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Back Muscle Endurance as Measure by Ito Test Duration

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Back Muscle Endurance as Measure by Ito Test Duration

by

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A thesis submitted in partial fulfillment
of the requirements for a degree of
Master of Science in Public Health
Department of Environmental and Occupational Health
College of Public Health
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ABSTRACT

Lower back pain remains one of the most common problems in public health throughout the industrialized world (Strine and Hootman) (Shiri, Solovieva and K.). The prevalence is about 39-54% annually and 60-65% in a lifetime (Hillman, Wright and Rajaranam) (Leboeuf-Yde, N. and Lauritzen). In the United States, lower back pain is the second most common cause of disability, and is the highest cause of disability among men (Center for Disease Control, 2009). An individual quantitative physical examination to detect muscle deficiencies would be very useful for proper placement of workers in demanding physical jobs where back injuries are common. Trunk muscle extensor endurance might be the best approach for this issue.

INTRODUCTION

Lower back pain remains one of the most common problems in public health throughout the industrialized world (Strine and Hootman) (Shiri, Solovieva and K.). The prevalence is about 39-54% annually and 60-65% in a lifetime (Hillman, Wright and Rajaranam) (Leboeuf-Yde, N. and Lauritzen), with estimates as high as 80% in adults (National Institute of Neurological Disorders and Stroke). Lower back pain can not only lead to physical deconditioning, but to psychological distress. In the United States, lower back pain is the second most common cause of disability, and is the highest cause of disability among men (Center for Disease Control, 2009).

Chronic back pain can lead to a downward spiral of decreasing physical activity, increased nociceptive sensations, mental health burden, and disability (Demoulin, Vanderthommen and Duysens). In the United States, lower back pain is the second most common cause of disability, and is the highest cause of disability among men (Center for Disease Control). The main components of physical deterioration involve lumbar spine discomfort, decreased muscle endurance, and neuromuscular inhibition. Studies show that multidisciplinary approach is beneficial for patient reconditioning and typically include physical therapy for core strengthening and trunk endurance training as well as biopsychosocial rehabilitation, back massages and acupuncture.

(Mayer, Gatchel and Kishino) (Donovan WH, Dwyer AP).

An individual quantitative physical examination to detect muscle deficiencies would be very useful for proper placement of workers in demanding physical jobs where back injuries are common. Trunk muscle extensor endurance might be the best approach for this issue.

The relationship between lower back pain and factors such as age, body mass index BMI, and occupational risks are well examined in the literature, and it shows a strong correlation between heavy works and lower back pain (Hartvigsen J1, Bakketeig LS). Various occupational physical stressors are associated with lower back pain, particularly for non-sedentary occupations. Some of these stressors include heavy body armor among police officers (Burton, Tillotson and Symonds), repetitive task of rubber tapping, cutting lines on the bark of rubber trees amongst rubber farmers (Udom, Janwantanakul and Kanlayanaphotporn), and prolonged bending (Tella, Akinbo and Asafa). The Social Security Administration classifies jobs as sedentary, light, medium, heavy, and very heavy work. A Scandinavian review found that lifting, specifically manual materials handling (not patient handling) as a risk factor for lower back pain (Hoogendoorn, van Poppel and Bongers).

This type of work would typically fall under the category of medium work which "involves lifting no more than 50 pounds at a time with frequent lifting or carrying of objects weighing up to 25 pounds" or heavy work which "involves lifting no more than 100 pounds at a time with frequent lifting or carrying of objects weighing up to 50 pounds" (Social Security Administration).

This research focuses on men, who work manual labor jobs in construction, and those that have a non-sedentary labor job is among the inclusion criteria further discussed in the methods section.

It is generally accepted that the prevalence of lower back pain increases with age, possibly due to reduced muscle strength and joint flexibility, as well as the occupational risks mentioned above. A study on manual material handling tasks, such as lifting and lowering a load, found that age related differences in the mechanical behavior of the lower back tissue results in a change in methods of movement that can lead to a higher risk of lower back pain (Shojaei, Vazirian and Croft). Occupational stressors also build up over time and increase low back pain with age. A study of age-specific lower back pain among male dancers found that 54.9% of dancers surveyed between 18 to 24 reported lower back pain and 63.4% of dancers over 25 years reported lower back pain. (Miletic, D, A Miletic and B Milavic)

Lower back pain has been related to body mass index and has been thoroughly studied but the findings were inconsistent. A study of adolescents found that among males, higher BMI was significantly associated with low back pain (Hershkovich, Friedlander and Gordon). Interestingly, a study on workers who regularly experienced whole body vibration, typically drivers of different large vehicles, found that BMI does not influence the risk of lower back pain in a population that is already exposed to the vibrations (Noorloos, Terseeg and Tiemessen). The most common test used to measure muscle endurance is the isometric muscle testing, which is cost effective and requires little equipment.

Isometric endurance testing is reliable (Toshikazu Ito, RPT, Osamu Shirado, MD, PhD) and relevant for predicting future back pain: isometric lower back muscle endurance deficiency has been shown to be a risk factor for lower back pain (LBP). Equipment to carry out isometric tests is inexpensive and easy to perform. They also limit the motion of the spine, making them ideal for patients with lower back pain issues.

A 2001 review of isometric back extension endurance tests concluded that the Sorensen test was the most clinically useful and ease of implementation for both subject and clinician (Moreau, Green and Johnson). Typically, the Sorensen test measures how long a subject can keep the unsupported trunk of the body horizontal while lying on a table. Variations of the Sorensen test exist, referred to as modified Sorensen tests. The Sorensen test is widely preferred, but may have drawbacks. Results can show a wide range of fatigue time, possibly attributed to the variety of test methods (Pitcher, et al, 2007). Studies have also shown that the hip extensor muscles can be an influential factor in fatigue time (Moffroid, Reid and Henry) (Kankaanpää, Laaksonen and Taimela). Some participants may also stop the exercise due to spinal pain, leg pain, or pain in the abdomen (Latimer, Maher and Refshauge).

The Ito test, first described by Toskikazu Ito in 1996 (Ito, Shirado and Suzuki), has become a widely accepted modification of the Sorensen test. The Ito test requires only a pad under the abdomen, being even simpler than the traditional Sorensen test. One study found the Ito test to be a valid substitute for the Sorensen, and possibly able to assess back muscle endurance more specifically than the Sorensen (Müller, Stassle and Wirth). The Ito test is the simplest variant test of the Sorensen as it can be easily performed outside a medical office; therefore it was chosen for this research. In this research the Ito test was performed only once, not twice (72 hours after the first one). in comparison to the article done by Ito in 1996. (Ito, Shirado and Suzuki)

Is important to mention that in this research the Ito test was performed only once not twice (72 hours after the first one) in comparison with article done by Ito, Shirado in 1996 (Toshikazu Ito, RPT, Osamu Shirado, MD, PhD).

Objective: To assess the relationship between age, BMI, and years working in labor to the Ito test duration exercise among male construction workers.

Hypothesis: Age, BMI and working labor are negative associated with Ito test duration, such as increased age, BMI and working labor will each decrease with Ito test duration.

Purpose: To review the usefulness of the Ito test as a test of trunk muscle endurance.

METHODS

All data collection took place at the Futbol 5 soccer complex in north Tampa, Florida in November 2016. Thirty participants, all males over the age of 21 and under the age of 45, took part in this study. This study and the following methods described were approved by the Institutional Review Board at the University of South Florida. They were all non-smokers with no previous back surgery or history of degenerative joint disease. History of back injury without surgery was not disqualifying. They were also not on any chronic pain medication. Workers in sedentary jobs were excluded. Participants were asked to complete short survey to verify that they met all of the study requirements. (Appendix 1)

The first step in the research procedure involved obtaining informed consent for participation. All individuals were asked if they were willing to participate, for free and with no direct benefit, in the research study. The investigator explained the reason for the study: to assess the correlation between age, BMI, and years working in labor to the time the participants can complete the Ito test.

The second step involved administering a brief survey (see attached questionnaire) to select participants that met the inclusion criteria. The willing participants that were selected for the study were then briefed on the Ito exercise. The explanation of the exercise was given at an elementary school language level to all participants. Participants were also informed that the test will be performed individually and only once.

Participants were warned of the risks involved in completing the exercise. If at any point the participant experienced back pain while carrying out the exercise, they were free to stop participating.

The participants were then asked to lie face down on the floor while holding the chest off the floor. The investigator then logged the times the participants could lift the upper trunk up off (Picture 1) of the floor and maintain their bodies in this position, without exceeding 5 minutes. (Appendix 2) All data collected was then manually put into SAS (SAS Institute, Inc., Cary, North Carolina, version 9.4), a statistical analysis software, and assessed using regression analysis.

RESULTS

An exploratory analysis was first performed to investigate the relationship between each independent variable (that includes age, BMI and years in current job) and the outcome (Ito test duration). An independent t-test was applied to investigate the bivariate relationship between each independent variable and the outcome. Ito test scores, among healthy workers was evaluated in an adjusted model that included age, BMI and years in current job using linear regression analysis.

Adjusted estimates and 95% confidence intervals were obtained for each independent variable. The regression procedure in SAS (SAS Institute, Inc., Cary, North Carolina, version 9.4) was used to conduct the analysis. All tests of hypothesis were two-tailed with a type 1 error rate fixed at 5%.

TABLES

Table 1 summarizes the study's descriptive statistics. Of the 30 participants in the study, ages ranged between 21 to 42, with a median of 31. Participants had a wide range of years working in manual labor: as little as three months to 20 years. Ito test durations varied between 42 seconds to almost three minutes.

Table 1. Summary statistics of subjects in the study

Age	N	30
	mean (SD)	30.7 (6.3)
	Median	31
	Min-Max	21-42
BMI	N	30
	mean (SD)	27.1 (4.0)
	Median	26
	Min-Max	20-35
Years in manual labor position	N	30
	mean (SD)	7.5 (5.9)
	Median	5
	Min-Max	0.25-20
Ito test duration, seconds	N	30
	mean (SD)	77.7 (34.7)
	Median	64.5
	Min-Max	42-177

Table 2 shows the results of the regression analysis. A sample size of 30 achieves 31% power to detect an R-Squared of 0.07 attributed to 1 independent variable(s) using an F-Test with a significance level (alpha) of 0.05000. The variables tested are adjusted for an additional 3 independent variable(s) with an R-Squared of 0.07.

Table 2. Adjusted model with Ito as outcome

Parameter estimate	Estimate	SE	p-value
Intercept	137.4	48.4	0.0087
Age	0.09	1.7	0.9569
BMI	-2.3	1.9	0.2394
Time	0.1	1.7	0.9376

FIGURES

Figures 1-3 show the scatterplots of the Ito test duration results based on the three independent variables: age, BMI, and years in a manual labor job.

The adjusted model with Ito time as an outcome show that none of the variables, age, body mass index or time working a manual labor job are statistically significant, even though they are all non-significantly correlated. Therefore body mass index, age, and years in a manual labor construction job are not valid predictor variables for Ito test duration

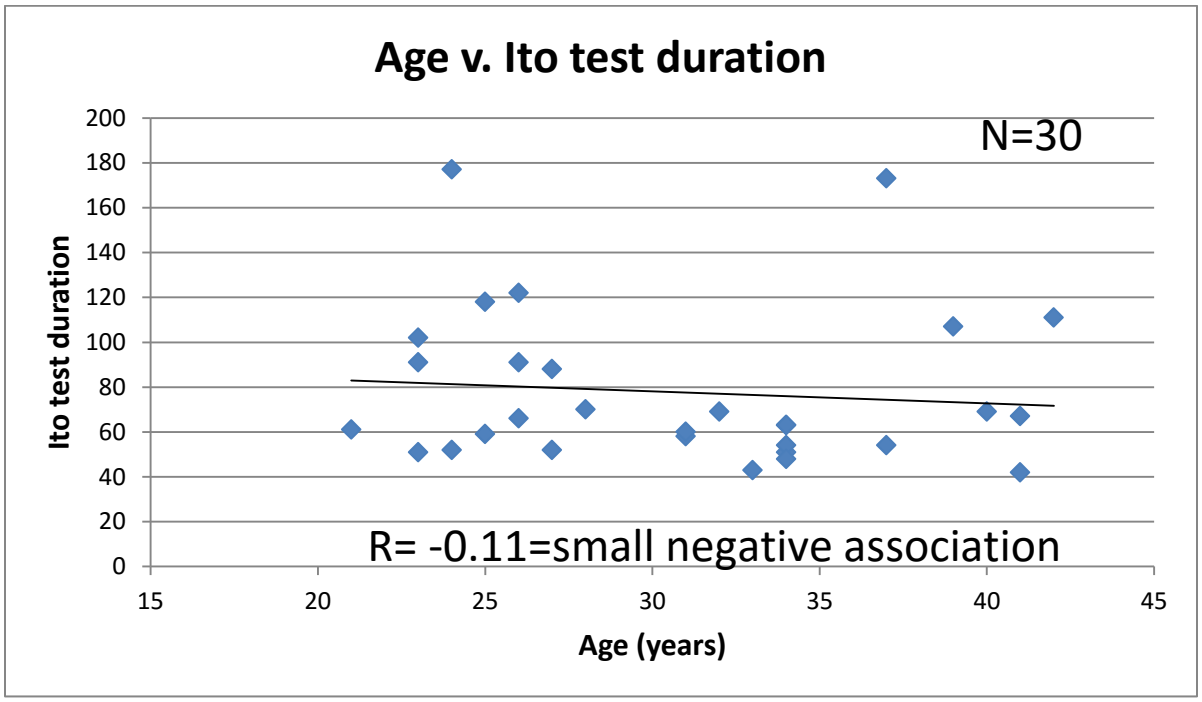

Figure 1. Ito test duration results with age as the independent variable

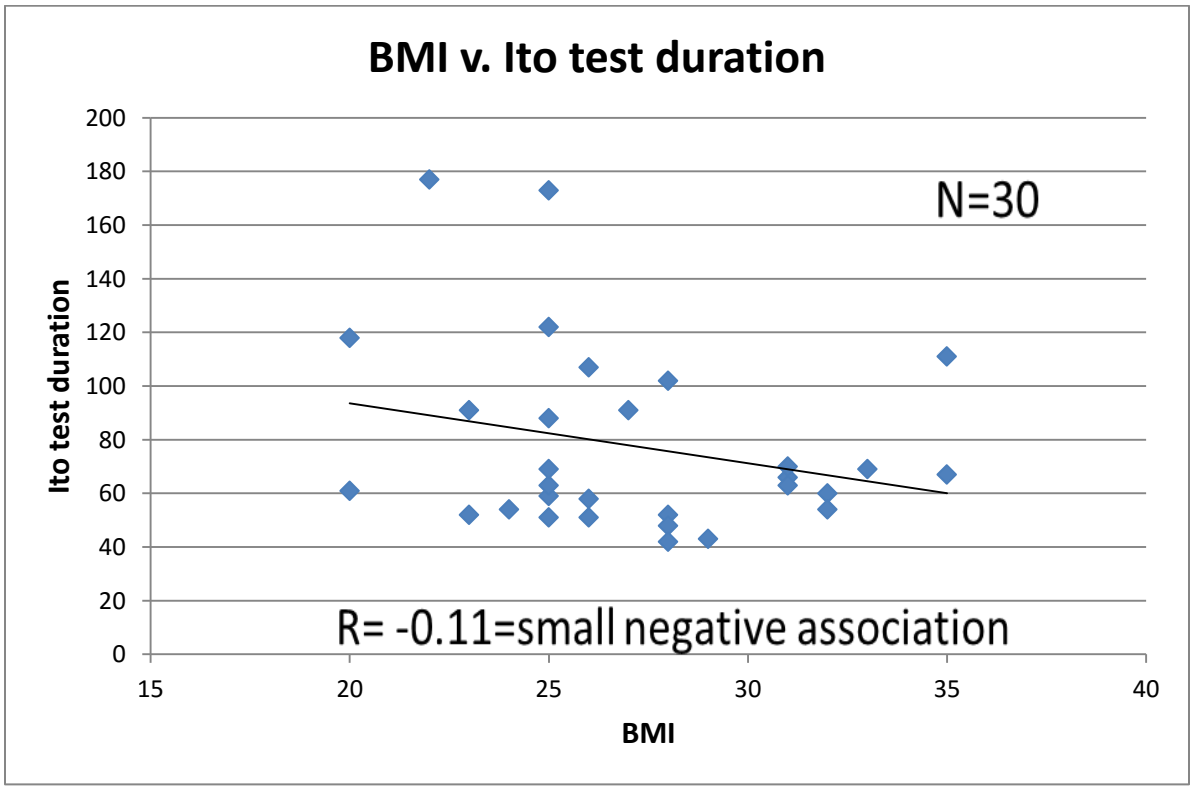

Figure 2. Ito test duration results with BMI as the independent variable

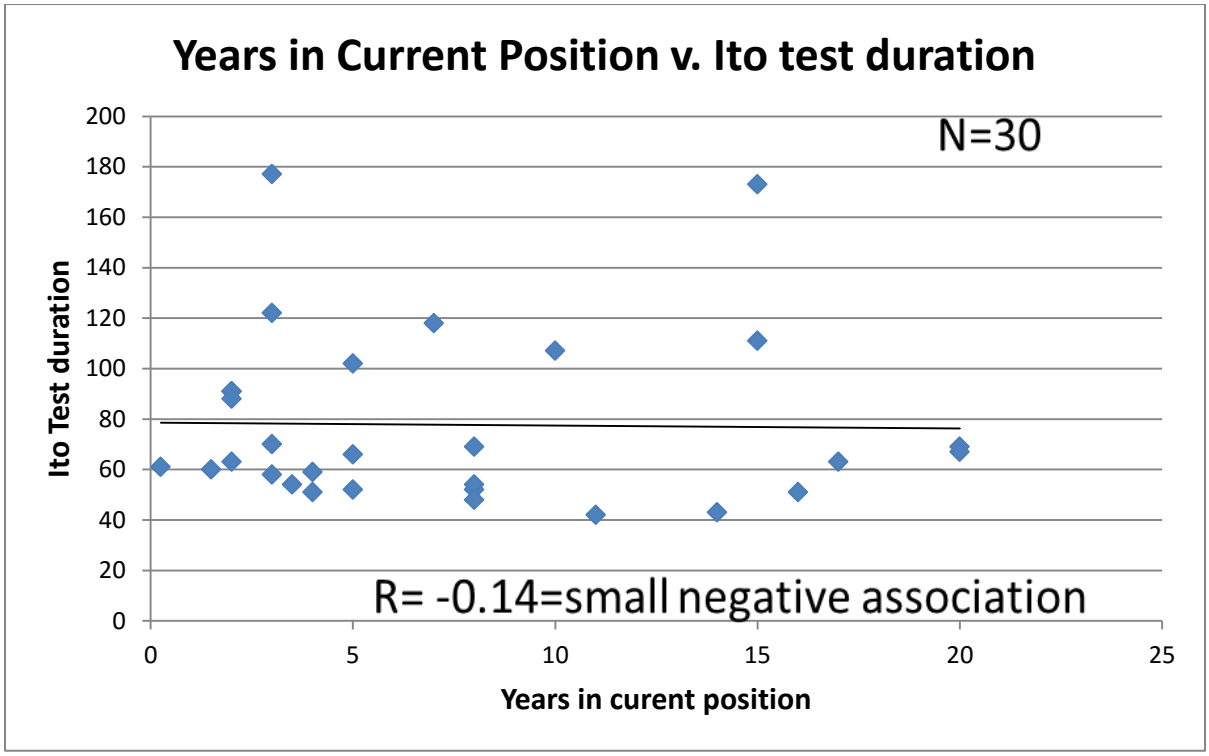

Figure 3. Ito test duration with years in manual labor as the independent variable

DISCUSSION

None of the independent variables were statistically significant as predictor variables for Ito test duration. The results for each independent variable had small negative associations when plotted, as Figures 1-3 show, but the scatterplots also reveal some interesting patterns. For example, the two participants who could hold the Ito test position for the longest were in their mid-20s, but the third and fourth longest times were by men in close to their 40s, one of whom was the oldest participant.

The BMI plot reveals a similar pattern: the participants with the highest BMIs were not the ones with the lowest Ito test durations. One of the participants with the highest BMI was a top performer of the Ito test. The participants with the three lowest Ito durations had BMIs very close to the mean of 27.1 and within one standard deviation. Similarly, with years in current position, the top four Ito test performers were spread out. The participant with the longest test duration had only been in manual labor for several years, while the third longest performer had been working in manual labor for close to 15 years. Most of the participants with under five years in manual labor were clustered together with Ito test durations of close to one minute.

Lack of statistically significant predictor variables is possibly due to the bias in selecting participants for the study. All participants work as manual laborers in construction jobs, but none of the participants reported workplace injuries.

It is possible that the men who participated in the study have developed lifting techniques that help them avoid injury in their jobs. The men have possibly developed habits to mitigate the occupational risks of construction work, and are regularly exercising their backs for work, strengthening them over time. The data could support this theory, as those with other 15 years in working manual labor did not perform much worse than those with zero to ten years.

Another critical factor that could have influenced the results is that all of the men participating in the study regularly play soccer once a week, a demanding physical activity. This factor was not built into research design, but could have influenced the results. It is possible that playing soccer, or any sort of regular exercise, helps trunk muscle conditioning.

Even though the men who participated in the study are physically active, able bodied men of working age, overall the Ito test scores were low compared to previous studies. Ito et al reports a mean time of 208.2 seconds of test duration in healthy males and 85.2 seconds for males with chronic lower back pain (Ito, Shirado and Suzuki). In this study, participants had a mean test duration of 77.1, with a range from 42-177, a full two minutes less than healthy males in the Ito study.

There could perhaps be unaccounted bias in the study that affected the outcome of the Ito test times. Studies show that personal factors such as motivation can affect the performance of participants (Demoulin, Vanderthommen and Duysens). The Ito tests for this research were conducted before the participants were going to play soccer so that fatigue would not impact the results. There are multiple possible reasons to explain why the Ito test results were significantly lower than expected from past Ito test studies, such as it lack of expectation, no visible clock, no competition between the participant, no real motivation and no compensation. It is also possible that the participants did not want to expend energy prior to a match.

Even though the independent variables were not found to be statistically significant, all of them had a slight negative relationship with Ito test duration. The small sample of only 30 participants may have influenced statistical significance. It is possible that increasing the power of the test by having a larger sample size could affect statistical significance of the independent variables.

CONCLUSION

While this study did not find BMI, age, or years in manual labor to be statistically significant predictors of Ito test duration, the study did reveal key findings. Regular physical activity such as soccer may help construction workers increase lower back endurance and avoid workplace injury. For future research, a control group of manual laborers who do not participate in a sport regularly may reveal more about the importance of sport and exercise. Additional research can also include having a control group of construction workers who have in fact experienced a work place injury. They would serve as a comparison group, but could also help reveal more about the validity of the Ito test in relation to low back risk in manual laborers.

An accurate and reliable predictor of future lower back pain in applicants seeking heavy work would be useful in employment and occupational medicine settings. However, one-time trunk muscle endurance testing such as the Ito test is not an adequate basis for work placement. Observing a prospective employee performing tasks that match the actual job demands would be more helpful. This type of functional testing would also give an opportunity to train employees how to avoid injuries in the future by using correct body mechanics before they start heavy work.

REFERENCES

Burton, AK, et al. "Occupational Risk Factos for the First-Onset and Subsequend Course of Low Back Trouble: A Study of Serving Police Officers." *Spine* 21.22 (1996): 2612-2620.

Center for Disease Control. *Prevalence and Most Common Causes of Disability Among Adults --- United States, 2005*. Atlanta: Morbidity and Mortality Weekly Report, 2009.

Demoulin, C,, et al. "Spinal muscle evaluation using the Sorensen test: a critical appraisal of the literature." *Joint Bone Spine* 73 (2006): 43-50.

Hershkovich, O, et al. "Associations of Body Mass Index and Body Height With Low Back Pain in 829,791 Adolescents." *American Journal of Epidemiology* 178.4 (2013): 603-609.

Hillman, M., et al. "Prevalence of low back pain the community: implications for service provision in Bradford, UK." *Journal of Epidimiological Community Health* 50 (1996): 347-352.

Hoogendoorn, WE, et al. "Physical load during work and leisure time as a risk factors for back pain." *Scandinavian Journal of Work, Environmental & Health* 25.5 (1999): 387-403.

Ito, T, et al. "Lumbar Trunk Muscle Endurance Testing: An Inexpensive Alternative to a Machine for Evaluation." *Archives of Physical Medicine and Rehabilitation* 77 (1996): 75-79.

Kankaanpää, M, et al. "Age, sex, body mass index as determinants of back and hip extensor fatigue in isometric sorensen back endurance test." *Archives of Physical Medicine and Rehabilitation* 79 (1998): 1069-1075.

Latimer, J, et al. "The reliability and validity of the Biering-Sorensen test in asymptomatic subjects reporting current or previous nonspecific low back pain." *Spine* 24 (1999): 2085-2090.

Leboeuf-Yde, C., Klougart N. and T. Lauritzen. "How common is low back pain in the Nordic population? Data from a recent study on a middle-aged general Danish population and four surveys previously conducted in the Nordic Countries." *Spine* 21 (1996): 1518-1526.

Mayer, TG, et al. (n.d.).

Miletic, D, A Miletic and B Milavic. "Age-related progressive increase of lower back pain among male dance sport competitors." *Journal of Back and Musculoskeletal Rehabilitation* 28 (2015): 551-560.

Moffroid, MT, et al. "Some endurance measures in persons with chronic low back pain." *Journal of Orthopedic and Sports Physical Therapy* 20.2 (1994): 81-87.

Moreau, CE, et al. "Isometric back extension endurance test: a review of the literature." *Journal of Manipulative and Physiological Therapeutics* 24.2 (2001): 110-22.

Müller, R, K Stassle and B Wirth. "Isometric back muscle endurance: An EMG study on the criterion validity of the Ito test." *Journal of Electromyography and Kinesiology* 20.5 (2010): 845-850.

National Institute of Neurological Disorders and Stroke. *National Institute of Neurological Disorders and Stroke*. December 2014. <https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Low-Back-Pain-Fact-Sheet>.

Noorloos, D, et al. "Does body mass index increase the risk of low back pain in a population exposed to whole body vibration?" *Applied Ergonomics* 39 (2008): 779-785.

Shiri, R, et al. "The Association between Obesity and the Prevalence of Low Back Pain in Young Adults: The Cardiovascular Risk in Young Finns Study." *American Journal of Epidimeology* 167.9 (2008): 1110-1119.

Shojaei, Iman, et al. "Age related differences in mechanical demands imposed on the lower back by manual material handling tasks." *Journal of Biomechanics* 49.6 (2016): 896-93.

Social Security Administration . *Code of Federal Regulations* . n.d. 28 November 2016. <https://www.ssa.gov/OP_Home/cfr20/404/404-1567.htm>.

Strine, T.W and J.M. Hootman. "US national prevalence and correlates of low back and neck pain among adults." *Arthritis Care and Research* 57.4 (2007): 656-665.

Tella, BA, et al. "Prevalence and impacts of low back pain among peasant farmers in South-West Nigeria." *International Journal of Occupational Medicine and Environmental Health* 26.4 (2013): 621-627.

Udom, C, P Janwantanakul and R Kanlayanaphotporn. "The prevalence of low back pain and its associated factores in Thai rubber farmers." *Journal of Ocupational Health* 58 (2016): 534-542.

Editorial Board. (2006). Joint Bone Spine,73(5). doi:10.1016/s1297-319x (06)00194-1

Hartvigsen, J., Bakketeig, L. S., Leboeuf-Yde, C., Engberg, M., & Lauritzen, T. (2001, August 15). The association between physical workload and low back pain clouded by the "healthy worker" effect: population-based cross-sectional and 5-year prospective questionnaire study. Retrieved March 23, 2017, from https://www.ncbi.nlm.nih.gov/pubmed/11493851

Donovan, W. H., Dwyer, A. P., White, B. W., Batalin, N. J., Skerritt, P. W., & Bedbrook, G. M. (n.d.). A multidisciplinary approach to chronic low-back pain in Western Australia. Retrieved March 23, 2017, from https://www.ncbi.nlm.nih.gov/pubmed/6461071

Antti Malmivaara; Jukkapekka Jousimaa; Timo Pohjolainen. (2014, May 19). Low back pain. Retrieved March 22, 2017, from http://www.ebm-guidelines.com/ebmg/ltk.free?p_artikkeli=ebm00435

APPENDIX 1

Survey

1- What is your name? _____

2- ITO Test Time (to be completed by investigator):_____

3- How old are you?_____

4- What is your height?_____

5- What is your weight?_____

6- Do you have any back surgeries Yes ☐ ☐

7- If yes, did you have any trouble after your surgery, please describe _____
_____

8- How many back strain injuries did you have in the last 5 years_____

9- Do you use chronic pain Medication? Yes ☐ No ☐

10- Are you currently taking any pain medication? Yes ☐ No ☐

11- Do you have any current medical problems? Yes ☐ No ☐

12- If yes, please name it: _____
_____
_____

13- Do you smoke? Yes ☐ No ☐

14- Did you ever smoke? Yes ☐ No ☐

15- If yes, when did you quit smoking? _____

16- What is your job?_____

17- How long have you been at your current position? _____

18- What are your hobbies or sports activities?_____

19- Could you provide me with your telephone number / email address_____

APPENDIX 2

DATA

Age	Height	Weight	BMI	Job	How Long at Current Position(years)	ITO Test Time
34	5'8	170	25	Construction	17	63
24	5'7	180	28	Carpet installer	5	52
31	5'9	180	26	Engineer	3	58
31	5'10	220	32	Construction (tile)	1.5	60
34	5'8	172	26	Construction	16	51
26	5'6	200	31	Truck driver	5	66
26	5'6	160	25	Construction	3	122
25	5'9	175	25	Construction	4	59
24	5'4	130	22	Construction	3	177
21	5'10	140	20	Construction	0.25	61
34	5'7	202	31	Construction	2	63
37	5'5	145	25	Painting	15	173
40	5'8	165	25	Construction	20	69
41	5'9	240	35	Welder	20	67
39	5'8	176	26	Drywall	10	107
41	5'6	173	28	Painting	11	42
37	5'6	200	32	Remodeling	3.5	54
23	6'1	190	25	Painting	4	51
42	5'6	220	35	Drywall	15	111
33	5'9	202	29	Painting	14	43
34	5'9	165	24	Satellite installer	8	54
32	5'10	230	33	Mechanic	8	69
28	5'4	180	31	Truck driver	3	70
27	5'8	154	23	Electrician	8	52
26	5'9	160	23	Construction	2	91
23	5'11	205	28	Granite worker	5	102
27	5'7	170	25	Mechanic	2	88
34	5'10	194	28	Welder	8	48
23	6'1	210	27	Construction	2	91
25	5'10	140	20	Construction	7	118

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9/20/2016

Ronald Figueredo, M.D.
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Tampa, FL 33612-3805

RE: **Expedited Approval for Initial Review**
IRB#: Pro00023496
Title: Back muscle endurance as measure by Ito test duration

Study Approval Period: 9/20/2016 to 9/20/2017

Dear Dr. Figueredo:

On 9/20/2016, the Institutional Review Board (IRB) reviewed and **APPROVED** the above application and all documents contained within, including those outlined below.

Approved Item(s):
Protocol Document(s):
IRB protocol

Consent/Assent Document(s)*:
Consent .pdf

*Please use only the official IRB stamped informed consent/assent document(s) found under the "Attachments" tab. Please note, these consent/assent document(s) are only valid during the approval period indicated at the top of the form(s).

It was the determination of the IRB that your study qualified for expedited review which includes activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories outlined below. The IRB may review research through the expedited review procedure authorized by 45CFR46.110 and 21 CFR 56.110. The research proposed in this study is categorized under the following expedited review category:

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

As the principal investigator of this study, it is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB. Any changes to the approved research must be submitted to the IRB for review and approval via an amendment. Additionally, all unanticipated problems must be reported to the USF IRB within five (5) calendar days.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-5638.

Sincerely,

E. Verena Jorgensen, M.D., Chairperson
USF Institutional Review Board