positive effect on impulse, which may be the key difference in the efficacy of pressure modulation and off loading between popular off loading methods. The less time insensate patients are allow to spend in contact with the ground the better. In the treatment of a diabetic foot ulcer, pressure modulation, commonly referred to as "off-loading," is most successful when pressure is mitigated in areas of high vertical and shear stress. During weight-bearing activities, the feet are exposed to these significant forces, particularly when the activity is dynamic, such as walking.

Common methods to off-load the foot include bed rest, wheelchair, crutch assisted gait, total contact casts, half shoes, therapeutic shoes, and removable cast walkers. Off-loading data for vertical forces, or "ground reactive forces", are well established for varying off-loading modalities and has been present in the literature for over 20 years. In the past scientists have primarily focused on the dermis and subcutaneous layers of tissue. Retrospective histology studies have a vast amount of information on physical and mechanical properties, but neglect to draw conclusions about each layer and its interaction with medical devices and their micro environment.

The main objective of this research was to analyze average and peak pressures under the plantar surface of the foot while walking inside 4 different diabetic ulcer off-loading devices. This included three different total contact cast systems and an extra depth diabetic shoe. Pressure distribution in each off-loading device was measured by a pressure sensor applied directly to the plantar surface of the foot. This data will be used in formulating the data necessary to assess "shear" forces and micro environment in a prospective study.

The goal of the prospective research would be to quantify the magnitude and duration of forces generated at the plantar surface of a foot where tissue breakdown mainly occurs. The core component of this research would be to develop a quantitative measurement for "shearing" or "frictional" forces. Until we can quantify the vertical and shearing forces, we do not fully understand the pathogenesis of diabetic foot ulcers, pressure ulcers and other aspects of wound healing. A unit of measurement would provides a quantitative, reproducible number could become the standard measurement of shear that completes the "off-loading picture" that encompasses the "healing chamber" afforded by the total contact cast.

Our team believes that the onset of tissue damage is deeply correlated to the prolonged shear forces applied to the plantar surface of feet during ambulation. Mitigating these forces is also a requirement to enable wounds to heal and is believed to be a major reason the total contact casts enjoys "gold standard" status as an off-loading modality. The quantitative and reproducible measure of shear for in-shoe plantar shear force through a single device has not been previously accomplished. The creation of such a device could potentially provide us with data to understand effective off-loading for Diabetic Foot Ulcers.

Conclusion

The onset of tissue damage is correlated to the prolonged ground reactive forces (vertical forces), in combination with shear forces (horizontal forces) applied to the plantar surface of feet during ambulation. The outermost layer of the plantar surface of the foot will continue to produce more skin cells as a result of pressure and overall forces applied to its surface. This is a defense mechanism the body naturally employs to protect itself from breakdown.

As a result of this defense mechanism, callusing will occur. However in most insensate diabetics this defense mechanism is impaired and leads to tissue breakdown. This is why proper diabetic foot ulcers should be properly off loaded using the best available options. Therefore the results of this research are far reaching and should mightily impact the medical community. The results of this study show that all of the off loading devices used in this study reduce the amount of total pressure in the fore foot during ambulation. This is important to relate to clinicians who may use other popular off loading devices such as extra depth shoes and inserts.

The comparison of extra depth diabetic shoes and total contact cast plantar pressure reduction are intuitive and paint a clear picture that one method/device is clearly superior over the other. However, the results of the comparisons between total contact cast are not as intuitive and suggest more research. The results of this research suggest that although the designs are different, functionality remains the same. Generally the concept of a total contact cast offers functional mobility for non compliant or severely wounded patients, and given the results of the research that concept can be reaffirmed with confidence. With proper application total contact cast should be considered the gold standard and best option for off loading diabetic foot ulcers along with two key recommendations, 1) Be sure to cast the wearer at 90 degree saggital plane alignment. 2) Recommend a removable pneumatic walking device for more efficient ambulation. As mentioned in the discussion section these two recommendations significantly separate the most efficient devices from the others. As a result patients will heal faster, walk more efficiently and ambulate in an ideal and safe environment conducive to pressure modulation and off loading.

Appendix C: Inclusion/ Exclusion Checklist

Inclusion/Exclusion Checklist

1. Is the participant 18 years old and capable of signing informed consent?
   YES [ ] NO [ ]

2. Is the participant's sensation intact (evidenced by feeling a Semmes Weinstein 5.07 monofilament wire when applied to points of leg, ankle and foot)?
   YES [ ] NO [ ]

3. Does the participant have a palpable foot pulse (either dorsalis pedis or posterior tibial artery)?
   YES [ ] NO [ ]

4. Does the participant weigh less than 250 pounds?
   YES [ ] NO [ ]

5. Is the participant able to safely walk with a cast weighing up to five pounds?
   YES [ ] NO [ ]

6. Does the participant have any previous experience with cast sensitivity?
   YES [ ] NO [ ]

7. Does the participant have known allergies to casting materials (fiberglass, silicone acrylate adhesives, polyurethane, cotton and/or synthetic fibers)?
   YES [ ] NO [ ]

8. Is the participant able to comply with the protocol?
   YES [ ] NO [ ]

9. Does the participant have any foot structure abnormality that would preclude the patient from wearing a cast?
   YES [ ] NO [ ]

10. Is the participant currently experiencing numbness, tingling, burning or itching sensations in legs, ankles or feet?
    YES [ ] NO [ ]

11. Does the participant have any open lesions on feet, ankles or legs that could interfere with cast application or assessment?
    YES [ ] NO [ ]

12. Does the participant currently have any dermatitis on feet, ankles or legs that could interfere with cast application or assessment?
    YES [ ] NO [ ]

13. Is the participant unable to lie down in a prone position for up to 30 minutes at a time?
    YES [ ] NO [ ]

14. Does the participant have diabetes?
    YES [ ] NO [ ]

15. Does the participant have any other medical conditions that could affect the application or removal of the TCCs?
    YES [ ] NO [ ]

Appendix D:

Data Collection Steps

Step One

- Inclusion/Exclusion and consent form
- Weight and marker application
- Force plate calibration per plate and then recording of 1 full gait cycle

Step Two

- F scan placement under cast, then cast application per instructions
- Place F-scan and shoe on contralateral foot during cast drying time

Step Three

- 2 minute walking trial
- Removal of cast

Repeat steps 2-3until all casts are applied

Important Keys

- Extra care with cast saw on removal to avoid damage on F scan box and strap
- Omit the appliance of all wound dressings under any casts
- Order of application: F-scan sensor next to skin, then stockinette then proceed with usual cast application steps

Order of Cast

1. TCC EZ
2. MEDI – KAST
3. BSN CUTIMED CAST

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