Introduction to Research Methods – Proposal

An investigation of long term effects of pregnancy on forefoot dimensions and orthotic intervention.

By: Paul A. Scotti

10007486

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1.0 TITLE

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2.0 AUTHOR

Paul A. Scotti

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3.0 INTRODUCTION

Women commonly report that their feet become larger during pregnancy and remain this way permanently. These changes could be due to changes in ligaments caused by the extra weight that is carried during pregnancy and by hormonally induced alterations of the connective tissue in the ligaments. A literature search revealed only two previous studies were performed on the feet of pregnant women measuring foot parameters despite the long time awareness of significant symptomatology or anecdotal claims of permanent physiologic change.

Changes occurring in the symphysis pubis of pregnant women have been a long accepted and well documented fact (1,2). Ligaments relax during pregnancy due to hormonal changes (3) and these changes are dynamic (4). Relaxin, a hormone that was identified by Hisaw in 1926, causes relaxation on the symphysis pubis as an aid to parturition (5), by increasing the total collagen content while dissociating the collagen fibres themselves (6). Dragoo (2003) demonstrated that relaxin specific receptors were found in anterior crutiate ligaments of women indicating that the hormone has a systemic effect (7). Peripheral joint

laxity has also been observed in pregnancy by Calgunrti in his 1982 study. They suggest hormonal influences such as relaxin alters the ligaments making them more lax.

In addition to relaxation of the pelvic joints, relaxin changes peripheral joint motion that results in faulty foot posture (8). Bird (1999) found increased laxity of the metacarpophalangeal joints in pregnant women that was suggestive of a peripheral action of relaxin (9). Block (1985) confirmed this in their study and went on to include that subtalar joint and midtarsal joints are also affected during pregnancy (4).

Weight gain during pregnancy corresponds to changes in foot dimensions. The average weight gain for a full term pregnancy is 25-30 pounds (10). The biomechanics of the foot are altered during pregnancy. Alterations in both the quality and quantity of joint motion also occur (8). Significant physiological changes in the feet are contributed to increased pronatory forces applied to the feet as a result of pregnancy (4). As weight increases, the centre of gravity is displaced anteriorly which results in increased subtalar pronation (11). Pregnant subjects exert a significantly higher mean midfoot pressure compared to non-pregnant control groups (12,13). The gait is further altered by increasing the base of gait and other pronatory forces to the foot (9,10). The plantar calcaneonavicular (spring) ligament is a vital stabilizer of the medial longitudinal arch by supporting the talar head. Laxity or rupture of the spring ligament permits planter flexion of the talus or over pronation. This motion results in valgus alignment of the calcaneus and a flatfoot deformity (14). Due to joint ligament laxity and increased pronatory forces to the feet, Wetz (2006) found a statistically significant increase in foot length and width in their pregnant subjects (15).

Mechanical stress has been shown to induce remodelling of tissue (16,17). Therefore, changes in the size of the feet during pregnancy are presumed to be due to increased laxity of the supporting ligaments in combination with added stress. These changes in the ligaments would be expected to persist and cause irreversible changes in the feet.

4.0 AIM OF STUDY

The proposed study is designed to answer three questions: do the dimensions of the feet change during pregnancy, and if so, are these changes still present up to a year postpartum. And thirdly, are these changes preventable or affected through continued use of custom molded foot orthotics initiated early in the first trimester. This study should show if orthotics should be prescribed in early pregnancy to prevent permanent foot change.

4.1 Literature Review

The literature in this area is sparse at best with only two studies done and the supporting literature is dated. This literature review will focus on those two relevant studies. Although the two studies are similar to the proposed study they have either not continue the study postpartum (17) or there are factors in the method that may have compromised the results (4). It is for this reason that this study is proposed and will address the short falls of the previous studies.

In the study by Wetz (2006) they obtained an adequate sample size of forty participants. Although they did demonstrate a statistically significant increase in both foot length and width what they did not do is follow their subjects postpartum to see if these changes are

temporary or permanent. Nor did they have a group with orthotics or some other kind of means of intervention to see if the results are also preventable.

Alvarez (1988) did follow their subjects postpartum but they too did not have an intervention group. The timeline for their initial data intake may have been late and that may account for why they did not find a statistically significant difference with their subjects foot parameters. Since the Relaxin hormone is produced as early as four weeks and reaches maximum potency in the first trimester (2) and their subjects were initially measured at thirteen weeks the effects of the hormone may have already happened before they collected their baseline data. This fact was admitted by the researchers themselves in their discussion. Their control group were women who never had a full term pregnancy, but would have already undergone any changes in foot dimensions within the first trimester. Also their subjects were not primagravida and that too would have compromised their baseline. Only twelve subjects completed the study.

5.0 ETHICAL CONSIDERATIONS

A possible problem arising from obtaining subjects could be cultural or religious in nature. Some cultures will not permit the touching of a woman by another man, even if it is only the foot. This may require the presence of a female representative collecting the data. It may also require scheduling the spouse to be present which will further complicate organizing return dates.

Ethical clearance will be attained from Queen Margaret University ethics committee. Ethical consideration will also be preapproved by the Midwife Alliance prior to posting of the

participant sign-up sheet. All participant will be volunteers and will have completed and signed an informed consent form (Appendix I) prior to intake.

The procedure for obtaining inform consent will be providing all test subjects with a copy of the research proposal, an explanation of their role in the study, demonstration of the data collection procedures and time lines of expected returns.

At no time will any of the test subjects experience pain or discomfort. The method of collecting data will be non-invasive and in no way will the subjects' privacy be compromised.

Subjects will be fully informed of all aspects and intensions of the study at the beginning and throughout the study. Since the study is purely quantitative there is no need for withholding information.

There are no known short or long term risks associated with this study. Subjects are free to withdraw at anytime if they wish.

All personal information will be kept private and will never be disclosed in print or any other media.

No benefits in any form will be received from a commercial party related directly or indirectly to the subject of this article. No funds will be received in support of this study.

6.0 METHOD

There will first be a small internet based survey (Appendix II) investigating the thoughts or impressions of this concept. The survey is not scientific but it will get a general consensus from a large sample size. The survey will be hosted by Survey Monkey (www.surveymonky.com). Their software will track and analyze the survey results. The

survey will be distributed across the internet like a chain letter through Facebook and emails trying to reach as many people as possible. It will be posted for a period of two months.

The primary study is a quantitative retrospective observational model designed to collect and evaluate serial measurements over a period of twenty months.

Each subject within the population of volunteers from the Midwife Alliance clinic in Toronto, Canada will be assigned a number in order to establish a sampling frame. The subjects will then be divided into equal numbers and randomized into either group a) no orthotics or group b) subjects being fitted for custom foot orthotics. The control group c) will be randomly selected from another volunteer group of non pregnant subjects from the West Toronto Foot & Ankle Clinic.

6.1 Sample Size Considerations:

The proposed sample size of 50 subjects is based on the two previous studies in this area, where they chose sample sizes of 20 and 40. A larger sample size may be impractical due to the length of study time. A group of 10 volunteers from a sign-up sheet at the West Toronto Foot & Ankle Clinic will serve as the control provided they have never been pregnant and fulfill all the other sample criteria.

Inclusion Criteria:

Subjects suitable for the study must meet the following criteria:

- medical confirmation of pregnancy
- must be within four weeks gestation
- must be primagravida
- chronological ages of between twenty-three and thirty-three
- weighing between 125lbs and 175lbs

6.3 Exclusion Criteria:

Subjects will be excluded from the study for the following reasons:

- if subjects have ever been pregnant for any length of time
- if subjects have ever had any surgeries of either foot that goes beyond the dermis
- any congenital or foot deformities
- either structural or functional foot deformities resulting from faulty biomechanics
- diabetes, polio, spina bifida or any other conditions that may develop neuropathy

6.4 Data Collection:

Once written informed consent has been provided all questionnaires and data collection will take place at Midwife Alliance clinic.

The length and width of the feet of the subjects in the study will be assessed at four and thirty-five weeks of gestation and again at eight weeks and one year postpartum.

The subjects will stand on a Brannock device (Fig.1) in single leg stance and accurate measurements will be performed using a digital metric vernier (Fig.2). The measurements will record the maximum lengths and widths in the sagittal and coronal planes on an Excel spread sheet (Appendix III).

Fig. 1, Standard Brannock device used for accurately measuring foot lengths and widths

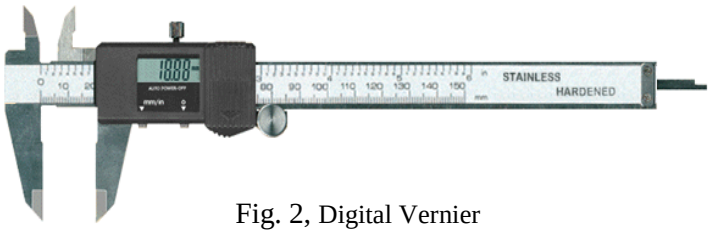

Fig. 2, Digital Vernier accurate to 1/100mm

At initial and subsequent visits all subjects will complete a descriptive statistics questionnaire (Appendix IV) concerning perceived changes in foot dimensions since last visit. Group b) will be fitted for custom foot orthotics and will be subjected to the exact questionnaires and measurements as group a) they will also fill out a second questionnaire (Appendix V) describing their compliancy and frequency of orthotic use. All measurements will be acquired by the sole researcher to maintain consistency, validity and reliability.

6.5 Results:

The data will be compared over the four measurement sessions looking for a statistically significant difference in foot size from the initial intake. At the end of the study any differences in foot size that may have occurred during the pregnancy portion of the study will then be compared to the post partum measurements to determine if a permanent change can be expected. These will then be compared to group b) and similarly to the control. A Student's paired-sample t-test will be utilized for data comparison. A successful outcome will be qualified by a statistically significant change in foot size parameters. These results and the subjective data obtained from the questionnaires will be discussed in the conclusion portion of the final paper.

7.0 TIMETABLE

The projected timeline for this study will be twenty-four months. See Appendix VI. For detailed flow chart.

8.0 RESOURCES

This study will require few resources other than time. Items will include measuring tools and a computer with spreadsheet and word processing. The most costly portion of the study will

be the orthotics. The materials and manufacturing cost will be supplied independently by the researcher.

9.0 Discussion

The interim results from the online survey are showing an overwhelming belief that there truly is an increase in foot size after childbirth. The promising data from the survey study led to the development of this research proposal.

Mechanical stress as a result of the loads that pregnancy presents on the foot (4,8,9,10,11,12,13,) in concert with the physiological effects of the relaxin hormone (1,2,5,6,9) may cause ligamentous laxity and could lead to the common complaint of foot enlargement and pain. It therefore seems plausible that the adverse effects of pregnancy on the foot can be reduced by the anti-pronatory forces and altered weight distribution offered by custom moulded foot orthoses (11).

There is very little research done in this area. The two previous studies on this subject were contradictory of one another and were therefore inconclusive. Neither study investigated into the long term effects or means of intervention which further fuelled the desire to pursue this study. Perhaps a positive outcome from this research may spark increased interest on the topic, and lead to further studies and a better understanding of the physiologic change that pregnancy has on feet.

10.0 Conclusion

It is hypothesised that there is an increase in foot size during and after pregnancy.

This study is designed to address the claim and show if orthotics prescribed in early pregnancy plays a role. This information could serve as a useful tool in the intervention of such change and possibly reduce adverse symptomatic effects in the future.

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Appendix I

Informed Consent

Informed Consent

Informed Consent Form for _____

This informed consent form is for the Midwife Alliance and invitees who wish to participate in the research titled "An investigation of long term effects of pregnancy on forefoot dimensions and orthotic intervention".

Principle Investigator: Paul A. Scotti, C.Ped (C), D.Ch
Organization: West Toronto Foot & Ankle Clinic Inc.
Project and Version: An investigation of long term effects of pregnancy on forefoot dimensions and orthotic intervention, V. 1.0

This Informed Consent Form has two parts:

- **Information Sheet** (to share information about the study with you)
- **Certificate of Consent** (for signatures if you choose to participate)

Note: You will be given a copy of this Informed Consent Form

Part I: Information Sheet

Introduction
I am Paul Scotti, representing the West Toronto Foot & Ankle Clinic. I am doing a research study on the long term effects of pregnancy on forefoot dimensions. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research. This consent form may contain words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or of another researcher.

Purpose of the research
Many mothers have said that their feet got bigger or wider after having children. We believe that you can help us by letting us measure your feet occasionally during your pregnancy and a year after you give birth. We want to find out if this is actually true by monitoring your measurements and comparing them to your first foot measurement. We also want to see if foot size changes can be reduced using orthotics. Some people will be wearing orthotics and the others will not. This will be determined by random selection.

Type of Research Intervention
This research will involve your participation in a private setting where you foot length and width will be measured followed by a brief questionnaire. This should take about a half hour to complete.

Participant Selection
You are being invited to join this study because participants must be in early stage pregnancy within the first four weeks. Participants must also have never given birth before.

Voluntary Participation
Indicate clearly that they can choose to participate or not. State, only if it is applicable, that they will still receive all the services they usually do if they choose not to participate. Explanation: It may be more applicable to assure them that their

choosing to participate or not will not have any bearing on their job or job-related evaluations. This can be repeated and expanded upon later in the form as well. It is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context. Although, if the interview or group discussion has already taken place, the person cannot 'stop participation' but request that the information provided by them not be used in the research study.

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate all the services you receive at this Centre will continue and nothing will change. If during the study you no longer wish to participate you can stop immediately and you may also request that the information provided by you not be used in the research study.

Procedures
We are asking you to help us learn more about the effects of pregnancy of the feet. We are inviting you to take part in this research project. If you accept, you will be asked to complete a short questionnaire about your feet, such as: problems with your feet, previous operations on the feet, shoe size, habits in standing, and the surfaces of the floors at home and at work. None of the questions should be personal or cause any embarrassment.

The survey will be provided by me and collected by me. If you do not wish to answer any of the questions included in the survey, you may skip them and move on to the next question. The information recorded is confidential, your name is not being included on the forms, only a number will identify you, and no one else except me will have access to the information.

Duration
The research takes place over a period of twenty months. During that time, you will visit the West Toronto Foot & Ankle Clinic a total of four times and will complete the shirt survey at each visit.

Risks
At no time will you experience pain or discomfort associated with the data collection process. The method of collecting data will be non invasive and in no way will your privacy be compromised. There are no known short or long tern risks associated with this study.

Benefits
Although there will be no direct benefit to you your participation is likely to help us find out more about how to prevent foot changes resulting from pregnancy and we may be able to help people in the future.

Confidentiality
I will not be sharing information about you to anyone outside of the research team. The information that I collect from this research project will be kept private. Any information about you will have a number on it instead of your name. Only I will know what your number is and I will lock that information up with a lock and key. It will not be shared with or given to anyone. No pictures will be taken at any point.

Sharing the Results
Nothing that you tell me today will be shared with anybody outside the research team, and nothing will be attributed to you by name. The knowledge that we get from this research will be shared with you before it is made widely available to the public. Each participant will receive a summary of the results. We will publish the results so that other interested people may learn from the research.

Who to Contact
If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact me by e-mail at: scotti@footankle.ca or by calling the clinic at: 416-253-6400.

This proposal has been reviewed and approved by the Midwife Alliance to make sure that research participants are protected from harm.

Part II: Certificate of Consent

I have been invited to participate in research about foot changes during pregnancy and their long term effects. I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study.

Print Name of Participant_____ **Date** _____

Signature of Participant _____ Day/month/year

If illiterate [1]

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ **Thumb print of participant**

Signature of witness _____

Date _____

Day/month/year

Statement by the researcher/person taking consent

I, Paul Scotti, have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the research process in detail.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this informed consent has been provided to the participant.

Researcher_____ **Date** _____

Paul A. Scotti Day/month/year

1 A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well

Appendix II

Internet Survey

(as seen at: http://www.surveymonkey.com/s/YX22R6Q)

1. Have you ever heard that a mother's feet got longer, wider or had any other changes after they had children?

- Yes
- No

2. If yes, were those changes permanent?

- Yes
- No
- I don't now

3. Are you or have you ever been pregnant

- Yes
- No

4. If yes, have you noticed and changes in your foot dimensions?

- Yes
- No

5. How many pregnancies have you had that were at least 12 weeks or more in duration?

- Yes
- No
- I don't now

6. During, or after which pregnancy did you first start noticing changes in foot size?

- 1^{st}
- 2^{nd}
- 3^{rd}
- Never

7. If you noticed a change in foot size, has it remained that way or has it returned back to normal?

- Yes
- No

8. During your first pregnancy, did you wear orthotics?

- Yes
- No

Appendix III

Data Collection Table			Length (mm)				Width (mm)			
Patient #	**Age**	**Weight**	**4 wks L R**	**35 wks L R**	**8 wks post L R**	**1 yr post L R**	**4 wks L R**	**35 wks L R**	**8 wks post L R**	**1 yr post L R**
1a			l	l	l	l	l	l	l	l
2a			l	l	l	l	l	l	l	l
3a			l	l	l	l	l	l	l	l
↓										
1b			l	l	l	l	l	l	l	l
2b			l	l	l	l	l	l	l	l
3b			l	l	l	l	l	l	l	l
↓										
1c			l	l	l	l	l	l	l	l
2c			l	l	l	l	l	l	l	l
3c			l	l	l	l	l	l	l	l
↓										

continued

Number = patient #

Letter = group

a = subjects no orthotics
b = subjects with orthotics
c = control group

Appendix IV

Questionnaire - Ongoing Subjective Foot Changes

Since your last questionnaire (if this is the first time completing the survey substitute “Since you discovered you were pregnant”):

1. Do you suffer from any foot pain?
a. Yes
b. No

2. Have your shoes gotten any tighter?
a. Yes
b. No

3. Have you notice any change in your foot length?
a. Yes
b. No

4. Have you notice any change in your foot width?
a. Yes
b. No

Appendix V

Questionnaire - Orthotic Compliance

How often did you wear your orthotics, in hours per day

Intake	0-3	3-6	6-9	9-12	12-15	15-18
1						
2						
3						
4						

Appendix VI

Timetable Proposed for Research

December 2010 ► March 2011

Completion of Research Proposal

Explanation of Research Process to Midwife Alliance

Organize Volunteer Sign-Up Sheet

Initiate Intake List

▼

April 2011 ► December 2012

20 Months for Data Collection

Data Collection from 60 Subjects

▼

January 2013 ► June 2013

Analysation of Data

Report Writing

▼

August 2013

Completion of Research Paper

Submission for Journal Publication