Device and Method to determine Perineal Artery occlusion during Road Bicycling

Sujeeth Parthiban, James M. Hotaling, Samuel J. Ohlander, Amit P. Baftiri, Sally Freels, Craig S. Niederberger

Abstract— **Greater than 60 million American men who ride bicycles are at risk of developing erectile dysfunction. One possible reason is occlusion of the perineal arteries. Researchers relied on indirect methods and stationary models to study this problem. We developed a novel system to quantify occlusion among bicycle riders during a road bike ride. Our verification and validation activities show that this system can be safely used on human subjects to measure perineal artery occlusion. The method described in this paper provides a valuable tool to the researchers to study or to develop new solutions that alleviate this problem. The outcomes of these efforts will help millions of cyclists worldwide.**

I. INTRODUCTION

Bicycling is an activity engaged by millions of people worldwide. An estimated 780000 Americans used bicycles as primary means of commute[1]. 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[2]. 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, the saddle supports more than fifty percent of his weight[3]. The association between bicycling and erectile dysfunction is well addressed in the scientific literature[4]. 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. Many published researches in this field focused on studying the saddle- perineum interface pressure[5,6]. The general consensus is to reduce/eliminate pressure over the perineum. Based on this idea, several new seat designs are introduced in the market. Several published literatures point that arterial insufficiency caused by compression of the perineal arteries as the main reason[4]. Also force measurements done during bicycling alone may not be conclusive. The differences in musculature and adipose tissue deposits in the perineum region among the general population can widely alter the force required to cause occlusion. This warrants a need for a system to measure force exerted directly on the perineal arteries and a method to correlate the force measured during cycling to a critical threshold that can vary between subjects. We developed a novel force sensing device to measure force on the perineal arteries reliably. We also developed a dependable method to determine occlusion threshold for each subject and to place the sensors.

II. METHODS

A. Selection of sensors

1 lb. Flexiforce® sensors (Tekscan, Boston, MA) were selected to measure force because they are thin, flexible and virtually unnoticeable to the riders. Flexiforce® sensors are shown to have better linearity, repeatability and time drift than other flexible force measurement solutions. They also have better dynamic accuracy[7]. 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 we modified the sensor recommended drive circuit to make the 1 lb. sensor measure forces in the range of 1 – 15 Newton.

B. Construction of the device and calibration

We chose to use Rabbit Core module as our microcontroller module. The device was developed using gEDA, an open source electronic design automation tool. gshem was used to develop the circuit. 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. Performance testing was done on the assembled device (Figure 1) to ensure battery longevity, data collection and storage. The device was calibrated using a custom built calibration apparatus (Figure 2). The principle of our calibration is to apply increasing amount of known compressive force to the Flexiforce® sensors and measure the output from the device. The output from the sensors can be plotted against the known force. Regression analysis can be used to interpolate unknown force values (Newton) from the known device output (millivolts).

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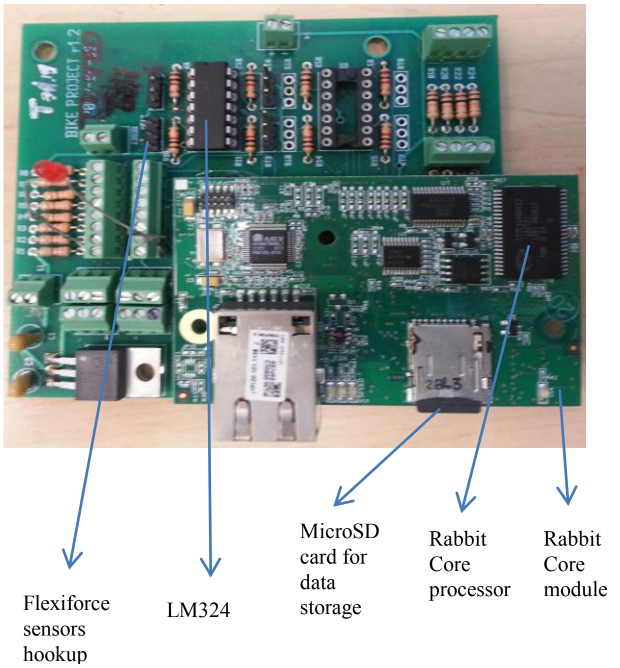

Figure 1: Populated printed circuit board with the microcontroller module. This device was used to collect and store the data from bicycle riders.

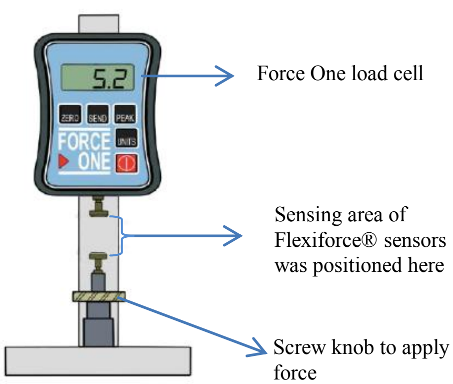

Figure 2: FORCE ONE™ calibrator. The custom built apparatus used to calibrate the *Flexiforce®* sensors.

C. Device verification

We verified 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. 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 evaluate drift in Flexiforce® sensors. Also the force was applied in a random fashion within the range to simulate real-time conditions. 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 was calculated by observing the difference between mean applied force and the average device output.

The Flexiforce® sensor manual recommends that the applied load should be distributed evenly across the sensing area to ensure accurate and repeatable force readings. But because of our application's requirement it may not always be possible to follow that recommendation. So we conducted an experiment to study how much the load distribution over the sensing area influences our device output. The diameter of the sensor was roughly divided into 9 equal sections 1 mm apart. Uniform force was applied using a puck across the entire sensing area. Then the puck was moved to the first division representing force application across 90% of the sensing area. The process was repeated till the last division.

D. Identification of Perineal arteries and determination of occlusion force.

A stainless steel rod matching the diameter of the sensor was fabricated. The Flexiforce® sensor was affixed to the circular end of the rod without interfering with the sensing area. This custom probe was connected to one of the channels of our device to measure force. Static weights were applied to this force probe and reliability of force measurement was ensured.

5 subjects were recruited from the university population. Subjects' heart rate was increased to 120 by moderate exercising (Stair climbing). Then, 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 using a GE LOGIQ® E9 (GE Healthcare, Milwaukee, WI, USA) Doppler ultrasound probe. The force sensing probe was placed right below the ultrasound transducer and gradually increasing force was applied on the perineum until cessation of blood flow in the perineal artery was observed in the ultrasound. This process simulates the *in vivo* occurrence of perineal artery occlusion by bicycle seats. A trigger switch was pressed at that point and force required to completely occlude the artery was recorded. Several methods to measure this occlusion force by placing the sensors directly on the ultrasound transducer, compressing the arteries using bicycle seats were attempted. These methods failed for different reasons. The entire procedure was done twice on the left and right perineal arteries to account for variability. Mean arterial occlusion force was calculated from these repeated measurements. The entire process was completed well before the subjects returned to their resting heart rate. We strived to measure occlusion force at consistent locations for all the subjects.

After each occlusion force measurement, the location was marked using surgical marker. Flexiforce® sensors were fixed at those positions overlying the perineal arteries (Figure 3) using Tegaderm™ (3M, St. Paul, MN, USA). It is practically not possible for a subject to exert force on the arteries without compressing either of the sensors.

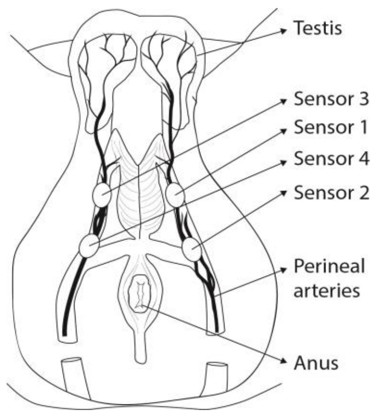

Figure 3: Position of sensors on the Perineum. The consistent positioning of the sensors over the perineal arteries is critical in obtaining repeatable data from different subjects. This was accomplished using Doppler Ultrasound.

E. Collection of perineal force data during road bicycling

Subjects bicycled on a standard city road course for 0.5 miles using a standard seat. 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. Subjects were instructed to remain seated during the entire course. Immediately following the ride, measurements were recorded when they are sitting on a normal office chair. Perineal force values were compared against the subject's occlusion force to determine duration of occlusion for each subject. We expressed it as proportion of ride time to maintain consistency.

III. RESULTS

The average drift of our device was 0.02 Newton with a maximum drift of 1 Newton and relative accuracy was 1%. We didn't observe any statistically significant difference between the output of our device and the applied force (Table I). These results indicate that the device can be used to measure dynamic force values in a reliable manner.

Table I: t-TEST COMPARING APPLIED FORCE TO THE AVERAGE DEVICE OUTPUT

Test condition	**Mean**	**Std. Error Mean**	**95% confidence intervals**	
			Lower	**Upper**
Applied force vs. average device output	10.55 10.49 0.10 (Difference)	0.91 0.86	-0.01	0.22

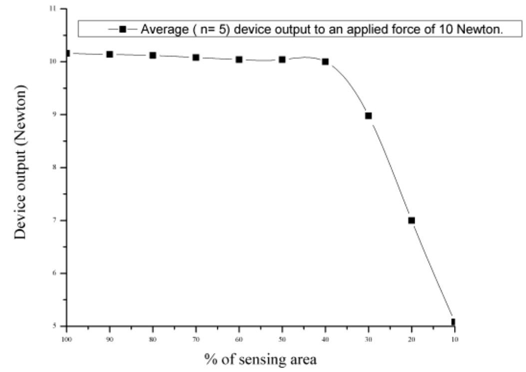

Figure 4: Device output for varying load distribution. The device output is very consistent when the load is applied over at least 40 % of the sensing area.

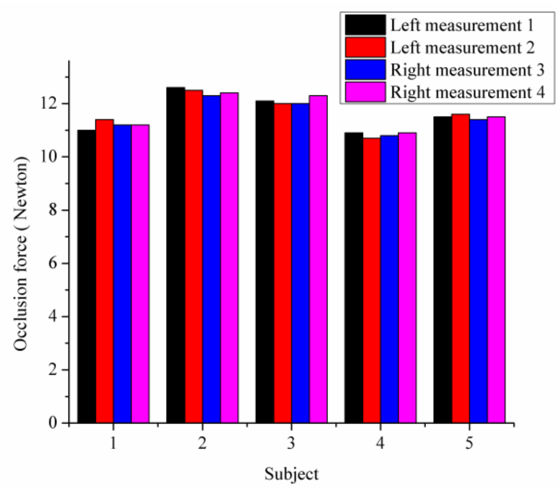

Figure 5: Occlusion force measurements of all the subjects.

Figure 4 demonstrates that the device output varies with varying load distribution. The maximum variability is 0.3 Newton and the average variability is 0.2 N, when at least 40% of the sensor area is utilized. It was determined that these results meet the requirements of our application.

Though there was variability in occlusion force measurements (11.66 ± 0.66) between the subjects it was expected. The repeated readings within the subjects are fairly clustered together highlighting the reliability of the measurement (Figure 5).

The results obtained for two of the subjects are shown in Figure 6. Force exerted on the perineal arteries varied during the ride. Variations were also observed in the force pattern among the subjects. All the subjects showed occlusion of perineal arteries for 56% – 85 % of the ride. On contrary, subjects didn't show any occlusion when sitting on the chairs and barely exerted force on the perineal arteries.

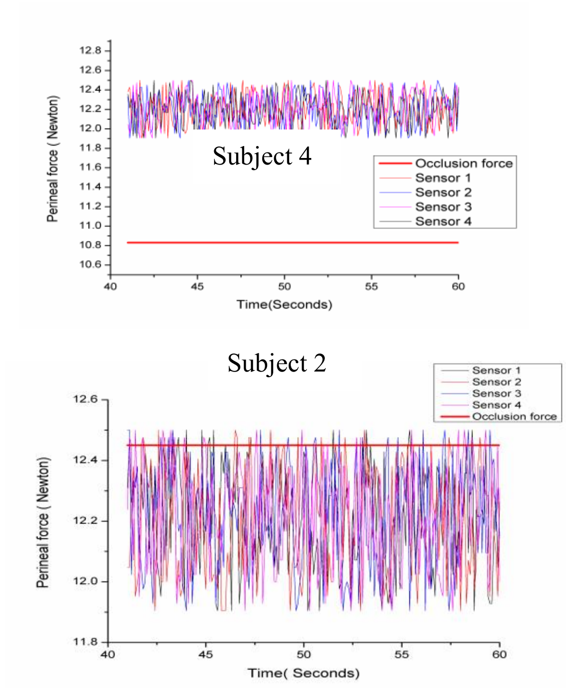

Figure 6: Perineal forces and occlusion force for 2 subjects were shown. Notice how occlusion force variation among the subject influences the duration of occlusion.

IV. Discussion

Force measurement 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 physical testing performed on our device concludes that it can measure highly dynamic loading cycles experienced during bicycling with reasonable accuracy.

Measurement of occlusion force is an important part of our study. It gives us the critical force when the blood flow to the penis is completely stopped. The occlusion force was used to estimate the duration of occlusion during road bicycling. Among our subjects, subject 2 showed the highest occlusion force of 12.45 Newton, while Subject 4 showed the lowest of 10.83 Newton. The perineal forces experienced by both the subjects were within a tight envelope of 11.8 Newton – 12.45 Newton. From the data, we can interpret that subject 4 spent majority his ride time above his occlusion force, while subject 2 rarely exceeded his threshold. So subject 4 is likely more vulnerable to developing erectile dysfunction than subject 2. Instead of using the subject specific measurements, if we made that interpretation based on the average occlusion force of 11.6 Newton (N = 5), we might have concluded that both of their arteries were occluded significantly. So we believe, determination of the occlusion force for each subject is a critical step and need to be incorporated in the study to provide meaningful data.

We were able to collect successful data from all the five subjects during road bicycling. The determination of occlusion force and collection of perineal forces were mainly conducted for validating our device and methods. All the subjects showed occlusion of perineal arteries during bicycling. This was expected because nosed seats were shown to exert significant amount of pressure on the perineum. On contrast, perineal forces while sitting on an office chair were not enough to cause any occlusion. This was again expected because, when sitting on the chair most of the weight is shared by our sit bones rather than the perineum.

It remains to be seen how the perineal artery occlusion varies between different seat designs. Also, detailed statistical analysis need to be performed on a larger study group to provide significant conclusions.

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