

**Assessing the Practice Patterns of Acupuncturists who Treat Fertility Patients in  
Los Angeles: The Clinical Use of the Stener-Victorin and  
Paulus Study Protocols**

**By**

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### **ABSTRACT**

In the past decade the two Traditional Chinese Medicine protocols, the Stener-Victorin protocol and the Paulus protocol, emerged as widely used procedures for the treatment of infertility. A good deal of theory and research has been published regarding those two protocols. The current study gathered data from practitioners regarding a number of variables and factors pertaining to their use of one or both of the designated protocols. A web based survey instrument was administered to Traditional Chinese Medicine practitioners who self identify as having some level of infertility specialty in their practices. The survey revealed that practitioners that had a greater amount of post graduate training in fertility TCM or western reproductive medicine were more likely to use the protocols, as were practitioners that worked with reproductive endocrinologists and those that treated a greater number of fertility patients per week.

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**TABLE OF CONTENTS**

Chapter One: Introduction.....	10
Chapter Two: Literature Review.....	12
Overview.....	12
Acupuncture and fertility.....	12
The Stener-Victorin protocol.....	16
The Paulus protocol.....	18
Literature review integration.....	25
Chapter Three: Method.....	26
Method designation.....	26
Rationale for survey method.....	26
Survey instrument.....	28
Survey administration.....	29
Subjects.....	30
Data analysis.....	32
Chapter Four: Results.....	37
Chapter Overview.....	37
Demographic data.....	37
Practice factors.....	40
Training factors.....	48
Treatment protocol data.....	52
Statistical analysis.....	60

Chapter Five: Discussion.....	70
Summary of findings.....	70
Implications for practice.....	70
Limitations of the current study.....	71
Recommendations for future research.....	72
Conclusion.....	73
References.....	74
Appendices:	
Appendix A: Glossary of Terms with Acronyms.....	78
Appendix B: Survey Instrument.....	81
Appendix C: Introductory letter and consent form.....	85
Appendix D: Exact statistical data for tables 1-35.....	88
Appendix E: IRB Approval Letter.....	94

## LIST OF TABLES & FIGURES

Figure 1. Uterine and ovarian arterial connection.....	15
Table 1. Gender of respondents.....	38
Table 2. Ethnicity of respondents.....	39
Table 3. Marital status of respondents.....	39
Table 4. Annual gross income of respondents.....	40
Table 5. Hours worked per week of respondents.....	41
Table 6. Years in practice of respondents.....	41
Table 7. Settings respondents work in.....	42
Table 8. Number of patients treated per week by respondents.....	43
Table 9. Number of fertility patients treated per week by respondents.....	43
Table 10. Respondents self-identification as fertility specialist data.....	44
Table 11. Respondents that advertise fertility treatments.....	44
Table 12. Frequency respondents work with reproductive endocrinologists (REs).....	45
Table 13. Frequency respondents work with obstetrician/gynecologists (OB/GYNs).....	45
Table 14. Frequency respondents with with nurse practitioners (NPs) that treat fertility.....	46
Table 15. Frequency respondents work with naturopathic doctors (NDs) that treat fertility....	46
Table 16. Frequency respondents work in fertility clinics doing acupuncture with assisted reproductive technologies (ART).....	47
Table 17. American Board of Oriental Medicine (ABORM) status of respondents.....	48
Table 18. Oriental medicine training location data.....	49
Table 19. Respondents with a separate OB/GYN course during training.....	49

Table 20. Respondents level of post-graduate training in fertility in western reproductive endocrinology.....	50
Table 21. Respondents level of post-graduate training in fertility in traditional Chinese medicine (TCM).....	51
Table 22. Doctorate program completion of respondents.....	51
Table 23. Respondents familiarity with the Stener-Victorin study acupuncture protocol.....	52
Table 24. Respondents that use the Stener-Victorin protocol with fertility patients.....	53
Table 25. Phase(s) in which the respondents use the Stener-Victorin protocol.....	53
Table 26. Respondents that follow the Stener-Victorin protocol exactly as per the Stener-Victorin study.....	54
Table 27. Frequency in which respondents use additional acupuncture points concurrently with the Stener-Victorin protocol.....	54
Table 28. Respondents familiarity with the Paulus study acupuncture protocol.....	55
Table 29. Respondents that use the Paulus study protocol with fertility patients.....	55
Table 30. Phase(s) in which the respondents use the Paulus protocol.....	56
Table 31. Respondents that used the paulus protocol exactly as per the Paulus study.....	57
Table 32. Respondents that used the Paulus protocol for embryo transfers only.....	58
Table 33. Location where respondents performed the Paulus protocol.....	58
Table 34. Frequency in which respondents used additional acupuncture points while following Paulus protocol.....	59
Table 35. Respondents that used other fertility protocols.....	59
Table 36. Location of respondent’s training and use of the Stener-Victorin protocol.....	62

Table 37. Location of respondent's training and use of the Paulus protocol.....	63
Table 38. Respondent's level of post-graduate training in fertility in TCM and use of the Stener-Victorin protocol.....	64
Table 39. Respondent's level of post-graduate training in fertility in TCM and use of the Paulus protocol.....	64
Table 40. Respondent's level of post-graduate training in fertility in western reproductive medicine and use of the Stener-Victorin protocol.....	65
Table 41. Respondent's level of post-graduate training in fertility in western reproductive medicine and use of the Paulus protocol.....	66
Table 42. Number of fertility patients treated per week and use of the Stener-Victorin protocol.....	67
Table 43. Number of fertility patients treated per week and use of the Paulus protocol.....	67
Table 44. Respondents that work with Reproductive Endocrinologists and use of the Stener-Victorin protocol.....	68
Table 45. Respondents that work with Reproductive Endocrinologists and use of the Paulus protocol.....	69

## CHAPTER ONE: INTRODUCTION

Infertility is defined as “1 year of unprotected intercourse without conception” and affects between 10-15% of couples (Speroff, 2005). In the past, there were limited treatment options for infertile couples but this is no longer the case. Over the past few decades, the arena of reproductive medicine has grown by leaps and bounds. There are now so many innovative treatment strategies to help couples who might have had no hope for a biological child of their own. While these new techniques and therapies known as Assisted Reproductive Technologies (ART) are indeed exciting and bring hope, they are by no means an end-all cure. Just as in all fields of medicine, there are risks involved and this kind of treatment in particular can take a heavy financial and emotional toll. The stress of multiple hormone injections, financial investment, and emotional roller-coaster can indeed have a negative effect on an individual’s fertility potential. (deLacey, 2009; Speroff, 2005).

Historically, acupuncture and Traditional Chinese Medicine (TCM) has a rich history in treating gynecological diseases, including infertility (Maciocia, 1998). In recent years, more studies have been published focusing in on the success rates of ART when acupuncture is included in the treatment. These studies have shown that the pregnancy rate of the patients undergoing acupuncture treatment concurrently with ART is higher by anywhere from 10-15% (Magarelli, 2009; Manheimer, 2007; Paulus, 2002; Westergaard, 2006). Two significant research studies that changed the face of fertility acupuncture were published by Stener-Victorin, et al. in 1996 and Paulus, et al. in 2002. These studies examined the effects of acupuncture on female reproduction and the specific acupuncture point protocols listed have been replicated and are used clinically by hundreds of acupuncturists across the United States. (Domar, 2006)

A recent research report which surveyed fertility acupuncturists' practice habits in Britain revealed that the Paulus protocol was the most popular to use clinically with infertility patients (Bovey, 2010). As the awareness and research on acupuncture and ART continues to grow and expand, it is important to understand the treatment strategies that acupuncture clinicians are utilizing most frequently.

The objective of this study is to explore the practice patterns and habits of fertility acupuncturists in the greater Los Angeles area. More specifically, the current study has investigated the clinical use of the Stener-Victorin protocol and the Paulus protocol. The current study focused on the two designated treatment protocols and did not include consideration of TCM infertility diagnostics. The study is also limited to an on-line survey only conducted via SurveyMonkey, with responses collected and analyzed by inferential statistics.

Appendix A includes a listing of terms and acronyms that were used repeatedly in the current study.

## **CHAPTER TWO: LITERATURE REVIEW**

### **Overview**

This literature review chapter will provide the scholarly foundation for the current study. In this chapter the researcher has reviewed the most current literature regarding the Stener-Victorin and Paulus protocols. The literature reviewed for both protocols includes considerations of basic processes as advanced by the protocol authors as well as summaries of subsequent studies or other considerations regarding each of the protocols. Those in the literature review sections are followed by a literature review integration section that sums up the current status of the two designed protocols and leads directly to the rationale for the current study. In conducting this literature review the researcher engaged key word searches through PubMed, Fertility & Sterility's journal website, and several other data bases that include the consideration of fertility and Traditional Chinese Medicine theory and procedures. For all searches the key words used included "Stener-Victorin", "Paulus", "Fertility + Acupuncture", "Infertility + Acupuncture", "IVF + Acupuncture", and "ART + Acupuncture". Additional searches were conducted through Dissertation Abstracts. Most of the sources that are reflected in this chapter were accessed online or through the Yo San University Library. A manual search of personal libraries and TCM textbooks as well as allopathic gynecology textbooks was conducted. In order to assure a comprehensive search and to access hard to acquire sources, several visits were made to other local university and college libraries.

### **Acupuncture & Fertility**

While reproductive medicine is a relatively recent field of gynecology, infertility has a long treatment history in Chinese medicine. Tortoise shells with herbal prescriptions etchings

dealing with childbirth issues date back to the Shang dynasty (1500-1000 BC) (Maciocia, 1998). Specifically, fertility pathology and treatment strategies are recorded in Sun Si Miao's book *Thousand Golden Ducat Prescriptions* (652 AD) and again in the voluminous *Great Treatise of Useful Prescriptions for Women* by Chen Zi Ming written in 1237 (Furth, 1999; Maciocia, 1998; Noll, 2010). Fu Qing Zhu wrote about fertility differentiation and treatment in his book *Fu Qing Zhu's Gynecology* written in the 1600's (Maciocia, 1998). Infertility was medically categorized as *qiu zi*, which is translated as "the quest for children" and was discussed in the medical literature as well as in the Daoist and Confucious texts. (Noll, 2010).

Since the publications of the Stener-Victorin study in 1996 and particularly the Paulus study in 2002, the use of acupuncture in conjunction with ART has dramatically increased (Bovey, 2010; Domar, 2006). There has been a significant inflation in the number of fertility patients seeking use of acupuncture in conjunction with medical reproductive therapies (deLacey, 2009; Domar, 2006). Overall, the current research available indicates that acupuncture does have a positive effect on IVF rates - that is, patients that received acupuncture treatment before and immediately after embryo transfer had higher rates of pregnancy than patients that did not receive acupuncture and relied on ART alone (Magarelli, 2009; Manheimer, 2007; Paulus, 2002; Westergaard, 2006).

There have been several studies to examine the mechanism of acupuncture and how it improves fertility and enhances ART procedures. Although there is still much research to be done in this arena to have a complete understanding, there are a few concepts that have been affirmed and accepted. Basically, there are four main mechanisms that are recognized

explanations for how acupuncture physiologically affects the reproductive system. Those mechanisms are summarized in the paragraphs below:

(1) Acupuncture has been shown to change the output of the central nervous system (CNS). Not only are beta-endorphin plasma levels altered and concentrated by acupuncture stimulation which in part explains how acupuncture mediates pain, but acupuncture also has an effect on the hypothalamic-pituitary-ovarian (H-P-O) and hypothalamic-pituitary-adrenal (H-P-A) axes (Cheong, 2009; Hung, 2008; Stener-Victorin, 2002; Stener-Victorin, 2010). Acupuncture influences the release of gonadotrophins (GnRH) and luteinizing hormone (LH), which changes the function of the reproductive organs and hormone levels (Hung, 2008; Stener-Victorin 2010). These changes in reproductive organs and hormones can improve fertility and fecundity. Electro-Acupuncture (EA), when implemented at a low frequency, can trigger the release of opioids (beta-endorphin included), serotonin, oxytocin and neuropeptides which regulate the reproductive system (Stener-Victorin, 2010).

(2) Stress is a significant factor for couples experiencing infertility and for those undergoing reproductive therapy (Hung, 2008; Liang, 2003; Magarelli, 2009). Another change in the CNS created by acupuncture therapy is the inhibition of the sympathetic nervous system (Westergaard, 2006). When the sympathetic nervous system is activated, the parasympathetic nervous system is dormant. Reproductive function falls under the domain of the parasympathetic system. Hence, it is important to have the ability to “quiet down” the sympathetic system so that the parasympathetic system can be activated, particularly in some highly stressed patients. The stress hormones cortisol and prolactin are secreted at different levels during times of higher stress; these hormone outputs can be altered by acupuncture to improve IVF outcomes

(Magarelli, 2009; Stener-Victorin, 2010). Stress affects the H-P-A axis and can decrease the function of the reproductive system (Stener-Victorin, 2010).

(3) Hormonal changes cascade down the H-P-O and H-P-A levels and affect oocyte quality, ovulation, the endometrium and the menstrual cycle (Hung, 2008; Speroff, 2005; Stener-Victorin, 2002; Stener-Victorin, 2006; Stener-Victorin, 2009; Stener-Victorin, 2010). Hence, acupuncture can have a regulating effect on these axes if there is an imbalance, particularly if the problem is an imbalance in the neurochemistry (Stener-Victorin, 2010). A direct effect can be targeted towards the ovaries when needles are placed along the Ren, Kidney, Stomach and Spleen meridians on the lower abdomen and the meridians along the lower leg in the somatic areas that correspond to the ovarian innervation (Stener-Victorin, 2010).

(4) Acupuncture can affect the blood flow of the uterine arteries and to the ovaries (Stener-Victorin, 1996; Stener-Victorin, 2010). In order for pregnancy to occur, the endometrium must be receptive to implantation (Rizk, 2008; Stener-Victorin, 1996). The uterine artery blood flow is one factor that directly influences endometrial receptivity, among other factors such as uterine contractility and hormonal influences (Rizk, 2008; Stener-Victorin, 1996). The pulsatility index (PI) is a measure that reveals the blood flow impedance; the higher the PI, the more sluggish the blood flow through the vessel (Stener-Victorin, 1996). Acupuncture can lower the PI, thereby

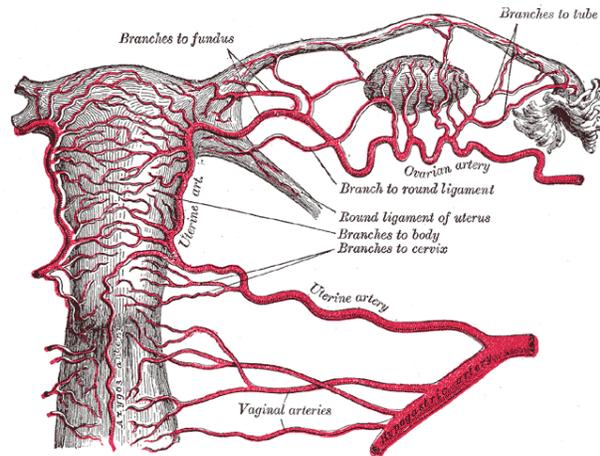


figure 1: uterine and ovarian arterial connection

improving blood flow through the uterine arteries and increasing circulation to the uterus, endometrium and ovaries, particularly when needles are placed in the low back and lower legs ('Stener-Victorin protocol') as described in the Stener-Victorin research and stimulated with low frequency EA (Stener-Victorin, 1996).

Since the objective of this research study is to examine the use of the Stener-Victorin and Paulus protocols, these two designated protocols will be examined in greater detail.

### **The Stener-Victorin Protocol**

In 1996, the study titled "Reduction of blood flow impedance in the uterine arteries of infertile women with electro-acupuncture" was published in the journal *Human Reproduction*. The authors, Elisabet Stener-Victorin, Urban Waldenstrom, Sven Andersson and Matts Wikland of the University of Gothenburg examined the effects of electro-acupuncture on infertile women. Little could these researchers have predicted that the protocol used in this study would become a treatment protocol used regularly by licensed acupuncturists treating fertility in the United States. While the sample in the study is very small, the results have piqued interest and controversy in the field of Reproductive Endocrinology (Deiterle, 2006; Smith, 2006; Paulus, 2002).

Ten women in total were the initial cohort for this study, and after two were excluded, eight were left to complete the study. These women all had infertility, an average age of 32.3 years, and each had a uterine artery pulsatility index (PI) of 3.0 or more. Each woman had the PI of her uterine arteries measured with transvaginal ultrasound and doppler. The final PI value was calculated by averaging out 3 cardiac cycles, at a particular time and when hormone levels

were at a specific level. All women were down-regulated with gonadotrophin releasing hormone analog. (Stener-Victorin, 1996)

Each woman was given the same electro-acupuncture protocol, with treatments administered twice a week for eight weeks. Acupuncture points used were: Urinary Bladder (UB) 23, UB 28, UB 57, and Spleen (SP) 6. UB 23 and UB 28 were attached to an electrical stimulator with a high frequency of 100 Hz pulses with 0.5 ms duration. UB 57 and SP 6 were attached and stimulated with a low frequency of 2 Hz pulses of 0.5 ms duration. The size of the needles was not mentioned, but they inserted them at a depth of 10-20 mm and achieved Deqi sensation. Over the course of the 8 week treatment period, the women had their PI's measured several times: at the beginning, directly after the eighth treatment, and again 10-14 days after the last treatment. The skin temperatures of the lumbosacral area and the forehead were also measured and recorded during the first, fifth and eighth EA treatments. (Stener-Victorin, 1996)

The concluding data reveals that the PI of the uterine arteries was significantly decreased after the 8 weeks of treatment and remained so at the follow up measurement 10-14 days after treatment. The researchers theorize that is is possibly due to inhibited sympathetic activity in general, and decreased activity in the sympathetic vasoconstrictor fibers that go to the uterus. Although the concluding evidence shed a promising light on EA treatment effects of the uterine artery's PI, the researchers acknowledge that a similar study on a larger scale is needed to solidify these findings. These final findings are beneficial to fertility acupuncturists because increased blood flow to the uterus can have a significant impact on improving rates of conception (Rizk, 2008; Stener-Victorin, 1996).

While this 1996 study is referred to in nearly all research reports concerning acupuncture and ART, only Paulus, et al. measured and recorded the uterine artery PI of infertile women involved in their research (Cheong, 2009; Dieterle, 2006; Hung, 2008; Magarelli, 2009; Manheimer, 2007; Paulus, 2002; Smith, 2006; Stener-Victorin, 2002; Stener-Victorin, 2006; Westergaard, 2006). Paulus et al. could not determine any measurable difference in the PI of the subjects' uterine artery as per the 1996 Stener-Victorin research (Paulus, 2002). The researchers attributed this to the possibility that a different set of acupuncture points was used (Paulus, 2002).

### **The Paulus Protocol**

The publication of the Paulus protocol played an important role in how acupuncture was launched into the field of Assisted Reproductive Technologies (ART). In 2002, *Fertility and Sterility* published the study, "Influence of acupuncture on the pregnancy rate in patients who undergo assisted reproduction therapy" written by Wolfgang Paulus, Mingmin Zhang, Erwin Strehler, Imam El-Danasouri and Karl Sterzik of the Christian-Lauritzen-Institut, Germany. One hundred and sixty women undergoing ART were given a specific acupuncture treatment 25 minutes before and after embryo transfer (ET). The women were from 21 to 43 years of age, with the average age of 32.5 years. Only those with good embryo quality were included in the study. The patients were divided into two groups - a control group and an acupuncture group - determined by computer randomization. All patients were given transvaginal progesterone from the day after the oocyte was retrieved until 14-16 days after ET. If there was a positive pregnancy test, the patients continued on the progesterone until gestational week 8. Before and after ET, all patients had a uterine ultrasound with a transvaginal probe, pulsatility index (PI) of

uterine arteries measured and recorded, and had blood samples drawn. Every women was placed in the same position and the same equipment was used for each procedure. A maximum of 3 embryos were transferred on day 2 or 3 post-retrieval with the patient resting for 25 minutes post-transfer (Paulus, 2002).

The acupuncture was administered both 25 minutes before and after ET, with a needle retention time of 25 minutes. The needle size used was 0.25x25 on the body and 0.2x13 on the ears, and the insertion depth was 10-20 mm with Deqi sensation attained with each bodily insertion. After the first 10 minutes, the needles were stimulated by manual rotation. The acupuncture points used before ET were: Pericardium (PC) 6, SP 8, Liver (LV) 3, Du 20, Large Intestine (LI) 4, and auricular points shenmen, zhigong, neifenmi, and naodian (2 in the right ear and 2 in the left ear). Post-ET acupuncture points consisted of: Stomach (ST) 36, SP 6, SP 10, LI 4 and the same auricular points but on the opposite side of where they were for pre-ET. These points were selected based on TCM and knowledge of modern physiology - using the Spleen and Stomach meridian points enhanced blood perfusion and moved qi in the uterus, and points that sedate the body and stabilize the endocrine system were included. LI 4 was included because of it's effect on inhibiting uterus motility (Paulus, 2002).

The results of this study indicate that acupuncture does have a positive effect on ART. The positive pregnancy rate of the acupuncture group was 42.5% compared to the control group rate of 26.3%. While the evidence of this study is compelling, the researchers concluded that more studies are warranted to determine the specific physiological effects of acupuncture on the reproductive system, and suggest a possible future trial involving placebo needling (Paulus, 2002).

Studies were conducted to eliminate some questionable variables in published research that had positive reports on acupuncture. The results of these trials were mixed; some studies that repeated similar studies as Paulus using the same acupuncture protocol yielded results that affirmed Paulus et al.'s findings while some found different results whereby there was no difference in pregnancy outcomes between the acupuncture group and the control group (Dieterle, 2006; Domar, 2009; Quintero, 2004; Smith, 2006; Wang, 2005; Westergaard, 2006).

Author, year, title	Sample size, Intervention	Outcome measurement	Conclusions	Comparison to Paulus, et. al
<p>Dieterle, S., Ying, G., Hatzmann, W., Neuer, A. 2006</p> <p><i>Effect of acupuncture on the outcome of in vitro fertilization and intracytoplasmic sperm injection: a randomized, prospective, controlled clinical study</i></p>	<p>225 subjects randomized</p> <p>Group I: 116 (study group) - acupuncture points that are indicated for fertility selected</p> <p>Group II: 109 (control group) - placebo acupuncture, points that do not influence fertility selected</p>	<ul style="list-style-type: none"> <li>• Biochemical pregnancy rates</li> <li>• Clinical pregnancy rates</li> <li>• Miscarriage rates</li> </ul>	<p>This study examined the effect of acupuncture on 2 groups of infertile women receiving IVF with ICSI.</p> <p>Clinical pregnancy rates were significantly higher in Group I patients Group I: 33.6% Group II: 15.6%</p> <p>As were the ongoing pregnancy rates: Group I: 28.4% Group II: 13.8%</p>	<p><i>Similar to Paulus:</i></p> <ul style="list-style-type: none"> <li>• examined the effects of acupuncture when used in conjunction with ART</li> <li>• Post transfer acu treatment administered 30 min after ET</li> <li>• Many of the same body and ear points</li> </ul> <p><i>Different from Paulus:</i></p> <ul style="list-style-type: none"> <li>• this study did not do a pre-ET acupuncture treatment</li> <li>• Point selection post-treatment not the same</li> <li>• Ear seeds used in this study</li> <li>• Followed patients up to 6 transfer cycles</li> <li>• Acupuncture 3 days later included</li> <li>• Sham acupuncture group included</li> <li>• Uterine artery PI not measured</li> </ul>

Author, year, title	Sample size, Intervention	Outcome measurement	Conclusions	Comparison to Paulus, et. al
<p>Domar, A., Meshay, I., Kelliher, J., Alper, M., Powers, R.D. 2009</p> <p><i>The impact of acupuncture on in vitro fertilization outcome</i></p>	<p>146 subjects randomized</p> <p>AC group - 78 Control group - 68</p> <p>The AC (acupuncture) group received the treatment protocol as described in the Paulus, 2002 study.</p>	<ul style="list-style-type: none"> <li>• Biochemical pregnancy rates</li> <li>• Clinical pregnancy rates</li> <li>• Chemical pregnancy loss rates</li> <li>• Outcome survey data</li> </ul>	<p>The acupuncture group had a slightly higher pregnancy rate (PR) but not enough of a difference to be considered statistically significant.</p> <p>PRs: AC group = 50% Control group = 42.6%</p>	<p><i>Similar to Paulus:</i></p> <ul style="list-style-type: none"> <li>• examined the effects of acupuncture when used in conjunction with ART</li> <li>• designed to replicate the Paulus study of 2002 - same acupuncture protocol used</li> </ul> <p><i>Different from Paulus:</i></p> <ul style="list-style-type: none"> <li>• included a survey asking patients about their anxiety levels and outcome optimism</li> <li>• control group laid quietly</li> </ul>
<p>Quintero, R. 2004</p> <p><i>A randomized, controlled, double-blind, cross-over study evaluating acupuncture as an adjunct to IVF</i></p>	<p>17 subject initially; 7 completed both arms.</p> <p>randomized</p>	<ul style="list-style-type: none"> <li>• Oocytes retrieved</li> <li>• Mature oocytes</li> <li>• Normal fertilization</li> <li>• Amount of gonadotrophins (IU)</li> <li>• Endometrial thickenss (mm)</li> <li>• Biochemical pregnancy rates</li> <li>• Clinical pregnancy rates</li> <li>• Ongoing pregnancy rates</li> </ul>	<p>When acupuncture is used in conjunction with IVF, a lower amount of gonadotrophins is required.</p> <p>Additionally, the PR for the standard AC w/ IVF group was 70%, while the sham group PR was 25%.</p>	<p><i>Similar to Paulus:</i></p> <ul style="list-style-type: none"> <li>• examined the effects of acupuncture when used in conjunction with ART</li> </ul> <p><i>Different from Paulus:</i></p> <ul style="list-style-type: none"> <li>• unknown if pre-ET acupuncture treatment given</li> <li>• Point selection unknown</li> <li>• Sham acupuncture group included</li> <li>• Different outcome measures</li> <li>• Uterine artery PI not measured</li> </ul>

Author, year, title	Sample size, Intervention	Outcome measurement	Conclusions	Comparison to Paulus, et. al
<p>Smith, C., Coyle, M., Norman, R. 2006</p> <p>Influence of acupuncture stimulation on pregnancy rates for women undergoing embryo transfer</p>	<p>228 subjects randomized</p> <p>AC group - 110 Control group - 118</p> <p>The AC group received the treatment protocol as described in the Paulus, 2002 study.</p> <p>The Control group received acupuncture points close by the ones described in the Paulus, 2002 study.</p>	<ul style="list-style-type: none"> <li>• Clinical pregnancy rates (fetal heart rate on ultrasound scan)</li> <li>• Ongoing pregnancy rates @ 18 weeks</li> <li>• SF36 Health status</li> </ul>	<p>No significant increase in the pregnancy rate between the two groups, although the percentages of those in the AC group are consistently higher. The study may have had a larger percentage of women over the age of 35 and those over 40 which would influence the PR.</p> <p>PR overall: AC Group = 31% Control Group = 23%</p> <p>PR for women &lt;35: AC group = 50% Control group = 33%</p> <p>Ongoing PR @ 18 weeks: AC group = 28% Control group = 18%</p>	<p><i>Similar to Paulus:</i></p> <ul style="list-style-type: none"> <li>• examined the effects of acupuncture when used in conjunction with ART</li> <li>• acupuncture performed before and after ET</li> </ul> <p><i>Different from Paulus:</i></p> <ul style="list-style-type: none"> <li>• sham acupuncture used in control group with sham needles</li> <li>• first treatment administered before egg collection</li> <li>• quality of embryos varied (only 'good' ones included in Paulus, 2002)</li> <li>• assessment of health questionnaire included</li> <li>• TCM diagnosis with appropriate acupuncture point selection made per subject</li> <li>• Uterine artery PI not measured</li> </ul>

Author, year, title	Sample size, Intervention	Outcome measurement	Conclusions	Comparison to Paulus, et. al
<p>Wang, W., Check, J., Liss, J., Choe, J. 2005</p> <p><i>A matched controlled study to evaluate the efficacy of acupuncture for improving pregnancy rates following in vitro fertilization-embryo transfer</i></p>	<p>64 subjects</p> <p>Control group = 32 AC group = 32</p>	<ul style="list-style-type: none"> <li>• Clinical pregnancy rates (fetal heart rate on ultrasound scan)</li> <li>• Ongoing pregnancy rates (past 1st trimester) OR delivered pregnancies</li> </ul>	<p>Acupuncture did not seem to improve pregnancy rates following IVF-ET.</p> <p>Clinical PR: Control = 53.1% AC = 40.6%</p> <p>Ongoing PR: Control = 43.7% AC = 37.5%</p>	<p><i>Similar to Paulus:</i></p> <ul style="list-style-type: none"> <li>• examined the effects of acupuncture when used in conjunction with ART</li> <li>• acupuncture performed before and after ET</li> </ul> <p><i>Different from Paulus:</i></p> <ul style="list-style-type: none"> <li>• Acupuncture point selection</li> <li>• Uterine artery PI not measured</li> </ul>
<p>Westergaard, L., Mao, Q., Kroglund, M., Sandrini, S., Lenz, S., Grinsted, J. 2006</p> <p>Acupuncture on the day of embryo transfer significantly improves the reproductive outcome in infertile women: a prospective, randomized trial</p>	<p>273 subjects randomized</p> <p>Control group = 87 ACU 1 group = 95 ACU 2 group = 91</p> <p>Control group had no acupuncture</p> <p>ACU1 group had acupuncture on the day of ET</p> <p>ACU2 group had acupuncture on the day of ET and again 2 days later.</p>	<ul style="list-style-type: none"> <li>• Implantation rates</li> <li>• Biochemical pregnancy rates</li> <li>• Clinical pregnancy rates</li> <li>• Miscarriage rates</li> <li>• Ongoing pregnancy rates</li> </ul>	<p>Acupuncture on the day of ET significantly improves pregnancy rates of IVF with ICSI when compared to no acupuncture. Acupuncture on the day of transfer plus 2 days post-transfer showed no additional benefit.</p> <p>Clinical PRs: Control = 21% ACU1 = 37% ACU2 = 33%</p> <p>Ongoing PRs: Control = 19% ACU1 = 34% ACU2 = 24%</p>	<p><i>Similar to Paulus:</i></p> <ul style="list-style-type: none"> <li>• examined the effects of acupuncture when used in conjunction with ART</li> <li>• acupuncture performed before and after ET</li> <li>• many of the same acupuncture points used pre-transfer</li> <li>• exact same points used post transfer</li> </ul> <p><i>Different from Paulus:</i></p> <ul style="list-style-type: none"> <li>• nurses administered acupuncture</li> <li>• 3rd group that received acupuncture 2 days post-transfer</li> <li>• Uterine artery PI not measured</li> </ul>

## **Literature Review Integration**

Assisted Reproductive Technologies have been firmly established in both Western and Traditional Chinese medical approaches (Lyttleton, 2004). The Traditional Chinese Medicine theories and procedures regarding the Stener-Victorin and Paulus protocols for fertility patients have been well documented in the literature (Bovey, 2010; Cheong, 2009; Dieterle, 2006; Domar, 2006; Hung 2008; Magarelli, 2009; Paulus, 2002; Smith, 2006; Stener-Victorin, 1996; Stener-Victorin, 2010; Westergaard, 2006). The Stener-Victorin and Paulus protocols are recognized as frequently used methods for fertility treatment in Traditional Chinese Medicine (Bovey, 2010; Domar, 2009; Magarelli, 2009). While there has been much written regarding the theory and procedures of these two popular fertility interventions, to date there have been no systematic studies published regarding practitioner preferences and the incidence of application of the Stener-Victorin and Paulus protocols. As a result, there is a gap or blind spot in the literature. It will be the objective of the current study to begin to fill that gap in the literature by completing a study that collects and analyzes survey data from Traditional Chinese fertility practitioners regarding a number of variables pertaining to the use of the Stener-Victorin and Paulus protocols.

## CHAPTER 3: METHOD

### Method Designation

Survey method was used to collect data in the current study. Survey method is considered to involve descriptive and cross-sectional procedures. In the current study, survey method engaged quantitative data. Because the objective of the current study is to discern the practice habits of clinicians regarding the use of two published acupuncture fertility protocols, survey method is deemed to be the most appropriate method as it allowed for the crafting of response items that are specifically worded to discern the nuances of each respondents experience and practice regarding the two designated acupuncture protocols.

### Rationale for the Use of the Survey Method

The survey is a useful instrument that is important for gathering data particularly when the research is based on the opinions and patterns of a population (Burke, 2006). Surveys can be divided into two main categories: the interview and the questionnaire (Trochim, 2006). This study included a questionnaire conducted exclusively on-line. More and more, individuals and communities are using the internet as a communication and information tool (Wright, 2005). Some advantages of conducting an on-line survey are:

- There is greater access to specific populations via email and individual websites that may otherwise be more difficult or time consuming to locate.
- There is an increased ease of use for the participant, who may answer the survey at their convenience and at any time of the day or night, and from any location that is convenient for them.

- A great deal of time is saved on the part of the researcher, as surveys are completed and organized by the site host so that the researcher is freed up to work on other tasks (Wright, 2005).
- There is less likelihood of losing or misplacing paperwork and letters, this applies to both the researcher and the participants, as well as the postal service or any other individuals that may handle the mail in transit (secretaries, family members, etc.).
- There is a decrease in costs for the researcher; on-line survey hosting sites are relatively inexpensive, and it eliminates postage fees and materials costs (paper, envelopes, ink, etc.) (Pohlman, 2010; Wright, 2005). Postage would entail both the stamp for the letter and materials being sent to the participant as well as the return envelope (Bovey, 2010; Lee, 2009).

Conversely, there are distinct disadvantages to keeping the survey limited to an on-line population. As we are all aware, not all segments of the population are proficient enough with computers, and not all people have access to an on-line computer. Other significant disadvantages include:

- The researchers lack of access to a valid email address - even when a practitioner has a functional website, an email is not always made public (Wright, 2005).
- The researcher may encounter several emails for one individual without realizing these are for the same person, and there may be multiple responses from one individual (Lee, 2009; Wright, 2005).
- Potential participants may see the initial email from the researcher as “spam” or “junk mail” and therefore disregard the email without opening or reading it.

While many of the disadvantages are important to acknowledge, the benefits of conducting an all on-line survey through SurveyMonkey outweigh the negatives. Because the survey in the current study has targeted a specific population, and that population stands to gain from the results of the survey, it was anticipated that many of the potential respondents will be interested in participating in the research.

### **Survey Instrument**

The survey instrument used in the current study included four sections:

1. **Demographics:** This section includes data regarding gender, ethnicity, income, hours worked, number of patients & fertility patients treated per week, marketing information, and ABORM status of the respondent.
2. **Training:** This section includes items that reflect the educational background of the respondent. Among the items are the name of the TCM school, the country where the respondent studied, as well as items that reflect whether the respondent has had OB/GYN training or other post-graduate training in fertility/reproductive medicine.
3. **Practice factors:** This section of the survey included items that reflect to whom the respondent is likely to refer patients (e.g. to Reproductive Endocrinologists, to other fertility specialists) and if the respondent works in collaboration with fertility clinics. Additionally, data such as the number of hours works, the number of patients treated per week, and the respondents practice setting are considered here.

4. Protocols: This section of the survey includes items that discern the practice patterns engaged by respondents regarding the uses of the two designated fertility acupuncture protocols.

At the end of the survey instrument there was a space for the respondent to include any additional comments. The survey included a total of 37 items and should take most respondents an estimated 15-20 minutes to complete. Response options are based on the nature of the question with most items including two to five options. Most items on the survey in the referral and protocol sections were formatted with a XXX. A copy of the survey form is included in the Appendix of this document.

The survey used in the current study is one that has face validity. This is a “type of validity that assures that “on its face” the operationalization seems like a good translation of the construct” (Trochim, 2006). The face validity of the current survey is supported by the fact that the items in the survey were crafted specifically to elicit the information that the researcher sought. There were no hidden agendas or obscure/ambivalent items. All items were clearly articulated using simple straight forward language with minimal jargon or technical terminology.

### **Survey Administration**

Contact with each potential respondent was engaged mostly on line. The initial emailed letter was sent to each potential respondent and included:

- Introductory letter: an introduction briefly explaining the Yo San DAOM program, the capstone project, the goals of the project, expectations of participants, information regarding SurveyMonkey, instructions on how to proceed and the background and contact information of the researcher.

- Survey link: At the bottom of the introduction letter was a link which when clicked automatically opened a new window directly to the survey. The consent form was embedded right into the survey as the first question. The consent form informed the potential respondent regarding the details of the survey and discussed the issue of confidentiality and anonymity. Participants had the option to click “Agree” or “Disagree” to electronically sign the consent form and continue on with the survey.

The survey design for this study was already posted for subject response via the SurveyMonkey website before the introductory emails were sent out. The SurveyMonkey link was activated for approximately 45 days so that all participants had the opportunity to go to the website and respond to the survey items. Data collection procedures were completed entirely online. Since the subjects were responding to an on-line survey, the data were stored and sorted automatically by the SurveyMonkey host site. The principal investigator had access to the data and was able to view and evaluate the progress of data collection on an ongoing basis as well as to assess when the full set of data are in. The researcher checked every several days to discern the number of subjects who had completed the survey; thus the researcher was able to identify when there was a need to send out a reminder email with the link included. Two reminder emails were sent out every two weeks from the time of the initial email.

## **Subjects**

A goal of the current study was to get a minimum of 30 subjects to complete the survey. Email invitations to participate in the research were sent to more than 150 practitioners. The

respondents to the survey were sought from a highly specific and clearly defined population.

The respondents had to meet the following qualifications:

- Each respondent must hold licensure with the California Acupuncture Board (CAB).
- Each respondent must be in practice as an acupuncturist in Los Angeles, California.
- Each respondent must advertise or otherwise identify him/herself as a fertility specialist on their website, Acufinder.com, or Healthprofs.com profile.
- Each respondent must have access to a computer and the internet with an active email account.
- Respondents must indicate informed consent and be willing to respond to the survey honestly and to the best of their ability.

Since the CAB has specific requirements for licensure, it can be assumed that each respondent is at least 18 years of age and has met the educational and background clearance requirements.

The sample of respondents can be described as a purposive sample. Purposive (non-probability) and expert sampling were used to identify individuals who met the inclusion criteria as detailed in the above bulleted items. “In purposive sampling, you sample with a purpose in mind. Expert sampling involves the assembling of a sample of persons with known or demonstrable experience and expertise in some area.” (Trochim, 2006). This group was identified primarily on-line by accessing publicly available information via the American Board of Oriental Medicine (ABORM) website, Acufinder.com, Healthprofs.com, Google search, websites of individual practitioners and experts. The criteria of the potential respondents as fertility practitioners is that each chosen to be invited to participate in the research have

“infertility”, “fertility enhancement” or “reproductive health” as terms specifically included on their websites. Those practitioners listed on Acufinder that have “infertility” checked on the list of specializations were included. For those potential respondents listed on the ABORM website, it can be assumed that the specialty is in fertility because of the nature of that board specialization. Once the respondents were identified, an introductory email with a link to the survey and online consent form were forwarded to each. For those practitioners that are located on-line and who have no email address listed, the researcher phoned the office in an attempt to secure a valid email address.

### **Data Analysis**

Each survey item was originally planned to be tallied as per the categorical options of the “demographic”, “education”, “clinical practices”, “referral” or “protocol” items on the survey, however, once the data was collected and reviewed these groupings were altered slightly. The survey items are grouped in the following sub-sections: “demographics”, “practice factors”, “training factors”, “treatment protocol”, and are followed by another section titled “statistical analysis”. Descriptive tallies are enumerated for each of the categorical items. All spreadsheet data was compiled by the SurveyMonkey website, they are likely to have high reliability, with minimal possibility of computational error. All Chi squares were run with GraphPad Software’s quickcalcs online calculator for scientists applet. As a result for the current research study there is no need to engage a process to demonstrate the inter-scorer reliability. The data is displayed in a table format displaying tallied data - frequency and percentages of answers will be presented adjacent to the survey question topic.

The data that emerged from the study were analyzed using both descriptive and inferential statistical methods. “Descriptive statistics describe the basic features of the data in a study and provide simple summaries about the sample and the measures; Inferential statistics is the process of trying to reach conclusions that extend beyond the immediate data” (Trochim, 2006). Descriptive statistics were used to summarize the responses of the sample and all of the “demographic”, “practice factors”, “training factors”, “treatment protocol” and “statistical analysis” items. Inferential statistics were utilized as appropriate to discern if there are presently any significant statistical differences regarding critical “treatment protocol” items and critical “demographic”, “training” or “practice” factors. The inferential statistic that will be used is the Chi square for significance of difference between groups.

There were five categories of Chi squares analyzes performed. The five categories are listed below. For each category there were two similar Chi squares contingency tables constructed: one regarding the Stener-Victorin protocol and one regarding the Paulus protocol for a total of ten Chi squares. After grouping variables are distinguished, the following subjects were assessed with Chi square:

1. Comparing individuals that trained in China with those that trained in the US.
2. Comparing the level of post-graduate TCM fertility training in individuals that use and do not use the protocols (i.e., grouping the respondents as having more than 50 hours of post-graduate training or having less than 50 hours of post-graduate training).
3. Comparing the level of post-graduate western reproductive medicine training in individuals that use and do not use the protocols (i.e., grouping the respondents as having more than 50 hours of post-graduate training or having less than 50 hours of post-graduate training).

4. Comparing the number of fertility patients treated per week in individuals that use and do not use the protocols (i.e., grouping the respondents as treating more than 20 fertility patients per week or less than 20 fertility patients per week).

5. Comparing practitioners that work with Reproductive Endocrinologists and use the protocols vs. those that work with RE's and do not use the protocols.

While this research project constitutes a preliminary study, the researcher has designated hypotheses based on the five Chi square categories:

1. Fertility acupuncturists that were trained in the US are familiar with and use the published protocols more so than fertility acupuncturists trained in China.

2. Fertility acupuncturists that have a greater number post-graduate training are familiar with and use the published protocols more so than fertility acupuncturists that have fewer hours of post-graduate training.

3. Fertility acupuncturists that treat a greater number of fertility patients per week are familiar with and use the published protocols more so than fertility acupuncturists that treat a fewer number of fertility patients per week.

4. Fertility acupuncturists that work with REs are familiar with and use the published protocols more so than fertility acupuncturists that do not work with REs.

In the above five mentioned Chi square scenarios, the dependent variables are the Stener-Victorin protocol and the Paulus protocol (and the use or non-use of them); and the independent variables are:

1. Location of training

2. Number of hours of postgraduate training (both in TCM and western reproductive medicine)
3. Number of fertility patients treated per week
4. Working with an RE.

### **Validity**

The survey used in the current study is one that has face validity. This is a “type of validity that assures that "on its face" the operationalization seems like a good translation of the construct” (Trochim, 2006). The face validity of the current survey is supported by the fact that the items in the survey were crafted specifically to elicit the information that the researcher sought. There were no hidden agendas or obscure/ambivalent items. All items were clearly articulated using simple straight forward language with minimal jargon or technical terminology.

External threats to validity would include:

- Respondent “goofing” around - intentional false responses.
- Respondents answering randomly without consideration or thought to the answer.
- Respondents answering in a deliberate oppositional manner with the intent to “muck up” the data.

An internal threat to validity would be the researcher making errors in computation of the tallies, means or other statistical data. Since the target population is composed of licensed professionals who have personal integrity and are likely to help a colleague they do not know, it is highly unlikely that they responded in a dishonest manner. Additionally, since answering the

survey is completely voluntary, there were no consequences for participation or non-participation and therefore respondents were most likely to respond honestly.

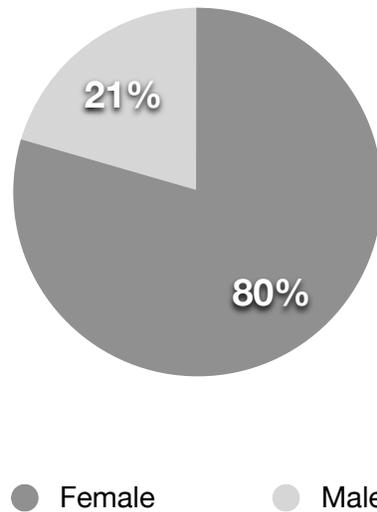
## CHAPTER FOUR: RESULTS

### Chapter Overview

This research project focused on the administration of a survey examined demographic data, practice patterns, training factors, and treatment protocol usage of acupuncturists that treat fertility patients in Los Angeles. The data that resulted from this survey are displayed in the tables below, organized by the above mentioned four categories. Other than for question #1 which was the participants agreement to the informed consent, respondents were given the option to skip any of the questions in the survey. As a result, the reader should note that the number of respondents varies among the survey questions, and the ensuing percentages are based in these figures. Additionally, the graphs illustrated in the tables do not display the exact figures but are merely a visual representation; the exact numerical percentages and figures of each survey item can be located in Appendix D.

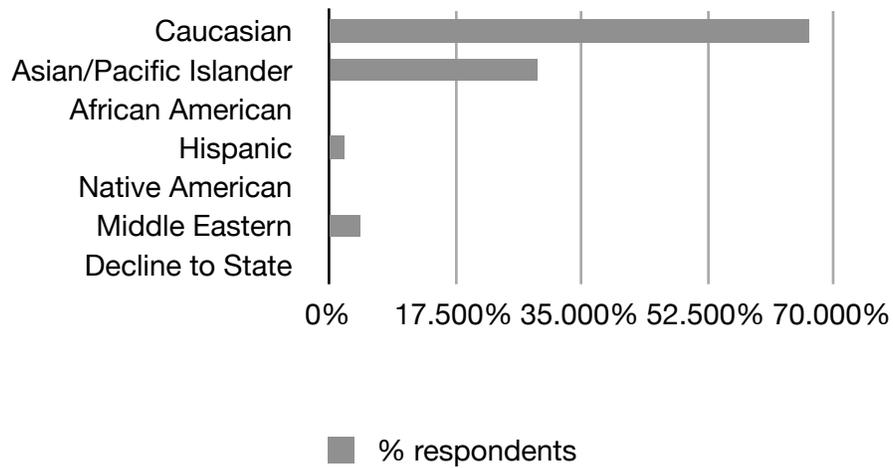
### Demographic Data

Of the 44 respondents that answered, 80% are female. This figure is not surprising for several reasons. First, the majority of patients seeking acupuncture therapy for fertility are females. It is likely and logical that females treating for fertility would prefer a female practitioner. Of practitioners that practice acupuncture and specialize in infertility, the majority are women (Bovey, 2010). Secondly, there is a higher population of female students in TCM schools in general and therefore a larger percentage of female practitioners in California (<http://collegeprowler.com>). (See table 1 below).

**Table 1: Gender of Respondents**

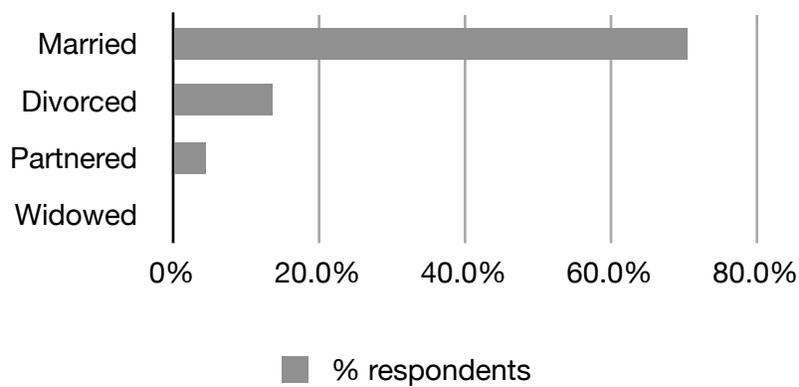
As illustrated in table 2 below, the majority of the respondents were Caucasian (approximately 68%) with the next closest ethnic group being Asian/Pacific Islander (30%). The observed data highlight the fact that with the exception of Asians, the profession of Traditional Chinese Medicine and especially for numbers of those who serve fertility patients continues to lag behind population expectations for other ethnicities. It should be noted that African-American (8.7% of the population of Los Angeles) and particularly Hispanic individuals (47.7% of the population of Los Angeles) (U.S. Census Bureau, 2010), who have a substantive representation in the Los Angeles population, are grossly underrepresented in the current sample.

**Table 2: Ethnicity of Respondents**



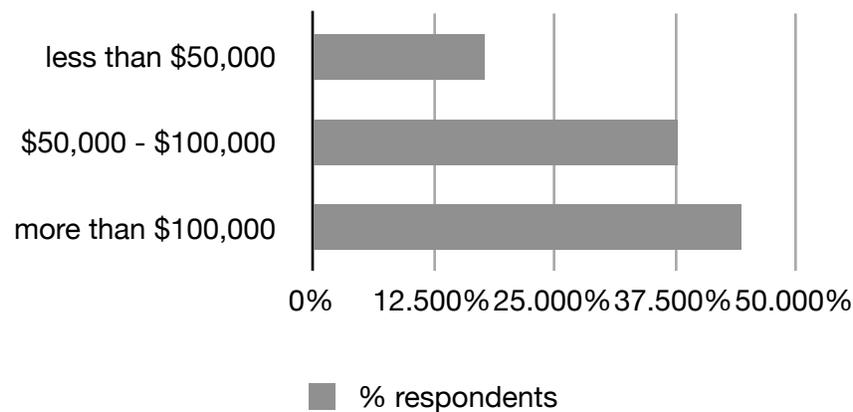
It was interesting to observe that 70% of the respondents indicated that they are married, with only approximately 12% indicating that they are divorced. This figure indicates that members of the TCM profession especially those who serve fertility patients represent a group that has stability, commitment and tenacity.

**Table 3: Marital status of Respondents**



As illustrated in Table 5, forty-five percent of the respondents reported that they earned over \$100,000 per year. The observed data are likely a positive sign for the profession and specifically for the specialty of fertility medicine, as it exceeds the nationwide mean income of Traditional Chinese Medicine practitioners (Payscale.com, 2011) This factor may be accounted for by the fact that the respondents were all from the Los Angeles area, which is considered to be an economically prosperous area. (See table 4 below).

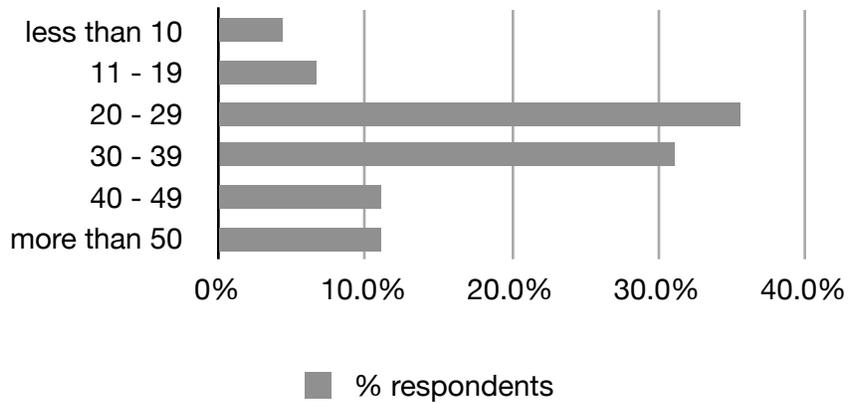
**Table 4: Annual gross income of Respondents**



### Practice Factors

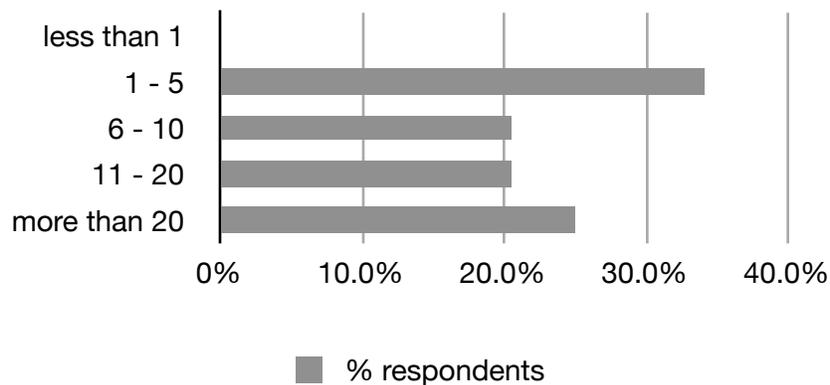
The data in this category examine the patterns of acupuncturists that treat infertility in Los Angeles. Over 66% of respondents report that they work between 20-39 hours per week. There was a wide range of answers to this response, ranging from 'less than 10' to 'more than 50'. The survey did not distinguish if those answering 'less than 10' did so by choice or by circumstance. (See table 5 below).

**Table 5: Hours Worked per Week of Respondents**



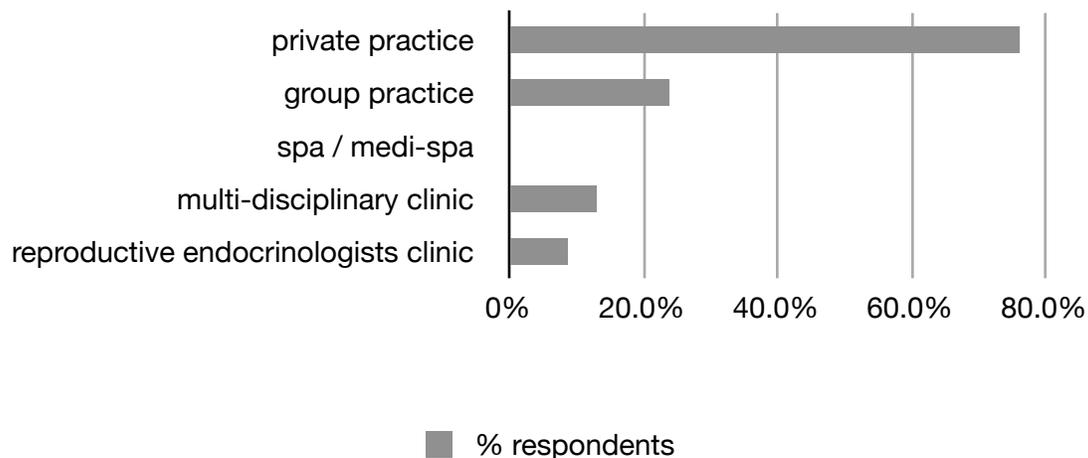
While the majority of the respondents report being in practice for 1-5 years, overall there was a wide range of responses in regard to the number of years being in practice from 6-20 years and those with more than 20 years. Practitioners with more clinical experience would have had more advanced training (due to continuing education licensing laws) and may therefore be more likely to have been exposed to the scientific literature regarding the protocols named in the survey. (See table 6 below).

**Table 6: Years in Practice of Respondents**



Seventy-six percent work in private practice and 0% reported working in a spa setting. These data are likely a reflection on the fertility specialty as it is common to see other types of practitioners in a spa setting (such as facial rejuvenation specialists). Additionally, these data are consistent with the trends of acupuncturists and practitioners of TCM in general that don't specialize in fertility, with an estimated 75% of California's licensed acupuncturists being in private practice (Dower, 2003). (See table 7 below).

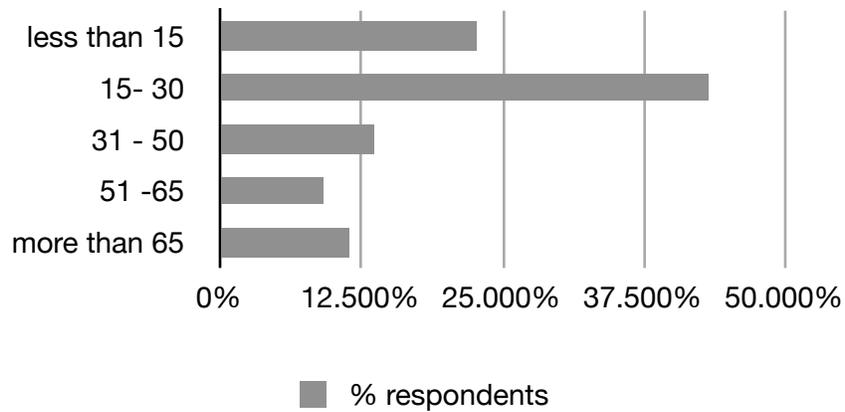
**Table 7: Settings Respondents Work in**



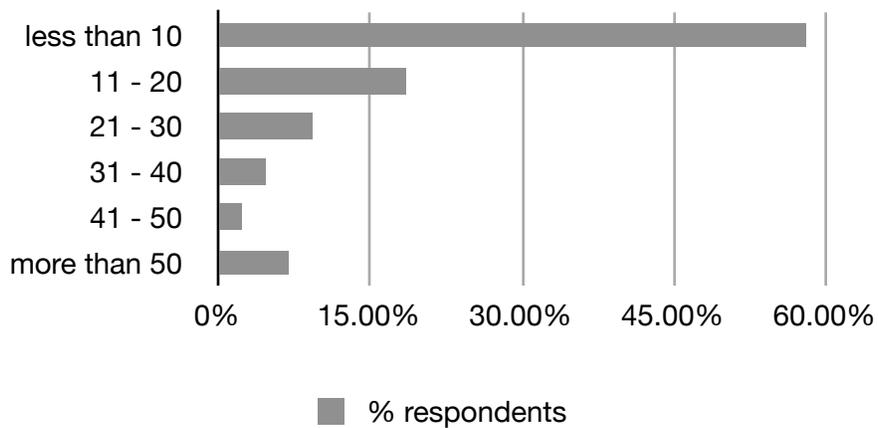
Forty-three percent of the 44 respondents said that they treat between 15-30 patients per week while 58% reported treating less than 10 fertility patients per week. The survey did not discern if the same patient was treated more than one time per week, so this may not accurately reflect the number of fertility treatments administered per practitioner per week. Additionally, the survey did not correlate the percentage of each respondent's practice - ie., table 8 displays the number of patients that the respondents treated per week and table 9 shows the number of

fertility patients treated per week, but the data on the tables are not comparable. (See tables 8 and 9 below).

**Table 8: Number of Patients Treated per Week by Respondents**



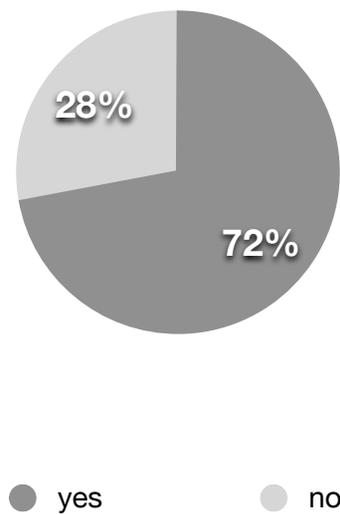
**Table 9: Number of Fertility Patients Treated per Week by Respondents**



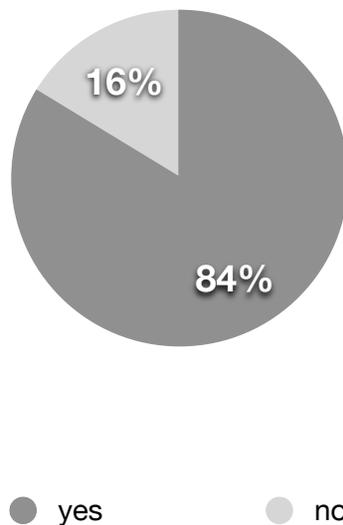
The majority of the respondents affirmed that they self-identified as a fertility specialist as well as advertising that they treat fertility. This may be indicative of the trend in popularity of

patients seeking practitioners that treat fertility. The research supporting the success of acupuncture and TCM with infertility patients may also have had an influence on these data. This may also be reflected by the abundance of post-graduate fertility training programs such as continuing education and Yo San’s DAOM program. (See tables 10 and 11 below).

**Table 10: Respondent Self-Identification as Fertility Specialist Data**

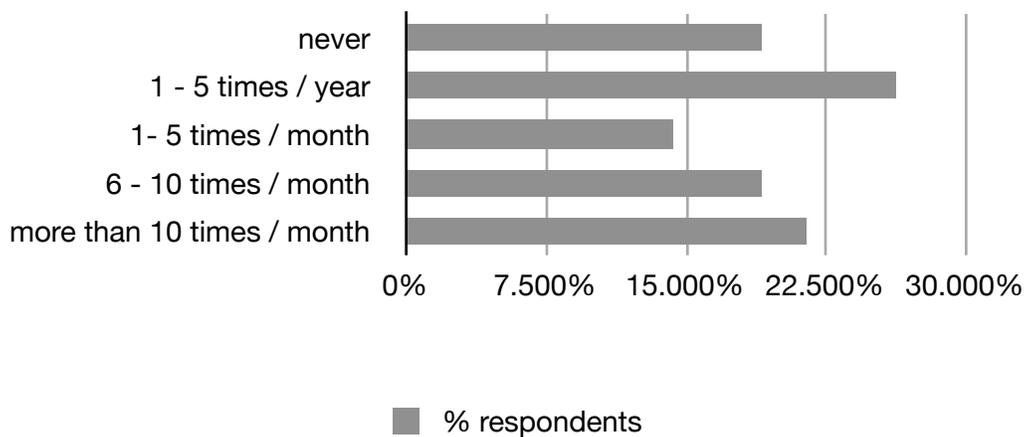


**Table 11: Respondents that Advertise Fertility Treatments**

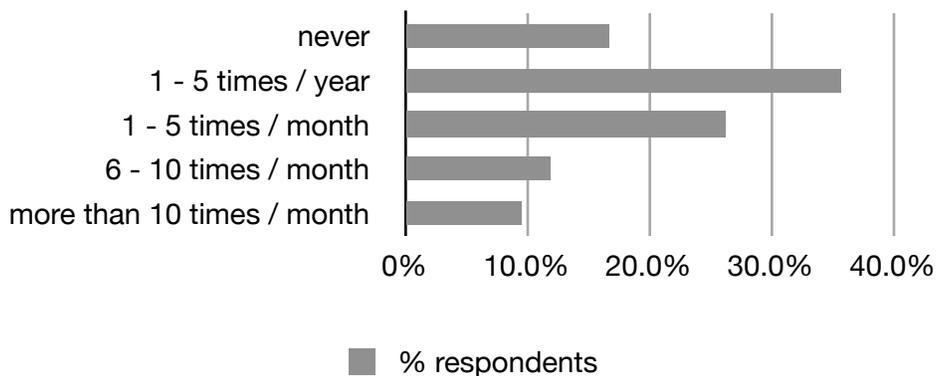


In another part of the survey, the respondents were questioned about the other health care providers that they collaborate with. There was a spectrum of responses to how often they work with a reproductive endocrinologist (RE) although the majority (26%) reported they work with an RE 1-5 times per year and 35% said they work with an OB/GYN 1-5 times per year. While this data reflects some integration of TCM with western medicine in the fertility specialty, it indicates that acupuncturists may be “under-utilized” in the field of gynecology and infertility. (See tables 12 and 13 below).

**Table 12: Frequency Respondents Work with Reproductive Endocrinologists (REs)**

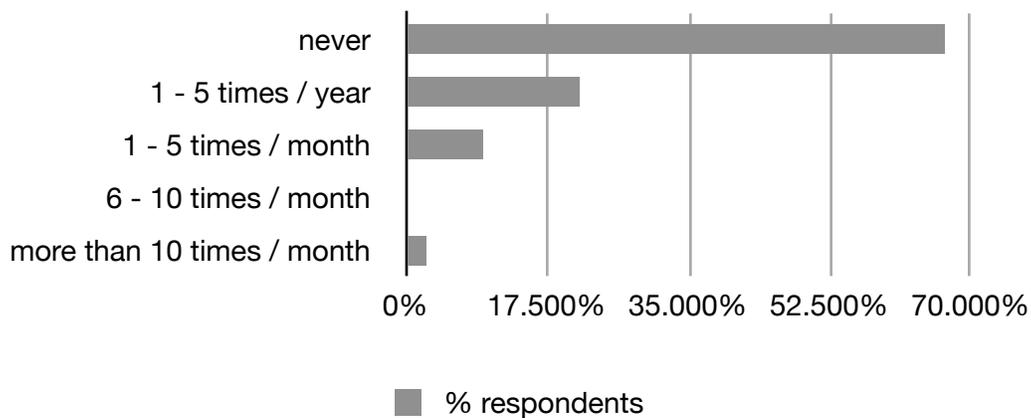


**Table 13: Frequency Respondents Work with Obstetrician/Gynecologists (OB/ GYNs)**

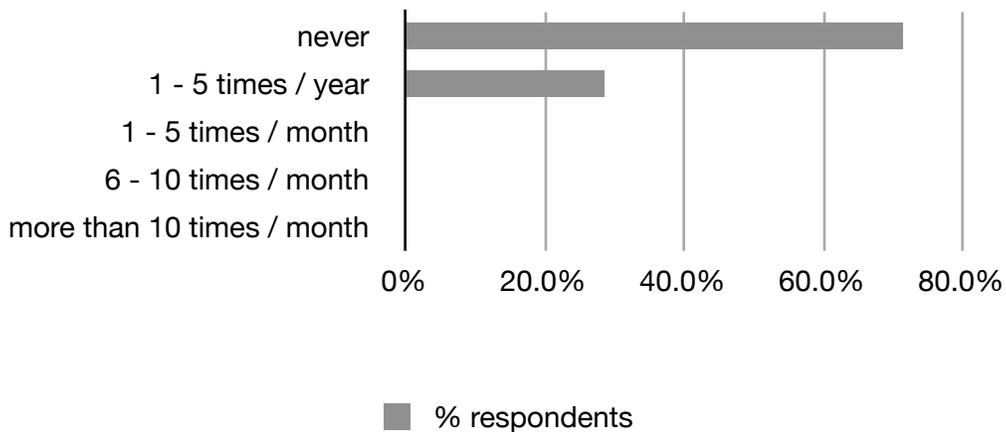


The majority of respondents never work with nurse practitioners and naturopathic doctors. In general, nurse practitioners do not treat fertility and are not trained to perform ART techniques as REs are. Naturopathic doctors have only recently gained licensure in the state of California and thus it is logical that there are not naturopathic doctors that are specializing in infertility at this point in time. (See tables 14 and 15 below).

**Table 14: Frequency Respondents Work with Nurse Practitioners (NPs) that Treat Fertility**

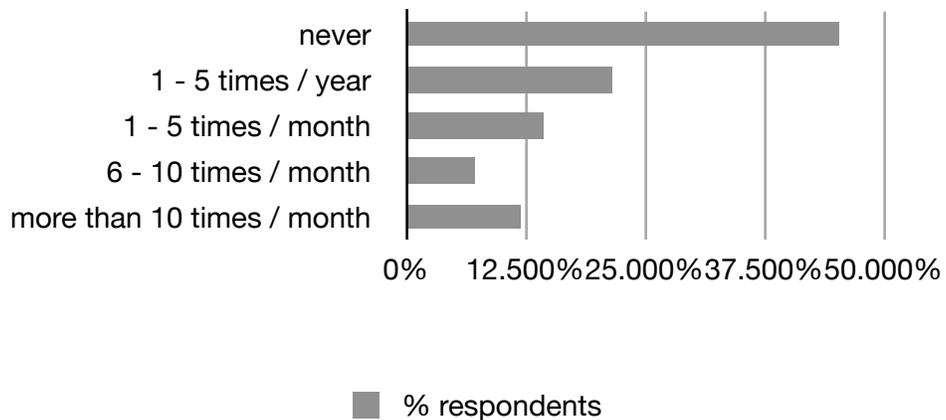


**Table 15: Frequency Respondents Work with Naturopathic Doctors (NDs) that Treat Fertility**



Forty-five percent said they never work in a fertility clinic doing acupuncture in conjunction with assisted reproductive technology (ART) and 12% of respondents reported that they work with ART procedures more than 10 times per month. Twenty-one percent of respondents replied that they do acupuncture with ART procedures between 1-10 times per month. This means that 33% of respondents perform acupuncture with ART procedures on a monthly basis. When this total is added to the respondents that do acupuncture with ART 1-5 times per year (24%), the figure increases to 57%. Therefore, overall in total there are more respondents that work in fertility clinics doing acupuncture with ART than those that do or have not. This is an encouraging statistic for the growth of the specialization of fertility acupuncture. (See table 16 below).

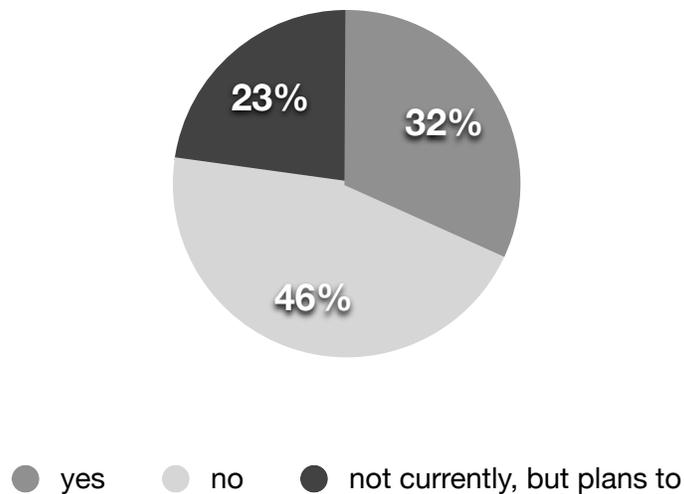
**Table 16: Frequency Respondents Work in Fertility Clinics Doing Acupuncture with Assisted Reproductive Technologies (ART)**



## Training Factors

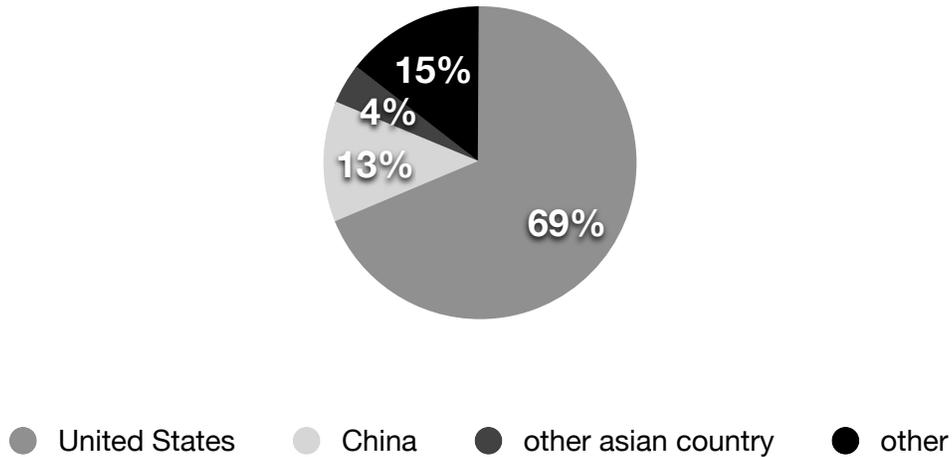
The data presented in this segment of the survey reflect the respondents education and training. Almost half (45.5%) of the respondents reported that they are not members of the American Board of Oriental Reproductive Medicine (ABORM) but 23% stated that they plan to become a member and 32% responded that they are already members. This denotes that half of the respondents value this specialty board certification. ABORM currently has 60 members in California and 158 members nationally (ABORM, 2011). (See table 17 below).

**Table 17: American Board of Oriental Reproductive Medicine (ABORM) Status of Respondents**



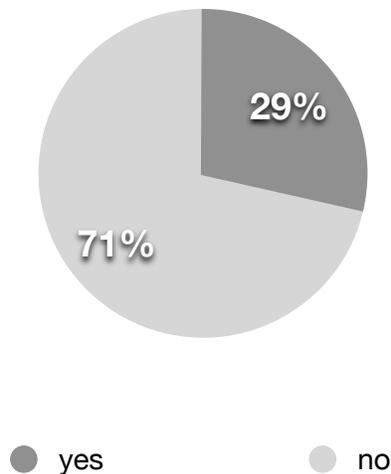
Sixty-nine percent of respondents received their training in the United States, and 19% of the remaining 31% trained in China or another asian country. It is expected that the majority of practitioners would be US trained, being that the survey took place in this country. It also makes sense that the majority of those respondents who did not train in the US trained in China or another asian country since this the where the medicine originated. (See table 18 below).

**Table 18: Oriental Medicine Training Location Data**



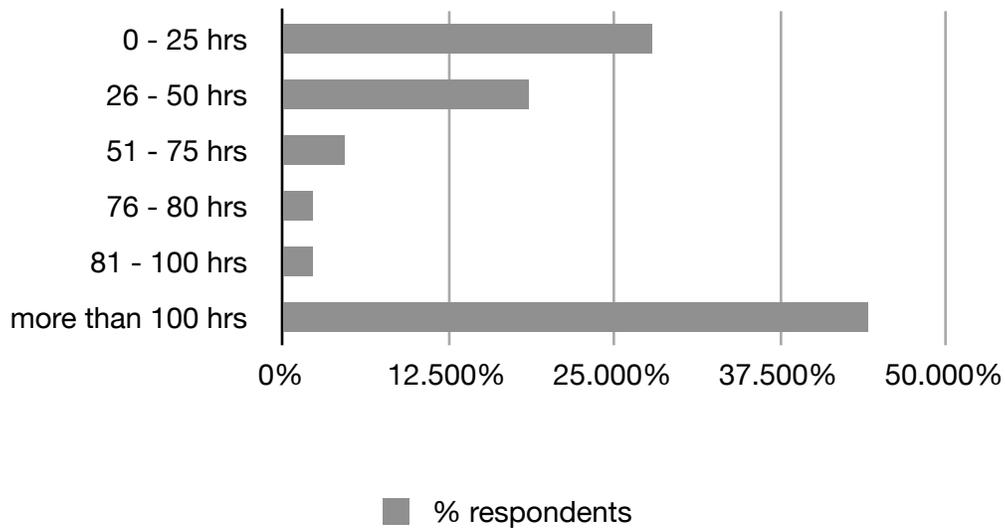
The majority of respondents (69%) answered that they had separate OB/GYN training as part of their education, however the survey question does not reveal the amount of OB/GYN education the respondents may have received in other coursework/classes during their training. For example, gynecology may have been integrated into a integrated medicine or an internal medicine course. Additionally, information regarding training before respondents TCM training (ie., previous nursing or medical training) were not reflected. (See table 19 below).

**Table 19: Respondents with a Separate OB/GYN Course During Training**

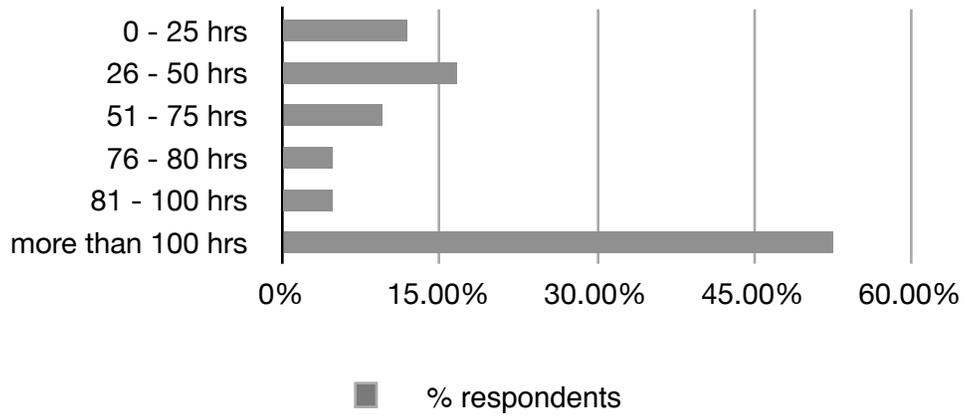


The majority of respondents reported a high level of post-graduate training in fertility in western reproductive medicine: 44.2% reported more than 100 hours of training and another 28% stated that they had done between 26-100 hours. Regarding post-graduate training in fertility in Traditional Chinese Medicine, again, the majority reported more than 100 hours of training (52.4%) and another 35.8% had completed between 26-100 additional hours. Twenty-eight percent of respondents have earned doctorate degrees, though not all in the field of TCM. These elevated figures reflect an advanced level of training of most fertility acupuncturists and support the idea that acupuncturists need supplemental training to effectively treat fertility patients. (See tables 20, 21 and 22 below).

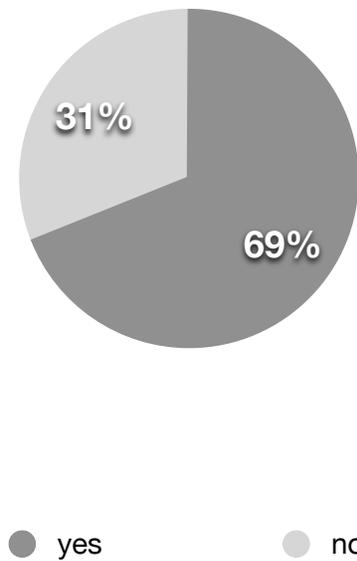
**Table 20: Respondents Level of Post-Graduate Training in Fertility in Western Reproductive Endocrinology.**



**Table 21: Respondents Level of Post-Graduate Training in Fertility in Traditional Chinese Medicine**



**Table 22: Doctorate Program Completion of Respondents**

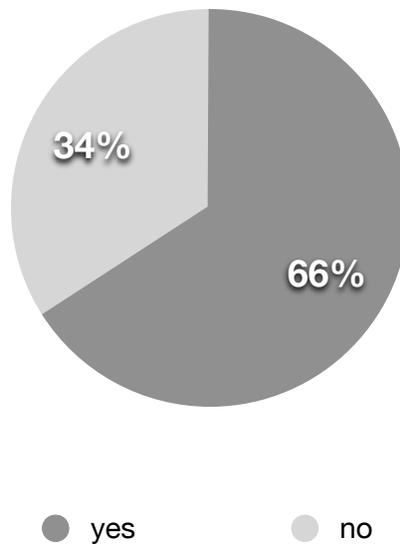


### Treatment Protocol Data

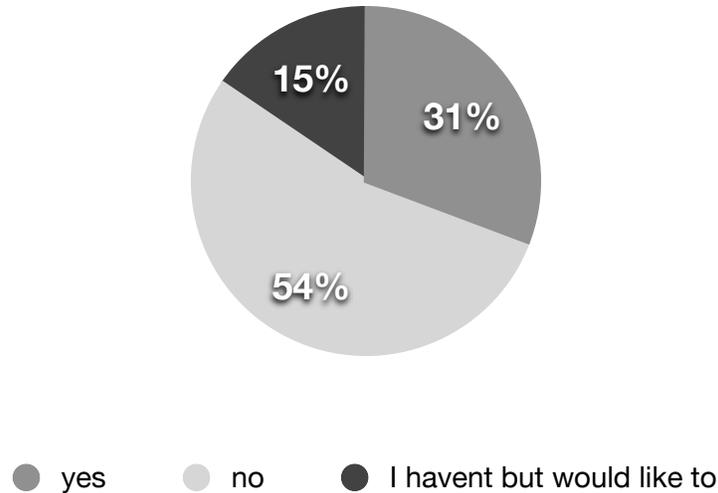
This section focuses on the data generated regarding the clinical use of the Stener-Victorin and Paulus protocols when treating fertility patients.

Sixty-six percent of respondents reported that they are familiar with the Stener-Victorin acupuncture protocol, but only 31% report that they use it in practice. This discrepancy may be due to several factors: there may be a lack of training or confidence in the protocol, the practitioner may not wish to follow a protocol, or the practitioner may have other preferences in selecting treatment strategies. (See tables 23 and 24 below).

**Table 23: Respondents Familiarity with the Stener-Victorin Study Acupuncture Protocol**

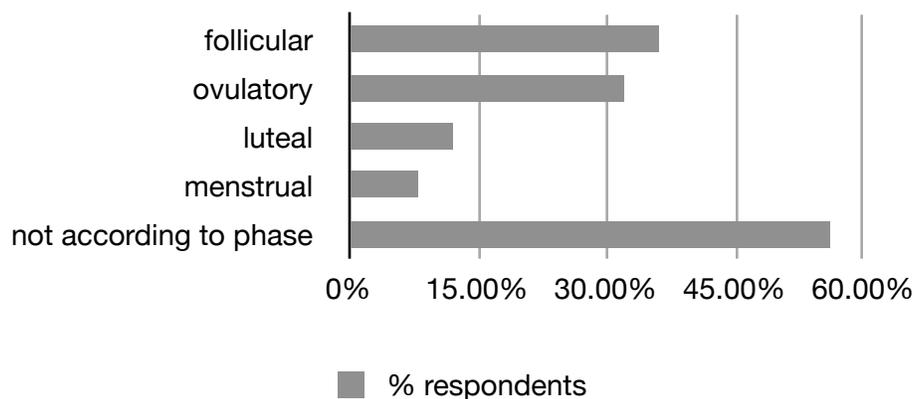


**Table 24: Respondents That Use the Stener-Victorin Protocol with Fertility Patients**



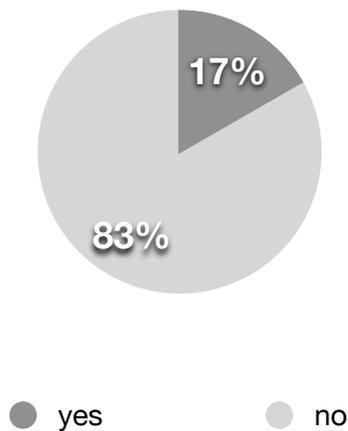
Most respondents do not use the protocol according to phase (56%), but those that do mostly use it in the follicular phase (36%) or the ovulatory phase (32%). These data are to be expected, since it was demonstrated in the original study that the Stener-Victorin protocol was effective in increasing the blood flow through the uterine arteries, a process that is increased during the follicular and ovulatory phases (Speroff, 2005). (See table 25 below).

**Table 25: Phase(s) in Which the Respondents Use the Stener-Victorin Protocol**

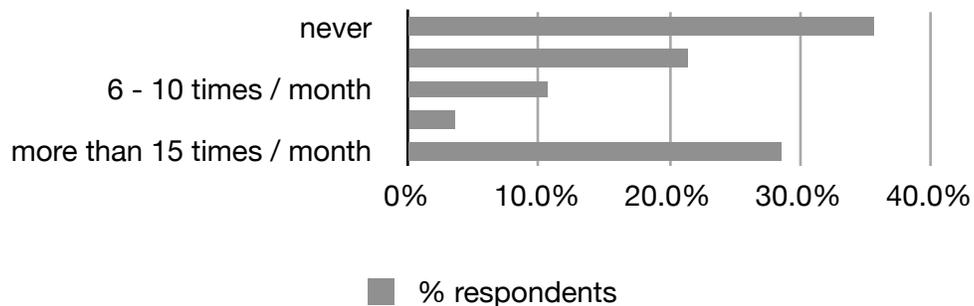


Eighty-three percent of respondents answered that they did not follow the Stener-Victorin protocol as exactly mentioned in the study. Thirty-six percent of respondents reported that they never used additional acupuncture points at the same time they are using the Stener-Victorin protocol, while 29% reported that they used additional acupuncture points along with the protocol more than 15 times per month. The addition of other acupuncture points when performing the protocol would allow the acupuncturist to tailor the treatment to the individual’s needs while still accomplishing the goals of the protocols effects. (See tables 26 and 27 below).

**Table 26: Respondents That Follow the Stener-Victorin Protocol Exactly as per the Stener-Victorin Study.**



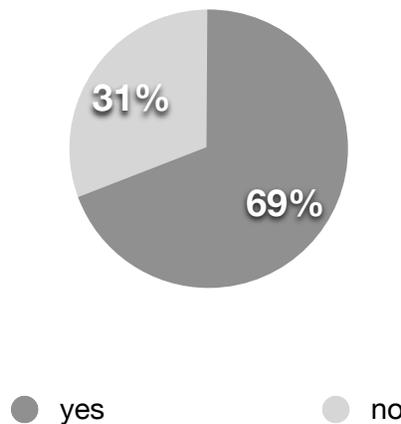
**Table 27: Frequency in Which Respondents use Additional Acupuncture Points Concurrently with the Stener-Victorin Protocol**



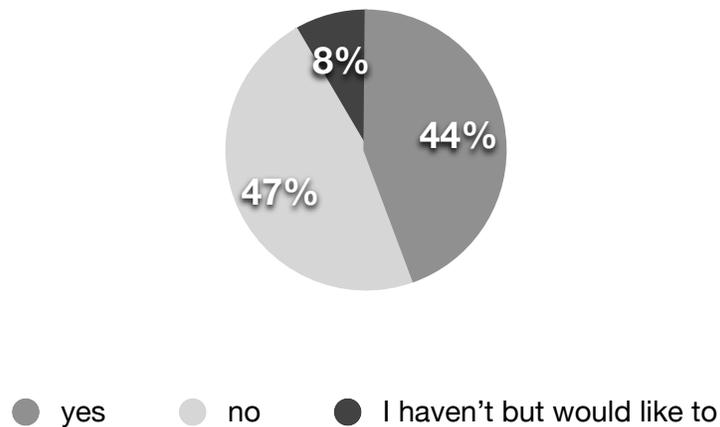
Paulus Protocol

Sixty-nine percent of respondents reported that they were familiar with the Paulus study protocol and 44% answered that they use it in clinical practice. As mentioned above with the Stener-Victorin protocol, the discrepancy between these figures could be due to a lack of training or confidence in the protocol, not wishing to follow a protocol, or having other preferences in selecting treatment strategies. In comparison to the Stener-Victorin protocol, a larger percentage of respondents utilize the Paulus protocol in practice. (See tables 28 and 29 below).

**Table 28: Respondents Familiarity With the Paulus Study Acupuncture Protocol**

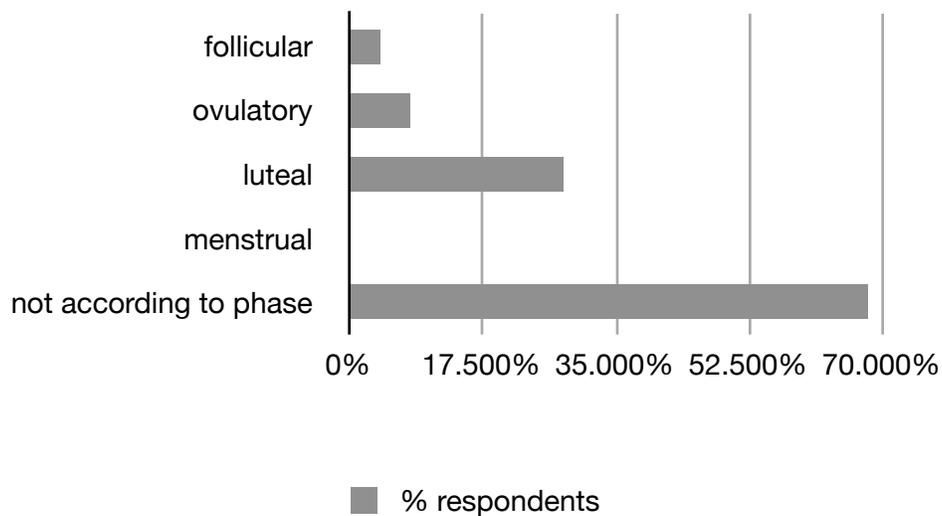


**Table 29: Respondents That use the Paulus Study Protocol with Fertility Patients**

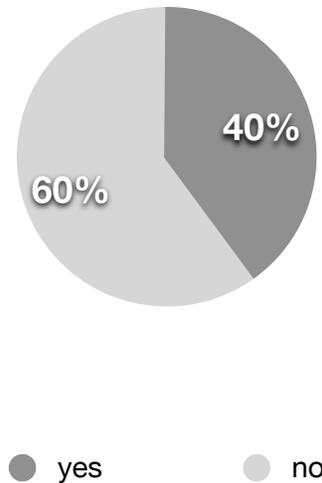


The majority (68%) responded that they do not use this protocol according to the cycle of the menstrual phase. These data are to be expected as this protocol was studied when an embryo transfer was performed; thus the patient is working with an RE and getting this procedure while on medication and having the natural menstrual cycle medically controlled. Therefore, the acupuncturist is using the protocol according to when the procedure is performed rather than the specific phase of the woman's menstrual cycle. When asked if they follow the protocol exactly as per the Paulus study, 40% answered no. It is likely that respondents who answered 'No' use additional acupuncture points in conjunction with the points listed in the protocol. (See tables 30 and 31 below).

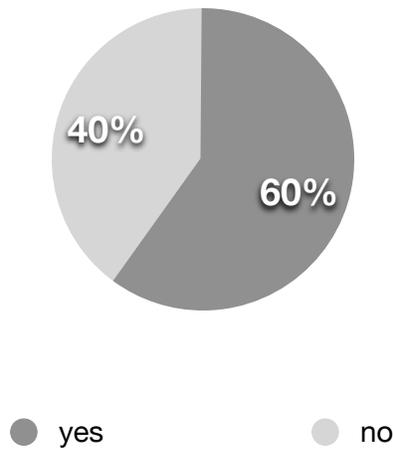
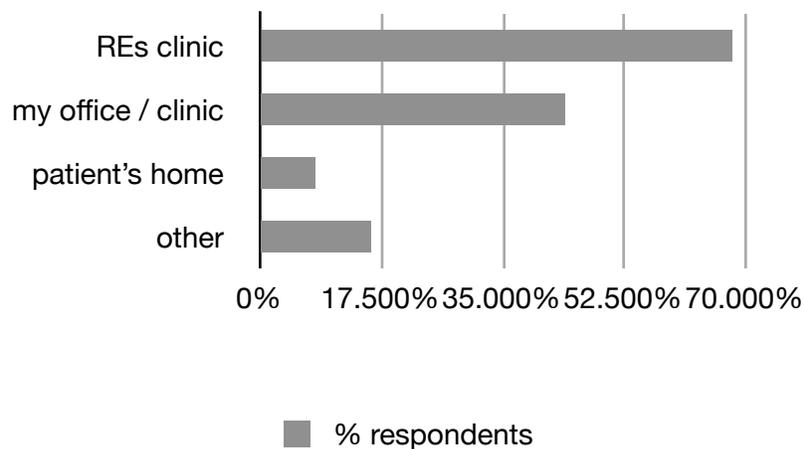
**Table 30: Phase(s) in Which the Respondents Use the Paulus Protocol**



**Table 31: Respondents that Used the Paulus Protocol Exactly as per the Paulus Study**



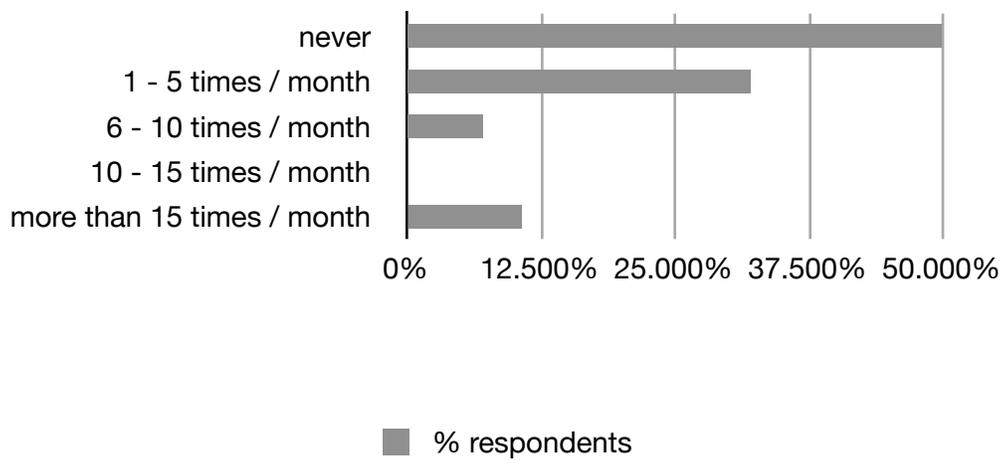
Sixty percent reported that they use the Paulus protocol for embryo transfers only. These data are to be expected as the original study was investigating the efficacy of the protocol when used with embryo transfers. The survey did not inquire about the ‘no’ responses to this question, so there is no way to understand the other circumstances in which the protocol is utilized. Sixty-eight percent answered that they perform the protocol at an REs clinic, with 44% responding that they perform the protocol at their own office. Again, this is logical as embryo transfers take place in REs clinical facilities. (See table 32 and 33 below).

**Table 32: Respondents that Used the Paulus Protocol for Embryo Transfers Only****Table 33: Location where Respondents Performed the Paulus Protocol**

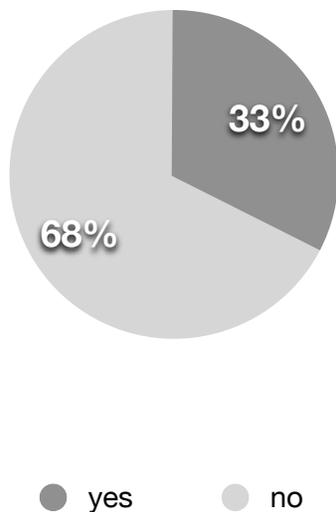
Most respondents (50%) said that they never use additional acupuncture points at the same time they are following the Paulus protocol. When asked about the use of other fertility protocols, 68% of respondents answered that they did not use any other specific protocols when treating fertility patients. The respondents that answered 'yes' listed which protocols they used

and these have been listed out with question #36 below. In addition, in response to the open ended question, some responded that they never use protocols because they prefer to treat according to the patient’s presentation and constitution. This is a common sentiment among licensed acupuncturists regardless of the field of study. (See tables 34 and 35 below).

**Table 34: Frequency in Which Respondents used Additional Acupuncture Points While Following Paulus Protocol**



**Table 35: Respondents that Used Other Fertility Protocols**



Other protocols listed include:

- individual based
- Weizenbaum / Huang huang
- Yu/Horn
- own combinations
- Lyttleton
- Berkeley
- Ni
- Cridennda
- Lifang Lian
- Randine Lewis

### **Statistical Analysis**

The survey used in the current study yielded tallied categorical data regarding a number of factors that were able to be analyzed using the Chi square test. Ten Chi square tests were run, The factors for which two by two Chi square contingency tables were constructed included the following:

- Use / non-use of the Stener-Victorin Protocol and the location of practice (USA/China)
- Use / non-use of the Paulus Protocol and the location of practice (USA/China)
- Use / non-use of the Stener-Victorin Protocol and the level of post-graduate training in fertility in TCM (less than 50 hours / more than 50 hours)
- Use / non-use of the Paulus Protocol and the level of post-graduate training in fertility in TCM (less than 50 hours / more than 50 hours)
- Use / non-use of the Stener-Victorin Protocol and the level of post-graduate training in fertility in Western Reproductive Endocrinology (less than 50 hours / more than 50 hours)

- Use / non-use of the Paulus Protocol and the level of post-graduate training in fertility in Western Reproductive Endocrinology (less than 50 hours / more than 50 hours)
- Use / non-use of the Stener-Victorin Protocol and the number of fertility patients treated per week (less than 20/more than 20)
- Use / non-use of the Paulus Protocol and the number of fertility patients treated per week (less than 20/more than 20)
- Use / non-use of the Stener-Victorin protocol and works with/does not work with Reproductive Endocrinologist
- Use / non-use of the Paulus protocol and works with/does not work with Reproductive Endocrinologist

The Chi squares were generated using Graphpad software's QuickCalcs online calculator for scientists. Two-tailed  $p$  values were computed. Two-tailed tests were selected because the factors could potentially range in two directions. The Chi squares values were computed using either the Fisher's exact tests or Pearson's Chi square without Yates correction. Fisher's exact test was used when the minimum expected cell size was less than five. Pearson's Chi-Squares were used when the values of all cells were each greater than five. (Personal communication with L. Deacon, 2011)

The ten contingency tables are included below with indication of the form of the Chi Square test engaged (Fisher's or Pearson) and the significance level (See tables 36 through 45). Only one test yielded statistical significance at the .05 level (see table 39). Significance was shown regarding the use of the Paulus protocol and the level of post-graduate training in fertility in TCM. Significantly more respondents with more than 50 hours of post-graduate training in

TCM fertility reported using the Paulus protocol when compared to those with less than 50 hours of training.

The use of the protocols and training location were the items compared in tables 36 and 37. While the  $p$  value of the table 36 Chi square is 0.643 and therefore not statistically significant, the percentages reveal that a greater number of practitioners that trained in the United States used the Stener-Victorin protocol in comparison to those that trained in China. Regarding the Paulus protocol, table 37 demonstrates there was not much of a difference U.S. trained practitioners that used the protocol and those that did not; and overall practitioners that trained in the US made up a higher percentage of those that stated they used the protocol in comparison to those that trained in China. The  $p$  value was again statistically not significant at 0.607.

**Table 36: Location of Respondent's Training and Use of the Stener-Victorin Protocol**

			Used the Stener-Victorin Protocol		Total
			yes	no	
Location trained to practice TCM	USA	count	10	20	30
		%	33.3%	66.7%	100.0%
	China	count	1	5	6
		%	16.7%	83.3%	100.0%
Total		count	11	25	36
		%	30.6%	69.4%	100.0%

Fisher's Exact Test  $p = 0.643$

**Table 37: Location of Respondent's Training and Use of the Paulus Protocol**

			Used the Paulus Protocol		Total
			yes	no	
Location trained to practice TCM	USA	count	14	15	29
		%	48.3%	51.7%	100.0%
	China	count	1	3	4
		%	25.0%	75.0%	100.0%
Total		count	15	18	33
		%	45.5%	54.5%	100.0%

Fisher's Exact Test  $p = 0.607$

Tables 38 and 39 compared the respondent's level of post-graduate training in fertility in TCM and use of the protocols. The respondents were divided into 2 groups: those that trained for more than 50 hours and those that had less than 50 hours. Table 38 looked at these variables compared to the use of the Stener-Victorin protocol. The  $p$  value of this Chi square is 0.690 which means no statistical significance, however, the percentages indicate that those practitioners with more hours of training had more use of the protocol than those with less hours. Table 39 compared the use of the Paulus protocol with the level of post-graduate training hours in fertility TCM, and here the  $p$  value was 0.048. This is a statistically significant finding. Significantly more respondents with more than 50 hours of post-graduate training in fertility TCM reported using the Paulus protocol compared to those with less training. More respondents reported that they used the Paulus protocol in comparison to using the Stener-Victorin protocol when the number of training hours was disregarded.

**Table 38: Respondent's Level of Post-Graduate Training in Fertility in TCM and Use of the Stener-Victorin Protocol**

			Used the Stener-Victorin Protocol		Total
			yes	no	
Level of post-graduate training in fertility in TCM	< 50 hours	count	2	8	10
		%	20.0%	80.0%	100.0%
	> 50 hours	count	9	19	28
		%	32.1%	67.9%	100.0%
Total		count	11	27	38
		%	28.9%	71.1%	100.0%

Fisher's Exact Test  $p = 0.690$

**Table 39: Respondent's Level of Post-Graduate Training in Fertility in TCM and Use of the Paulus Protocol**

			Used the Paulus Protocol		Total
			yes	no	
Level of post-graduate training in fertility in TCM	< 50 hours	count	1	8	9
		%	11.1%	88.9%	100.0%
	> 50 hours	count	14	12	26
		%	53.8%	46.2%	100.0%
Total		count	15	20	35
		%	42.9%	57.1%	100.0%

Fisher's Exact Test  $p = 0.048$

*Significantly more respondents with more than 50 hours post-grad training in fertility in TCM reported using the Paulus study protocol compared to those with less training.*

The level of post-graduate training in western reproductive medicine and the use of the protocols were compared in tables 40 and 41. Table 40's  $p$  value is 0.721 which is statistically insignificant. The percentages reveal that practitioners with more than 50 hours of post-graduate training were more likely to use the Stener-Victorin protocol in comparison with those that had less training hours. Similarly, respondents with more training in western reproductive medicine were more likely to use the Paulus protocol compared to those with less training as demonstrated in table 41. Table 41 was the only Pearson's Chi square; the Pearson's chi square value is 1.82 and  $p$  value is 0.203. Overall, without differentiating the number of hours of post-graduate training, more respondents used the Paulus protocol than the Stener-Victorin protocol.

**Table 40: Respondent's Level of Post-Graduate Training in Fertility in Western Reproductive Medicine and Use of the Stener-Victorin Protocol**

			Used the Stener-Victorin Protocol		Total
			yes	no	
<b>Level of post-graduate training in fertility in Western Reproductive Endocrinology</b>	< 50 hours	count	4	13	17
		%	23.5%	76.5%	100.0%
	> 50 hours	count	7	14	21
		%	33.3%	66.7%	100.0%
<b>Total</b>		count	11	27	38
		%	28.9%	71.1%	100.0%

Fisher's Exact Test  $p = 0.721$

**Table 41: Respondent's Level of Post-Graduate Training in Fertility in Western Reproductive Medicine and Use of the Paulus Protocol**

			Used the Paulus Protocol		Total
			yes	no	
<b>Level of post-graduate training in fertility in Western Reproductive Endocrinology</b>	< 50 hours	count	5	11	16
		%	31.3%	68.8%	100.0%
	> 50 hours	count	10	9	19
		%	52.6%	47.4%	100.0%
<b>Total</b>		count	15	20	35
		%	42.9%	57.1%	100.0%

Pearson Chi-Square = 1.82,  $p = 0.203$

The use of the protocols was compared to the number of fertility patients treated per week. The respondents were grouped according to whether they treated more than 20 fertility patients or less than 20 fertility patients per week. Table 42 examined the data regarding the use of the Stener-Victorin protocol. The Fisher's exact test  $p$  value is 0.442, and the percentages show that respondents that treated more than 20 fertility patients per week were more apt to use the protocol in comparison to those that treat less than 20 fertility patients per week. The Paulus protocol Chi square did not demonstrate a significant difference between those who treated more or less than 20 fertility patients per week regarding use of the protocol. The  $p$  value of table 43 is 1.00. When comparing the percentages of respondents use of the protocols, overall more reported using the Paulus protocol than the Stener-Victorin protocol regardless of the number of fertility patients treated per week.

**Table 42: Number of Fertility Patients Treated per Week and Use of the Stener-Victorin Protocol**

			Used the Stener-Victorin Protocol		Total
			yes	no	
Fertility patients treated per week	< 20	count	7	20	27
		%	25.9%	74.1%	100.0%
	> 20	count	4	6	10
		%	40.0%	60.0%	100.0%
<b>Total</b>		count	11	26	37
		%	29.7%	70.3%	100.0%

Fisher's Exact Test  $p = 0.442$

**Table 43: Number of Fertility Patients Treated per Week and Use of the Paulus Protocol**

			Used the Paulus Protocol		Total
			yes	no	
Fertility patients treated per week	< 20	count	10	15	25
		%	40.0%	60.0%	100.0%
	> 20	count	4	5	9
		%	44.4%	55.6%	100.0%
<b>Total</b>		count	14	20	34
		%	41.2%	58.8%	100.0%

Fisher's Exact Test  $p = 1.00$

Lastly, the use of the protocols was compared to the respondents that reported working with a reproductive endocrinologist. Table 44 has a Fisher's exact test  $p$  value of 1.00 and the percentages do not show a significant difference in use of the Stener-Victorin protocol regardless of whether they work with reproductive endocrinologists or not. However, this is not the case when looking at the use of the Paulus protocol. This is not surprising because the protocol is specifically used with embryo transfers which occur in reproductive endocrinologist clinics. The  $p$  value for table 45 is 0.207. A much greater percentage of respondents that work with reproductive endocrinologists reported using the Paulus protocol (48.3%) compared to those who do not work with reproductive endocrinologists (16.7%).

**Table 44: Respondents That Work with Reproductive Endocrinologists and Use of the Stener-Victorin Protocol**

			Used the Stener-Victorin Protocol		Total
			yes	no	
<b>Works with Reproductive Endocrinologist</b>	yes	count	9	22	31
		%	29.0%	71.0%	100.0%
	no	count	2	4	6
		%	33.3%	66.6%	100.0%
<b>Total</b>		count	11	26	37
		%	29.7%	70.3%	100.0%

Fisher's Exact Test  $p = 1.00$

**Table 45: Respondents That Work with Reproductive Endocrinologists and Use of the Paulus Protocol**

			Used the Paulus Protocol		Total
			yes	no	
<b>Works with Reproductive Endocrinologist</b>	yes	count	14	15	29
		%	48.3%	51.7%	100.0%
	no	count	1	5	6
		%	16.7%	83.3%	100.0%
<b>Total</b>		count	15	20	35
		%	42.9%	57.1%	100.0%

Fisher's Exact Test  $p = 0.207$

## CHAPTER FIVE: DISCUSSION

### Summary of Findings

The current research study utilized an internet based survey to gather demographic, training and practice data from a sample of 43 acupuncturists that specialize in fertility in Los Angeles. The data summarized in Chapter Four depicted a sample that is mostly female (80%) and Caucasian (68%), with the majority having trained as acupuncturists in the United States (60%) and the majority reported having a specific OB/GYN component in their training (69%). The data further portrayed a group that works less than full time in the profession, and that interacts frequently with other health care professionals who are most likely to be reproductive endocrinologists or gynecologists. Additionally, the data indicated that approximately half of the sample valued specialty certification such as ABORM. While only a minority of the sample had earned doctoral degrees (28%), other data analyzed indicated awareness among the respondents that additional training is necessary for practitioners who treat fertility patients. One factor yielded statistical significance: significantly more respondents who had more than 50 hours of post-graduate training in fertility reported using the Paulus protocol than those with less than 50 hours of post-graduate training.

### Implications for Practice

The findings of this survey have confirmed that fertility acupuncturists with more training in either fertility TCM or western reproductive medicine are more likely to use the Stener-Victorin and Paulus acupuncture protocols. Theoretically, acupuncturists in any specialty would have better results when using advanced training techniques; thus we can assume that

acupuncturists that treat fertility would have better clinical results when they have advanced training in fertility theory and treatments.

While statistically not significant, other Chi squares demonstrated percentages that imply that acupuncturists that treat more fertility patients per week are more likely to use the protocols. Likewise, percentages show acupuncturists that work with reproductive endocrinologists are also more likely to use the protocols and therefore have advanced treatment modalities.

Since the Stener-Victorin and the Paulus protocols have demonstrated efficacy in the scientific literature, it is likely that acupuncturists who use them experience clinical success with their fertility patients. The use of one or both of the protocols provides a common language for practitioners that can be articulated in communications with other health care providers, in journal articles, at professional conferences and in informal discussions with colleagues. The protocols are valuable tools that should be a part of the repertoire of techniques considered by practitioners who treat patients for fertility issues.

### **Limitations of the Current Study**

While the survey was useful in assessing the practice patterns of acupuncturists in regard to their use of the Stener-Victorin and Paulus protocols, all survey research has limitations due to factors inherent in the content, semantics, and format of the survey instrument. The current study had several limitations. Since the survey was on-line only, many fertility acupuncturists that do not have access to internet usage were eliminated from participating. It is plausible that many older, more experienced acupuncturists that do not communicate via internet have been

excluded. Additionally, as respondents were given the opportunity to skip questions, some survey questions went unanswered and decreased the amount of data collected. The wording of some of the questions and response choices may have been unclear to some of the respondents who therefore opted to skip.

The nature of the survey method in itself is impersonal, leaving no opportunity for the researcher to perceive the attitudes and other motivational factors of the respondent or to address any clarifications. Survey responses are anonymous, confidential and objective, but the lack of connection with the researcher provides a level of obscurity regarding the validity of the responses. However, the data in this survey are likely to have high validity as there is no benefit to the respondents for replying with false information; additionally the respondents are a professional populace that are licensed and therefore have a greater level of integrity with a low probability of giving inaccurate responses. The possibility remains that some factors might have been more fully and effectively engaged by collecting data in a face to face in-depth interview.

### **Recommendations for Future Research**

The current study gathered important data, and those findings have raised additional research questions. As a follow up to the current study, a survey should be administered to provide more detailed information regarding the success rates of acupuncturists that use the Stener-Victorin and Paulus fertility protocols. Such a survey should be designed to yield data regarding pregnancy and live-birth rates of patients that were treated with each of the fertility protocols.

Additional survey research is warranted regarding how fertility practitioners fulfill their required continuing education. It is unknown if practitioners who specialize in fertility seek only continuing education opportunities that are fertility related, and if not, what percentage is dedicated to advanced fertility training. Consideration should be given to doing in-person interviews of practitioners regarding their training in the Stener-Victorin and Paulus protocols as well as their procedural application and success rates with the protocols. A face to face structured interview would likely yield a good deal of valuable information regarding how closely practitioners comply with the published processes of each protocol and how the specific procedures in each protocol are received by fertility patients.

## **Conclusion**

Acupuncture and TCM have established therapeutic value in the field of reproductive medicine. As this trend continues to rise, it is imperative that practitioners of TCM that specialize in fertility understand the most clinically effective treatment strategies and protocols available. The survey designed in this study examined the use of two protocols that appear in the scientific literature and are used clinically by fertility acupuncturists in the United States: the Stener-Victorin protocol and the Paulus protocol. The data collected and analyzed in this research study have shown that acupuncture practitioners that have more hours of TCM and western post graduate training are more likely to use the protocols clinically, as are those practitioners that trained in the United States, treat a greater number of fertility patients per week and work with reproductive endocrinologists.

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**APPENDIX A - Glossary of Terms with Acronyms**

Abbreviation	Term	Definition
ABORM	American Board of Oriental Medicine	Specialty board that certifies licensed acupuncturists that specialize in infertility
ART	Assisted Reproductive Technology	Procedures employed by RE/I's involving techniques and technology that help couples achieve pregnancy such as IVF.
ASRM	American Society of Reproductive Medicine	An established, reputable organization that unites practitioners, teachers and researchers in the field of reproductive medicine
CAB	California Acupuncture Board	The licensing and governing board of licensed acupuncturists in the state of California
DAOM	Doctor of Acupuncture and Oriental Medicine	Practitioners of TCM that have advanced training in a specialty
EA	Electro-Acupuncture	An acupuncture modality where small clips attached to wires are clipped on to inserted needles – these wires are plugged into a stim unit and an electrical current is delivered to the target tissue.
ET	Embryo Transfer	A procedure of ART, where the in-vitro fertilized embryo is placed via catheter into the woman's uterus.
GnRH	Gonadotrophin Releasing Hormone	Drugs that are used to alter the pituitary out put of endogenous gonadotrophins which allows the physician to control and manipulate the menstrual cycle and ovulation
HPA	Hypothalamus – Pituitary – Adrenal	A cascading axis in the body where the brain and endocrine glands transmit chemicals and hormones to stimulate each other to increase or decrease performance – this axis involves the hypothalamus, pituitary and adrenal glands
HPO	Hypothalamus – Pituitary – Ovary	A cascading axis in the body where the brain and endocrine glands transmit chemicals and hormones to stimulate each other to increase or decrease performance – this axis involves the hypothalamus, pituitary and ovaries
Infertility		1 years of unprotected intercourse without conception.
IVF	In Vitro Fertilization	A procedure of ART performed by RE/I's where the sperm is collected from the male, the ovum is collected from the female and the two gametes are united. The fertilized ovum is then transferred back into the woman's uterus.
LAc	Licensed Acupuncturist	In the United States, the title given to licensed practitioners that practice acupuncture and TCM

Abbreviation	Term	Definition
MD	Doctor of Medicine	Practitioners that practice allopathic medicine
ND	Naturopathic Physician	Practitioners that practice naturopathic medicine
NP	Nurse Practitioner	Nurses that have advanced training and treat patients as primary care practitioners with limited supervision by an MD
OB/GYN	Obstetrics/Gynecology	The field of medicine specializing in womens health and pregnancy & childbirth
OMD	Oriental Medical Doctor	The title previously given to licensed acupuncturists and practitioners of TCM, before the mid 1990's
Paulus Protocol		An acupuncture protocol studied by Paulus, et al in a 2002 study which indicated that acupuncture in conjunction with IVF improves the PR. This protocol was performed 25 minutes before and 25 minutes after ET
PI	Pulsatility Index	A measurement used to assess the blood flow through an artery
PR	Pregnancy Rate	The rate at which pregnancy occurs
RCT	Randomly Controlled Trial	A research trial that involves random selection with a designated control group and one or more
RE/I	Reproductive Endocrinologist/Infertility	A medical doctor that is an OB/GYN with a further subspecialty in treating fertility and reproductive endocrine disorders
Stener-Victorin Protocol		An acupuncture protocol studied by Stener-Victorin, et al in a 1996 study which indicated that electro acupuncture improves blood flow through the uterine artery
Survey Method		A research method that employs interviews and/or questionnaires to gather data from target population
TCM	Traditional Chinese Medicine	The field of medicine incorporating all pillars of Chinese Medicine, including acupuncture, herbal medicine, nutritional therapy, and exercises (qi gong, tai chi) as established in China in the 1950's

(Lyttleton 2004, Speroff 2005)

## **APPENDIX B - The Survey Instrument**

**Survey Questionnaire**

Please check only ONE response unless indicated.

Demographics

1. Gender:  M  F
2. Ethnicity:  Caucasian  Asian or Pacific Islander  African-American  
 Hispanic  Native American  Middle Eastern  Other  Decline to state
3. Martial Status:  Single  Married  Divorced  Partnered  Widowed
4. Annual Income (gross):  
 less than \$50,000  \$50,000 – \$100,000  more than \$100,000

Clinical Practices

5. How many hours per week you work as an acupuncturist?  
 less than 10  11-19  20-29  30-39  40-49  
 more than 50
6. How many years have you been in practice as an acupuncturist?  
 less than 1  1-5  6-10  11-20  more than 20
7. What setting do you work in? (check all that apply)  
 private practice  group practice  spa / medi-spa  multi-disciplinary clinic  
 Reproductive Endocrinologist clinic  other: \_\_\_\_\_
8. How many patients do you treat per week? (All types of patients)  
 less than 15  15-30  31-50  51-65  more than 65
9. How many fertility patients do you treat per week?  
 less than 10  11-20  21-30  31-40  41-50  
 more than 50
10. Do you identify yourself as a fertility specialist?  
 yes  no
11. Do you market/advertise that you treat fertility?  
 yes  no
12. Are you a fellow of the American Board of Oriental Reproductive Medicine (ABORM)?  
 yes  no  not currently, but I plan to

Education

13. Where did you train to practice Oriental Medicine?  
 United States  China  Other Asian country  Other
14. Did you have a separate OB/GYN course during your training?  
 yes  no
15. Please rate the level of your post-graduate training in fertility:  
 Western Reproductive endocrinology:  
 0-25 hours  26-50 hours  51-75 hours  76-80 hours  
 81-100 hours  more than 100 hours  
 Traditional Chinese Medicine:

- 0–25 hours       26–50 hours       51–75 hours       76–80 hours  
 81–100 hours       more than 100 hours

16. Have you completed a doctorate program?

- yes       no

17. If yes, What kind of doctorate did you earn:

- PhD       DAOM       OMD       MD       other

#### Referrals

18. How often do you work with Reproductive Endocrinologists (RE)?

- never       1–5 times/year       1–5 times/month       6–10 times/month  
 more than 10 times/month

19. How often do you work with Obstetrician/Gynecologists (OB/GYN)?

- never       1–5 times/year       1–5 times/month       6–10 times/month  
 more than 10 times/month

20. How often do you work with Nurse Practitioners (NP) that treat fertility?

- never       1–5 times/year       1–5 times/month       6–10 times/month  
 more than 10 times/month

21. How often do you work with Naturopathic Doctors (ND) that treat fertility?

- never       1–5 times/year       1–5 times/month       6–10 times/month  
 more than 10 times/month

22. How often do you work in fertility clinics doing acupuncture with Assisted Reproductive Technologies (ART)?

- never       1–5 times/year       1–5 times/month       6–10 times/month  
 more than 10 times/month

#### Protocols

23. Are you familiar with the Stener–Victorin study acupuncture protocol?

- yes       no

24. Do you use the Stener–Victorin protocol with fertility patients?

- yes       no       haven't used it but would like to

If Yes:

25. In which phases do you use the Stener–Victorin protocol? Check all that apply.

- follicular       ovulatory       luteal       menstrual  
 I do not use this protocol according to phases

26. Do you follow the Stener–Victorin protocol exactly as per the Stener–Victorin study (including electro-acupuncture)?

- yes       no

27. How often do you use additional acupuncture points at the same time you are following the Stener–Victorin protocol?

- never       1–5 times/month       6–10 times/month  
 10–15 times/month       more than 15 times/month

28. Are you familiar with the Paulus study acupuncture protocol?

- yes       no

29. Do you use the Paulus study protocols with fertility patients?  
 yes       no       haven't used it but would like to

If Yes:

30. In which phases do you use the Paulus protocol? Check all that apply.  
 follicular       ovulatory       luteal       menstrual  
 I do not use this protocol according to phases

31. Do you follow the Paulus protocol exactly as per the Paulus study (treatment 25 minutes before and after embryo transfer)?  
 yes       no

32. Do you use the Paulus protocol for Embryo Transfers only?  
 yes       no

33. Where do you perform the Paulus protocol?  
 RE's clinic       my clinic       patient's home  
 other: \_\_\_\_\_

34. How often do you use additional acupuncture points at the same time you are following the Paulus protocol?  
 never       1-5 times/month       6-10 times/month  
 10-15 times/month       more than 15 times/month

35. Do you use any other specific fertility protocols when treating fertility patients (such as Magarelli/Cridennda, Yu/Horn, etc)?  
 yes       no

36. If yes, briefly describe:

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Please include any additional comments:  
Thank you for your participation!

**APPENDIX C - Introductory letter and consent form**

January 07, 2011

Dear Colleague,

Hello, I am pleased to introduce myself. My name is Cynthia Splies, I am a licensed acupuncturist practicing in Ventura, CA. I have been practicing since 2004 and am currently a doctoral candidate at Yo San University's Reproductive Medicine DAOM program. A large part of the curriculum is the capstone project where the candidates have the opportunity to conduct original research in the field of TCM and fertility. For my research project, I am conducting a survey to assess the practice patterns of Licensed Acupuncturists that specialize in fertility in the Los Angeles area.

You have been selected to participate in this survey because you identified yourself as an acupuncturist that treats fertility patients. By participating in this study, you will be an important component of this research. The benefit of this research would be to understand the way in which local fertility acupuncturists use the published fertility protocols in clinical practice. The TCM fertility community as well as reproductive endocrinologists and other fertility health care providers stand to benefit their patients by providing viable treatment options. The reproductive acupuncture community as a whole stands to gain increased credibility and validation. The outcomes of this research may influence the manner in which fertility protocols are taught to acupuncturists.

The survey is brief, and will not take more than 15-20 minutes of your time. Please click the link below to an online survey website, SurveyMonkey. Here you will find an online consent form as well as the actual questionnaire. Your information and all answers provided are kept anonymous and confidential. After the study is completed, you will be asked to provide your feedback. A copy of the completed research will be sent to you via email.

*If you agree to participate, please read the steps below and then proceed as follows:*

1. Read and sign the consent form (electronic signature) by clicking the link below.
2. Continue on to answer the survey questions to the best of your ability. Please be honest with each answer so that the data is an accurate reflection of your clinical work. If you feel uncomfortable with ANY of the questions, please feel free to skip that question.
3. Submit the completed survey.

Please feel free to contact me if you have any questions or concerns:

cindy@acupuncturebycindy.com

Cynthia Splies, L.Ac.  
1975 S. Victoria Ave.  
Ventura, CA 93003

Thank you for your consideration, I appreciate your participation in this research.  
In Health,

Cynthia Splies, L.Ac., DAOM (c)  
Yo San University  
cell: 805-320-3029

[Link to SurveyMonkey survey & consent form]  
Consent Form

The purpose of this research project is to assess the practice patterns of fertility acupuncturists in Los Angeles. This is a research project being conducted by Cynthia Splies, L.Ac at YoSan University. You are invited to participate in this research because you have been identified as a licensed acupuncturist practicing in Los Angeles that treats fertility patients.

Your participation in this research study is voluntary. You may choose not to participate. If you decide to participate in this research survey, you may withdraw at any time. If you decide not to participate in this study or if you withdraw from participating at any time, you will not be penalized.

The procedure involves filling an online survey that will take approximately 15-20 minutes. Your responses will be confidential and we do not collect identifying information such as your name, email address or IP address. The survey questions will be about your demographics, education, and practice patterns. Of particular interest in this study is the clinical use of two published fertility protocols: Stener-Victorin and Paulus.

We will do our best to keep your information confidential. All data is stored in a password protected electronic format. To protect your confidentiality, the survey will not contain information that will personally identify you. The results of this study will be used for scholarly purposes only and may be shared with Yo San University representatives.

If you have any questions about the research study, please contact Cynthia Splies at 805-320-3029 or cindy[@]acupuncturebycindy.com. This research has been reviewed according to Yo San University IRB procedures for research involving human subjects.

#### **ELECTRONIC CONSENT**

**Clicking on the "agree" button below indicates that:**

- **you have read the above information**
- **you voluntarily agree to participate**
- **you are at least 18 years of age**

**If you do NOT wish to participate in the research study, please decline participation by clicking on the "disagree" button.**

**[AGREE]**

**[DISAGREE]**

**APPENDIX D - Exact statistical data for tables 1-35**

Table 1. Gender of Respondents

Female	Male
79.50%	20.50%

Table 2. Ethnicity of Respondents

Caucasian	Asian/Pacific Islander	African American	Hispanic	Native American	Middle Eastern	Decline to State
66.70%	28.90%	0.00%	2.20%	0.00%	4.40%	0.00%

Table 3. Marital Status of Respondents

Single	Married	Divorced	Partnered	Widowed
11.40%	70.50%	13.60%	4.50%	0.00%

Table 4. Annual Gross Income of Respondents

	less than \$50,000	\$50,000 - \$100,000	more than \$100,000
% respondents	17.80%	37.80%	44.40%

Table 5. Hours Worked per Week of Respondents

	less than 10	11 - 19	20 - 29	30 - 39	40 - 49	more than 50
% respondents	4.40%	6.70%	35.60%	31.10%	11.10%	11.10%

Table 6. Years in Practice of Respondents

	less than 1	1 - 5	6 - 10	11 - 20	more than 20
% respondents	0.00%	34.10%	20.50%	20.50%	25.00%

Table 7. Settings Respondents work in

	private practice	group practice	spa / medi-spa	multi-disciplinary clinic	reproductive endocrinologists clinic
% respondents	76.10%	23.90%	0.00%	13.00%	8.70%

Table 8. Number of Patients Treated per Week by Respondents

	less than 15	15- 30	31 - 50	51 -65	more than 65
% respondents	22.70%	43.20%	13.60%	9.10%	11.40%

Table 9. Number of Fertility Patients Treated per Week by Respondents

	less than 10	11 - 20	21 - 30	31 - 40	41 - 50	more than 50
% respondents	58.10%	18.60%	9.30%	4.70%	2.30%	7.00%

Table 10. Respondent Self-Identification as Fertility Specialist Data

	yes	no
% respondents	72.10%	27.90%

Table 11. Respondents that Advertise Fertility Treatments

	yes	no
% respondents	83.70%	16.30%

Table 12. Frequency Respondents Work with Reproductive Endocrinologists (REs)

	never	1 - 5 times / year	1 - 5 times / month	6 - 10 times / month	more than 10 times / month
% respondents	19.00%	26.20%	14.30%	19.00%	21.40%

Table 13. Frequency Respondents Work with Obstetrician/Gynecologists (OB/GYNS)

	never	1 - 5 times / year	1 - 5 times / month	6 - 10 times / month	more than 10 times / month
% respondents	16.70%	35.70%	26.20%	11.90%	9.50%

Table 14. Frequency Respondents Work with Nurse Practitioners (NPs) that treat fertility

	never	1 - 5 times / year	1 - 5 times / month	6 - 10 times / month	more than 10 times / month
% respondents	66.70%	21.40%	9.50%	0.00%	2.40%

Table 15. Frequency Respondents Work with Naturopathic Doctors (NDs) that treat fertility

	never	1 - 5 times / year	1 - 5 times / month	6 - 10 times / month	more than 10 times / month
% respondents	71.40%	28.60%	0.00%	0.00%	0.00%

Table 16. Frequency Respondents Work in Fertility Clinics Doing Acupuncture with Assisted Reproductive Technologies (ART)

	never	1 - 5 times / year	1 - 5 times / month	6 - 10 times / month	more than 10 times / month
% respondents	45.20%	21.40%	14.30%	7.10%	11.90%

Table 17. American Board of Oriental Reproductive Medicine (ABORM) status of Respondents

	yes	no	not currently, but plans to
% respondents	31.80%	45.50%	22.70%

Table 18. Oriental Medicine Training Location Data

	United States	China	other asian country	other
% respondents	91	76	28	26

Table 19. Respondents with a Separate OB/GYN Course During training

	yes	no
% respondents	69.00%	31.00%

Table 20. Respondents Level of Post-Graduate Training in Fertility in Western Reproductive Endocrinology.

	0 - 25 hrs	26 - 50 hrs	51 - 75 hrs	76 - 80 hrs	81 - 100 hrs	more than 100 hrs
% respondents	27.90%	18.60%	4.70%	2.30%	2.30%	44.20%

Table 21. Respondents Level of Post-Graduate Training in Fertility in Traditional Chinese Medicine.

	0 - 25 hrs	26 - 50 hrs	51 - 75 hrs	76 - 80 hrs	81 - 100 hrs	more than 100 hrs
% respondents	11.90%	16.70%	9.50%	4.80%	4.80%	52.50%

Table 22. Doctorate Program Completion of Respondents

	yes	no
% respondents	28.60%	71.40%

Table 23. Respondents Familiarity with the Stener-Victorin Study Acupuncture protocol

	yes	no
% respondents	65.90%	34.10%

Table 24. Respondents That Use the Stener-Victorin Protocol with Fertility Patients

	yes	no	I havent but would like to
% respondents	30.80%	53.80%	15.40%

Table 25. Phase(s) in Which the Respondents Use the Stener-Victorin Protocol

	follicular	ovulatory	luteal	menstrual	not according to phase
% respondents	36.00%	32.00%	12.00%	8.00%	56.00%

Table 26. Respondents That Follow the Stener-Victorin Protocol Exactly as per the Stener-Victorin Study.

	yes	no
% respondents	16.70%	83.30%

Table 27. Frequency in Which Respondents use Additional Acupuncture Points Concurrently with the Stener-Victorin Protocol

	never	1 - 5 times / month	6 - 10 times / month	10 -15 times / month	more than 15 times / month
% respondents	35.70%	21.40%	10.70%	3.60%	28.60%

Table 28. Respondents Familiarity With the Paulus Study Acupuncture Protocol \

	yes	no
% respondents	69.20%	30.80%

Table 29. Respondents That use the Paulus Study Protocol with Fertility Patients

	yes	no	I haven't but would like to
% respondents	44.40%	47.20%	8.30%

Table 30. Phase(s) in Which the Respondents Use the Paulus Protocol

	follicular	ovulatory	luteal	menstrual	not according to phase
% respondents	4.00%	8.00%	28.00%	0.00%	68.00%

Table 31. Respondents that Used the Paulus Protocol Exactly as per the Paulus Study

	yes	no
% respondents	40.00%	60.00%

Table 32. Respondents that Used the Paulus Protocol for Embryo Transfers Only

	yes	no
% respondents	60.00%	40.00%

Table 33. Location where Respondents Performed Paulus Protocol

	REs clinic	my office / clinic	patient's home	other
% respondents	68.00%	44.00%	8.00%	16.00%

Table 34. Frequency in Which Respondents used Additional Acupuncture Points While Following Paulus Protocol

	never	1 - 5 times / month	6 - 10 times / month	10 - 15 times / month	more than 15 times / month
% respondents	50.00%	32.10%	7.10%	0.00%	10.70%

Table 35. Respondents that Used Other Fertility Protocols

	yes	no
% respondents	32.5	67.5

**Appendix F: IRB Approval Letter**