A Novel Method to Determine the Impact of Different Saddle Designs on Male Cyclists' Perineal Blood Flow

BY

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THESIS

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This thesis is dedicated to my Parents, (Parthiban & Swarnalatha) and my fiancée (Saranya), without whom it would never have been accomplished.
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<td>TGF</td>
<td>Transforming growth factor</td>
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<td>PGE</td>
<td>Prostaglandin E</td>
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<td>NANC</td>
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<td>PO₂</td>
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SUMMARY

Bicycling is an activity engaged by millions of people worldwide. An estimated 780000 Americans used bicycles as primary means of commute. The health benefits of bicycling include increased cardiovascular strength, weight loss and relaxation. But cyclists are prone to sports related injuries. Overuse injuries are reported in 85% of the cycling population. Cyclists complain pain and numbness in their neck, knee, groin, hands and back. Saddles are the most important and ignored part of the bicycle. When a person is riding a bicycle, more than fifty percent of his weight is supported by the saddle only.

The association between bicycling and erectile dysfunction is well addressed in the scientific literature. Male bicycle riders complain pain and soreness in the genital region after long distance bicycling due to compression of the perineum by the bicycle seats. Perineum consists of nerves and blood vessels, which are compressed between the body weight and bicycle saddles. Unfortunately most popular bicycle saddles adopt a narrow design profile forcing the rider to exert all his body weight on the perineum.

Many published researches in this field focused on studying the saddle- perineum interface pressure. But clinical evidence points that arterial insufficiency caused by compression of the perineal arteries as the main reason. Nevertheless, many saddle designs exist in the market claiming to reduce the pressure on the perineum.
SUMMARY (Continued)

The primary goal of this thesis work is to measure forces exerted on the perineal arteries during bicycle riding and quantify arterial occlusion for different seat designs. We developed a custom device to dynamically measure force on the perineal arteries. A pilot study was conducted to quantify total arterial occlusion for different seat designs. The results from our study were used to make general conclusions about overall population.

This thesis work contributes new information about perineal arterial occlusion among male bicyclists. The novel methodology described in this thesis will immensely benefit engineers who strive to solve this problem. Ultimately this work would aid bicycle riders to protect themselves from cycling induced erectile dysfunction.
1. INTRODUCTION

1.1 Bicycling

The U.S. Census Bureau released American Community Survey data collected in 2010 demonstrating that since 2000, Americans increased their use of bicycles as a primary means of commuting by nearly 40% (U.S. Census Bureau (2000), U.S. Census Bureau 2010). In United Kingdom, 1.9 million people cycle at least once a week (Sport England 2013). Bicycling accounts for 27% of the total trips made in Netherlands (Pucher and Buehler 2008). U.S bicycle and accessories sales in 2012 was 6.1 billion dollars (Townley 2012). With growing environmental awareness among people and rising fuel costs, many people are considering bicycling as an alternate means of transportation that causes no pollution.

1.2 Health benefits of bicycling

Lack of regular exercise has been identified as an important risk factor for many serious disease conditions. Regular moderate exercise has been advised to reduce the risk. Bicycling offers major health benefits. Researchers demonstrated the health benefits of bicycling including cardiovascular strength, weight loss, increased high-density lipoprotein cholesterol, activation of insulin, increased lung capacity and relaxation. (Sommer, Goldstein et al. 2010) Bicycling had been shown to improve the exercise endurance of chronic heart failure patients (Kennedy 2008). Active commuting, including bicycling provides a relatively low impact means of activity that can help improve cardiovascular risk (Hamer and Chida 2008). With obesity becoming a rapidly expanding global epidemic, the usage of cycling for commuting should be actively encouraged.
1.3 Bicycling and overuse injuries

Cycling is generally considered as a “risk-free” cardiovascular activity. Destot, 1896 talked about overuse injuries associated with bicycle riding in his published case reports dating back to the 1890s (Destot 1896). The incidence of injuries has increased sharply with continuous increase in bicycling population and people involving in adventurous forms of cycling. Though most common injuries can be classified as physical trauma, overuse injuries are seen in 85% of the bicycling population. Some common problems associated with prolonged bicycling are numbness in the hand, feet and genital region. Cyclists’ palsy is a common problem reported by 31% of recreational cyclists (Wilber, Holland et al. 1995). Ulnar nerve compression because of prolonged handlebar pressures has been identified as the main cause (Capitani and Beer 2002). Prolonged pressure to wrist during cycling also causes compression of median nerve causing carpal turner syndrome symptoms in cyclists (Kennedy 2008). Padded gloves, padded handlebars and frequent change in riding posture are recommended to reduce and prevent these problems (Munnings 1991, Richmond 1994).

1.4 Bicycling and erectile dysfunction

Erectile dysfunction is a common problem, especially among aging men. But studies have estimated that 1 in 4 men under the age group of 40 seek treatment for erectile dysfunction and half of them suffered severe erectile dysfunction(Capogrosso, Colicchia et al. 2013). Investigators have repeatedly demonstrated a persistent epidemiologic relationship between bicycle riding and erectile dysfunction(Sommer, Goldstein et al. 2010). Isolated cases of erectile dysfunction incidence after long distance bicycling was reported in 1980s(Goodson 1981). Kulund and Brubaker, 1978, published the first observational study demonstrating the
incidence of erectile dysfunction after long distance bicycling. They observed 7% incidence of pudendal/penile numbness among the participants of 1976 bike centennial tour (Kulund and Brubaker 1978). Another important survey conducted by researchers at University of Cologne revealed that the incidence of impotence among amateur cyclists was almost three times higher than that of the normal population (Sommer, Goldstein et al. 2010). In another study, 4.2% of cyclists reported that they suffered from erectile dysfunction which lasted for a week after a long distance ride (Dettori, Koepsell et al. 2004).

1.5 Statement of the problem

Erectile dysfunction is a multifactorial process; among cyclists, the primary contributing factor is most likely perineal artery occlusion (Jeong, Park et al. 2002, Mumarriz 2002). Perineal arteries, which supply blood to the penis, get compressed during bicycle riding. This causes occlusion of the perineal arteries and significant reduction in the blood flow to the penile tissues. During normal blood supply to the penile tissues, prostaglandin E (PGE) is activated, suppressing collagen synthesis induced by transforming growth factor-β₁ (TGF-β₁). But arterial insufficiency caused by occlusion of perineal arteries, leads to up-regulation of TGF-β₁. TGF-β₁ activates collagen and connective tissue synthesis in the penile tissues. It also restricts vascular smooth muscle cell growth in the penile tissues. Both these factors were identified as counterproductive to achieving erection (Munarriz, Yan et al. 1995, Nehra, Goldstein et al. 1996).
1.6 Purpose of the study

Previous studies have investigated this mechanism via indirect measures such as transcutaneous oxygen saturation in the penis, Magnetic Resonance imaging of the pelvis, Doppler ultrasonography, cavernosal artery peak systolic velocity measurement, computational modeling and pressure mats on a stationary bike (Schwarzer 1999, Spears 2003, Lowe 2004, Bressel 2005). Bressel, Bliss and Cronin, 2009 in their study discussed new saddle designs that were shown to greatly reduce the perineum-seat interface pressure compromises the stability of the riders (Bressel, Bliss et al. 2009). Those seats were tested on stationary models, which don’t require the riders to balance and steer the bicycle. No prior study has collected direct forces applied to the perineal arteries in vivo during a road ride outdoors, which represent the typical conditions for a male rider.

The main objectives of our study were:

1. To measure direct forces exerted on the perineal arteries during road bicycling.
2. To measure the force required causing perineal artery occlusion for each subject individually.
3. To test whether stationary models were comparable to road ride models.
4. To quantify perineal artery occlusion for different seat designs.

If our study can demonstrate significant perineal artery occlusion during bicycle riding, then we hypothesize that arterial occlusion as a result of bicycling can lead to erectile dysfunction.
1.7 Significance of the study

Millions of people worldwide use bicycles for recreation, sport, exercise or commuting. Demonstrated health benefits of bicycling suggest that this activity should be seriously encouraged. It is the engineers’ responsibility to make bicycling as safe as possible by building better bikes, designing proper protective gears and providing favorable conditions. This dissertation work focuses on protecting the sexual health of millions of male bicycle riders across the world.

In research, it is often necessary to understand the underlying problem before developing a viable solution. Though perineal artery occlusion has been suggested as the possible mechanism for this problem, none of the previous studies quantified it directly. The study discussed is the first of kind in this field to measure real time perineal forces and determine perineal artery occlusion for each subject individually. We are providing the scientific community a novel device to record real time perineal forces, a new method to determine perineal artery occlusion force for each subject and an innovative approach to test bicycle seats for perineal artery occlusion during a road ride.

The work presented in this dissertation will advance the scientific knowledge by answering the question “Does perineal artery occlusion happen significantly during bicycle riding?” Also based on previous research works, there are new seat designs without the protruding nose that are claimed to solve this problem. Our work investigates whether no-nose seats are better designed to reduce the perineal artery occlusion. This thesis work adds comprehensive methods for engineers to test new seat designs.
2. BACKGROUND AND LITERATURE

2.1 Anatomy of the perineum

The Perineum (Figure 1) is the diamond shaped region roughly between the anus and scrotum. Anatomically, the perineum is defined as the region between the pubic symphysis and the coccyx. The diamond shape of the perineum is divided into two triangular areas, the anterior urogenital triangle and the posterior anal triangle. Penis, scrotum, perineal musculature, perineal arteries, perineal nerves are all located in the urogenital triangle of the male perineum. The anal triangle includes the anus, rectal nerves and rectal arteries. This thesis focuses on the structures in the urogenital triangle of the male perineum (Campbell, Wein et al. 2007).

The Penis (Figure 2) is a cylindrical structure made up of three tissue layers. Two layers of corpora cavernosa and a layer of corpus spongiosum are bundled together to form the penile tissues. The human penis lacks a baculum (erectile bone), so erection is achieved by absorption of blood by the penile tissues. The blood vessels and nerves from the pelvis traverse the perineum to supply the penis. Penis is supplied by two arterial systems. The non-erectile tissues of the penis are supplied by a superficial system arising from the lateral inferior pudendal arteries. The deeper system of blood vessels arising from the internal pudendal arteries supplies the erectile tissues, corpora cavernosa and corpus spongiosum. The common penile artery arises from the internal pudendal artery. It branches into dorsal artery, bulbourethral artery and cavernous branches supplying the penile tissues. The pudendal nerve fibers innervate the erectile tissues of the penis. The dorsal penile nerve, a branch of the pudendal nerve innervates the skin of the penis (Campbell, Wein et al. 2007).
Figure 1 Anatomy of the perineum. The perineal arteries are the main focus of our study. (Source: Wikimedia Commons. Faithful reproduction of a lithograph plate from Gray’s Anatomy, 20th U.S edition)
Figure 2 Anatomy of Penis. The blood supply to the penis plays a vital role during erection. (Source: Wikimedia Commons. Faithful reproduction of a lithograph plate from Gray's Anatomy, 20th U.S edition)
2.2 Erection

Sexual excitement in male leads to a complex series of neurovascular events causing erection of the penis. The central nervous system, peripheral nervous system and the penile tissues cooperate in a complex way (Figure 3) to achieve erection. Penile erection is controlled by the spine; however the brain can initiate erection in the presence of external stimuli such as vision, olfaction and imagination (Carson III and Dean 2007).

Erection is achieved by the relaxation of penile tissues allowing increased blood flow into erectile tissues of the penis. There is an accompanied increase in the cavernosal pressure, which compresses the venules reducing the venous drainage. Both these actions increase pressure within the erectile tissues producing erection (Figure 4). The fibers of the parasympathetic system (Figure 5) extend into the arteries supplying the erectile tissues. They are innervated by the non-adrenergic, non-cholinergic (NANC) nerves. Upon stimulation, these nerve endings release the neurotransmitter nitric oxide. Nitric oxide initiates a series of intracellular enzyme cascade resulting in erection.

Nitric Oxide activates the enzyme guanylate cyclase, which increases cGMP levels. The increased formation of cGMP stimulates the outflow of Ca2+ ions from the cavernosal smooth muscle cells, inducing erectile tissue relaxation (Figure 6). Later penile detumescence is achieved by the action of the enzyme phosphodiesterase-5 which degenerates cGMP and increased venous drainage from the erectile tissues (Wagner and Mulhall 2001).
Figure 3 Complex interactions of three physiological systems in achieving penile erection. Redrawn from (Carson III and Dean 2007)
Figure 4 Mechanism of erection. During erection increased arterial blood flow and reduced venous drainage causes increase in blood pressure inside penile tissues. Adapted from (Wagner and Mulhall 2001). Copyright clearance enclosed in appendices.
Figure 5 Role of central and peripheral nervous systems in controlling erection. Adapted from (Wagner and Mulhall 2001). Copyright clearance enclosed in appendices.
Figure 6 Role of Nitric Oxide in smooth muscle relaxation and erection. Adapted from (Wagner and Mulhall 2001). Copyright clearance enclosed in appendices.
2.3 Erectile Dysfunction

Erectile dysfunction can be defined as the inability to achieve or maintain an erection long enough to engage in sexual intercourse (McVary 2007). The incidence of erectile dysfunction increases with age. Aytaç, McKinlay & Krane, 1999 estimated that there will be 322 million erectile dysfunction cases by the year 2025 (Aytaç, McKinlay et al. 1999). Erectile dysfunction can happen if any of the complex steps involved in achieving erection is compromised. Metabolic syndromes, cardiovascular diseases, neuropathologic conditions, tobacco use, diabetes mellitus and other endocrine disorders can cause erectile dysfunction (McVary 2007).

2.4 Possible pathophysiology of bicycling induced erectile dysfunction

Several questionnaire based studies and case reports suggest people complain about erectile dysfunction and impotence after long distance bicycling (Marceau, Kleinman et al. 2001, Akuthota, Plastaras et al. 2005, Huang, Munarriz et al. 2005). Erectile dysfunction due to bicycling is likely because of the compression of the neurovasculature bundle in the perineal region. During cycling, a person’s body weight should be evenly distributed in their hands, feet and ischial tuberosities (sit bones). But natural riding position shifts half of the body weight to the perineum region. Perineum lacks the soft tissue structure to bear such an excessive load. The weight of the rider compresses the arteries and veins of the perineum between the bicycle saddle and pubic arc (Leibovitch and Mor 2005). These recurring forces can damage the nerves via nerve hypoxemia and/or a primary neuropathic process (Sommer, Goldstein et al. 2010).
damage to the nerves depends on the duration rather than the magnitude; even low magnitude forces are shown to cause damage within hours (Rempel, Dahlin et al. 1999, Mackinnon 2002).

Another possible mechanism is compression and occlusion of the perineal arteries (Figure 7). Blood flow to the penis is a vital part of achieving and maintaining erection. Vascular insufficiency due to disease conditions, lifestyle and pudendal trauma can lead to erectile dysfunction (Moreland 1998). Moreland, 1998 in his paper hypothesized that smooth muscle/connective tissue balance plays a significant role in achieving erection. At flaccidity, penile tissue partial pressure of oxygen (PO$_2$) concentration is lower (25 – 40 mm Hg) and it favors connective tissue synthesis. However during an erection the higher PO$_2$ (90 -100 mm Hg) concentration degrades the connective tissues enabling relaxation of the smooth muscle cells. They identified TGF – β$_1$ and PGE as key molecular factors. TGF – β$_1$ is activated at lower oxygen concentration and induces collagen synthesis. At higher oxygen concentration, PGE is activated degrading the collagen. Thus, PGE plays a critical role in smooth muscle cell relaxation. The pathways of PGE and TGF – β$_1$ cooperate together to achieve the correct smooth muscle/connective tissue balance. This can get altered during penile hypoxemia (Moreland 1998) (Figure 8). Thus, perineal artery occlusion and the potential penile tissue hypoxia during bicycle riding can lead to erectile dysfunction.
Figure 7 Illustration of compression of perineal arteries during bicycle riding. This compression has been identified in literature as possible cause of erectile dysfunction among cyclists. Adapted from (Sommer, Goldstein et al. 2010). Copyright clearance enclosed in appendix.
Figure 8 Possible mechanism of vascular insufficiency induced ED among cyclists and the role of TGF – β1 & PGE
2.5 Related literature

2.5.1 Epidemiologic studies

Epidemiologic studies relating bicycling and erectile dysfunction was first published in the late 1970s. A survey was conducted during the 1976 Bikecentennial tour to identify cycling related injuries. Though, only 89 of the 1200 cyclists participated, the survey revealed a 7% incidence of pudendal/penile numbness (Kulund and Brubaker 1978). In the subsequent years, several authors reported the development of sexual dysfunction after long distance cycling (Goodson 1981, Desai and Gingell 1989, Oberpenning, Roth et al. 1994). Weiss surveyed all the 132 participants of an 8-day bicycle tour. 10.7% of the participants disclosed severe perineal numbness (Weiss 1985). Andersen & Bovim, 1997 conducted a questionnaire based cross sectional study among the participants of the Norwegian bike tour. Of the 160 responding males, 35(22%) reported symptoms of pain/numbness in the pudendal area. Penile numbness was reported by 33(21%) cyclists and symptoms of impotence was reported by 21(13%). 11 cyclists reported impotence symptoms lasting for longer than a week and three of them reported symptoms lasting for more than a month. The paper also reports an interrelationship between genital numbness and cycling distance/time. The only drawback of this study is that it had no validated questionnaire to assess erectile dysfunction like the International Index of Erectile Function (IIEF) (Andersen and Bovim 1997).

An Internet based survey was conducted by Taylor et al., 2004 to assess erectile function among 688 cyclists. Their questionnaire was based on International Index of Erectile Function (IIEF) guidelines. Their results showed that the prevalence of erectile dysfunction was 17%. After controlling for age, they concluded that the overall prevalence of erectile dysfunction
among the cycling population was not statistically different (TAYLOR III, Kao et al. 2004). But another cross-sectional study revealed that, after controlling for age the impotence rate among long-distance cyclists was 13.1% and among non-cyclists was 3.9% (Sommer, Goldstein et al. 2010). Another important epidemiologic study analyzed the association between bicycling and erectile dysfunction in the general population of middle-aged men (40 – 70 years). They used the data gathered from 1709 cycling men during the Massachusetts Male Aging Study (MMAS). Cycling more than 3 hours per week was shown as an independent risk factor for erectile dysfunction with an odds ratio of 1.72. Men who cycle less than three hours per weeks had an odds ratio of 0.61 (Marceau, Kleinman et al. 2001).

Nocturnal penile tumescence (NPT) (sleep related erection) is widely used as a parameter to define potency and sexual health. Schrader et al. from the National Institute for Occupational Safety and Health (NIOSH) conducted a study among 29 men, who bicycled an average of 5.4 hours a day and 5 non-biking man. Their results revealed that bicycling men had statistically reduced erectile function during sleep compared to non-cycling men. The percentage of erection time during sleep among non-bicyclists was 42.8, while cyclists had an erection for 26.2% of the sleeping time. These measurements were made by Rigiscan plus systems (SCHRADER, BREITENSTEIN et al. 2002).

Thus with several studies positively linking bicycling and erectile dysfunction, researchers deployed different methods to study this problem. Downward orientation of the saddle, cycling in an upright position, no-nose saddles and padded saddles were some suggestions from these studies to prevent this problem.
2.5.2 Clinical investigations

Schwarzer et al., 2002 used a pulse oximeter like device to measure transcutaneous oxygen pressure in 20 healthy athletic men without history of erectile dysfunction. They tested four different saddle designs. They initially measured transcutaneous oxygen pressure before cycling in a standing position and compared it to the values obtained during bicycling on a seated position to obtain the decrease in penile perfusion. A stationary bicycle was used during the testing. Their results revealed that saddles compress the perineal arteries as evident from the significant decrease in penile perfusion. They also observed variations in the results of the different saddle designs. In their results, a narrow, heavily padded saddle showed a decrease in penile perfusion of 82.4%. A narrow seat with medium padding showed a 72.4% decrease, while a wide unpadded saddle showed a 63.6% decrease in penile perfusion. The saddle, which showed the least decrease of 20.3%, was a no-nose saddle with medium padding. Their study demonstrates that a saddle that prevents the compression of perineal arteries helps to maintain better penile perfusion during cycling. Another important conclusion from their study is that amount of padding doesn’t necessarily help in better penile perfusion (Schwarzer, Sommer et al. 2002).

Penile blood flow was measured by Jeong, Park, Moon & Ryu, 2002 using laser Doppler flowmeter. They tested 20 healthy volunteers on narrow and wide saddle designs. Measurements from a standing position were used as baseline. They measured penile blood flow in a seated position before and after 5 minutes of bicycling. They observed significant reduction in penile blood flow on both saddle designs by just sitting on them. However, increase in blood flow was observed after bicycling when using a wide saddle (Jeong, Park et al. 2002).
Both these studies demonstrate the effect of saddle designs on perineal blood flow and penile perfusion.

Rodano, Squadrone, Sacchi & Marzegan, 2002 recruited five experienced cyclists to test four different saddle designs. They used a piezoelectric sensing system called T-Scan. They measured the pressure distribution on two saddles with a flat surface and two saddles with a cutout in the perineal region. They identified that saddles with perineal cutouts shifted more pressure load to the anterior region. Traditional flat surfaced saddles showed more pressure in the posterior region. Also, they identified that the pressure distribution highly varied among the subjects on the same saddle. They attributed this variation to the difference in riders’ anatomy and riding posture. They assumed that the high posterior pressure acts only on the pelvic bones and muscles as opposed to the anterior force, which acts on the perineal nerves and arteries. Cyclists also complained of pain and discomfort on the saddle with cut-outs. Based on their results, assumptions and observations they concluded that flat traditional saddles are better for perineal health (Rodano, Squadrone et al. 2002). The major limitations of their study include small sample size and not calculating the magnitude of pressure/load. The load acting on the nerves and arteries hold more clinical relevance.

As studies indicated that perineal cutouts are not the solution to this problem, more researchers focused on ways to limit the pressure exerted on the perineum by the nose of the saddles.

Gemery, Nangia, Mamourian & Reid, 2007 developed a computational three dimensional model of human pelvis with all the major arteries of the perineum region. The model was developed from computer tomography images. They used scanned models of the seat.
to study the effects of riding position and seat designs on the perineal pressure. From their results they identified that the most likely region for compression of the perineal arteries is between the top of the forward portion of the bicycle seats and the undersurface of the pubic symphysis. They also identified that the extent of compression depends on the riders’ position. The results from their studies showed that seats with a middle groove reduced the risk of arterial compression. Overall they concluded that riders’ position is more important to reduce arterial compression than the seat designs (Gemery, Nangia et al. 2007). The major limitation of their study is that they didn’t account for the dynamic loading conditions that happen during actual riding.

Another investigation that studied the saddle orientation was conducted by Spears et al., 2003. They developed a three-dimensional finite element model of perineum – pelvis from computer tomography images. They scanned a commercial saddle and its surface was changed to create different saddle widths and orientations. Their pelvis- perineum-saddle model was validated by in vivo experiments. 189 Newton of static load was used to simulate riding conditions and maximum stress in the perineum was studied. They identified that stress in the anterior part of the perineum, which comprises the arteries and nerves were greatly reduced when using a wide saddle and when the saddle was tilted downwards. Based on their results they recommended wide saddles and downward orientation to reduce the stress on perineal arteries and nerves (Spears, Cummins et al. 2003). Their model does not account for dynamic loading conditions that happen during in vivo cycling.

With the advent of new pressure sensing systems like Novel Pedar & Pliance pressure sensors (Novel electronics Inc., St. Paul, MN), Bicycle pressure – sensing array system (FSA
system, Vista medical Ltd, Winnipeg, Canada) researchers used them to study saddle – perineum interface pressure.

Research personnel from the National Institute for Occupational Safety and Health investigated the pressure exerted on the perineum of the bicyclists by the saddles. They recruited 33 bicycle patrol officers during the International Police Mountain Bike Association annual meeting (2003). They chose to evaluate four saddle designs, three of them were no – nose designs. The subjects bicycled on a stationary ergometer using any one of the four saddles and were given time to adapt on the saddle and ergometer. Subjects were allowed to adjust seat height, handlebar height according to their requirements. Data was recorded for a brief period of 40 – 60 seconds using the Novel Pedar & Pliance pressure sensors. This system is basically an array of pressure sensors placed on the bicycle saddle. Pressure measurement was made in the handlebar and pedal using the same system. They quantified the pressure distribution on the whole saddle and in the perineum region. The location of the perineum region was approximated mathematically using ischial tuberosities as anatomical landmarks.

They reported average saddle pressure, peak saddle pressure, average perineal pressure and peak perineal pressure in their results. The average saddle pressure and peak saddle pressure were not statistically different among the saddles. But the average perineal pressure and peak perineal pressure were more than two times for the nosed saddles than the no-nose designs. The difference in perineal pressure was not statistically significant among the no-nose saddles. They also didn’t notice an increase in handlebar or pedal pressure when switching from a nosed to no–nose saddles.
Based on their results they suggested no–nosed saddles significantly reduced perineal compression and can be used to reduce the risk of erectile dysfunction (Lowe, Schrader et al. 2004). Some limitations of the study include small sample size (only 8 subjects on each seat), mathematical assumption of the perineum region and adopting a stationary model.

The same group of researchers conducted another study, where they recruited 121 bicycling police officers across 5 U.S metropolitan cities. They tested the effect of changing to ergonomic no-nose saddles on the sexual health of male riders. They assessed erectile function, penile sensitivity, saddle-perineum pressure and nocturnal penile tumescence. All the parameters were measured before and after 6 months of changing to a no-nose seat. Erectile function was assessed using International Index of Erectile Function (IIEF). Penile sensitivity was measured using computerized biothesiometery and nocturnal penile tumescence was measured using Rigiscan® Plus (Timm Medical Technologies, Eden Prairie, MN). Saddle–perineum pressure was measured using the Novel Pedar & Pliance pressure sensors. Subjects used their own saddle for before pressure assessment and no-nose designs for the 6-month follow-up assessment.

They observed a 66% reduction in saddle-perineum pressure when using a no-nose seat. Marked improvement was observed in IIEF scores and biothesiometery measurements. However, there was no improvement in the Rigiscan® Plus readings. More importantly only 3 of the 90 reassessed participants reverted back to using the nosed saddle.

Combining all these results, they concluded no-nose saddles are recommended for better penile health (Schrader, Breitenstein et al. 2008). This is the only study that assessed penile health after certain duration of switching to no-nose seats. It will be an added advantage if the study included control groups.
Based on these research studies, NIOSH recommends the workers who use bicycle as a part of their occupation to use no-nose saddles (Schrader, Lowe et al.).

Another study, which shows the effect of no-nose seats on penile hemodynamics, was conducted by Munarriz et al. They recruited 33 subjects for their study. Subjects were tested on a nosed and no-nose seat design. Penile erection was achieved by injection of vasoactive agents. Then right and left cavernosal artery peak systolic velocity (CAPSV) was measured using ultrasound. The measurements were made under four different conditions; while supine, sitting upright on the examination table, straddling a saddle and sitting on a seat. They compared the CAPSV values while straddling against sitting on the examination table. Nosed saddles resulted in 97.4% reduction of CAPSV values, while no-nosed, two cheek saddles resulted in only 2.2% reduction of CAPSV values. They concluded that using narrow, nosed saddles might significantly affect penile hemodynamics (Munarriz, Huang et al. 2005).

Bressels et al. used Magnetic Resonance Imaging to study the compression of perineal cavernous spaces by the bike seats. Initially 5 participants bicycled an ergometer fitted with a pressure-sensing mat (FSA system, Vista medical Ltd.) on the seat to record seat-perineum interface pressure. They created a custom load application device, to simulate the pressure recordings measured earlier. The subjects were imaged without any seat pressure and with simulated seat pressure. They identified regions of maximum compression below the pubic symphysis. They proposed newer seat designs should aim to reduce compression near the pubic symphysis region and alleviate any possible compression of nerves and arteries (Bressel, Reeve et al. 2007).
Another recent publication by the same author provides us data about pressure required to compress perineal cavernous spaces. They recruited 6 volunteers from the university population and measured the seat-perineum interface pressure using similar methods described above (Bressel, Reeve et al. 2007). The authors used the custom load application device to apply 10%, 40% and 80% load of the mean seat-perineum interface pressure. They observed significant reduction in the cavernous spaces diameter during 40% and 80% loaded conditions. They concluded newer seat designs should aim for reduction of 60% or more of the seat-perineum interface pressure.

Another attempt to quantify the magnitude of load applied to the perineum of the bicyclists was described by Wilson & Bush, 2007. They used Tekscan (Boston, USA) Body Pressure Measurement System™ to measure seat pressures on 10 male recreational bicyclists. They calculated the magnitude of vertical and shear forces and expressed them as percentage of body weight. The maximum vertical force they observed in the saddle-body contact area was about 52% of the subject’s body weight. This was about the same amount of force supported by the buttocks when a person is sitting in a chair or in an automobile. But perineum lacks the padding the buttocks have, so the arteries and nerves in those regions are prone to injury (Wilson and Bush 2007).

While most investigators tested out existing seat designs, Breda et al., 2005 in their paper discussed the development of a new saddle and tested it by measuring the partial pressure of penile transcutaneous oxygen. They recruited 29 cyclists for their study. They compared their SMP saddle with a normal racing saddle. Their results showed that SMP saddle provided better penile perfusion when compared to the standard saddle (Breda, Piazza et al. 2005).
While most investigators adopted stationary models, field based methodology was used by Bressel, Bliss & Cronin. Using stationary bicycle models and ergometers to study this problem has significant limitations. Subjects did not need to use their body to stabilize and steer the bicycle. Also they mentioned that no-nose seats may reduce the anterior perineum pressure but may cause serious fall injuries if stability is compromised during road bicycling. They recruited 17 male and 13 female cyclists for their study. They used the FSA bicycle pressure-sensing array system (Vista Medical Ltd, Winnipeg, Canada) to collect perineum-saddle interface pressure. They also measured handlebar pressures using the same system. They tested a standard seat, seat with a perineal cutout and a no-nose seat. Subjects also scored each seat based on their perceived stability.

There was no difference in the overall pressure among the saddles. Like previous studies, no-nosed seat showed significantly lower anterior saddle pressure. However, the handlebar pressure was significantly high for no-nose seats. Subjects rated nosed seats significantly more stable during riding than no-nose designs.

Based on their results they concluded that though no-nose seat designs reduced the anterior saddle pressure, but it compromised the stability of the rider. Also the increased handle pressure can cause other overuse injuries like the cyclist’s palsy. So, seat pressure data alone shouldn’t be used when designing and testing new seats (Bressel, Bliss et al. 2009).

Schrader, Breitenstein & Lowe, 2008 used a road bicycling model and found a similar increase in the handlebar load. But they suggested that with proper seat height and bike fit, the excess load in hand and feet can be reduced.
Many literature in this field focuses on the relationship between bicycling and erectile dysfunction in men. But there are few studies, which studied the impact of bicycling in women. Researchers expect similar trauma to the pudendal nerves and arteries among female bicyclists also because of certain anatomical resemblances (Sommer, Goldstein et al. 2010).

Researchers conducted a survey among 282 female cyclists to understand more about the incidence of bicycle related injuries among women. 51 members of a running club, whom didn’t bicycle, served as controls. 34% of female bicyclists reported perineal numbness; however the relationship between perineal numbness and sexual function is not correlated. The number of hours and miles the riders bicycle dictated the severity of the symptoms (Sommer, Goldstein et al. 2010).

Guess et al., 2006 investigated the relationship between bicycling and sexual function among 48 competitive bicyclists. 22 runners were chosen as controls. Sexual function was assessed neurologically and by standardized questionnaire. Eight genital regions, which are supplied by the pudendal nerve, were chosen to perform Biothesiometry measurements. Medoc Model Vibratory Sensory Analyzer 3000 (VSA, Advanced Medical Systems, Ramat Yishai, Israel) was used to test the vibratory thresholds. Dennerstein Personal Experience Questionnaire and the Female Sexual Distress Scale were also used to assess sexual function. They observed significantly higher vibratory threshold among bicycling women then controls, indicating neurological damage among bicyclists. They concluded that there is a significant association between bicycling and genital sensation in women (Guess, Connell et al. 2006).

Another study conducted by Slaimpour et al., 1998 among young women bicyclists concluded female bicyclists complained about orgasmic dysfunction, hematuria, perineal
paresthesia and vulvar lymphoedema after long distance bicycling (Sommer, Goldstein et al. 2010).

2.5.3 Current treatment and preventive methods

The treatment for erectile dysfunction due to bicycling should follow the existing guidelines for the treatment. However, in the literature certain pharmacologic and non-pharmacologic therapies have been suggested.

The general consensus is that steps should be taken to minimize the impact of bicycle seats on the neurovasculature bundle of the perineum region. This can be achieved by changing the bicycle saddle, adopting a better cycling position and changing the type of bicycle.

Various research studies shows that no-nose saddles are better in preventing the sexual health (Schwarzer, Sommer et al. 2002, Munarriz, Huang et al. 2005, Gemery, Nangia et al. 2007, Schrader, Breitenstein et al. 2008). Some studies question whether no-nose saddles can be safely used during actual road bicycling. Studies prove that no-nose saddles increase the handlebar pressure and decrease the stability of the riders (Bressel and Cronin 2005). Also, competitive cyclists prefer to use the nose of the saddles for balance when performing tight maneuvers. Despite all these issues, current scientific evidence strongly suggests the use of wide, unpadded no-nose saddles, which allows proper positioning of the sit bones.

Another modification that can be adopted is riding the bicycle in a more upright position. Studies have shown that cycling in a 90-degree position resulted in 40% more penile perfusion than in a 60-degree position (Gemery, Nangia et al. 2007). Nevertheless, this data doesn’t hold true among competitive cyclists. Racers have better penile perfusion in 30-degree position than
in the 90-degree position. The suggested reason was typically competitive cyclists place less body weight on the seat and uses the weight to push more vigorously on the pedals. But for recreation cyclists adopting an upright riding position, changing to a standing position every 10 minutes were suggested to maintain better penile perfusion (Sommer, Goldstein et al. 2010). Cyclists can also benefit from changing the type of bicycle. Mountain bicycles have been associated with higher risk of erectile dysfunction than road bicycles (Dettori, Koepsell et al. 2004).

PDE5 inhibitors like sildenafil have been shown to provide better oxygenation to the penile tissues during cycling (Sommer, Goldstein et al. 2010). Such drugs can be used by long distance cyclists to provide better perfusion to the penile tissues.
3. METHODS

3.1 A novel system to measure force on perineal arteries during bicycling

3.1.1 Need for a device

Several researchers used indirect methods to study this problem. Computational modeling, finite element analysis, Magnetic resonance imaging, pressure sensor mats on bicycle seats, Doppler flowmeter, ultrasound imaging, penile tissue oxygenation measurements were some of the methods used by researchers to study this problem. (Schrader, Breitenstein et al. 2002, Schwarzer, Sommer et al. 2002, Spears, Cummins et al. 2003, Bressel and Cronin 2005, Munarriz, Huang et al. 2005). But only two studies included a methodology to adopt a field based approach and account for environmental factors like balancing, which are critical for road bicycling (Bressel, Bliss et al. 2009). These studies used expensive pressure sensing systems. Further their focus was to measure the pressure over the perineum region. The perineum consists of other musculature, so the pressure exerted over the perineum do not accurately reflect the force exerted on the arteries. The force that causes arterial occlusion holds clinical relevance. This warrants for a low cost device capable of dynamically measuring the force exerted on the perineal arteries during road bicycling.

In this chapter, we report the development of a portable device that uses flexible force sensors to record force over a concentrated area. The device was validated under in vitro and in vivo conditions. Development of such a novel device would enable researchers to directly measure force on the perineal arteries during road bicycling.
3.1.2 Product requirement definition (PRD).

The device should be able to report reliable and accurate (± 0.5 Newton) force in Newton. It should be portable so that the riders can carry the device during road bicycling. The microcontroller and the necessary drive circuits should be small, light weighted not to affect the riding dynamics. It should operate on low power and possess enough memory to collect data for long durations (3–4 hours). The sensors to collect the force on the perineal arteries need to be thin and flexible. The device needs to be safe to use directly on human subjects.

3.1.3 Identification of force sensors.

1 lb. Flexiforce® sensors (Tekscan, Boston, MA) (Figure 9) were selected to measure force because they are thin, flexible and virtually unnoticeable to the riders. The sensor is a flexible printed circuit board and comes in different ranges of 1lb, 25lb, and 100lb. The sensor is composed of two layers of polyester film and a conductive material like silver is applied on each layer. Another layer of pressure sensitive ink is applied on each layer before sealing the layers with adhesive (Nacy, Tawfik et al. 2013). The sensor acts as a variable resistor in the circuit. It has high resistance under unloaded condition and resistance decreases as load is applied. The decrease in resistance to the applied force is not linear. On the other hand, the measured conductance is highly linear (Figure 10). So the sensor should be incorporated in a circuit to measure conductance as shown in the recommended drive circuit (Tekscan) (Figure 11).
Figure 9 Flexiforce® sensor. These sensors are used to collect force exerted on the perineal arteries. Adapted from Tekscan website. (http://www.tekscan.com/flexiforce.html)
Figure 10 Sensor characteristics. Change in resistance to applied force is not linear while measured conductance is linear. This requires sensors to be incorporated in circuit to measure conductance. Adapted from Tekscan user manual (Tekscan)
Figure 11 Recommended drive circuit for the sensor. Based on this our device circuit was developed. Adapted from Tekscan user manual (Tekscan).
Flexiforce® sensors are shown to have better linearity, repeatability and time drift than other flexible force measurement solutions. They also have better dynamic accuracy (Vecchi, Freschi et al. 2000). Our initial pilot studies suggested that the force exerted on the perineal arteries is in the range of 3 – 15 N. 1 lb. sensors can measure forces in the range of 1 – 5 Newton. 25 lb. sensors lacked the 0.5 Newton resolution needed for our application. The ideal one for our application would be a 5 lb. sensor. But 5 lb. sensors are not available off-the-shelf and custom sensors are not an economically feasible option. So the drive circuit needs to be modified to make the 1 lb. sensor measure forces in the range of 1 – 15 Newton. The force range of Flexiforce® sensors can be modified by adjusting the reference resistance ($R_F$) and/or the drive voltage ($V_T$) in the recommended drive circuit (Figure 12).

3.1.4 Selection of a suitable microcontroller module.

A microprocessor will be required to automate the data collection process, perform basic signal processing and to control other components like switches and LEDs. Module-based microprocessors were our choice as they are easier to program, contains in-built analog to digital convertors (ADC), offers extensive memory for data storage and necessary hardware for easier data transfer. Ideally, the microprocessor module should have some form of solid storage device (SD or micro SD) slot to back up the data. After research, we chose Rabbit core module 4300 (Digi International, Minnetonka, MN) (Figure 3.4). They are small (47mm x 61 mm x 20mm), have on board 12 bit ADC, micro SD card slot that can be used to store up to 2GB of data, 512K SRAM making them less power hungry and more program friendly. Also they can be programmed using Dynamic C®, which adapts C programming syntax.
Figure 12 Rabbit core module 4300. It acts as CPU of the device. The associated microSD card is used to store the data.
3.1.5 Circuit development and migration to printed circuit board.

The drive circuit to power the sensors and measure the conductance was developed based on the Flexiforce® sensors’ recommended drive circuit (Figure 13). The device should accommodate four sensors to measure force values along the artery. It should also have the necessary switches and LEDs to control the device. To optimize the circuit, the single operational amplifier in the drive circuit was replaced by a quad operational amplifier to accommodate the four sensors. Four AAA batteries powered the drive circuit. The power from another four AAA batteries were stepped down using a voltage regulator to 3.3 Volts and used to operate the Rabbit core module 4300.

The circuit was initially developed in a breadboard. A simple program was written to measure the change in conductance. Once the breadboard prototype was tested for basic functionality, the device was developed using gEDA, an open source electronic design automation tool. gshem was used to develop the circuit (Figure 14). PCB was used to generate the layout of the printed circuit board. The GERBER files were sent to a fabrication facility to obtain the blank printed circuit board. We used surface mount soldering to attach the Rabbit core module 4300 and through hole soldering to attach other components like resistors, capacitors, operational amplifiers and terminals.
Figure 13 Schematic of the device developed in gschem.
Figure 14 Populated printed circuit board with the microcontroller module. This device was used to collect and store the data from bicycle riders.
The populated printed circuit board (Figure 3.6) was tested visually for wiring faults. Then Rabbit core module 4300 was integrated, sensors were attached and tested to display values. Finally the program (Appendix C) to control the device was developed using Dynamic C. The device operates in two modes. When the switch is in OFF state and the device is powered up, the device displays values from the force sensors in a computer screen. A serial emulator can be used to see the values from the serial port. A simple program was written in Processing 1.5.1 to display the force values graphically (Figure 3.7). When the switch is flipped to ON state, the device stores the force values from the sensors to its RAM and micro SD card. The values from each sensor are stored as comma separated. The device was tuned to collect data at a frequency of 10Hz. So the final file will be a .CSV file with values from the sensors in separate columns and time stamp at first column. Each time when the switch is flipped between ON and OFF states, a separate file with a unique name is created (Figure 15). This allows us to differentiate the files once it is transferred. The entire device was fitted into a custom box. The functionality was tested again by taking the device for small bike rides. Also, the device was tested on a lengthy bike ride to test its battery life. The device was successfully collecting data even after 4 hours of continuous riding.
Figure 15 Performance of the sensors. A simple program was written in Processing 1.5.1 to display the force values graphically. This served as an initial proof of concept experiment to check the functionality of the device with the sensors.
3.1.6 Calibration of the device.

The next step in the development of the device was calibration. Calibration was done to convert the raw output in millivolts to a meaningful value such as force in Newton. After several literature searches, we adopted the method used by Pearsall et al (Townley 2012). They calibrated the sensors using a material testing machine to apply controlled force to the sensors. The material testing machine available to us can apply force in the range of 10 – 100 Newton, with a resolution of 5 Newton. But the expected force range of our device was 1 – 15 Newton with a resolution of 0.5 Newton. The calibration of our device was made possible by building a custom calibration apparatus using Wagner FORCE ONE™ FDIX load cell (Wagner Instruments, Greenwich, CT). These load cells are capable of measuring tensile and compressive forces up to 250 Newton with a resolution of 0.2 Newton (Instruments 2010).

The principle of our calibration is to apply increasing amount of known compressive force to the Flexiforce® sensors and measure the output from the sensors. The output from the sensors can be plotted against the known force. Regression analysis can be used to interpolate unknown force values from the known sensor outputs.

The FORCE ONE™ FDIX load cell was mounted on a custom stainless steel mount. Accommodations were made to place the sensors between two precision milled cylindrical surfaces that matched the sensor diameter. The knob at the bottom can be rotated to apply increasing amount of compressive force on the sensor. The entire apparatus was called as FORCE ONE™ calibrator (Figure 16). In order to validate the accuracy of FORCE ONE™ calibrator we decided to compare the results of our FORCE ONE™ calibrator with the results of
Instron® 8500 high rate system (Instron, Norwood, MA). We modified our circuit to measure force in the range of 10 – 50 Newton and replaced the 1lb. sensor with 25lb. sensor. The sensors are conditioned as described in the manual (Pucher and Buehler 2008, Tekscan). Then the sensors are calibrated using both FORCE ONE™ calibrator and Instron® 8500 high rate system as outlined in our calibration principle. The results of the experiment were compared to assess the reliability of FORCE ONE™ calibrator.

To calibrate the device, FORCE ONE™ calibrator was used to apply compressive forces on the sensors. Force in the range of 0 – 25 Newton with increments of 0.2 – 0.6 Newton at a frequency of 0.03 Hz was applied. Each sensor was calibrated twice, making a total of eight trials. The average output was obtained by taking the average of all the eight trials. The results from the experiment were plotted and MATLAB (The Mathworks, Inc., Natick, MA) curve-fitting tool was used to fit a third order polynomial curve. Interpolation can be used to obtain the unknown force values from the known sensor outputs.
Figure 16 FORCE ONE™ calibrator. The custom built apparatus used to calibrate the Flexiforce sensors.
3.1.7 Device verification and validation.

The accuracy of the device was verified *in vitro*. The aim of the experiment was to verify whether the device was able to report accurate and reliable force values under dynamic, cyclic loading conditions. The Flexiforce® sensors were preconditioned as described in the manual (Tekscan). The FORCE ONE™ calibrator was used to exert different ranges of force at particular frequencies. Known amount of force in the range of 1 – 20 Newton was applied on the Flexiforce® sensors. The device output was noted at 5 seconds, 10 seconds, 30 seconds and 60 seconds after the force application. This was done to account for drift in Flexiforce® sensors. Also the force was applied in a random fashion within the range to simulate *in vivo* conditions. The entire experiment was repeated twice. The readings from both the experiments were used to calculate the average device output. A two sample paired t-test was used to compare the applied force value and the average device output. The overall drift rate of the device was obtained by comparing the reported values at 5 seconds and 60 seconds after force application. The relative accuracy of the device to the FORCE ONE™ calibrator was calculated by observing the difference between mean applied force and the average device output.

For the validation study, two subjects with similar biometric characteristics (Table I) were recruited from the university population. Two Force sensors were affixed over the subjects’ perineum. One sensor was placed on the right and left side, approximately overlying the perineal arteries. Both subjects bicycled on a standard road course using a normal seat. The experiment was repeated on another day for both the subjects. The goal of the experiment was to observe whether the results vary within and between the subjects.
Table I

DEMOGRAPHIC DATA OF SUBJECTS PARTICIPATED IN VALIDATION STUDIES.

<table>
<thead>
<tr>
<th>Demographic information</th>
<th>Subject 1</th>
<th>Subject 2</th>
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</thead>
<tbody>
<tr>
<td>Height (Centimeters)</td>
<td>174.2</td>
<td>170.8</td>
</tr>
<tr>
<td>Weight (Kilograms)</td>
<td>74.1</td>
<td>76.6</td>
</tr>
<tr>
<td>Age (Years)</td>
<td>24</td>
<td>26</td>
</tr>
</tbody>
</table>
3.2 Study to determine perineal artery occlusion among male bicyclists

3.2.1 Identification of Perineal arteries and determination of occlusion force.

Our study design required proper positioning of the force sensors over the perineal arteries. Also perineal artery occlusion force needed to be measured for each subject. We decided to identify the perineal arteries and determine the perineal artery occlusion force for each subject individually using Doppler ultrasound. Twenty healthy men ages 18-64 were recruited from the community. Oral presentations and advertisement flyers were used in the process of recruitment. The entire protocol was orally explained to the subjects and they signed the informed consent form approved by the University of Illinois at Chicago institutional review board (Protocol # 2007-0284).

Subjects were asked to lie down on an examination table in the supine, frog-legged position to allow access to the perineum. An experienced ultrasonographer identified the left and right perineal arteries (Figure 17) using a GE LOGIQ® E9 (GE Healthcare, Milwaukee, WI, USA) Doppler ultrasound probe. A custom force sensing probe was developed using the Flexiforce® sensors. A urology resident used that probe to apply increasing force on the perineum until cessation of blood flow in the perineal artery was observed in the ultrasound (Figure 18). Force required to completely occlude the artery was noted. The procedure was repeated twice on the left and right perineal arteries. Mean arterial occlusion force was calculated for each perineal artery. Flexiforce® sensors were fixed at cutaneous positions bilaterally overlying the perineal arteries in both proximal and distal locations (Figure 19) using Tegaderm™ (3M, St. Paul, MN, USA).
Figure 17 Identification of perineal arteries using Doppler ultrasound. The red streak indicates blood flow.

Figure 18 Cessation of blood flow in the perineal artery after application of critical force.
Figure 19 Position of sensors on the Perineum. The consistent positioning of the sensors over the perineal arteries is critical in obtaining repeatable data from different subjects. This was accomplished using Doppler Ultrasound.
3.2.2 Collection of perineal force data during road and stationary bicycling.

The sensors were then attached to our device which the riders carry in a small backpack. For the road condition, subjects bicycled on a standard city road course for 0.5 miles on each of six bicycle seats (Figure 20). Perineal force data was collected at 10 Hertz. Seats were kept at uniform angle parallel to the ground. Seat post height was adjusted to the subjects’ requirements. Subjects always rode the same bike (Trek FX™) to maintain uniformity. The seats varied in size, shape, and padding. Three had the conventional nose (A, B, C) and three were no-nose designs (D, E, F). For the stationary condition, the protocol was repeated on the same bicycle mounted on a trainer. Recorded perineal forces were compared to the subject’s occlusion force measured using Doppler ultrasound.
Figure 20 Test seats. A, B and C are nosed seats. A (WTB® Silverado) is a standard seat with no padding. B (Forte Softtail) has standard shape but with special padding. C (Forte Easyrider) has wider geometry with special padding. D (Ergo The SEAT®), E (Spiderflex REC) and F (New Concepts Moonsaddle™) are no-nose designs.
3.2.4 Statistical analysis

Initially we plotted the perineal force data of each subject against their riding time. We also plotted their left and right occlusion forces. This helped us to visualize the change in perineal forces over time. The data was smoothed using the adjacent – averaging method for the purpose of better visualization. From the graphs, we observed that subjects’ perineal forces exceeded their occlusion force for a significant amount of time.

But stationary bicycling resulted in significantly smaller perineal forces. We compared the perineal forces of the subjects riding the same seat under both the conditions. Perineal forces exceeded occlusion force for the majority of road ride time whereas in stationary riding perineal forces rarely exceeded the occlusion force.

Once we began to gather data from more subjects it became highly difficult for us to compare them visually. We got 12 graphs for each subject and 20 subjects made it 240 graphs. It was extremely difficult to compare all the data visually. So a method to quantitatively measure occlusion was needed.

From an engineering perspective, the magnitude of perineal forces was an important aspect. However the occlusion of the arteries and duration of occlusion are of physiological significance because it can be a direct indictor of penile tissue hypoxia. So we decided to quantify the duration of occlusion. Occlusion can be defined whenever the subject’s recorded perineal forces exceeded their occlusion force measured in the lab.
We calculated the duration of time each subject occluded his perineal arteries. We expressed that value as proportion of ride time to maintain uniformity among subjects. Occlusion time proportion was assessed as the primary outcome measure. A binary outcome of 1 was assigned whenever the perineal forces in any of the four sensors exceeded the occlusion force. The left perineal force values were compared against the left arterial occlusion force and right force values were compared against the right arterial occlusion force. The binary indicators were added up to calculate the occlusion time. Occlusion time was divided by the total ride time to obtain occlusion time proportion. The occlusion time proportions of each subject were plotted against the subject’s BMI for each seat under both the conditions. We obtained 12 different graphs.

Then we used our sample data to draw conclusions about the impact of bicycle saddles on the perineal blood flow of overall male population. As our earlier analysis, occlusion time proportion was assessed as primary outcome measure and a binary outcome 1 was assigned whenever perineal force measurements exceeded the respective occlusion force.

Statistically, our data can be classified as longitudinal data. Each perineal force measurement for a single subject is assumed as a separate trial at different time intervals. Our data is collected at a frequency of 10Hz. We observed an average 3421 measurements of force across each of four sensors for a single subject. In total for 20 subjects, our data set consisted of 754,940 measurements of force. When working with repeated measures data, the statistical model should always account for autocorrelation. Successive force measurements at a very small time interval tend to be similar and models not accounting for this trend yield results with very small standard errors. In other words, accounting for autocorrelation eliminates any bias in the results due to similarity between repeated measurements.
From our data we are more interested in observing the effect on overall population (population-averaged effects). Marginal models are generally used to obtain the effect on overall population. Generalized estimating equation (GEE) models are usually a better alternative to obtain point estimates (mean) and standard errors (confidence intervals) than generalized linear models. The GEE model accounted for potential autocorrelation among the force measurements.

GEE models were fit using PROC GENMOD in SAS version 9.2 (SAS, Cary, NC, USA) specifying binary outcome, identity link, and exchangeable correlation structure. We estimated occlusion time proportion for each combination of seat and condition.

Standard errors of proportion estimates were similar in magnitude to standard errors treating the average proportion from each trial as a single continuous measurement and working with a sample size of 20. Specifically there was a very accurate measure of proportion for each subject under each condition, but the inference was still based on 20 subjects. The effect of condition (road vs. stationary) was tested overall in a model without interaction between seat and condition, as well as contrasts for each type of seat in the full interaction model. Tests were done to compare seats (B, C, D, E, and F) against seat A within the road ride condition as seat A has the prototypical bike saddle shape with no padding and can be considered as a standard seat.
4. RESULTS AND DISCUSSION

4.1 Results

4.1.1 Calibration Results.

The calibration results obtained using Instron and FORCE ONE™ calibrator are linear with very minor variations between them (Figure 21). The statistical analysis comparing Instron and FORCE ONE™ calibrator results show that FORCE ONE™ calibrator can be used effectively to calibrate our device (Table II). The calibration activity shows that the device has a triphasic output and polynomial curve fitting was necessary. The equation obtained from the polynomial curve was used to convert the raw output in millivolts to force in Newton (Figure 22).
Figure 21 Instron Vs. FORCE ONE™ calibrator. Comparing the functioning of our custom built FORCE ONE™ calibrator against Instron.
Table II

t-TEST RESULTS COMPARING INSTRON & FORCE ONE™ CALIBRATOR

<table>
<thead>
<tr>
<th>Test condition</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>Std. Error Mean</th>
<th>95% confidence intervals</th>
<th>t</th>
<th>df</th>
<th>Significance level (α)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instron Vs. FORCE ONE™ calibrator</td>
<td>13.02</td>
<td>5.17</td>
<td>1.72</td>
<td>0.47</td>
<td>0.71</td>
<td>-0.21</td>
<td>8</td>
</tr>
<tr>
<td>FORCE ONE™ calibrator</td>
<td>12.43</td>
<td>5.06</td>
<td>1.69</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Figure 22 Calibration plot and curve fitting. This equation was used to convert output in millivolts to force in Newton.

\[ y = \text{Intercept} + B_1x + B_2x^2 + B_3x^3 \]

- **Intercept**: -0.54543
- **B1**: 0.01652
- **B2**: -2.46085E-5
- **B3**: 5.33328E-8

**Residual Sum of Squares**: 17.12611
- **Adj. R-Square**: 0.99278

**Weight**: No Weighting

**Standard Error**:
- Intercept: 0.44692
- B1: 0.00454
- B2: 1.24787E-5
- B3: 9.80536E-9
4.1.2 Verification and Validation Results.

The average drift of our device was 0.02 Newton with a maximum drift of 1 Newton. The relative accuracy of our device was 1%. These numbers illustrate the accuracy of our device. The verification activity shows that there was no statistically significant difference in the output of our device when compared to the applied force (Table III). The results from the subjects participated in our device validation shows that force exerted on the perineal arteries varies during the ride. Variations can also be observed in the force distribution patterns among the subjects (Figures 23). Statistical analysis comparing the force value recordings within and between the subjects confirms the observations made from the graphs (Table VII).
Table III

\textit{t-TEST COMPARING APPLIED FORCE TO THE AVERAGE DEVICE OUTPUT}

<table>
<thead>
<tr>
<th>Test condition</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>Std. Error Mean</th>
<th>95% confidence intervals</th>
<th>t</th>
<th>df</th>
<th>Significance level ((\alpha))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applied force vs. average device output</td>
<td>10.55</td>
<td>5.70</td>
<td>0.91</td>
<td>-0.01 - 0.22</td>
<td>-1.7</td>
<td>38</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>10.49</td>
<td>5.40</td>
<td>0.86</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Figure 23 Force exerted on the subject’s perineal arteries during bicycling. These graphs highlight the variation of arterial forces within and among the subjects.
<table>
<thead>
<tr>
<th>Pair</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>Std. Error Mean</th>
<th>Result at 0.05 α</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Subject 1 - Trial 2 – Right” vs. “Subject 1 - Trial 1 - Right”</td>
<td>10.82</td>
<td>0.95</td>
<td>0.02</td>
<td>Significant difference</td>
</tr>
<tr>
<td></td>
<td>9.78</td>
<td>0.85</td>
<td>0.01</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1.04(difference)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Subject 1 - Trial 1 - Left” vs. “Subject 1 - Trial 2 - Left”</td>
<td>8.61</td>
<td>0.77</td>
<td>0.0</td>
<td>Significant difference</td>
</tr>
<tr>
<td></td>
<td>8.06</td>
<td>0.98</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.54(difference)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Subject 2 - Trial 1 - Right” vs. “Subject 2 - Trial 2 - Right”</td>
<td>7.60</td>
<td>0.96</td>
<td>0.02</td>
<td>Significant difference</td>
</tr>
<tr>
<td></td>
<td>7.28</td>
<td>0.65</td>
<td>0.01</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.32(difference)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Subject 2 - Trial 2 - Left” vs. “Subject 2 - Trial 1 - Left”</td>
<td>7.14</td>
<td>0.60</td>
<td>0.01</td>
<td>Significant difference</td>
</tr>
<tr>
<td></td>
<td>6.32</td>
<td>2.35</td>
<td>0.06</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.82(difference)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Subject 1 - Trial 1 - Right” vs. “Subject 2 - Trial 1 - Right”</td>
<td>9.78</td>
<td>0.84</td>
<td>0.01</td>
<td>Significant difference</td>
</tr>
<tr>
<td></td>
<td>7.60</td>
<td>0.97</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.17(difference)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Subject 1 - Trial 2 - Left” vs. “Subject 2 - Trial 2 - Left”</td>
<td>8.07</td>
<td>0.98</td>
<td>0.03</td>
<td>Significant difference</td>
</tr>
<tr>
<td></td>
<td>7.14</td>
<td>0.61</td>
<td>0.01</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.93(difference)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4.1.3 Study – Preliminary results.

The variations in the force exerted during road and stationary bicycling can be understood by observing the force distribution graphs of a single subject under road and stationary conditions (Figures 24 and 25). The overall variability of occlusion among the subjects and the significant difference in occlusion time proportions during road and stationary bicycling is illustrated in Figure 26.
Figure 25 Perineal forces and occlusion force of a subject on seat A under stationary ride condition. The subject rarely exceeds occlusion threshold in contrast to Figure 25.
Figure 26 Overall occlusion variability. The individual dots represent subject level occlusion proportions as an average across all the four sensors. The shaded diamonds represents the overall mean (n=20) and 95% confidence intervals. The huge variability observed between the subjects lead us to perform a robust statistical analysis using GEE model. This graph is for understanding subject level occlusion variability only and inference must be made from the outcome of GEE models.
Table V

VARIABLE OCCLUSION AMONG THE SUBJECTS. This table shows the number of subjects who met or exceeded the worst case scenario (0.9 occlusion time proportion)

<table>
<thead>
<tr>
<th></th>
<th>&gt;0.9</th>
<th>&gt;0.8</th>
<th>&gt;0.7</th>
<th>&gt;0.6</th>
<th>&gt;0.5</th>
<th>&gt;0.4</th>
<th>&gt;0.3</th>
<th>&gt;0.2</th>
<th>&gt;0.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of subjects on Seat A</td>
<td>4</td>
<td>6</td>
<td>11</td>
<td>13</td>
<td>13</td>
<td>14</td>
<td>15</td>
<td>15</td>
<td>17</td>
</tr>
<tr>
<td>Number of subjects on Seat B</td>
<td>2</td>
<td>3</td>
<td>6</td>
<td>12</td>
<td>13</td>
<td>14</td>
<td>14</td>
<td>15</td>
<td>16</td>
</tr>
<tr>
<td>Number of subjects on Seat C</td>
<td>3</td>
<td>10</td>
<td>14</td>
<td>15</td>
<td>15</td>
<td>15</td>
<td>15</td>
<td>17</td>
<td>18</td>
</tr>
<tr>
<td>Number of subjects on Seat D</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>9</td>
<td>11</td>
<td>12</td>
<td>12</td>
<td>12</td>
<td>13</td>
</tr>
<tr>
<td>Number of subjects on Seat E</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>5</td>
<td>9</td>
<td>11</td>
<td>11</td>
<td>13</td>
</tr>
<tr>
<td>Number of subjects on Seat F</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>9</td>
<td>9</td>
<td>10</td>
<td>12</td>
<td>12</td>
</tr>
</tbody>
</table>
Figure 27 Number of subjects who exceeded the pre-defined occlusion criteria. The analysis was performed for ranges of pre-defined criteria from 0.1-occlusion proportion (best case) to 0.9-occlusion proportion (worst case) Variable occlusion among the subjects. On seat D, 2 subjects showed occlusion proportion exceeding 0.9 whereas for seat A 4 subjects exceeded that threshold.
4.1.4 Preliminary results - summary.

We observed significant occlusion time proportion for most of the subjects. Another important trait was occlusion time proportions were significantly less during stationary bicycling than during road bicycling for most of the subjects in all the seats. These critical inferences lead us to perform detailed statistical analysis of our data.

4.1.5 Study results - summary.

Twenty riders completed the study (mean age: 36.35 ± 12.5, BMI: 23.70 ± 2.6) with a mean occlusion force of 10.03 ± 1.29 N on the right and 10.03 ± 1.5 N on the left. Our GEE model shows that, for all seats and conditions, the occlusion time proportion was significant (Figure 28). Road ride trials produced a higher occlusion time proportion compared to stationary road trials. This was observed for all seat types. The effect of road versus stationary condition is shown in Table VII. As an average across all seat types, the increase associated with road ride was marginally significant (p=.07); within seats, the increase was significant for C (p=.04), D (.03), and F (p=.01). The comparison of seats (B, C, D, E, and F) against seat A is shown in Table VIII. D, E, and F seats were associated with significantly lower occlusion time proportion compared to A (p<.001, p=.002, and p=.04 respectively). In a model grouping nosed seats versus no-nose seats, nosed seats had significantly higher occlusion (p<.001).
Table VI

PROPORTION OF TIME ABOVE OCCLUSION FORCE IN ANY OF FOUR SENSORS: POINT ESTIMATES AND STANDARD ERRORS FROM GEE MODEL\textsuperscript{a}

<table>
<thead>
<tr>
<th>Seat</th>
<th>Condition</th>
<th>Estimate</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Road Ride</td>
<td>.70</td>
<td>.09</td>
</tr>
<tr>
<td>A</td>
<td>Stationary Ride</td>
<td>.58</td>
<td>.07</td>
</tr>
<tr>
<td>B</td>
<td>Road Ride</td>
<td>.65</td>
<td>.08</td>
</tr>
<tr>
<td>B</td>
<td>Stationary Ride</td>
<td>.60</td>
<td>.06</td>
</tr>
<tr>
<td>C</td>
<td>Road Ride</td>
<td>.76</td>
<td>.07</td>
</tr>
<tr>
<td>C</td>
<td>Stationary Ride</td>
<td>.57</td>
<td>.08</td>
</tr>
<tr>
<td>D</td>
<td>Road Ride</td>
<td>.55</td>
<td>.10</td>
</tr>
<tr>
<td>D</td>
<td>Stationary Ride</td>
<td>.36</td>
<td>.07</td>
</tr>
<tr>
<td>E</td>
<td>Road Ride</td>
<td>.41</td>
<td>.08</td>
</tr>
<tr>
<td>E</td>
<td>Stationary Ride</td>
<td>.30</td>
<td>.07</td>
</tr>
<tr>
<td>F</td>
<td>Road Ride</td>
<td>.47</td>
<td>.09</td>
</tr>
<tr>
<td>F</td>
<td>Stationary Ride</td>
<td>.27</td>
<td>.06</td>
</tr>
</tbody>
</table>

\textsuperscript{a}20 subjects; 23,369 to 45,356 observations per subject; 754,940 total observations. Binary outcome, identity link, and exchangeable correlation structure specified. Exchangeable working correlation is $\rho = .2097.$
Table VII
EFFECT OF CONDITION ON OCCLUSION TIME PROPORTION (ROAD RIDE VERSUS STATIONARY RIDE)

<table>
<thead>
<tr>
<th></th>
<th>Estimate</th>
<th>SE</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average across seats:</td>
<td>+.13</td>
<td>.07</td>
<td>.07</td>
</tr>
<tr>
<td>Conditional on seat:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>+.12</td>
<td>.10</td>
<td>.24</td>
</tr>
<tr>
<td>B</td>
<td>+.04</td>
<td>.10</td>
<td>.67</td>
</tr>
<tr>
<td>C</td>
<td>+.19</td>
<td>.09</td>
<td>.04</td>
</tr>
<tr>
<td>D</td>
<td>+.19</td>
<td>.09</td>
<td>.03</td>
</tr>
<tr>
<td>E</td>
<td>+.11</td>
<td>.07</td>
<td>.10</td>
</tr>
<tr>
<td>F</td>
<td>+.20</td>
<td>.08</td>
<td>.01</td>
</tr>
</tbody>
</table>

*aFrom GEE model without interaction terms (exchangeable working correlation is \( \rho = .3575 \)).

*bEstimates for conditional effects are from full interaction model as in Table VI.
Table VIII
EFFECT OF SEAT TYPE ON OCCLUSION TIME PROPORTION
CONDITIONAL ON ROAD RIDE

<table>
<thead>
<tr>
<th></th>
<th>Estimate</th>
<th>SE</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>B vs. A&lt;sup&gt;a&lt;/sup&gt;</td>
<td>-.06</td>
<td>.06</td>
<td>.37</td>
</tr>
<tr>
<td>C vs. A&lt;sup&gt;a&lt;/sup&gt;</td>
<td>+.06</td>
<td>.06</td>
<td>.29</td>
</tr>
<tr>
<td>D vs. A&lt;sup&gt;a&lt;/sup&gt;</td>
<td>-.15</td>
<td>.07</td>
<td>.04</td>
</tr>
<tr>
<td>E vs. A&lt;sup&gt;a&lt;/sup&gt;</td>
<td>-.29</td>
<td>.07</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>F vs. A&lt;sup&gt;a&lt;/sup&gt;</td>
<td>-.23</td>
<td>.07</td>
<td>.002</td>
</tr>
<tr>
<td>Effect of Nosed Seat&lt;sup&gt;b&lt;/sup&gt; (A, B, or C vs. D, E, or F)</td>
<td>+.23</td>
<td>.06</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

<sup>a</sup>From full interaction model as in Table VI.

<sup>b</sup>From GEE model with indicator for nosed seat, condition (road ride versus stationary ride) and the interaction between nosed seat and condition.
Figure 28 Proportion of Time above Occlusion Force in Any of Four Sensors. This graph indicates occlusion time proportion when any of the four sensors exceeded the occlusion threshold. This represents the physiological condition when at least one branch of the perineal artery is occluded and there may be blood flow through another branch.
Figure 29 Proportion of Time above Occlusion Force in right or left sensors. This graph indicates occlusion time proportion when both right and left sensors exceeded the occlusion threshold. This represents the physiological condition when both the branches of arteries are occluded and no blood flow.
Figure 30 Maximum continuous occlusion time proportions. This represents the maximum duration when both the branches of arteries continuously occluded before reestablishing some blood flow.
4.2 Discussion

Force measurement can be done using variety of transducers such as strain gauges, piezoelectric crystals, hydraulic, Pneumatic, capacitive load cells, linear variable differential transducer (LVDT) etc. Most of them are either bulky or involve complex circuitry making them unsuitable for our application. The force sensors we used measure force based on the change in resistance of a force sensitive ink. They are extremely thin, reliable and adapt a simple circuitry to measure force.

Systems used by previous researchers such as Novel Pedar & Pliance pressure sensors (Novel electronics Inc., St. Paul, MN), Bicycle pressure – sensing array system (FSA system, Vista medical Ltd, Winnipeg, Canada) are similar to our device. But they are expensive and require a computer running proprietary software to collect and store the data. Though these systems show sophisticated pressure distribution maps of saddle-subject interface, for this problem we are more concerned about the concentrated forces on the arteries. The advancement in the field of variable resistance based force sensing and off-the-shelf availability of microcontroller modules enabled us to quickly develop this device. The cost of the entire device was less than $400.

Instron® 8500 high rate system (Instron, Norwood, MA) is considered as gold standard for most material testing applications and previous work (Townley 2012) proved that such systems can be used to calibrate Flexiforce® sensors. In our results we showed that the custom developed FORCE ONE™ calibrator can be used effectively to calibrate the Flexiforce®
sensors. Thus, FORCE ONE™ calibrator is an efficient, cost effective, portable alternate system to expensive material testing systems like Instron.

The output of the device in millivolts changes in proportion to the applied force. But the device should be able to report force in engineering units such as Newton. The third order polynomial equation obtained by fitting a curve to our calibration results can be used to convert the raw output in millivolts to force in Newton.

Example:

Raw output from device = 600mV

Polynomial equation

\[ y = -0.55 + 0.02x - 2.46 \times 10^{-5}x^2 + 5.33 \times 10^{-8}x^3 \]

Plugging the value of 600 for x value in the equation

\[ y = -0.55 + 0.02(600) - 2.46 \times 10^{-5}(600)^2 + 5.33 \times 10^{-8}(600)^3 \]

We get 12.95, which is the force in Newton.

The conversion of millivolts to force was done externally using Microsoft excel (Microsoft Corporation, Seattle, WA) instead of incorporating it in our program.

The performances of force measurement systems are usually described by its physical characteristics such as range, error of measurement, repeatability, reproducibility, drift etc. Reporting reliable force values with reasonable accuracy was essential for our device. Also the force readings should be repeatable as it was expected to measure highly dynamic loading cycles experienced during bicycling. The range of our device is 1 – 20 Newton. Our in vitro
experiments show that the largest error of measurement was 1.1 Newton with an average error of measurement of 0.4 Newton. This was 2% of the rated capacity of our device. Our device was sensitive enough to measure change in force of 0.2 Newton. Further our results show that the device can report repeatable force values under highly dynamic loading conditions. The mean difference between applied force and the average device output was 0.10 Newton and t-test analysis (P - value = 0.10) proved that there was no statistically significant difference between the applied force and average device output.

Another important criterion for testing a device is validation. Validation is a process of testing the device in its host environment and inspecting whether or not all the design requirements are met. Our validation process involved testing the device with two subjects multiple times during actual bicycle riding. Our validation study helped us to identify problems which cannot be observed in a lab setting. One significant issue we identified was damage to the sensors because of sweat. The conductive ink in the sensors is laminated between two polyester layers and the layers are sealed using adhesive and spot-welded. This leaves minute pores in the sensors. During actual testing, sweat entered through these pores and damaged the conductive ink of the sensors making them unusable. This problem was solved by covering the sensors with Tegaderm™ (3M, St. Paul, MN, USA).

But significantly our validation studies showed that the device can be safely used on human subjects to measure force on the perineal arteries during bicycle riding. We expected that there would be no statistical difference when the device was used on the same subject at different times. But our results show that both the subjects showed significantly different force readings in all the sensors. We proved the repeatability of our device using in vitro experimentation. We
have to consider that changes in riding mechanics can alter the force exerted on the perineal arteries. We state that the significant difference was influenced by other environmental factors rather than the device’s variability. The variability in the pattern and amount of force exerted on the perineal arteries between the subjects were expected. The riding mechanics (speed, posture, style etc.) varies widely among the subjects.

For our study, a priori sample size determination was not done. We had no prior data on occlusion proportion among general population. In fact our study was the first to look at occlusion time proportions. One of the main goals of our study was to determine if significant occlusion occurs among male bicyclists. Also, to observe if there is significant difference in occlusion proportions among nosed and no-nose seats. Significant occlusion can be 0.10(best case) or 0.90(worst case) or any value in between. Based on our overall results, we conducted a post-hoc power analysis using independent samples t-test. Our sample size of 20 will have at least 80% power to detect any mean difference of .22. Also, from our statistics we proved that there is a significant difference (P <0.001) in occlusion proportions between nosed and no-nose seats. This further strengths the power of our sample size, providing objective evidence that our sample size would be sufficient to determine significance.

Without any clinical evidence it is difficult to define what amount of occlusion can lead to erectile dysfunction. So we ran our analysis considering 10% arterial occlusion as best case and 90% arterial occlusion as a worst-case scenario. We observed that at least 2 subjects showed more than 90% arterial occlusion in all the seats and at least 12 subjects showed more than 10% arterial occlusion in all the seats.
The results showed huge individual variations among the subjects in terms of occlusion proportion. Variability was observed even within the subjects bicycling on different seats. The possible reasons for these variations include subjects’ anatomical differences and riding style. No two subjects sit and ride on the seat in a similar fashion. Also, the difference in results among the seats is expected because of the difference in seat design and padding.

Our results revealed that road bicycling resulted in a longer duration of arterial occlusion than stationary bicycling. The difference was higher and significant for no-nose seats. Studies conducted by Bressel et al. (Bressel, Bliss et al. 2009) reported no difference in seat interface pressure between road and stationary models. This finding suggests that without sensors placed directly on the location of the perineal arteries, arterial occlusion is not measured; rather, general perineal force is assessed. In order to determine actual risk of erectile dysfunction, accurate measurement of force applied to the perineal arteries is necessary, which is not provided by a pressure sensing mat separate from the rider’s own perineum.

There was no statistically significant difference in arterial occlusion between Saddles A and B, which had similar shape but different padding. This was in agreement with previous results published by Schwarzer et al. (Schwarzer, Sommer et al. 2002)

All the tested seats occluded the perineal arteries, with saddle E showing the least occlusion proportion of 0.41. Additionally, the comparison of nosed saddles (A,B,C) and no-nose saddles (D,E,F) showed that no-nose seats were associated with significantly less arterial occlusion time. In an investigation of the effect of the no-nose seat design, Lowe et al. (Lowe, Schrader et al. 2004) concluded that no-nose seats, “significantly reduced pressure distributed in the perineal region of the cyclist during stationary bicycling (Lowe, Schrader et al. 2004).” While our study
did not contradict their findings, we contend that no-nose seats are not necessarily safe. Our analysis revealed that no-nose seats still produced perineal forces greater than arterial occlusion forces at least 41% of the ride time.

Where limitations may exist is the determination of what amount of arterial occlusion constitutes clinical relevance. One could infer that a seat that demonstrated less perineal force constituted an improvement in design. However, if every seat resulted in perineal forces greater than that necessary to occlude the perineal arteries for a substantial proportion of riding time, it is reasonably concluded that none are safe. Schrader et al. (Schrader, Breitenstein et al. 2008) in their paper recognized that the inability to discriminate pressure from the posterior regions of the thigh from the contact pressure affecting the soft tissues of the perineum was a significant impediment to the study design (Schrader, Breitenstein et al. 2008). Our work addressed this limitation by measuring concentrated forces directly over the perineal soft tissues.

Our study did not measure erectile function, and we are not able to assess how perineal artery occlusion directly correlates with penile health. A model to study the impact of total perineal artery occlusion on erectile function may provide insight into the clinical significance of perineal artery occlusion. Ultimately, we envision a warm ischemic model of the penis that could evaluate the cumulative burden of bicycling on penile function. Subjects’ time constraints prevented us from conducting lengthy rides and no time was given to the subjects to adapt to each seat. Additionally, most of our subjects were avid bicycle riders, and consequently may have served to bias our study group.
5. CONCLUSION AND SUGGESTED FUTURE WORK

Despite well documented evidence that arterial occlusion causes erectile dysfunction among cyclists, previous studies did not include the methodology to directly measure force on the perineal arteries. Researchers applied pressure mats to bicycle seats and quantified pressure on a region of the seat assumed to be localized to the perineal arteries, but the exact positions of the arteries change unpredictably during active cycling. By constructing a force measuring system with sensors placed using ultrasound for each subject, our study accounted for the unique anatomy of each individual rider. Further, our portable force-logging device enabled us to conduct the studies on the road and account for environmental factors.

We conclude that although seats without a nose are associated with less duration of total occlusion than seats with a nose, all seats occlude the perineal arteries completely for a minimum 41% of riding time duration. Thus, all tested seats are likely associated with erectile dysfunction. Our system serves as a novel way to validate bicycle seat design, which may ultimately improve and protect men’s penile health.

This dissertation work has several unique contributions to the field of research.

1. Our inexpensive, portable force logging device will immensely benefit researchers and engineers in this field to test and study new seat designs.
2. Our study was the first to place sensors directly on the perineal arteries and measure the magnitude of perineal forces.
3. No-nose seats showed significantly higher occlusion time proportions during road cycling than stationary cycling. So, future-testing protocols should adopt road bicycling model that more accurately reflect perineal arterial occlusion.

4. For 45% of the study population no-nose seats showed significant occlusion. So clearly no-nose seats are not the universal solution.

5. The average occlusion time for all tested seats was 52% of riding duration. In other words, **there is 52% chance that a male bicycle rider will occlude his arteries when riding outdoors using any type of seat. No–nose seats are not necessarily better than nosed seats in preventing erectile dysfunction.** All tested seats can lead to erectile dysfunction.

Some suggestions for the future work include:

1. A microcontroller chip can replace the microcontroller module and surface mount components can be used on the printed circuit board to further reduce the size and weight of the device.

2. The wired connection between the device and the computer can be replaced with a wireless technology like Bluetooth® to allow real-time data monitoring.

3. Include a methodology to study how riders’ position on the seat affects the perineal artery occlusion.

4. Perform an evaluation on bicycling shorts and its influence on the perineal artery occlusion.

5. Identify solutions to alleviate perineal artery occlusion among cyclists.
CITED LITERATURE


VITA

Sujeeth Parthiban

Objective

Seeking a biomedical engineer position where I can use my research and product development skills.

Education

• PhD in Bio medical engineering, University of Illinois at Chicago, GPA: 3.85 / 4.00, 2009 – 2014.
• Bachelor of Technology in Bioengineering, SASTRA University, GPA: 9.25 / 10.00, 2005 - 2009.

Work experience

Research Senior Engineer I – Zimmer, Warsaw. 12 / 13 - Current

• Vital team member of FDA 21 CFR 820 Design History File (DHF) Remediation.
• Spearheaded verification/validation activities and updated test reports used in 510(K) submissions.
• Mechanical testing of orthopedic implants to evaluate safety and effectiveness in accordance with industry standards and FDA guidance documents.
• Worked closely with manufacturing and complied process changes after 510(K) submission to understand its impact on device safety and performance.
• Key team member to review the entire design control process and participated in design reviews.
• Prepared design control documents necessary for FDA audit.

Graduate Research Assistant - University of Illinois at Chicago, Chicago. 08 / 12 - 10/13

• Developed “Smart” apparel with sensors embedded to improve sports performance in cyclists.
• Lead researcher in developing a Bluetooth 4.0 based health and fitness device to prevent sports injuries.
• Developed CAD models in Pro-Engineer to rapidly prototype design ideas using 3D printer.
• Used ANSYS software to model blood flow in perineal arteries (computational fluid dynamics).
• Performed finite element analysis using ANSYS & ABACUS to identify design flaws in CAD models.
• Worked with human subjects (mostly athletes) for research studies.
• Studied force/pressure distribution and its impact during bicycling.
• Involved in ergonomic redesigning of laparoscopic medical instruments with haptic feedback.
• Performed validation studies of the laparoscopic medical device using animal models.
• Studied tissue damage due to localized forces during minimally invasive surgeries.

Research Assistant - University of Illinois at Chicago, Chicago. 08 / 09 - 07 / 12
• Developed a novel force sensing medical device from idea to pre-clinical prototype stage.
• This medical device was licensed and in the process of commercialization by a company.
• Devised IRB approved protocol to recruit human subjects for clinical study.
• Verification & validation testing of medical device prototypes.
• Collaborated with multidisciplinary team of physicians, surgeons and engineers.

Volunteer/ Intern – Rush University medical center, Chicago. 05 / 11 – 08 /12
• Studied stress associated with varus and valgus misalignment in knee implants.
• Developed finite element models of normal and misaligned knee implant.
• Studied mechanical properties of ACL and tribology of knee joints using MTS Instron.
• Software used: Pro-E, ANSYS, ADINA.

Academic projects

ME 447, Design and analysis of total knee replacement system:
• Used Pro - E to design modular components of total knee replacement system.
• Used Pro-E assembly tool to assemble individual components.
• Used ABAQUS to run analysis on the model and identified potential failure areas.
• Proposed optimum thickness of the UHMWPE component based on the analysis.

BIOE 594, Implant design
• Proposed a theoretical model of hip implant for obese patients.
• Obese patients are at higher risk for implant failure because of the abnormal load and accelerated physiologic corrosion.
• Designed a modified hip plant which can bear higher load with minimum change in dimensions.
BIOE 515, Spine Biomechanics

- Developed complex finite element model of spine (including bone, soft tissues and discs) to study the effect of nucleotomy.

Computer skills

C, MATLAB, LabVIEW, Pro Engineer (PRO E / Creo elements), ANSYS, ADINA, HEEDS, Electronic design automation tools (gEDA), DOORS, Processing, Word, Excel, PowerPoint.

Technical skills

Design: CAD, rapid prototyping, machining and fabrication.
Electronics: Embedded systems, signal processing, circuit design.
Mechanical: Force sensors, instrument calibration, instron testing, finite element analysis.

Awards


Publications


APPENDICES

Appendix A – Copyright clearance for figures 2.4, 2.5 and 2.6

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Appendix B – Copyright clearance for figure 2.7

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Appendix C – Program of the device

Dynamic C final source code for Bike project using Rabbit hardware

As soon as the device is ON it starts collecting the DATA and displays it when connected to a display device. It also stores the data which can be later collected using FTP.

BY SUJEETH PARTHIBAN ON 06/14/2010.

/*

#define auto // Default variable type is auto, otherwise is static
#define DO_FAT // Define if use FAT filesystem
#define TCPCONFIG 100 // Use custom TCP/IP settings
#define TIMEZONE -6
#define FTP_ROOTDIR "/A" // Should begin and end with ".".

#define xmem // Map memory to xmem part

// For FAT usage
#define INPUT_COMPRESSION_BUFFERS 4
#define FAT_USE_FORWARDSLASH
#define FAT_BLOCK
#define "fat.lib"

// For FTP usage
#define HTTP_NO_FLASHSPEC
#define SSPEC_FLASHRULES
#define FTP_EXTENSIONS
#define "dctcp.lib"
#define "ftp_server.lib"

// Define user groups
#define ANONYMOUS 0x0001
#define NOBODY 0

// Anonymous can read, nobody can write
SSPEC_RULESTART
SSPEC_RULE( "/A", "fat-A-realm", ANONYMOUS, ANONYMOUS, SERVER_FTP )
SSPEC_RULEEND

#define ADC_SCLKBAUD 115200ul
#define NUMSAMPLES 1 // change number of samples here
#define STARTCHAN 0
#define ENDC chan 3 // End channel 7 is the maximum
#define GAINSET GAIN_1 // Other gain macros possible
#define PERIOD 100 // Define the Period here in mSec
#define BUFFER_COUNT 2 // create buffers
#define BUFFER_SIZE 128 // Define buffer size -128

// Pin configuration is defined here
#define RCM40xx.LIB

C:\Users\sujeeth\Dropbox\work\UIC\lab\bike programs\MODIFIED BIKE PROGRAM for bike1.c Wednesday, October 09, 2013 12:19 PM
Appendix C (continued)

// Add these lines to redirect run-mode printf output at 115200 baud to serial port A

#define STDIO_DEBUG_SERIAL SADR  // desired serial port is selected
#define STDIO_DEBUG_BAUD 115200   // desired baud rate is selected
#define STDIO_DEBUG_ADDCR // for carraige return

/*
**********************************End FLASH constants *********************************
*/

/*
ADC
*********Begin ADC Functions **********
*/

// set the STDIO cursor location and display a string
void DispStr(int x, int y, char *s)
{
    x += 6x20;
    y += 6x20;
    printf ("\x1B=\%c%c%s", x, y, s);
}

////////////////////////////////////////////////////////////////////////
// millisecond delay
////////////////////////////////////////////////////////////////////////
nodebug
void msDelay(unsigned int delay)
{
    auto unsigned long done_time;

    done_time = MS_TIMER + delay;
    while( (long) (MS_TIMER - done_time) < 0 );
}

/*/ 
Begin ADC conversion and sampling here
*******************************************************************************/

/*
When the ADC function is called inside of logger, a lead along with the
number of samples collected from that lead is passed to this function to
be digitized.
*/
nodebug
unsigned int sample_ad( int channel, int num_samples )
{
    auto unsigned long rawdata; // analog data collected by lead
    auto unsigned int sample;  // keeps track of number of samples
    auto unsigned int cmd;     // used to store results of the formula below

    //convert channel and gain to ADS7870 format in a direct mode

    return (rawdata & 0x3f);  // strip off the sign bit
}
Appendix C (continued)

```c
// 1st mode is FTP tick, FTP is always running, mode idle is not necessary
// Second mode is logging
enum E_MODE
{
    MODE_IDLE = 0, // defines default mode
    MODE_LOGGER = 1, // defines mode where buffers are being filled dumped to file
    MODE_ERROR = -1 // defines error mode
} mode;

unsigned int buf[ BUFFER_COUNT ][ BUFFER_SIZE ]; /* buf includes first and second buffer, i.e.,
buf[0][] and buf[1][],
so that they can make a turn to receive data. */

unsigned int bufferR[ 3000 ]; // for displaying first 60 seconds of data, 60x5x10
unsigned int buf_num;         // the buffer currently being filled
unsigned int buf_len;         // number of elements in the current buffer
int buf_full;                 /* index of the full buffer, -1 if none are full. It can be a
kind of flag.
If buf[0][] is full, then buf_full is 0. If buf[1][] is full,
then buf_full is 1.
We can use buf_full to decide which buffer content should be
saved. */
unsigned long int sample_time; /* time of last conversion, Used "long int" type to make sure the
sample time
   can be counted correctly because its unit is millisecond. */

unsigned int counter;         // To mark every new scan can be counted. We let it be ranged from 0
to 2^16-1 (65535).

void init_logger( void )
{
    buf_num = 0;        // keeps track of the buffer being filled
    buf_len = 0;        // keeps track of the number of elements in each buffer
    buf_full = -1;      // keeps track of the index of full buffer
    counter = 1;        // counts each scan of ADC

    anaIn( 0, SINGLE, GAINSET ); // do first conversion.. may take a while

```

96
Appendix C (continued)

```c

sample_time = (unsigned long int)MS_TIMER; // initial conversion time

} />

Begin logging routine
**************************************************************************
void logger(void)
{
  unsigned long int the_time; /* Using "unsigned long int" type to make sure the_time can be
recorded correctly because its unit is millisecond. */
  unsigned int chan; // For channel scan loop

  the_time = (unsigned long int)MS_TIMER; // retrieves current time

  if( the_time - sample_time >= PERIOD ) // last conversion was over PERIOD ms ago
  {
    sample_time += PERIOD; // current conversion's time

    // cycles through all the leads
    for( chan = STARTCHAN; chan <= ENDCAN+1; chan++ )
    {
      // inserts "counter" before recording the first channel data
      if( chan == STARTCHAN )
      {
        //--1;// To mark each new scan of ADC
        buf[ buf_num ][ buf_len++ ] = counter;
        counter++;
      }
      else
      {
        // inserts the digitized data in the buffer being filled
        buf[ buf_num ][ buf_len++ ] = sample_ad( chan-1, NUMSAMPLES );
      }
    }

    // if the buf_num is full, moves to next buffer to receive data.
    if( buf_len >= BUFFER_SIZE )
    {
      buf_full = buf_num; /* Here buf_num is the buffer index. The flag buf_full is
set as this buffer's index to show this buffer is full and its
content can be saved. */
      buf_len = 0;
      buf_num++;
      if( buf_num >= BUFFER_COUNT )
      {
        buf_num = 0; // To make sure buf_num is ranged between 0 and 1.
      }
    }
  }
}

/* *************************************************/
```

97
End logging routine
*************************/

/* ******************************************
Begin Main Program and call routines in the main program
*******************************************/

void main()
{
    auto int rc,       // return code
    i, k,            // for find FAT partition
    uid,             // handle,
    sw;              // switch code: ON (1) and OFF (0)

    unsigned long int the_time;
    unsigned long done_time;

    auto int channel, n;
    auto unsigned int avg_sample;
    auto char sf[70];
    //auto char data[ DATA_SIZE ];
    auto float sd_inputs[ENDCHAN*1];

    unsigned int count;
    char fname[ 12 ];
    long prealloc;
    FATfile file, countfile;
    fat_part *part;

    brdInit();            // This function initializes parallel ports, this is needed
                          // for the ADC, hardware switch and LEDs.

    counter = 1;          // Assign the first scan mark is 1
    mode = MODE_IDLE;    // FTP running, nothing is being recorded
    BitWRPort(PADR, &PADRShadow, 1, 0); // Turn on a LED to show the device is on

    // Note: sspec_automount automatically initializes all known filesystems.
    rc = sspec_automount( SSPEC_MOUNT_ANY, NULL, NULL, NULL );
    if ( rc )
        // If failed
    part = NULL;         // find first mounted partition
    for ( i = 0; i < num_fat_devices * FAT_MAX_PARTITIONS; ++i )
    {
        if ( ( part = fat_part_mounted[ i ] ) != NULL )
        {
            break; // found a mounted partition, so use it
        }
    }

    sock_init();        // This function initializes the tcpip for FTP connection.
ftp_init(NULL); // This function initializes the FTP server.

// Add users and ensure users are in the correct group(s).
uid = sauth_adduser("anonymous", ",", SERVER_FTP);
sauth_setwriteaccess(uid, SERVER_FTP);
ftp_tick(); // FTP daemon is always on

for(;;)
{
    switch( mode ) // always enters MODE_IDLE case first
    {
    case MODE_IDLE:
        BitWrPortI( PADR, &PADRShadow, 0,1 ); // Turn off LED 1
        BitWrPortI( PADR, &PADRShadow, 0,0 ); // Turn off LED 0
        BitWrPortI( PADR, &PADRShadow, 1,0 ); // Turn on LED 0
        //ADCinfo(); // FTP running
        ftp_tick();
    }
    
    sw = BitRdPortI( PBDR,4 ); // Check for switch 4 and store the value in SW

    if( sw == 1 ) // If switch is flipped to "ON", mode changes to logging.
    {
        mode = MODE_LOGGER;
        break;
    }

    // Initially start up A/D oscillator and charge up cap
    anaIn(0,SINGLE,GAINSET);
i=0;
j=0;

    for(channel = STARTCHAN; channel <= ENDCAN; channel++)
    {
        // Sample each channel
        ad_inputs[channel] = sample_ad(channel, NUMSAMPLES);
    }

    // display[0] = '\0';
    for(channel = STARTCHAN; channel <= ENDCAN; channel++)
    {
        printf("%f",ad_inputs[channel]); /* Printing the force in newtons. Formula should be */

    }

    msDelay(500); // Use this to set frequency
    printf("%d\n",i);
i = i+1;
}
break;

case MODE_LOGGER:
    BitWrPortI( PADR, &PADRShadow, 0, 0 ); //Turn off LED 0
    BitWrPortI( PADR, &PADRShadow, 0, 1 ); //Turn on LED 1
    BitWrPortI( PADR, &PADRShadow, 1, 1 ); //Turn on LED 1

    init_logger(); // calls logging function above to start recording.

    prealloc = 0;

    /* Open COUNT, if there is no COUNT file create it and store a number to begin with. */
    fat_Open(
        part, // partition pointer from fat_AutoMount
        "COUNT.TXT", // Name of file. Always an absolute path name.
        FAT_FILE, // Type of object, here, a file called COUNT.txt.
        FAT_CREATE, // Create the file if it does not exist.
        &countfile, // Pointer to the file that is filled with data.
        &prealloc // Number of bytes to allocate if file does not exist.
    );

    //If the file already exists read the file and increase the count by 1.
    fat_Read( &countfile, ( char*)&count, 2 );
    count++;

    // converts the unsigned binary integer value into the equivalent string
    utoa( count, fname );

    // append count (from above) to .txt and set as file name
    strcat( fname, ".bin" );

    // look in file at the absolute position
    fat_Seq( &countfile, 0, SEEK_SET );

    // write to file
    fat_Write( &countfile, ( char*)&count, 2 );

    // done writing, close file
    fat_Close( &countfile );

    // Do not pre-allocate any more than the minimum necessary amount of storage.
    prealloc = 0;

    // Open the same file for reading
    rc = fat_Open(
        part, // partition pointer from fat_AutoMount
        fname, // name of file
        FAT_FILE, // type is file
        FAT_CREATE, // create if not there
        &file, // fill in with details
        &prealloc // allocate bytes
    );
Appendix C (continued)

while( mode == MODE_LOGGER )
{
    logger();

    if( buf_full != -1 ) // buf_full should always be 0 or 1 depending on
        // which buffer is full.
    {
        the_time = (unsigned long int)MS_TIMER; // time is retrieved

        rc = fat_Write(
            &file, // File, as set by fat_Open()
            (char*)buf[ buf_full ], // type cast to char and write
            2*BUFFER_SIZE // Number of characters to write.
        );
        buf_full = -1;
    }

    the_time = (unsigned long int)MS_TIMER;
    fpt_tick();

    sw = BitRdPortI(PBDR,4); // Check for switch 4 and store the value in SW
    if( sw == 0 )
    {
        fat_Close( &file ); // close the file just written to

        // Delay 1 second to make sure data file be fully closed to prevent later
        // operation destroy this file.
        done_time = MS_TIMER + 1000;
        while( ( long ) ( MS_TIMER - done_time ) < 0 );
    }

    mode = MODE_IDLE;
}
}
break;

default:
    BitWrPortI( PADR, &PADRShadow, 1,5 ); // When in error mode light up LED 5 and 6
    BitWrPortI( PADR, &PADRShadow, 1,4 ); //When in error mode light up LED 5 and 6
    exit(1);
}
break;
}

while ( 1 )
{
    if ( kbhit() )
Appendix C (continued)

```c
{
    // Unmount all of the mounted FAT partitions & devices before exit
    for ( i = 0; i < num_fat_devices * FAT_MAX_PARTITIONS; i += FAT_MAX_PARTITIONS )
    {
        if ( fat_part_mounted[ i ] )
        {
            fatUnmountDevice( fat_part_mounted[ i ])->dev );
        }
    }

    exit( rc );
}
}`
Appendix D - Subject consent form

University of Illinois at Chicago
Consent/Authorization for Participation in Research Protocol Title: Study of Bicycle Seat Effects on Male Perineal Blood Flow
Principal Investigator: Craig Niederberger, M.D.
Phone No. 312-996-2779

You are being asked to be a subject in a research study. The study will involve 2 steps to measure bicycle seat effects on blood flow to a man’s perineum. The perineum is the region behind a man’s scrotum, which is in contact with seats when a man sits down. Before you decide whether to participate, you should know what the study is about, the possible risks and benefits, and what you will have to do in this study.

Your participation in this study is voluntary. Your decision whether or not to participate will not affect your current or future relationship with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship. Please read this form and ask any questions you may have; if you decide to take part in the study, you will be asked to sign this form to verify that choice.

Who is doing the research, and why is it being done?
The research is being conducted by Dr. Craig Niederberger in the Department of Urology at the University of Illinois at Chicago (UIC). The purpose of the study is to determine if bicycle seats affect blood flow to the perineum. Bicycle riding places perineal pressure which in turn affects perineal blood flow which can potentially affect a man’s ability to have an erection. Bicycle seat use has never adequately been tested for its effect on perineal blood flow. Each year, newer and “better” seats are released but what the true benefit to the rider has not been properly explained. The purpose of this study is to see if perineal blood flow can be adequately measured and what is the effect of a bicycle seat on this blood flow.

What procedures are involved?
There are 2 steps to determine perineal blood flow and how bicycle seats affect this flow. The first step will be to use doppler ultrasound to measure the perineal blood flow in the Ultrasound suite of University Illinois Chicago Medical Center. Ultrasound uses sound waves, which the patient cannot hear, to measure blood flow. At this ultrasound visit, patients will be asked to lie down on their back, with their legs in a frog-leg position on an exam table. This will allow access to the perineum. An ultrasound probe will be used to measure the flow through the perineal/cavernosal arteries which run through the perineum and ultimately supply blood for erections. By applying increasing pressure, the occlusion pressure will be measured along with blood flow at various applied perineal pressures. Also, we will stop the procedure if you feel any discomfort, although we do not anticipate any. This first study visit will take 30 minutes to complete.
The second step will involve a typical bicycle ride using the subjects own bicycle where perineal pressures will be measured. The investigators will not ride along side the subject. We use disposable sensors and a clear adhesive tape (tendor) to attach the sensors to the perineum. No shaving of the perineum will be required. The recording device is credit card size and will attach to the bicycle. The ride will take 30 minutes and will be on the Lake Shore Drive bike path where there is no rugged terrain and no extremes in altitude. The second study visit will take 45 minutes to complete. This will conclude your requirements.

**What about the potential risks and discomforts and benefits from this study?**

There are minimal risks to you during participation in this study.

At no point will your medical record be accessed but there is a minimal risk of loss of confidentiality with regards to your name, date of birth, and contact info. This information will be placed on a password-protected computer, accessible only by Dr. Niederberger and the research staff, but there is a possible loss of confidentiality since absolute confidentiality cannot be guaranteed.

There is also the risk of riding a bicycle which has low probability of risk as you are an experienced rider. These potential risks involve, potential falls/accidents, weather related accidents (where the ride will be stopped). Should any trauma occur, we will stop the ride and you will receive medical attention immediately.

There is minimal risk related to the transducers, as they are insulated, have no electrical current in them, are tiny and pose no health risk to the subject.

You will not directly benefit by participating in this study, but others in the future may benefit from what we learn.

**Will you be paid for your participation in this research?**

There will be no compensation for your participation.

**What about privacy and confidentiality?**

Researchers will store information gathered about you on a password protected computer. Care will be taken to keep this information confidential, but there is a possible loss of confidentiality since absolute confidentiality cannot be guaranteed. You should know that in any research publications and scientific meetings coming from the research, you will not be identified individually.

There are University, state and federal agencies and officials who ensure the protection of human subjects in research, and they might access your research records in line with their official duties or as required by law.
Who should you contact if you have questions?
The researcher conducting this study is Dr. Craig Niederberger. You may ask any questions you have now. If you have questions later, you may contact the researcher at: 312-996-2779

What are your rights as a research subject?
If you feel you have not been treated according to the descriptions in this form, or you have any questions about your rights as a research subject, you may call the Office for the Protection of Research Subjects (OPRS) at 312-996-1711 (local) or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu.

Signature of Subject
You have read (or someone has read to you) the above information. You have discussed the procedures, risks and benefits of the study with the researchers. You have been given an opportunity to ask questions and your questions have been answered to your satisfaction. You agree to participate in this research. You will be given a copy of this signed form for your information and to keep for your records. The original copy will be stored in the research file.

______________  ______________
Signature          Date

_____________________
Printed Name

I have discussed the above research study, including the purpose, procedures, risks, and benefits, with the subject. I encouraged questions and answered all questions that were asked. The subject is aware that he/she does not have to participate in the research and may later withdraw their Authorization.

______________  ______________  ____________________
Signature of Person obtaining consent     Date     Printed Name
(Same as Subject's)

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