

# **Unexplained Subfertility and Osteopathic Treatment A Clinical Trial**

Master Thesis zur Erlangung des Grades

Master of Science in Osteopathie

an der **Donau Universität Krems**

niedergelegt von

**Astrid Kapper**

Salzburg, Dezember 2006

Übersetzt von Mag. Denise Ejury

# ERKLÄRUNG

Hiermit versichere ich, die vorgelegte Masterthese selbständig verfasst zu haben.

Alle Stellen, die wörtlich oder sinngemäß aus veröffentlichten oder nicht veröffentlichten Arbeiten anderer übernommen wurden, wurden als solche gekennzeichnet. Sämtliche Quellen und Hilfsmittel, die ich für die Arbeit genutzt habe, sind angegeben. Die Arbeit hat mit gleichem Inhalt noch keiner anderen Prüfungsbehörde vorgelegen.

-----

Datum

-----

Unterschrift

## List of Contents

1.	Introduction .....	1
2.	Basics .....	3
2.1.	Principles of Osteopathy .....	3
2.2.	Anatomy of the Female Genital .....	3
2.2.1.	The Ovary.....	4
2.2.2.	Fallopian Tubes .....	5
2.2.3.	The Uterus .....	6
2.2.4.	The Vagina .....	7
2.2.5.	Arteries .....	8
2.2.6.	Veins.....	8
2.2.7.	Lymph Vessels .....	9
2.2.8.	Nerve Supply .....	9
2.2.8.1.	Sympathetic Nervous System.....	9
2.2.8.2.	Parasympathetic Nervous System .....	10
2.2.8.3.	Afferent, Sensory Nerve Supply .....	10
2.3.	Physiology of Starting a Natural Pregnancy .....	10
2.3.1.	Feedback-Mechanism for the Regulation of the Female Cycle .....	10
2.3.2.	Changes during the Cycle of the Endometrium of the Uterus .....	11
2.3.3.	Changes during the Cycle of the Fallopian Tubes .....	12
2.3.4.	Blood Flow Changes in the Ovarian and Uterine Arteries during the Normal Menstrual Cycle.....	12
2.3.4.1.	Reduction in Intraovarian Arterial Blood Flow Resistance .....	12
2.3.4.2.	Changes of Blood Flow in the Human Follicle.....	13
2.4.	Differences in the Menstrual Cycle of Women with Unexplained Infertility.....	13
2.4.1.	Hormonal Differences .....	13
2.4.2.	Haemodynamic Differences and Correlation with the Endometrial Thickness .....	14
2.5.	Current Management of Unexplained Subfertility.....	14
3.	Methodology .....	16
4.	Results .....	20
4.1.	Findings of the First Questionnaire .....	20
4.2.	Findings of the Second Questionnaire .....	23
4.3.	Comparison of the First and Second Questionnaire and Pregnancy Rate.....	25
4.4.	Questionnaire for the Osteopaths .....	28
4.5.	Records of the Duration of the Menstrual Cycle.....	34
4.5.1.	Table of the Six Menstrual Cycles of Each Woman .....	34
4.5.2.	Table of the Duration of the Menstrual Cycles in Classes.....	34
5.	Discussion .....	39
6.	Summary .....	43
7.	Appendix .....	45
8.	Bibliography.....	54
9.	List of Illustrations .....	57
10.	Abstract .....	58

## 1. Introduction

The idea to do a similar study to 'A woman with the problem of infertility receiving osteopathic treatment has an increased chance of becoming pregnant' by Monika Kirchmayr (2002) was born when I heard her self-criticism in the master-course about the small number of women and no control group. The result was very promising and really worth trying to enlarge the group. Concerning the control group I found myself in the same position as my colleague. It seemed not fair to me to create a control group or to put them on a waiting list, as they have already been waiting for many years.

I asked colleagues to help me to find women with the problem of unexplained infertility and to treat them because I knew it would be hard to find the number of 20 women who wanted to participate.

The problem of unexplained subfertility is discussed very intensively concerning current best evidence for the management, risks and high costs.

In literature it is said that IVF is superior to FSH/IUI which is superior to no treatment but the effect is small in couples with unexplained infertility (cp. Collins, 2003). Collins concludes that a large multicentred factorial trial is needed to evaluate the relative value of existing empirical treatments as evidence is not robust.

Whereas a review of randomised controlled trials states that IVF is relative to expectant management, clomiphene citrate, IUI with or without ovarian stimulation and GIFT in terms of live birth rates for these couples remains unknown (cp. Pandian, 2002).

### Definition of Unexplained Subfertility and Infertility

According to the WHO infertility exists when the couple does not conceive for 24 months.

This definition should be used in clinical practice and research (cp. Larsen, 2005, abstract).

Subfertility generally describes any form of reduced fertility with prolonged time of unwanted non-conception (Gnoth et al. 2005).

The term unexplained subfertility is used when according to current knowledge no physiological or anatomical abnormalities can be found (Batstra et al. 2002).

It seems that serum progesterone for the detection of ovulation; hysterosalpingography and or laparoscopy for tubal patency and semen analysis are the basic tests for the diagnosis of unexplained infertility (Aboulghar et al. 2003).

These terms are used synonymously and I decided to use subfertility, besides in quotations.

### Prevalence

Infertility is a common problem affecting 15% of couples. 50 to 60% of the women aged 20-30 years conceive after three month, 60 to 75% after six month, 75 to 80 % after one year (Stamm et al. 1987, p.70).

Unexplained subfertility constitutes about 15% of patients (Aboulghar et al. 2003). Other reviews give 5-10% (Adamson et al. 2003).

### Research Questions

1. Does Osteopathic Manual Treatment Increase the Pregnancy Rate in Women with Unexplained Subfertility?

The twelve month cumulative pregnancy rate for patients on the waiting list for IVF is 5.9% (3.7-8.7%) for longstanding unexplained subfertility patients (Evers et al. 1998). The authors conclude that one cycle of IVF or ICSI is superior to twelve month expectant management.

2. Could Osteopathy be recommended to Women with Unexplained Subfertility?

### Hypotheses

In the osteopathic view structure and function are interdependent.

Osteopathic treatment might improve the pregnancy rate in women with unexplained subfertility.

In order to get results supporting my hypotheses I hoped to find 20 women who wanted to participate in this clinical trial. After several months trying to get in contact with gynaecologists and additionally with psychologists I had to realize that I was not able to get the number of women I hoped. It was possible to find ten women (five in Salzburg and with the help of colleagues three in Vienna, one in Linz and one more in Voralberg) who wanted to participate in this trial.

I really have to thank my mother and my husband and friends who looked after my children Lina and Maximilian who allowed me to study and write this master thesis.

Besides I thank Monika Kirchmayr very much for her efforts of positive critique.

## 2. Basics

### 2.1. Principles of Osteopathy

In 1874 Dr. Andrew Taylor Still developed a new method to start the process of healing.

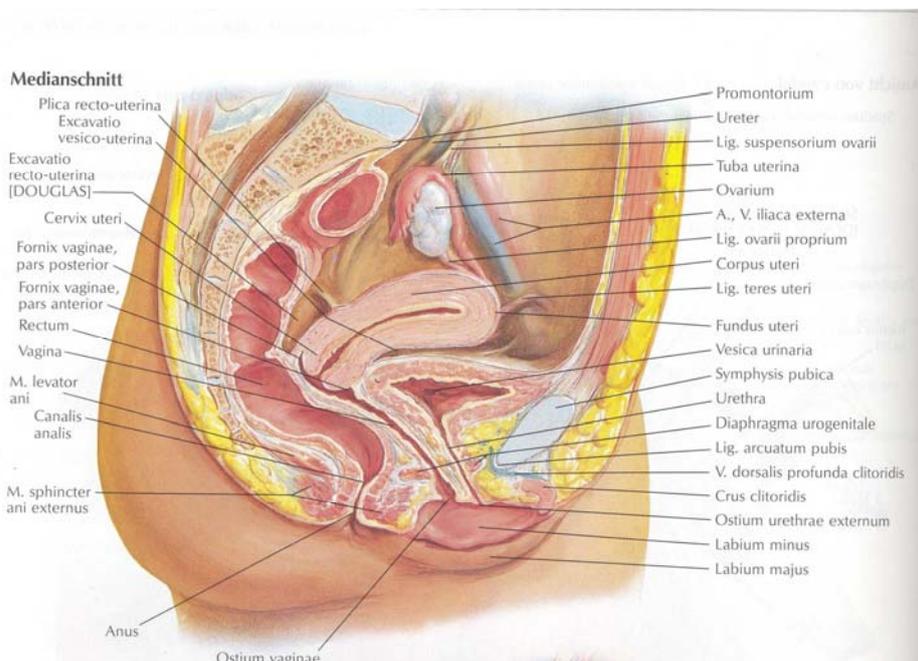
- The body is an integrated unit.
- The body is a self-regulating organism whose homeostatic mechanisms provide an inherent capacity for healing and repair.
- Structure and function are interdependent (Gibbons et al. 2000, p.5).
- The osteopathic manual treatment wants to integrate these principles.

The osteopath aims to remove mechanical and structural restrictions in order to get a free circulation and interchange of all fluids. Health results out of the structures being in a good state and the fascial, biomechanical, muscular, nervous, circular and endocrinological systems communicating harmonically (cp. Liem, 1998, p. 5).

Therefore the anatomy of the reproductive organs, with their connective tissues, their blood supply and drainage, their innervations and their fascial and endocrine connections and functions have to be studied.

### 2.2. Anatomy of the Female Genital

Ovary, uterus, uterine tubes are situated in the lesser pelvis.



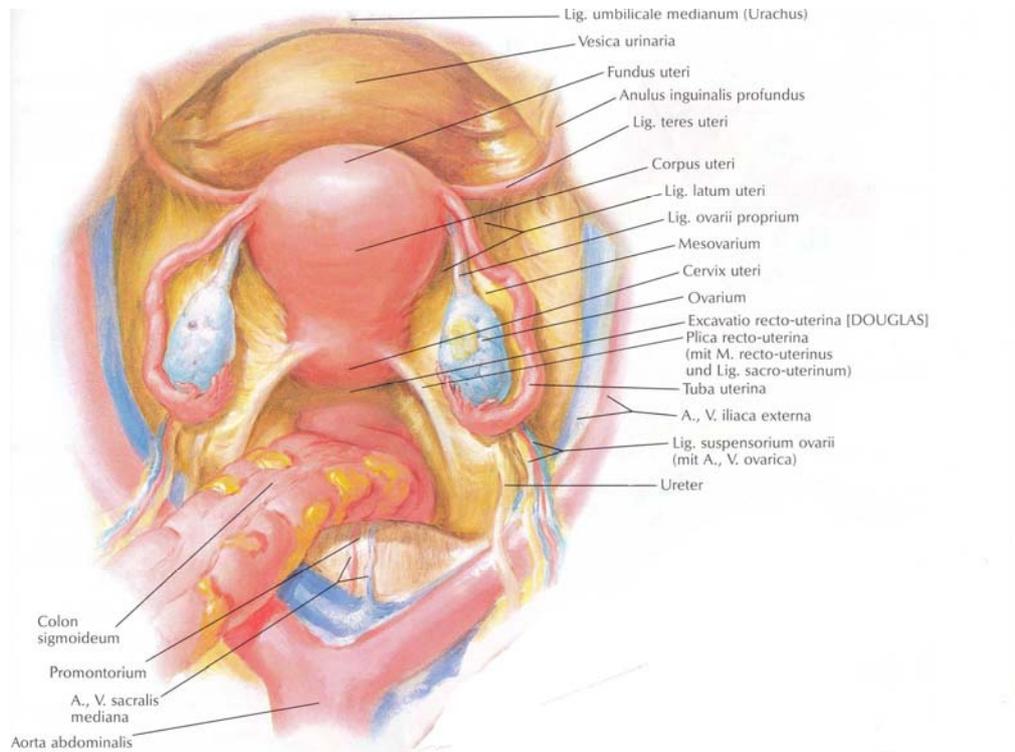
**Illustration 1: Pelvis with Intestines**

### 2.2.1. The Ovary

The ovary contains egg cells which are released at certain times as fertile ova.

It is also an endocrine gland producing sexual steroids such as estrogen and progesterone.

The ovary controls the female cycle and influences the whole body.



**Illustration 2: Lesser Pelvis, Cranial View**

The size is around 4x2x1 cm.

Its weight is 6-8g.

In women in upright position who have never given birth the ovary lies on the broad ligament in the fossa ovarica (M. obturatorius v. iliaca externa, A. umbilicalis, A. obturatoria, N. obturatorius, Vasa iliaca interne, urether) ( Benninghoff, 1993, p. 131).

#### Attachments

The suspensory ligament of the ovary keeps it in place at the pelvis inlet. The suspensory ligament is connected with the pole of the ovary and the pelvic wall and the fascia of the muscle psoas and it contains the vasa ovarica and the nerves (Hebgen, 2005, p. 159).

The ovaries are attached by the proper ligament of the ovary (3-4cm, round) to the uterus which guides the ramus ovaricus of the uterine artery. The ligament contains smooth and

elastic muscle fibres. The ovary can change its position actively and passively by the means of both ligaments, which is important to the mechanism collecting the ovum.

The ovary and the ligaments are covered by a double layer of peritoneum (broad ligament) with the mesovarium leading blood, lymph vessels and nerves to the hilus ovary (Benninghoff 1993, p. 131).

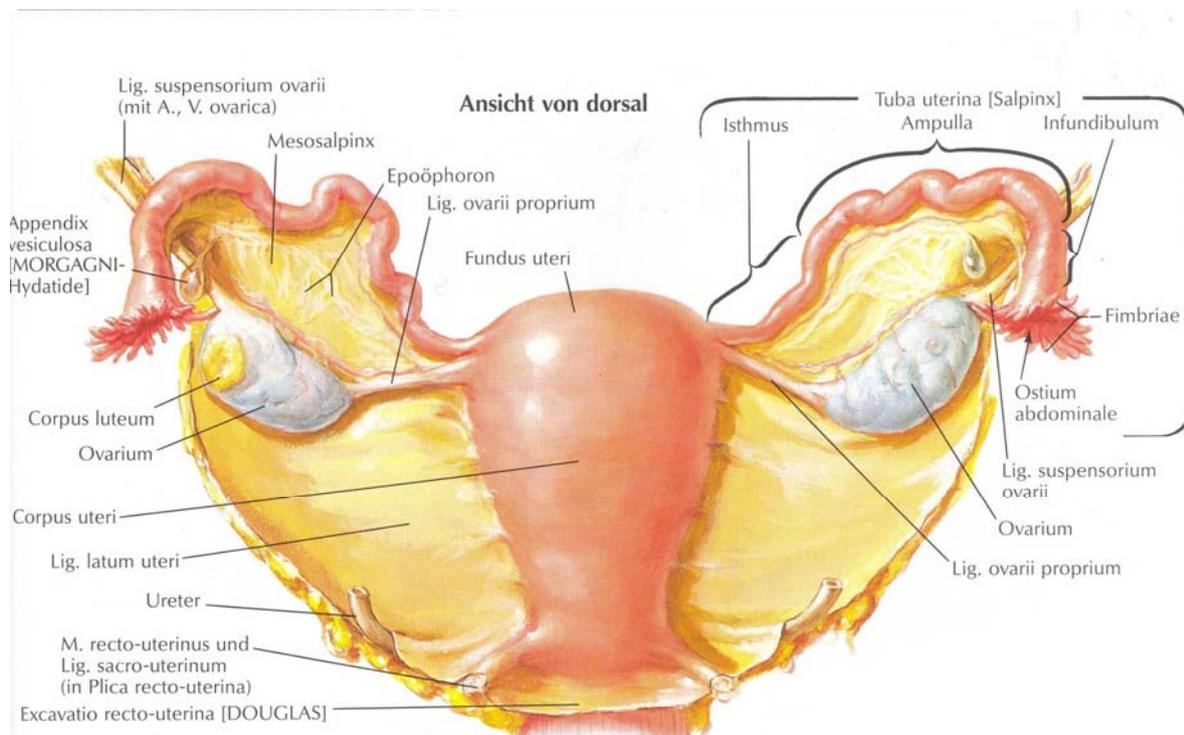
Besides the right ovary has a topographic relation to the caecum and the appendix.

### 2.2.2. Fallopian Tubes

The tube collects the egg which is transported to the uterus with the help of active movements.

The sperms are guided in the other direction.

Besides the tube has closing mechanisms (certain arrangement of vessels) to stop raising infections.



**Illustration 3: Uterus and Uterine Tube**

Length: 10-14cm

It is a muscular tube with a mucus lining and is covered by the peritoneum.

The four parts are called:

*Infundibulum tubae uterine*: 1-2 cm

Looks like a spread-out, funnel-shaped hand. Its opening has fimbriae about 1.5cm long. The longest which is called fimbriae ovary is attached to the ovary.

*Ampulla tubae uterinae*: 7-8cm

It encloses the ovary and is 4-10mm thick.

*Isthmus tubae uterinae*: 3-6cm

It is straight and 2-4mm thick.

Uterine part of the tube: *Pars uterinae tubae*

It is leading along the wall of the uterus to the opening of the tube, called the ostium uterinum tubae.

The muscular layer has a complicated construction (erection) differentiated in 1. autochthonous muscle, 2. perivascular muscle, 3. subperitoneal muscle fibres which work together in order to collect the ovum and transport it to the uterus.

### **Attachments:**

The tube is suspended between the superior angle of the uterus and the ovary or rather the suspensory ligament of the ovary following the upper part of the broad ligament. The ampulla and isthmus parts are attached to the broad ligament called mesosalpinx.

Through these attachments it is possible to straighten and shift the tube in order to collect the ovum (cp Bennighoff, 1993, p 128-130).

### **2.2.3. The Uterus**

The uterus is a pear-shaped muscular hollow organ and its length is 7-9cm.

It allows the sperms to pass and prevents germs from raising.

It is the place of the implantation of the blastocyst and it grows enormously during pregnancy.

It contracts rhythmically depending on hormones and it has the capacity to expel the baby.

The upper 2/3 are the body of uterus, the lower third is the cervix and in between there is a slight constriction termed isthmus where the internal orifice of the uterus is located. The external orifice is situated at the vaginal end of the cervix.

The uterine wall measures 1-2cm and consist of 3 layers:

*Endometrium*:

The mucus lining is influenced in its structure by the sexual hormones according to the cycle.

*Myometrium:*

It is approximately 1cm thick consisting of a plexus of smooth muscles and vessels. The myometrium contracts regularly, depending in intensity and frequency on hormones.

*Perimetrium:*

The perimetrium consists of a peritoneal coating and a subserous layer. The smooth surface enables the uterus to shift against the slings of the small intestine.

The uterus is coated on its anterior, posterior and cranial surface. On both sides the parametrium leads the vessels and is part of the attachments.

In standing position the anterior face of the uterus is situated above the bladder pressing on it, the posterior part is touching the colon sigmoideum and/or the slings of the small intestine.

**Attachments and supporting structures:**

The broad ligament (Ligamentum latum) connects the uterus to the lateral pelvic walls.

Around the cervix it thickens and is termed parametrium.

The round ligament (Ligamentum teres) passes from either side of the lateral angle of the uterine tubes through the abdominal inguinal ring and along the inguinal canal to the greater pudendal labia.

The proper ligament of the ovary (Lig. Ovarii proprium)

All these structures are covered by a layer of the peritoneum reaching from the uterus to the pelvic wall.

The pelvic floor which is the muscular inferior occlusion of the pelvis (cp. Benninghoff, 1993, p. 123-127).

The lig. vesicouterinum connecting uterus and bladder.

The ligg. sacrouterina are reaching from the ventral sacrum S2-4 to the isthmus uteri.

The fascia prevesicalis starting on the front of the cervix runs to the excavatio vesicouterina and the fascia rectocervicalis on the backside combines itself with the ligg. sacrouterina and forms the torus uterinus (cp. Barral, 2004, p. 86-87).

#### **2.2.4. The Vagina**

The vagina is situated between the urinary bladder or rather the urethra and the rectum. As an acid barrier it protects the inner genital and it provides a passageway for cervical discharge and menstrual blood (cp. Benninghoff, 1993, p. 121).

### 2.2.5. Arteries

There is no central blood vessel but a number of paired arteries anastomosing with each other or the opposite side. Therefore the blood supply is almost always ensured.

Ovary:

- ovarian artery >Aorta abdominalis
- uterine artery >A. iliaca interna

Tube:

- ovarian artery >Aorta abdominalis
- uterine artery

Uterus:

- uterine artery

Vagina:

- uterine artery
- inferior vesical artery
- middle rectal artery
- internal pudendal artery

(Benninghoff, 1993, p. 141).

### 2.2.6. Veins

The veins follow the arteries and create numerous venous plexuses. The lateral plexuses to the cervix are called plexus venosus cervicalis uteri and in the area of the body of the uterus they are called plexus venosus uterinus and in the area of the vagina the plexuses are called plexus venosus vaginalis. The last one has a relation to the plexus venosus vesicalis. The plexus ovaricus is situated at the hilum of the ovary.

Their function is not known but stases may create pain in the small pelvis.

The drainage is mostly done by the internal iliac vein. The right ovary vein drains directly to the inferior vena cava, the left one flows through the left renal vein to the inferior vena cava

(Benninghoff, 1993, p. 141).

### 2.2.7. Lymph Vessels

The small pelvis has an extensive system of lymph vessels.

Ovary and Tube:

The lymph vessels follow the suspensory ligament of the ovary with the vasa ovarica to the lumbar lymph nodes at the level of the inferior pole of the kidneys.

Body:

The lymph is collected in the subserous plexus: plexus lymphaticus corporis uteri and plexus lymphaticus cervicis uteri. The main drainage is done by the vasa lymphatica superior via the vasa ovarica to the lumbar lymph nodes. The anterior lymph vessels pass from the interstitial portion of the tube via the round uterine ligament to the superior inguinal lymph nodes. The lateral body is drained into the external iliac lymph nodes.

Cervix:

The lymphatic drainage goes via the broad ligament to the external iliac lymph nodes and to the lymph nodes of the fossa obturatoria.

Vagina:

The lymph flows to the external iliac lymph nodes and the superficial inguinal lymph nodes (Benninghoff, 1993, p. 142).

### 2.2.8. Nerve Supply

#### 2.2.8.1. Sympathetic Nervous System

The splanchnic nerves have their cell nuclei at the level of the spinal cord at T10-L2 and reach the para-aortal ganglial plexuses called the celiac plexus, the superior and inferior mesenteric plexus, and the renal plexus.

Together with the vessels of the ovary the nerve fibres from the superior mesenteric plexus and the renal plexus form the ovarian plexus. The ovarian plexus follows the suspensory ovarian ligament and provides the ovary and the tube where they join with branches of the uterovaginal plexus.

The fibres of the inferior mesenteric plexus continue to the inferior and superior hypogastric plexus and finally to the cervix and the vagina. Laterally and posteriorly of the cervix they form the uterovaginal plexus whose fibres are running to the cervix, the vagina and the uterus. In the region of the sacrum the sympathetic nerve trunk generally has got four paired ganglia and sometimes an unpaired one. Maybe their fibres go to the uterovaginal plexus and with branches of the sacral plexus to the skin of the perineum (Benninghoff, 1993, p. 142).

### 2.2.8.2. Parasympathetic Nervous System

The female genital and the viscera are innervated by the sacral parasympathetic nervous system, except the ovary.

Deriving from the spinal cord at the level of the sacrum the parasympathetic fibres form the pelvic splanchnic nerves and go to the inferior hypogastric plexus and the uterovaginal plexus (Benninghoff, 1993, p.142).

### 2.2.8.3. Afferent, Sensory Nerve Supply

These fibres follow the autonomic nervous fibres. The sensory fibres of the ovary, the tube, the fundus and the corpus of the uterus reach the spinal cord at the level of T10-L 1. The sensory fibres of the cervix mainly of the orifice of the uterus run to T 11-T12 via the hypogastric and ovarian plexuses (Benninghoff, 1993, p.143).

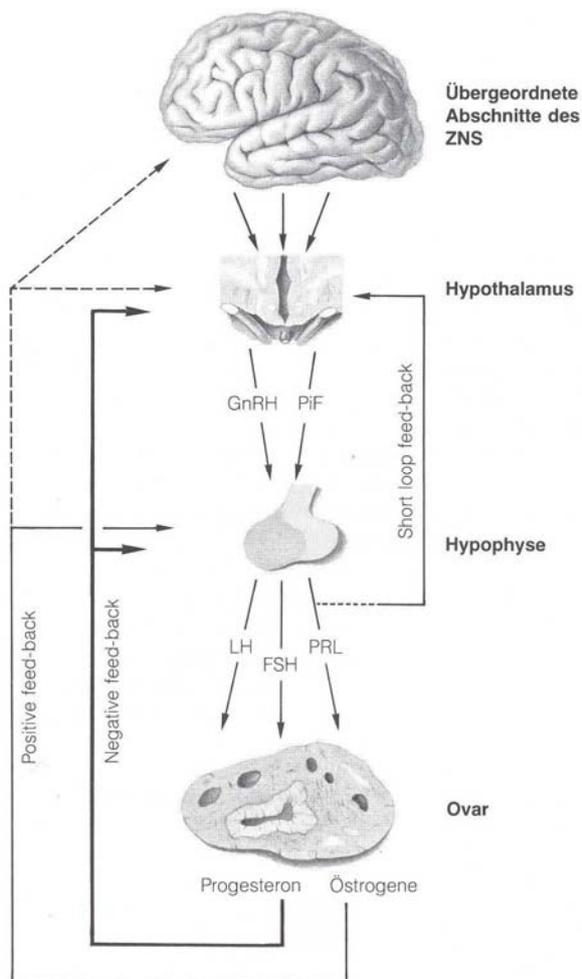
## **2.3. Physiology of Starting a Natural Pregnancy**

### **2.3.1. Feedback-Mechanism for the Regulation of the Female Cycle**

The normal ovulatory cycle takes 28-30 days.

It is divided by the ovulation in 1. the follicular phase and  
2. the luteal phase.

The regulation of the cycle is an interplay of at least three endocrine organs and one organ of success. Every 90 minutes the hypothalamus discharges a gonadotrophin-releasing hormone (GnRH) into the portal system which is lead to the anterior lobe of the pituitary gland. The pituitary releases the follicle-stimulating hormone (FSH) and the luteinizing hormone (LH) which affects the ovaries, the tubes and the uterus. During the follicular phase the growing tertiary follicles of the ovary produce oestrogen. During the luteal phase the corpus luteum produces progesterone. These hormones are part of the feedback-mechanism between the hypothalamus, the pituitary gland, the uterus and the ovary.



**Illustration 4: Feedback-Mechanism between Ovaries, Pituitary Gland and Hypothalamus. GnRH = gonadotrophin-releasing hormone; PiF = prolactin-inhibiting factor; LH = luteinizing hormone, FSH = follicle-stimulating hormone, PRL = prolactin.**

These organs are also influenced by the autonomous nerves. Therefore one could talk about an endocrine- nervous regulation of these organs whereas the hormonal part is stronger (cp. Benninghoff, 1993, p. 148).

### 2.3.2. Changes during the Cycle of the Endometrium of the Uterus

The hormones of the ovary cause changes of the endometrium. These four phases are termed: proliferative phase, secretory phase, ischemic phase, desquamative phase.

Proliferative phase (part of the follicular phase):

After menstruation the basis of the endometrium measures about 0.5-1mm and it thickens under the influence of oestradiol. At the time of ovulation it is 5mm thick.

Secretory phase (part of the luteal phase):

One day after ovulation the progesterone secretion of the corpus luteum stops the proliferation of the endometrium. The glands of the mucous membrane proliferate and present a snaky or wavy appearance. They are producing secretion. The arteries look like a screwpull and are termed spiral arteries and come close to the surface of the epithel. These arteries are surrounded by the predevidual cells which content glycogen and lipoids. Now the thickness of the endometrium is 8mm and it is ready to take the egg (cp. Benninghoff, 1993, p. 152-153). The endometrium produces the secretion which provides an environment in the uterus which ensures the `nutrition` of the blastocyst and the endometrium allows the implantation of the blastocyst (Benninghoff, 1993, p. 159).

### **2.3.3. Changes during the Cycle of the Fallopian Tubes**

At the end of the follicular phase the height of the cells (fimbriae) is 25-35 micrometer. The secretory cells thicken and especially at the time of ovulation they produce secretion. During the luteal phase the height is 10-15 micrometer (Benninghoff, 1993, p. 154).

### **2.3.4. Blood Flow Changes in the Ovarian and Uterine Arteries during the Normal Menstrual Cycle.**

#### **2.3.4.1. Reduction in Intraovarian Arterial Blood Flow Resistance**

In 1996 there was a study in the UK for the purpose of hemodynamic changes in the uterine and intraovarian vessels during the menstrual cycle and to relate the vascular changes to hormonal index values. On the side of the dominant follicle, the follicular and ovarian stroma peak systolic blood flow velocity rose significantly during the menstrual cycle and Tan SL. et al. found a significant correlation between the blood flow velocity and the serum FSH (follicle-stimulating hormone), the LH (luteinizing hormone), and the progesterone concentration. The decline in the uterine artery resistance during the midluteal phase may reflect an optimal vascularity for the implantation of the blastocyst (cp. Tan SL et al. 1996). Another study assessing uterine and ovarian perfusion during the periovulatory period showed that cycles of conceptions have a lower vascular impedance in the uterine arteries (cp. Yokota et al. 2000).

In 2005 the Japanese Nakagawa et al. published their study about intraovarian arterial blood flow before and after follicle rupture in the natural cycle. The changes in the intraovarian arterial resistance in relation to the outcome of infertility treatment were analysed.

They also concluded that a reduction in the intraovarian blood vessel resistance was necessary to achieve pregnancy in a natural cycle (cp. Nakagawa et al. 2005).

#### 2.3.4.2. Changes of Blood Flow in the Human Follicle

In 1998 Brannstrom et al. examined preovulatory changes of blood flow in different areas of the human follicle. His recorded measures were: the pulsatility index (PI), the resistance index (RI), the peak systolic velocity (PSV), and the time-averaged maximum velocity (TAMXV) in the uterine arteries and three areas of the dominant follicle (apical, lateral and basal parts); the follicular volume; the day and time of the onset of the LH surge and the time of each scan. This study says that during the ovulatory process there are changes in the regional blood flow of the follicle with a marked increase of the flow to the base of the follicle and a concomitant decrease of blood flow in the apex. These changes may be essential for the release of a mature oocyte (cp. Brannstrom et al. 1998).

## **2.4. Differences in the Menstrual Cycle of Women with Unexplained Infertility**

### **2.4.1. Hormonal Differences**

In 1997 Leache et al. were monitoring gonatropin and steroid hormone levels in twelve women with unexplained infertility. In comparison to twelve healthy women, who were matched for age and body mass index, his examinations indicated that there was a subtle alteration in various hormone measures across the cycle in women with unexplained infertility. He found a significantly increased level of FSH and LH in the follicular phase in women with unexplained infertility (cp. Leach et al. 1997). His colleague Subramanian compared the bioactive and immunoactive prolactin in the serum samples which were obtained across the menstrual cycle. The midcycle elevations of bioactive and immunoactive prolactin seen in fertile women were absent in twelve women with the problem of unexplained infertility (cp. Subramanian et al. 1997).

Another colleague examined the luteal phase of those women. During the luteal phase women with rigorously defined unexplained infertility had subtle hormonal anomalies (cp. Blacker et al. 1997).

In 2003 Randolph tried to determine whether women with unexplained infertility had an altered GnRH secretion, as reflected by serum LH secretion patterns. He also found a significantly elevated concentration of the FSH and the LH serum level in the early follicular phase. The data did not support the hypothesis that unexplained infertility was caused by an

abnormality in the pulsatile GnRH secretion or an abnormal pituitary sensitivity to GnRH. The results were consistent with a difference in negative feedback from the ovary to the pituitary which was suggestive of a diminished ovarian reserve (cp. Randolph et al. 2003).

#### **2.4.2. Haemodynamic Differences and Correlation with the Endometrial Thickness**

Women with unexplained infertility present a higher resistance of flow at the level of the uterine artery and also a significant increase in the anticardiolipin antibodies was observed which may be involved in uterine vascular modifications (Battaglia et al. 1998).

Steer also found that the resistance to uterine blood flow in the midluteal phase might be a contributing factor to some cause of infertility and the pulsatility index correlated with the endometrial thickness (Steer et al. 1994).

Women with unexplained infertility demonstrated a significantly reduced artery velocity in all phases of the menstrual cycle, a significantly elevated uterine and subendometrial artery impedance in the periovulatory and midluteal phases, and a significantly reduced endometrial texture in the midproliferative phase (cp. Edi-Osaggie et al. 2004).

### **2.5. Current Management of Unexplained Subfertility**

There is no wide agreement on the management of couples with unexplained subfertility.

In 2002 Pandian et al. presented a review of randomised controlled trials. This review aimed to determine whether IVF improved the live birth rate compared to 1. expectant management, 2. clomiphene citrate (CC), 3. IUI, 4. IUI with controlled ovarian stimulation and 5. GIFT.

They found nine randomised controlled trials. In two trials they could not extract data separately for cases of unexplained infertility, two trials were non-randomised and one reported no valid rates. The review looked for live birth rates. Four trials were left for analysis. The reviewer's conclusion was that the effect of IVF in comparison remained unknown.

The critique is that the studies are limited by their small sample size, so that large differences might be hidden. Future trials should not only report rates per woman, but also include adverse effects and costs of the treatments compared to the outcome (Pandian et al. 2002).

Currently the best evidence is consistent with a progression from low-tech to high-tech treatment, but it is not convincing enough to support a rigid management protocol (Collins, 2003).

Low-tech means stimulated intra-uterine insemination and high tech refers to in-vitro fertilisation. For longstanding unexplained infertility the study of a waiting list for in-vitro

fertilisation suggests that one cycle of IVF or intracytoplasmic sperm injection (ICSI) is better than expectant management (which means intercourse in the fertile phase) for twelve months (cp. Evers et al. 1998).

The major factor affecting the spontaneous pregnancy probability (prospect) is the time of unwanted non-conception which determines the grading of subfertility. In Germany most of the pregnancies occur in the first six cycles with expectant management (80%). The authors assume that ten percent of the couples are seriously subfertile although untreated the live birth rate among these couples will reach nearly 55% in the next 36 months. Therefore the authors propose expectant management for six months for couples with a reasonably good prognosis (cp. Gnoth et al. 2005).

Steures compared IUI with controlled ovarian hyperstimulation for six months with expectant management for six months. The 253 couples with unexplained subfertility and a 30-40% probability of a spontaneous pregnancy within twelve months were divided in randomised groups. In these cases a large beneficial effect of IUI with controlled hyperstimulation could be excluded. In these couples expectant management for six months was justified (Steures et al. 2006).

### 3. Methodology

The design is a retrospective and prospective study without controls and not a randomised clinical trial because I did not consider a control group as reasonable.

Women with the problem of unexplained subfertility have already experienced a long period of suffering and waiting. For ethical reasons it seems not fair to put them on a waiting list.

The within-subject-design, a special form of repeated measure design, enables the comparison in two stages within the same group:

1. 24 months without osteopathical treatment
2. period from the first to the last osteopathical treatment plus one month.

This period results from a maximum of eight treatments.

The first three treatments take place within six weeks, all further treatments after the menstruation during the follicle phase. As a result there are about six months with osteopathic treatment.

Number of women: ten women

Half of the test persons (n=5) were assigned to me personally by women gynaecologists settled in Salzburg, the others were treated in Vienna (n= 3), in Linz (n=1) and in Vorarlberg (n=1) by other osteopaths who agreed on following my draft.

All four osteopaths started their education at the Vienna School for Osteopathy in 1995 and finished it either in 2001 or 2003. The osteopaths were asked to fill in a questionnaire concerning osteopathic diagnosis, number of treatments, days of the cycle, and which osteopathic approach is taken each treatment. This questionnaire gives an overview of the women's characteristics and a protocol of the treatment

As I hoped to enlarge the number of women I took nearly the same criteria for inclusion and exclusion as in the study of Monika Kirchmayr.

#### Inclusion criteria

- Wish to get pregnant since at least 24 months with regular intercourse
- Existing cycle
- Tubal patency
- Age between 25-40 years
- Male infertility has been excluded

#### Exclusion criteria

- Hormonal treatment (at the same time)
- Acute inflammations and infections of the urogenital area
- Tumor diseases
- Insufficiency of the pituitary gland

I took a longer period of unwanted non-conception namely 24 month as in the study of Kirchmayr because it is recommended by the WHO in clinical practice and research among different disciplines (Larsen, 2005).

#### Clinical controls:

The women treated by Monika Kirchmayr did a protocol of the menstrual cycle and took the basal body temperature and controlled the ovulation with LH-strips.

The women in this study were asked for a protocol of the menstrual cycle, because I wanted to know if there was a regular cycle and the treatment should have occurred in the follicular phase. Recording their menstrual cycle the women had to pay some attention to their cycle and their body.

In this study the women did no recording of the basal body temperature (BBT) for two reasons. First extreme caution is urged when it is used in clinical research. Even for experienced physicians it is very difficult to interpret the temperature curves and detect the day of ovulation (cp. Bauman, 1981). The basal body temperature raises one-two days after ovulation. The fertile period of six days ends with the day of ovulation (Wilcox et al. 1995). If the couples try to time their intercourse, the signal (the raising basal body temperature) comes too late (Dunson et al. 1999).

The second reason is a personal and practical one. The women (n=5) I treated had already done precise recording of the basal body temperature before and reported that they did not want to do it again. They said that it raised their stress level and influenced their quality of life too much. Another woman said that her job as a nurse did not allow the necessary regular amount of sleep.

The women did no test with a urinary LH-strip.

These tests are designed to show a colour change when urinary LH is 40-50 IU/l. This value represents the peak of the preovulatory LH wave which lasts an average of 14 hours.

According to the manufacturer's information the chance of a positive test result with one test per day varies from 77% for LH-color to 92% for Ovuquick test (6-8 minutes) and 93% for OvuStick which takes 60 minutes. Kremer writes that in independent tests of these LH-tests there are false positive and negative results (Kremer et al. 1988).

Comparing transvaginal ultrasound and OvuStick kits Vermesh gives 87,5% for detecting ovulation in 14 spontaneous and 17 clomiphene citrate-induced cycles. Therefore the authors conclude that it is a useful method to predict ovulation (Vermesh et al. 1987).

The interpretation of the blue colour of these sticks and variations in colour intensity might be difficult as it varies with the temperature (20° C and below 16° C). The test kit result is not influenced by these temperatures (Roberts et al. 1987). But buying a test kit means higher costs for the women.

The urinary LH surge was observed to occur 24 hours before the follicle rupture (Collins, 1996). If the probability of conception declines soon after ovulation, couples who abstain from intercourse until they have evidence of ovulation may miss earlier opportunities for conception (Wilcox et al. 1995).

Considering that it is rather unlikely to have no LH secretion in women with unexplained subfertility (Leach, 1997 and Randolph, 2003), the use of LH-strips for this study is not necessary.

Additionally there is the possibility of wrong results, user's mistakes and a rather short period of warning time if the couple wants to time their intercourse. For these reasons I did not introduce this test. The women I treated (n=5) already knew about these LH-strips and they had stopped using them months before.

The first questionnaire should give a profile of the women which makes it possible to notice large differences among the group.

The questionnaire was nearly the same as in the study of Kirchmayr because I wanted to be able to notice large differences between the two groups.

The women are asked to fill in the first questionnaire at the beginning of the treatment. The criteria of inclusion and exclusion will be asked for in the case history and in questionnaire 1.

The second questionnaire will be filled in seven months later (appendix).

The first questionnaire consists of 26 questions concerning the criteria of exclusion and inclusion (number 1, 15, 16, 19, 20, 23, 24, 26), health (number 2-9, 12-14, 17, 18, 21, 22) and own opinion about stress level (number 10, 11).

The second questionnaire consisting of 11 questions will be done seven month later after a maximum of eight treatments. Question number 1 to 8 (stress level and health) are already asked in the first questionnaire, number 9 to 11 concern pregnancy and the own opinion about profits.

## 4. Results

The results of the first questionnaires reflect the women's characteristics. The most important things described are the average age and the duration of unwanted non-conception of the women and how they estimate their health and stress level.

The findings of the second questionnaires reflect the changes which are shown in comparison to the first questionnaire in the diagrams.

### 4.1. Findings of the First Questionnaire

- On closer examination of the women's age it turns out that at the beginning of the treatment the women are between 31 and 40 years old. Four women are younger than 35 years and six women are older than 35 years which results in an average age of 35.7 years.
- Evaluating the period of unwanted non-conception it becomes apparent that one woman has wanted to conceive for two years, three women for three years, two women for four years, two women for five years, one woman for six years and another one for ten years which gives an average of 4.5 years.
- Referring to the state of health three of the women describe their health as very good and seven women as good.
- With reference to smoking habits nine women answer they do not smoke and one woman says she smokes sometimes.
- Concerning their habits of sports eight women answer that they practice sports regularly. Two do no sports at all.
- Regarding the quality and balance of diet one woman judges her diet very good, seven women call it good and two say it is average.

- In view of the consumption of alcohol two women answer that they drink less than one eighth vine per week, three drink one eighth per week, three one quarter per week and two women half a litre vine per week.
- Considering digestion, circulation and breathing two women sometimes have constipation, three women have low blood pressure, one of them also has allergic asthma, another woman complains about being short of breath.
- Relating to problems of the thyroid gland, headache and depression it turns out that hypofunction of the thyroid gland is found in two women, three complain about headache, and one tells about her depression.
- In regard to the menstrual cycle four women mention having a very regular menstrual cycle lasting 28 days. Three women say it lasts between 28-36 days, two women have a shorter cycle lasting 24-28 days, and one woman says it varies between 24-29 days.
- On closer examination of the means of contraception it becomes apparent that seven women used the pill between three and twenty years. One woman used only condoms, three used them after they stopped using the pill. Another woman used the persona computer after stopping with the pill. Two never used any kind of contraception!
- Concerning abortion eight women never had an abortion. There was one woman who had one abortion, and another one who had two abortions.
- With a view to the frequency of intercourse it comes out that five women have intercourse several times a week, four women weekly, and one woman once a month.
- After careful consideration of the several methods of investigation it turns out that the hormone status and the fallopian tubes of all of the ten women were checked and all of the ten male partners were checked. Six women did temperature measurement and five women had used LH-strips, one of them with a kit.

- Considering the use of alternative medicine in the past six women never asked for help. Four women were treated by means of either acupuncture, Chinese medicine or homeopathy (n=2).
- In view of thoughts and the personal opinion of a particular reason 'why?' five women give no reason. Five women say they think there is a reason. Three are convinced that stress at home and at work is the reason why they cannot conceive. One woman points out that the reason is out of her sphere of activity, another woman says the reason is in her mind which means that she puts herself under stress.
- Regarding changes in weight it is noted that none of the women lost or gained weight quickly in the last three years.
- Looking at the stress level at work it turns out that six women call their stress level high, and four say it is average.
- Referring to the stress level in private life it is put on record that three women estimate their stress level as high, three call it average and four women say it is low.
- With reference to taking medicine seven women state that they do not take any medicine, whereas three do. In the last three years two women had to take antibiotics.
- In respect of any kind of serious illness it is noted that none of the ten women ever had a serious illness in the past.
- Concerning operations five women had an operation, two women had a scrape. One woman had a removal of an ovary cyst two years ago. Three women had an appendectomy 27 years ago.
- In regard to infections it has to be mentioned that six women did not have any infections. Three women had an infection of the urinary tract. Four had infections of the vagina, namely fungus infections; one of them also had pyelitis.

- Considering pain in the abdominal area two women have no pain. Seven women complain about period pain. One woman has pain of her scar because of the removal of an ovary cyst.
- Relating to pain in the area of the spinal column it turns out that two women have no pain. Eight women do have pain. Four women have pain in the neck, four in the area of the sacrum. Two women also complain about pain in the upper spine and three also in the lower back.

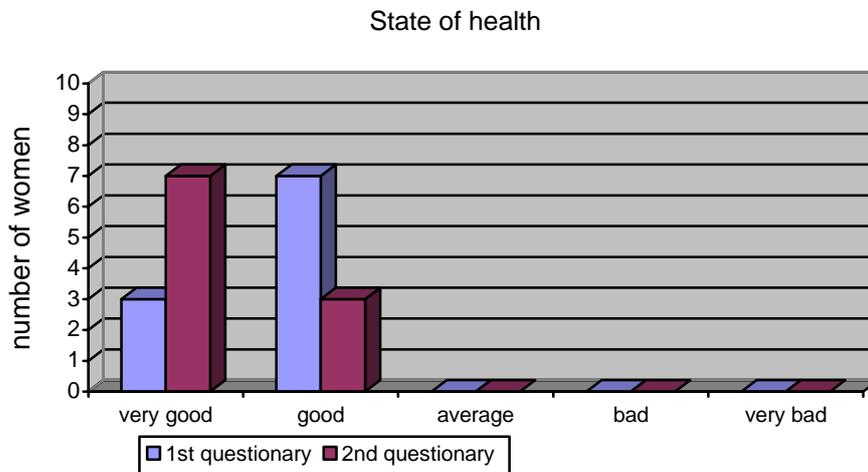
#### **4.2. Findings of the Second Questionnaire**

- Referring to the state of health seven months later six women describe their state of health as very good, four women call it good.
- Considering digestion, circulation, breathing, elimination two women still have problems with the low blood pressure. One woman still suffers from being short of breath.
- Relating to problems with the thyroid gland, headache and depression it turns out that two women have a hypofunction of the thyroid gland and three women have regular headaches.
- Referring to the stress level at work it is put on record that six women estimate their stress level at work as high, three women say it is average and one woman says her stress level is low.
- Looking at the stress level in private life it turns out that two women still estimate their stress level as high, four women say it is average and four women estimate their level as low.
- Considering pain in the abdominal area seven women have no pain anymore, whereas three women still have period pain.

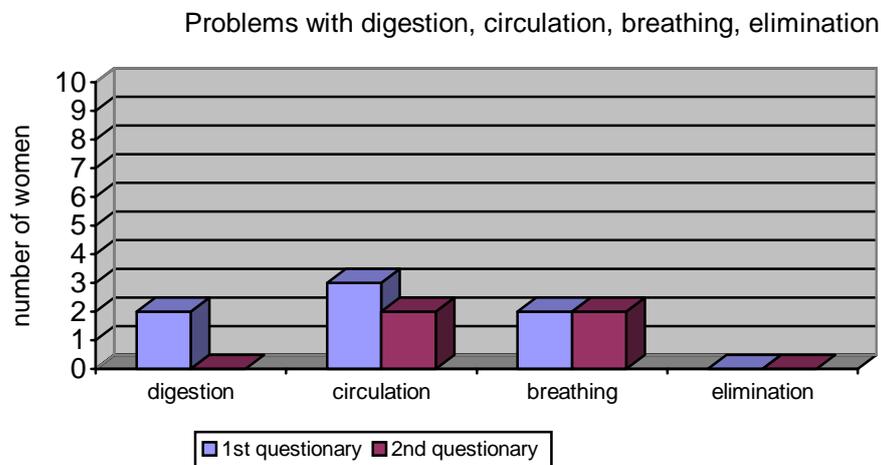
- Relating to pain in the area of the spinal column it comes out that three women have no pain in the area of the spinal column and seven women still complain about pain.
- With reference to taking medicine it is stated that eight women do not take any medicine and two still take the medicine necessary because of hypofunction of the thyroid gland.
- In view of the pregnancy rate it has to be mentioned that one woman conceived after six months. She had osteopathic treatment for six times. Nine women did not conceive in the last six months.
- On closer examination of the profits of osteopathic treatment it is put on record that all women agree on having profit out of the treatment. All of them mention a deep relaxation, three women say they have a better understanding of their body and a better body perception, three women welcome especially the disappearance of period pains, one woman say her back pain has gone and another one say her posture has improved. Additionally two women mention that they feel happier, full of the joys of life, more energetic.

For these reasons all women would recommend osteopathic treatment.

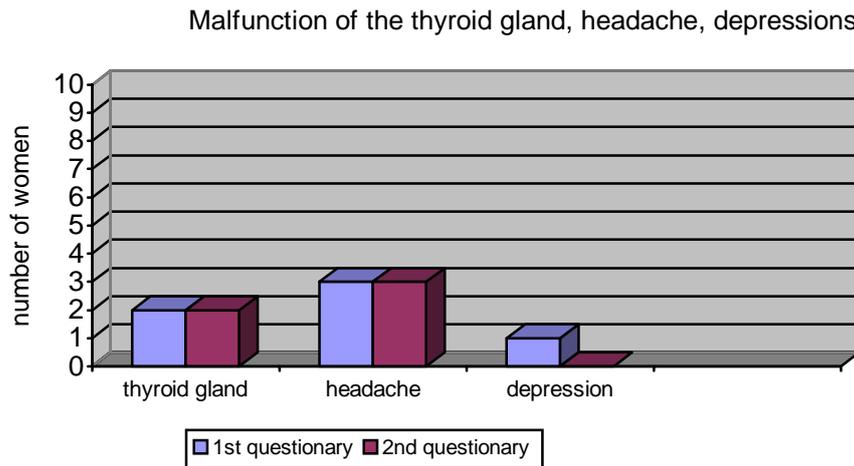
### 4.3. Comparison of the First and Second Questionnaire and Pregnancy Rate



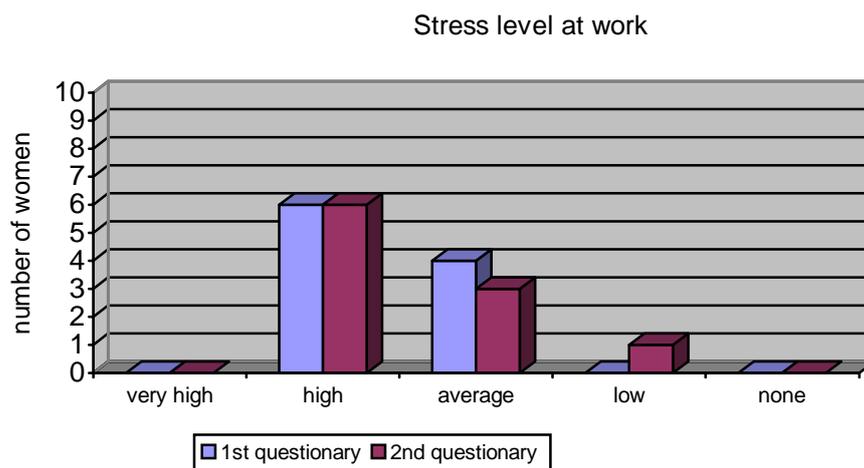
As the graph shows the women generally feel healthy to very healthy, and it is shown that there is an interchange of the distribution between the first and second questionnaire. Seven months later four women said their state of health had improved from good to very good.



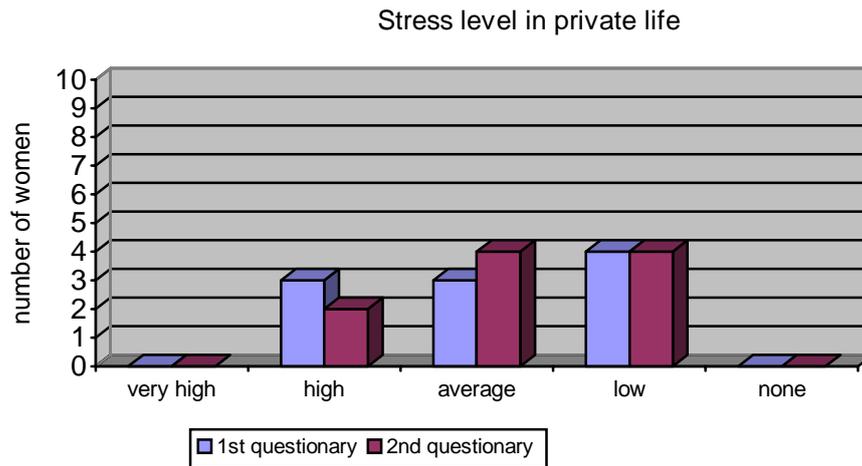
This graph shows that in the first questionnaire two women reported problems with the digestion namely constipation two or three days before the onset of the period. These women said the problems were gone. There was one woman who reported no problems with her low blood pressure in the second questionnaire. There was no change in the woman who felt short of breath and the other woman who reported allergic asthma in spring time.



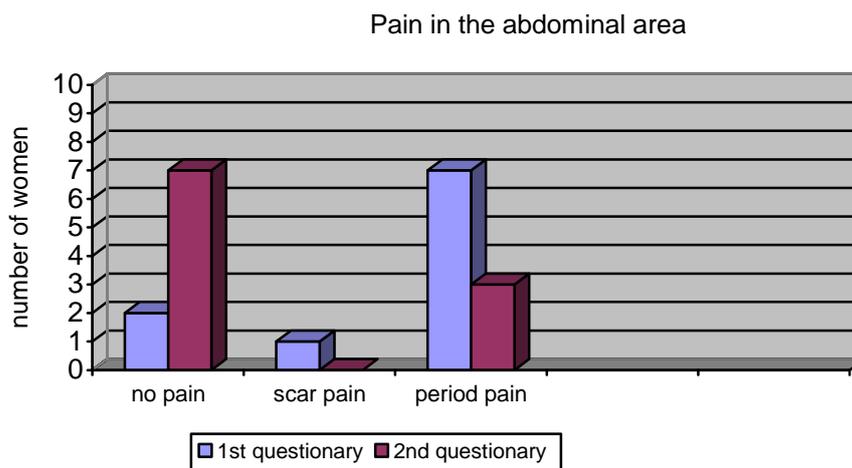
This graph shows that there is no difference between the women who reported on headache and hypofunction of the thyroid gland. The one who reported on her depression answered in the second questionnaire that she did not have depressions anymore.



As the graph shows the women mostly estimate their stress level high to average. There is nearly no change concerning the stress level at work seven months later.

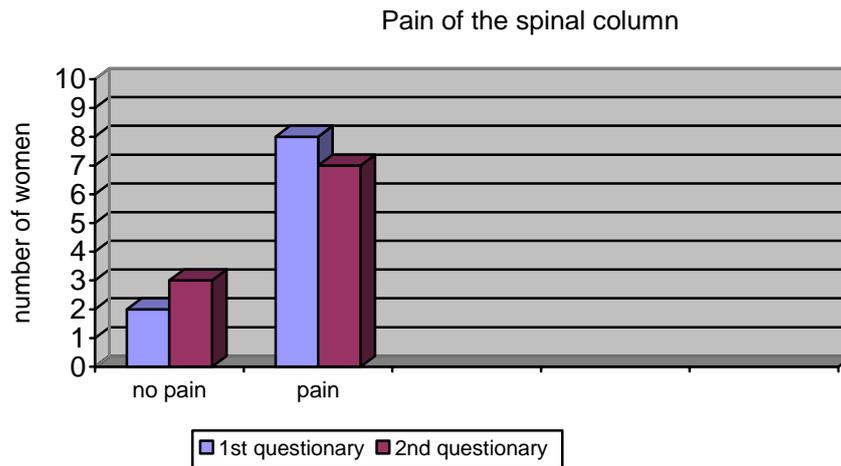


As this graph shows the stress level in private life of the group was evenly distributed from low to high, with no remarkable change seven months later.

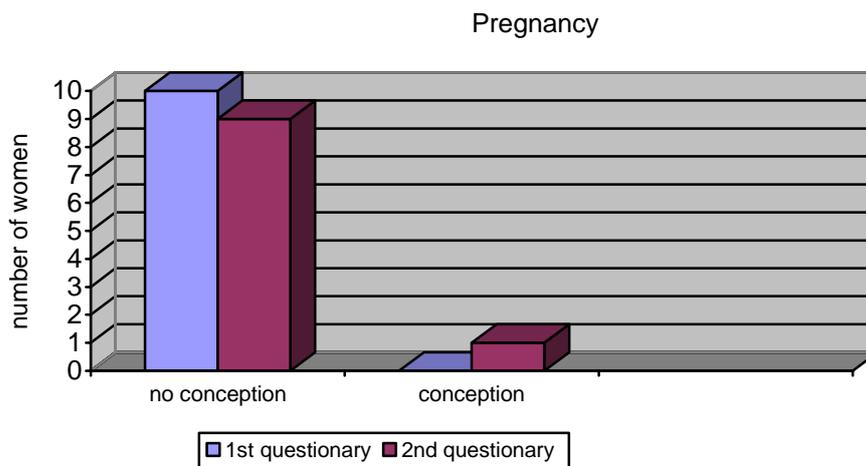


Comparing these bars there is a noticeable shift from stated pains to no pain in the second questionnaire.

In the first questionnaire eight women filled in that they had either period pain or scar pain. After seven months five women had a change for the better. Four women said that they had no period pain anymore. The woman who had pain of a scar reported after the third treatment that she did not feel it anymore.



Only the two youngest women reported no pain of the spinal column in the first questionnaire. As it is shown eight women filled in at least one area of the spinal column where they felt pain repeatedly. There is nearly no change concerning pain in the spinal column.



In regard to the pregnancy rate it is shown that one woman did conceive in the last seven months. Nine women failed to conceive.

#### 4.4. Questionnaire for the Osteopaths

The osteopaths are asked to give an osteopathic diagnosis and to tell the priorities of their treatment. The first five women are treated by the author therefore a more detailed description is possible because the whole case history is well known.

Concerning woman six to ten the descriptions are shorter and report the information given in the questionnaires for the osteopaths. This information is not ment for analysis but to present an overview of the women´s characteristics and their treatments.

- First woman

Her age is 33 years. She has tried to conceive for five years. She tells that she suffers from depression since an attempt of her former gynaecologist scanning her ovulation by ultrasound and telling the best time for intercourse. She has to take medicine and visits a psychotherapist regularly. She has a hypofunction of the thyroid gland which needs medication. She complains about heavy period pain.

The osteopathic findings are a very weak PRM (primary respiratory mechanism), no midline, the uterus is restricted in mobility and motility, a dysfunction of the right hip, and the sacrum; and a compression of C0/C1.

She receives treatment for eight times. The treatment pays attention to her cranial- sacral system referring to the sacrum, the ventricles and C0-C1 by fluid techniques. A focus referring to her midline again and again. She needs structural and fascial work on the right hip and the sacrum as well. She receives visceral treatment for the uterus and its attachments. The midline has improved very well and she tells that her depression is under control without medicine. She fails to conceive but she is content because the period pain is gone.

- Second woman

Her age is 33 years. She has failed to conceive for six years. She reports a good health but recently she had pneumonia. Her posture needs an improvement in the upper thoracic spine although she feels no pain in the spinal column. She has pain only in the area of the scar because of the ovary cyst operation. Besides she reports period pain which is too heavy to stand it without pain killers.

The osteopathic findings are a distortion of the pelvis with a sacral dysfunction, suspected adhesions after an operation, which create tension and fixation of the small intestine and stases in the small pelvis, compression of d11-L1 because of the kyphosis of the upper spine, and her PRM is reduced.

She receives treatment for eight times with emphasis on the visceral and fascial problem referring to the scar and structural work to improve her posture. In the cranial sacral system she receives treatment for her central axis which improves the PRM.

Her posture improves and the pain in the area of the scar is gone completely as well as the period pain. She does not conceive but she is very happy about the improvement concerning pain.

- Third woman

Her age is 35 years. She has wanted to become pregnant for three years. She is affected by Mb. Scheuermann and arthroses of the ilio sacral joint. She complains about pain in the area of the upper ribs and period pain.

The osteopathic findings are a low PRM, and a restriction in the central axis, ptosis of the whole intestines

restriction of the left kidney in mobility and motility.

Restrictions over the whole upper spine as expected in patients with Mb. Scheuermann

She receives cranial sacral treatment, fluid techniques improving the PRM and the midline, balance of the pelvis, visceral treatment of the kidney and the ptosis, very soft structural techniques for the spinal column.

She does not conceive and stops with osteopathy after six months and wants to seek help in an IVF treatment. She really likes this kind of treatment and describes her profits affecting the whole body which feels more comfortable.

- Fourth woman

Her age is 37 years. She has tried to conceive for four years. She sometimes feels pain in the area of the ilio sacral joint and she needs medication for her period pain. Alternately she and her partner are often on business trips which might be part of their problem of not conceiving.

The osteopathic findings are a dysfunction of the pelvis, with a high muscle tension of the psoas muscle, restricted uterus on the left side which all seems to be fixed by a high tension in the dura and the fascias , and a low PRM.

The cranial treatment to improve the PMR and reduce the tension of the dura is followed by a visceral treatment of the uterus and its attachments to the pelvic walls, and a structural and fascial treatment of the pelvic joints and muscles.

This woman does not conceive but it is unsure if the couple has intercourse in the fertile phase as both of them are often on business trips. She thinks they have intercourse regularly enough as to the inclusion criteria. There is a change of the period pain for the better.

- Fifth woman

She is 35 years old. She has wanted to conceive for five years. She has a hypofunction of the thyroid gland and suffers from headache at the same time the period starts (menstrual headache) and has constipation just one or two days before the onset of the period. She complains about pain in the neck and period pain. She feels very healthy and practices a lot of sports.

The osteopathic findings are a high tension in the dura and the fascial system, compression of C0-C2, dysfunction of the pelvis regarding the sacrum and the right hip, restriction of the uterus in mobility to the right, restriction of the small intestine.

The woman receives a cranio sacral treatment of the dura and the sacrum, release of the cervical fascias and the upper neck, visceral treatment of the uterus and small intestine and balance of the pelvis. She also needs structural work at the spine and the hips.

She does not conceive. Her headache does not change in frequency but in intensity. Her digestion has changed as there is no constipation anymore.

- Sixth woman

Her age is 38 years. She has failed to conceive for ten years. She complains about occasional period pain and low blood pressure.

The osteopathic findings reported are uterus restriction in mobility and motility, tension in the broad ligament, restriction in the cranial system and a lesion of the SSB, compression of D12, high tension of the diaphragm and of the pelvic floor.

The woman receives visceral treatment of the uterus and the broad ligament and an emotional release. She needs a correction of the SSB and D12, fascial unwinding of the diaphragm and treatment of the hormonal axes.

This woman does not conceive but says that she feels more relaxed.

- Seventh woman

Her age is forty years. She has failed to conceive for three years and had two abortions. She suffers from headache and is short of breath. The osteopathic findings reported are a low PRM, the midline needs attention, the woman is in an emotional arousal. Fascial tension in the small pelvis is reported as well as high tension of the diaphragm.

The woman is treated by a fluid drive in the pelvis and the spinal axis. She needs a balance of the pelvis, and an emotional release. She receives visceral treatment of the lesser pelvis, and again an emotional release, balance of the diaphragm, and attention of her midline. She becomes pregnant after six months.

- Eighth woman

Her age is 37 years. She has failed to conceive for two years. She is confronted with constipation. Her appendectomy was in 1979 but a hernia of the scar was treated in September 2001. She also complains about period pain and pain in different areas of the spinal column. She had two abortions.

The osteopathic findings reported are a dysfunction of the right hipjoint, restriction of the cranial system, interosseous lesion of the sacrum, restriction of the uterus in mobility to the left and to the caecum and the broad ligament.

The woman receives visceral treatment of the uterus as to mobility and motility, as well as the broad ligament and the caecum. Her pelvis and the hipjoint is treated in addition to the sacrum lesion by the means of cranial sacral osteopathy.

This woman does not conceive but in her own opinion she profits of the lacking period pain and she does not complain about constipation anymore.

- Ninth woman

Her age is 39 years. She has wanted to become pregnant for three years. She thinks she is very healthy and tells that she has period pain and pain in the lower back.

The osteopathic findings reported are a serious and traumatic dysfunction of the pelvis, dysfunction of d8-d9, dysfunction of C2-C3, low PRM, tension in the broad ligament in the area of the fallopian tubes.

The woman receives treatment of the right hipjoint, the pelvic floor coccyges, the uterus and the rectum as well as structural work affecting D8-D9 and C2-C3. She needs cranial treatment to improve the PRM and the hormonal axis as well as visceral treatment especially for the broad ligament in the area of the fallopian tubes

She does not conceive but she has no more pain in the back which is welcomed.

- Tenth woman

Her age is 31. She has failed to conceive for four years. She suffers from headache and low blood pressure. Her whole spinal column is affected by high muscle tension which causes pain.

The osteopathic findings reported are an somatoemotional arousal, which might cause the tension in the diaphragm, high tension of the psoas muscle, no midline, maybe a result of the cranial sacral system like the dysfunction of the sacrum as well. She has got a high tension of the tentorium and a interosseous lesion of the occiput.

The woman needs a lot of attention of her cranio sacral system with an emotional release, a treatment of the occiput , the tentorium, the diaphragm and the pelvic floor. Her midline is supported and she receives structural treatment of the sacrum and the psoas muscle.

The woman does not conceive. There is no difference concerning her headache and low blood pressure but she feels a relaxation after six months.

The treatment of these women covered all osteopathic systems. The women had got their individual treatment based on the case history and the clinical examination which was taken by each osteopath. The women were treated affecting the structural system, the cranio sacral system and the fascial - visceral system.

Concerning the women who were treated in Salzburg by myself the distribution of cranial, visceral and structural treatment was evenly spread regarding all the records of the treatments. Certainly special attention was paid to the reproductive organs and the hormonal glands. For the other five women who had been treated by colleagues the distribution had also been spread evenly, and it seemed that the women also presented individual differences.

#### 4.5. Records of the Duration of the Menstrual Cycle

The records of the menstrual cycle started after the first osteopathic treatment and were done by the women themselves.

##### 4.5.1. Table of the Six Menstrual Cycles of Each Woman

Cycle	Duration									
	1 <sup>st</sup> woman	2 <sup>nd</sup> woman	3 <sup>rd</sup> woman	4 <sup>th</sup> woman	5 <sup>th</sup> woman	6 <sup>th</sup> woman	7 <sup>th</sup> woman	8 <sup>th</sup> woman	9 <sup>th</sup> woman	10 <sup>th</sup> woman
1 <sup>st</sup>	28	28	26	32	28	28	36	28	28	30
2 <sup>nd</sup>	25	28	22	30	23	28	31	27	28	30
3 <sup>rd</sup>	28	28	28	28	23	28	28	27	32	35
4 <sup>th</sup>	28	26	31	28	25	26	28	28	27	35
5 <sup>th</sup>	28	27	33	28	28	25	28	26	24	26
6 <sup>th</sup>	28	27	28	28	27	32	29	32	28	30

The chart shows the duration of the six cycles during the period of the treatment of the ten women.

##### 4.5.2. Table of the Duration of the Menstrual Cycles in Classes

For the presentation in the diagrams the duration of the cycles is summarized in steps of three days which is necessary because of the small number of women. The basis of the classification is the normal duration of the cycle +/- one day and should include all possible cycles.

This diagram classifies the number of women whose 1<sup>st</sup> cycle lasted 21-23days, 24-26days, 27-29days, 30-32days, 33-35days, >35days. Cycle two to six follow the same scheme.

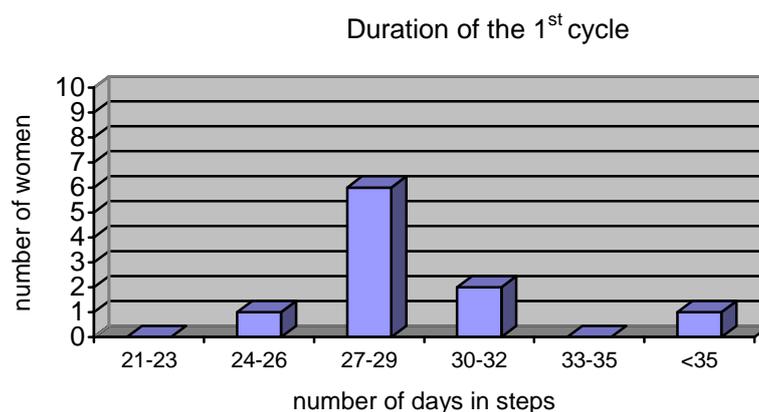
Table of Duration of the Menstrual Cycle in Classes

Cycle	Number of women summarized in classes referring to the duration of the menstrual cycles					
	21-23	24-26	27-29	30-32	33-35	>36
1 <sup>st</sup>	0	1	6	2	0	1
2 <sup>nd</sup>	2	1	4	3	0	0
3 <sup>rd</sup>	1	0	7	1	1	0
4 <sup>th</sup>	0	3	5	1	1	0
5 <sup>th</sup>	0	4	5	0	1	0
6 <sup>th</sup>	0	0	7	3	0	0

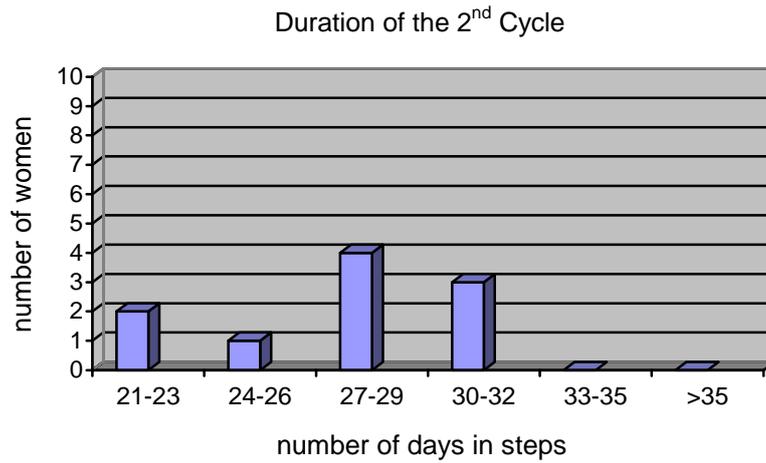
The answers of the questionnaires show that the duration of the menstrual cycle is 28 days in four women, 28-36 days in three women, 24-28 days in two women and one woman reports a variation between 24-29 days.

The records of the duration of the menstrual cycle taken during the treatment correspond to the information given in questionnaire 1.

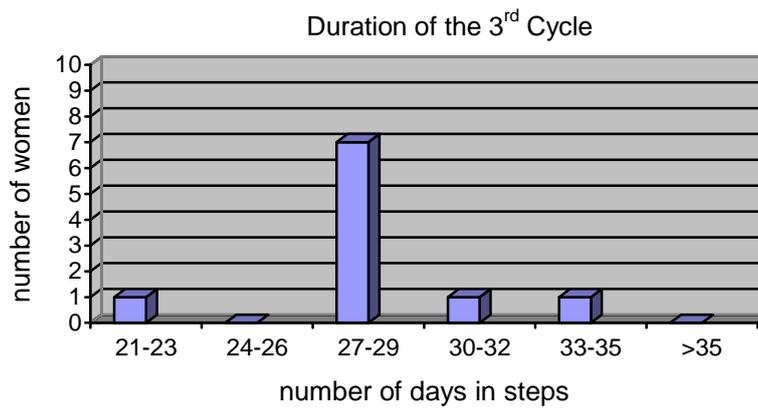
Up to and including cycle four the diagrams represent variations on the data given in the questionnaires concerning the duration of the cycles. Cycle five differs to the effect that there has been a small shift towards the shorter cycles. Cycle six also is a possible variation on the data given in the questionnaires concerning the duration of the cycles. There is a remarkable shift towards the centre.



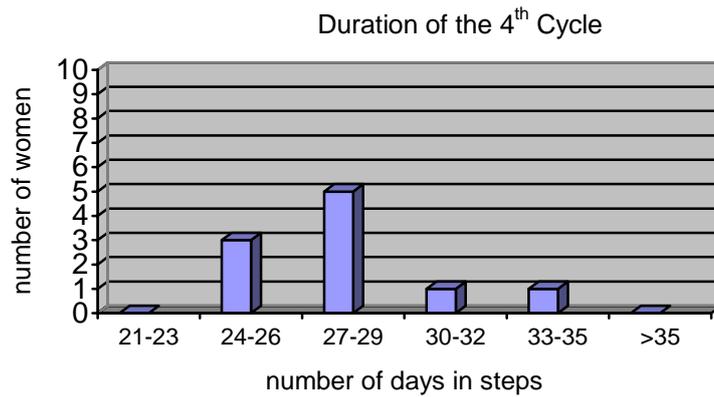
As it is shown in the diagram the distribution of the duration of the first menstrual cycle is from 24 days to 36.



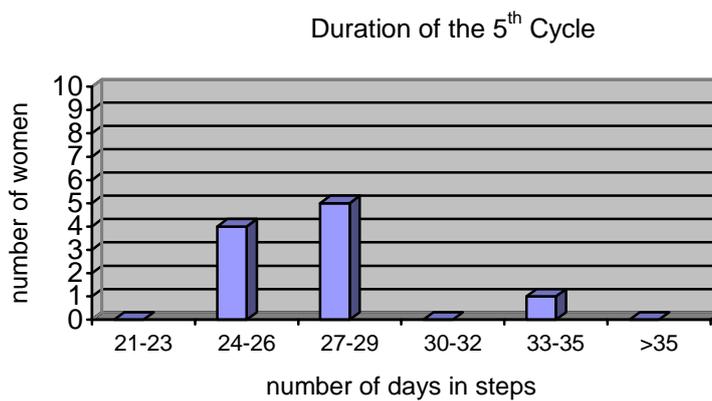
The graph shows that four women have a cycle length from 27 to 29 days, three from 30 to 32 days, two from 21 to 23 days and one from 24 to 26 days.



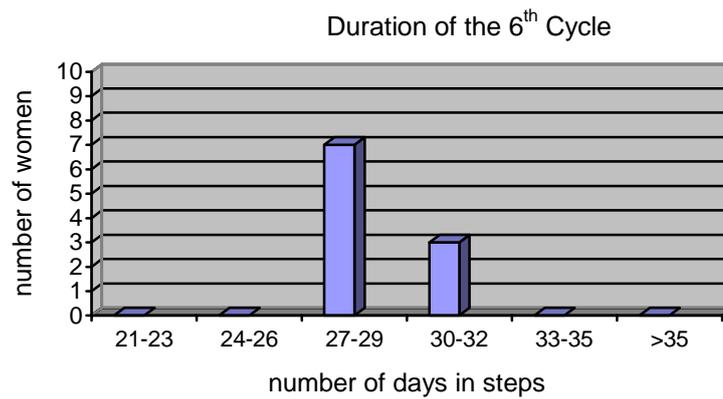
As the graph shows most women's cycles have a duration of 27 to 29 days. The distribution of the shortest and the longest cycle varies between 21 and 35 days.



This graph pictures that cycles of most women last 27 to 29 days but the distribution of the shortest and the longest cycle varies between 24 and 35 days.



As the graph shows the menstrual cycle lasts 24 to 26 days in four women, 27 to 29 days in five women, 33 to 35 days in one woman. A tendency to a shorter duration of the cycles is shown in some women.



The diagram shows that all of the women have a menstrual cycle lasting between 27 and 32 days and seven women are in the section of 27 to 29 days.

This shift to the centre to the section of 27-29 days and also to the section of 30-32 days could have taken place even without osteopathic treatment but in the author's personal opinion it is interesting.

## 5. Discussion

Founded on the study of Kirchmayr “A woman with the problem of infertility receiving osteopathic treatment has an increased chance of becoming pregnant” the hypothesis that osteopathic treatment might rise the pregnancy rate is set up.

Various investigations are started to get a large pool of possible participants. Within three months 15 women want to participate whereas five have to be excluded for different reasons. One woman because of age, one suffers from endometriosis with the suspicion of lacking tubal patency, another one has been treated osteopathically for two years, one decides to take part in the IVF program and another one does not want to afford an osteopathic treatment. The search for participants turns out to be rather difficult and therefore only ten women are treated. These difficulties to find participants in the field of osteopathy might result of the fact that osteopathy is not part of the Austrian medical system and still not known very well. The management of subfertility is in the responsibility of the gynaecologists and there exists no circle of interchange among the psychologists in Salzburg.

The criteria of inclusion and exclusion should allow a reasonable probability to get pregnant, although these women did not conceive for years (mean 4.5 years). The period of treatment lasting six months was the same as in the other study and was considered as long enough to allow a change to take place. In the study of Kirchmayr four women conceived in the first three months, one woman after six months and two after nine months.

Maybe the period of six months is too short from the point of view that even with frequent intercourse many ovulatory cycles are not capable of conceiving anyway (Willcox et al. 1995). But as this study is done within the master course for osteopathy time is a limiting factor.

Reflecting again on the clinical controls which are not introduced namely LH-strips and temperature measurement it maybe would have been good to do these tests in order to make the women pay more attention to their body. On the other hand it is examined that women with unexplained subfertility have normal menstrual cycle characteristics and LH secretion (Blacker et al. 1997 and Randolph, 2003).

Following the lately published studies (2.4.2.) which describe differences in blood flow velocity and uterine artery resistance which is examined with the transvaginal colour Doppler

sonography it would be interesting to know if it were possible to influence hemodynamic differences.

The subtle hormonal anomalies (2.4.1.) are seen in the serum levels of gonadotropin and steroid hormones which have been taken daily and are consistent with a difference in a negative feedback from the ovary to the pituitary gland. It also would be interesting if it were possible to notice a lower serum level of these hormones.

Both of the interesting clinical controls are not possible in an osteopathic surgery. The research question of this study is if osteopathic treatment could rise the pregnancy rate and therefore it seems sufficient to control the cycle.

The records of the menstrual cycles in the period of treatment show that the women have a regular cycle and these records about the duration of the menstrual cycle correspond to the records given in the first questionnaire. This correspondence is expected and does not indicate that there should be any menstrual disorders.

The diagrams of the duration of the menstrual cycles show a shift of the shortest and the longest cycles towards the normal duration of the female cycle which might be a slight indication of a positive influence of osteopathy. Certainly this is not an evidence which can be generalized.

The result that only one woman conceived was surprising and unexpected, because in the study of Kirchmayr five women conceived after six months and two after nine months. This difference in the result raises many questions.

Which differences could be found in these two studies and give a hint?

There is the same small sample size which allows a result which is not representative in general and has the problem of a great probability of mistakes.

In this study the women were treated by four different osteopaths, who all studied at the Vienna School of Osteopathy and were all experienced.

In this study there were three male osteopaths and one woman osteopath (myself) who treated the women, but gender should not be considered as a strongly influencing factor.

The group of women show some obvious differences although the criteria of inclusion and exclusion should provide nearly the same characteristics. This is another problem of a small sample size.

There is a difference in the women's age.

The average age in the study of Kirchmayr is 33.8 years and in this study the average is 35.7 years. As presented in natural population data the fecundity usually ends between the age of

39 and 41 and the conception rate declines for women older than 30 years which is indicated by findings in artificial insemination literature (Frank et al. 1994).

The period of unwanted non-conception is on average 3.3 years in the study of Kirchmayr and in this group 4.2 years. The decision to have a different inclusion criterion concerning the period of unwanted non-conception namely 24 months could have influenced this difference. But examining the shortest period of unwanted non-conception in the study of Kirchmayr it turns out that the shortest period is two years, which is equal to the inclusion criterion of this study.

Considering that Gnoth said (2.5.) that time determines the grading of subfertility this difference in time proposes the assumption of a even less fertile group who participated in this study.

Again the small number of the group might hide further differences which could have influenced the result.

The hypothesis that osteopathic treatment might rise the pregnancy rate cannot be supported by this data collection and further investigations with more participants would be very welcome.

It seems that the different results have their roots in the different characteristics of the groups. In further examinations it could be very helpful to determine the criteria of inclusion and exclusion even more tightly considering age and the period of unwanted non-conception. Especially the duration of non conception not longer than 3.3 years seems to provide a more promising situation for an osteopathic treatment.

The second research question whether osteopathic treatment could be recommended to women with the problem of unexplained subfertility can be reflected from two different points of view. Considering the fact that only one woman out of ten conceived after the treatment the question cannot be answered with yes.

Again it should be kept in mind that maybe the duration of unwanted non-conception is strongly influencing the result of this study. Maybe the recommendation has to be put in relation to the duration of unwanted non-conception.

Reviewing the answers given by the women to the question if they would recommend osteopathy there is broad agreement. The women receiving osteopathic treatment gain profits concerning their period pain, constipation as well as their ability to relax. This improvement is

noticed in the evaluation of the questionnaires and mentioned by the women themselves with emphasis.

The possible welcomed change regarding period pain was part of the study of Riepler-Reisecker in 2006 titled 'Influence of Osteopathic Treatment on Congestive Disorders and Premenstrual Syndrome'.

More women estimate their state of health as very good in the second questionnaire which reflects the changes described in the profits the women gain.

Therefore it could be stated that osteopathy can be recommended in the field of gynaecological problems but considering the value in the area of unexplained subfertility further and very careful examinations have to be carried out.

Referring to the questionnaires for the osteopaths the demanded diagnosis and treatment records are not classified for analysis, distribution of findings and treatment. Therefore there would be needed a more detailed questionnaire which reduces the wide variation of the description of the diagnosis and treatment.

As far as it is possible to compare the author's and the other osteopath's findings it seems that there is roughly the same distribution concerning the cranio-sacral, the visceral and the structural osteopathic treatment.

The aim of the questionnaire for the osteopaths is to have a treatment protocol and a short description of the woman's needs in the osteopathic point of view.

It is not planned to analyse the diagnosis and the treatment. Looking back it now seems worth trying to get a scheme for diagnosis and treatment in order to get data which can be classified and analysed. This might give an answer to the arising question which conditions or diagnosis favour a success of osteopathic treatment.

The role of osteopathy in cases of unexplained subfertility is not clear yet.

It seems necessary to find out which special conditions favour an osteopathic treatment which possibly assists the woman's profit not only in general female health attitudes but also in becoming pregnant.

This study supports the assumption that the duration of unwanted non-conception has to be regarded very carefully in order to care for the women in a responsible way.

## 6. Summary

The subject of female gynaecological disorders or problems is always a very interesting and concerning pregnancy a very delicate one which needs a very careful and kind approach in the field of osteopathy.

The purpose of this study is to first answer the question if osteopathic treatment increases the pregnancy rate in women with unexplained subfertility. As function and structure from the osteopathic point of view are interdependent osteopathic treatment might improve the pregnancy rate in such cases.

The second question is if osteopathic treatment can be recommended to women with unexplained subfertility.

The study of Kirchmayr with the topic 'a woman with the problem of infertility receiving osteopathic treatment has an increased chance of becoming pregnant' presents promising results and encourages further research.

In literature of medical research the problem of unexplained subfertility is discussed very intensively regarding the best evidence for the management, the risks of more invasive treatments like IVF or IUI and the high costs. Following Collins currently the best evidence is consistent with a progression from low-tech to high-tech treatment, but it is not convincing enough to support a rigid management protocol. Gnoth proposes expectant management for six months for couples with a reasonable good prognosis.

The design of this study is a repeated measure design namely a within-subject-design. For ethical reasons there is no group of controls which is explained in chapter 3, Methodology. The participants are ten women with unexplained subfertility who meet the criteria of inclusion and exclusion. For six months the women receive osteopathic treatment and do a precise recording of their menstrual cycle.

At the beginning and at the end of the period of treatment the women fill in a questionnaire which provides the necessary information (concerning age, health, duration of non-conception, habits and stress level) to get an overview of the characteristics of the group. The second questionnaire enables a comparison of the alterations in regard of period pain, stress level, state of health and conception.

As only half of the women are treated by the author there is a questionnaire for the three osteopaths as to diagnosis and osteopathic treatment which gives a rough summary of the cases and the osteopathic treatments applied.

The most important and at the same time surprising result compared to the study of Kirchmayr is that only one woman conceived within these six months. This does not support the hypothesis that osteopathic treatment rises the pregnancy rate in women with unexplained subfertility.

This result demands a closer examination of the conditions of the two studies.

In comparison to the study of Kirchmayr the most obvious differences are seen in the characteristics of the two groups referring to age and duration of unwanted non-conception. The age of the women and especially the period of subfertility seem to be factors which influence the chance of conception.

But it also has to be stated that the small sample size might not be representative for the whole population who is affected by unexplained subfertility. In relation to the small sample size further difference may be hidden.

Referring to the second question from the women's point of view all of them recommend osteopathy because they feel more relaxed and have less pain especially period pain.

In the author's opinion under certain conditions osteopathic treatment can be recommended to women with unexplained subfertility as the study of Kirchmayr gives a conception rate of seven out of ten.

This study seems to point out that the recommendation has to be reflected very carefully because the results show a much lower conception rate namely one out of ten women. The successful support of the women by osteopathic treatment appears to be partly depending on the duration of unwanted non conception.

It should be considered to add a maximum duration of unwanted non-conception to the exclusion criteria in further studies in the sense of responsibility.

Further investigations are required to answer the arising question for exactly which conditions osteopathic treatment may provide an increased chance of becoming pregnant.

## 7. Appendix

### Questionary 1

Date:

Name:

Profession

Age:

1. *Have you been treated osteopathically during the last two years?*

Yes

No

2. *How would you describe your general state of health?*

Very good

good

average

bad

very bad

3. *Do you practice sports regularly?*

Yes

No

Which kind of sport?

How often?

4. *Do you smoke?*

Yes

No

Since when?

5 *How would you describe the quality and balance of your diet?*

Very good

good

average

bad

very bad

6. *How much alcohol do you consume during one week?*

7. *Do you know about any allergies or food indigestibilities?*

Yes

No

Which?

8. *Are there any problems concerning:* *Which?*

digestion:

circulation:

breathing:

excretion:

9. *Are there problems like:*

hypofunction of the thyroid gland

hyperthyroidism

headache

depression

others

10. *Have you gained or lost weight quickly in the last three years?*

Yes

No

11. *How would you estimate the stress level at your work?*

Very high

high

average

low

none

12. *How would you estimate the stress level in your private life?*

Very high

high

average

low

none

13. *Do you take any medicine?*

Yes

No

Which?

14. *Have you had to take medicine in the last three years?*

Yes

No

Which?

15. *Have you had any serious illness?*

Yes

No

Which and when?

16. *Have you had any surgery?*

When?

uterus

fallopian tubes

ovaries

bladder

appendix

others

17. *Have you had any infections affecting:*

urinary tracts

vagina

uterus

fallopian tubes

ovaries

kidneys

18. *Do you feel any pains in the abdominal area?*

Yes

No

e.g. period pains

19. *Do you feel any pains affecting the spinal column?*

Yes

No

neck

upper back

lower back

sacrum

coccyx

20. *For how long have you wished to get pregnant?*

2 years

3 years

4 years

5 years

6 years

more

21. *Do you have a regular cycle of menstruation between 26-32 days?*

Yes

No

How many days?

22. *Which kind of contraceptive did you use?*

How long?

pill

iup

iup with hormones

condom

none

others

23. *Have you ever had an abortion?*

Yes

No

How many?

24. *How often do you have sexual intercourse?*

monthly

weekly

several times a week

25. *Which investigations have you already had in order to clarify your situation?*

hormonal status

examination of the fallopian tubes

temperature measurement

checkup of your partner

LH-strips, computer

others

26. *Have you ever required the help of methods of alternative medicine?*

Yes

No

Which?

27. *Is there from your point of view any special reason why you cannot get pregnant?*

Yes

No

Which?

Thank you for your help!

I agree that the questionnaires 1 and 2 are used by Mrs Astrid Kapper for her dissertation within the scope of the master-course for osteopathy without my name.

Signature:

**Questionary2**

Name:

Date:

1. How would you describe your general state of health?

Very good       good       average       bad       very bad 

2. Are there any problems concerning:      Which?

 digestion: circulation: breathing: excretion:

3. Are there problems like:

 hypofunction of the thyroid gland hyperthyroidism headache depression others

4. How would you estimate the stress level at your work?

Very high       high       average       low       none 

5. How would you estimate the stress level in your private life?

Very high       high       average       low       none 

6. Do you feel any pain in the abdominal area?

Yes No

7. Do you feel any pains affecting the spinal column?

Yes

No

8. Do you take any medicine?

Yes

No

Which?

9. Did you conceive in the last 6 months?

Yes

No

When?

10. Did you gain any profits of the osteopathic treatment?

Yes

No

Would you describe the changes briefly

11. Would you recommend osteopathy to other women?

Yes

No

Why?

Thank you for your help!

Astrid Kapper

## Questionary for the Osteopath

Name:

Name of the patient:

Osteopathic diagnosis:

Date: Which day of the cycle?

1. Treatment on:

Focus of the treatment:

2. Treatment on:

Focus of the treatment:

3. Treatment on:

Focus of the treatment:

4. Treatment on:

Focus of the treatment:

5. Treatment on:  
Focus of the treatment:

6. Treatment on:  
Focus of the treatment:

7. Treatment on:  
Focus of the treatment:

8. Treatment on:  
Focus of the treatment:

## 8. Bibliography

Aboulghar MA, Mansour RT, Serour GI, Al-Inany HG. Diagnosis and management of unexplained infertility: an update. *Archives of Gynaecology and Obstetrics*. 2003;267(4):177-88.

Adamson GD, Baker VL. Subfertility: causes, treatment and outcome. *Best Practice and Results in Clinical Obstetric and Gynaecology*. 2003; 17(2):169-85.

Barral JP. *Viszerale Osteopathie in der Gynäkologie*. Urban und Fischer. 2004

Batstra L, van de Wiel HB, Schuiling GA. Opinions about 'unexplained subfertility'. *J Psychosom Obstet Gynaecol*. 2002; 23(4):211-4.

Battaglia C, Sgarbi L, Salvatori M, Maxia N, Gallinelli A, Volpe A. Increased anticardiolipin antibodies are positively related to the uterine artery pulsatility index in unexplained infertility. *Hum Reprod*. 1998;13(12):3487-91.

Bauman JE. Basal body temperature: unreliable method of ovulation detection. *Fertil. Steril*. 1981;36(6):729-33.

Benninghoff A. *Makroskopische Anatomie, Embryologie und Histologie des Menschen*. Band 2 Urban & Schwarzenberg, 1993

Blacker CM, Ginsburg KA, Leach RE, Randolph J, Moghissi KS. Unexplained infertility: evaluation of the luteal phase; results of the National Center for Infertility Research at Michigan. *Fertil Steril*. 1997; 67(3):437-42.

Bortz J, Lienert GA. *Kurzgefasste Statistik für die klinische Forschung*. Springer, 2003

Brannstrom M, Zackrisson U, Hagstrom HG, Josefsson B, Hellberg P, Granberg S, Collins WP, Bourne T. Preovulatory changes of blood flow in different regions of the human follicle. *Fertil Steril*. 1998;69(3):435-42.

Collins J. Stimulated intra-uterine insemination is not a natural choice for the treatment of unexplained subfertility. Current best evidence for the advanced treatment of unexplained subfertility. *Humane Reproduction*. 2003; 18 (5):907-12.

Edi-Osagie EC, Seif MW, Aplin JD, Jones CJ, Wilson G, Lieberman BA. Characterizing the endometrium in unexplained and tubal factor infertility: a multiparametric investigation. 2004; 82(5):1379-89.

Evers JL, de Haas HW, Land JA, Dumoulin JC, Dunselman GA. Treatment-independent pregnancy rate in patients with severe reproductive disorders. *Humane Reproduction*. 1998; 13(5):1206-9.

Frank O, Bianchi PG, Campana A. The end of fertility: age, fecundity and fecundability in women. *J. Biosoc Sci* 1994; 26(3):349-68.

Gibbons P, Tehan P. Manipulation of the spine, thorax and pelvis. Churchill Livingstone, 2000

Gnoth C, Godehardt E, Frank-Herrmann P, Friol K, Tigges J, Freundl G. Definition and prevalence of subfertility and infertility. *Humane Reproduction*. 2005; 20(5):1144-7.

Hebgen E. Viszeralosteopathie-Grundlagen und Techniken. Hippokrates, 2005

Kirchmayr M. A woman with the problem of infertility receiving osteopathic treatment has an increased chance of becoming pregnant. Vienna School of Osteopathy, 2002

Kremer J, de Bruijn HW, de Wolf BT. Predicting the day of ovulation with a do-it yourself test. *Ned Tijdschr Geneeskd*. 1988 ;132(34):1566-9.

Larsen U. Research on infertility: which definition should we use? *Fertility and sterility*. 2005; 83(4):846-52.

Leache RE, Moghissi KS, Randolph JF, Reame NE, Blacker CM, Ginsburg KA, Diamond MP. Intensive hormone monitoring in women with unexplained infertility: evidence for subtle abnormalities suggestive of diminished ovarian reserve. *Fertil Steril*. 1997;68(3):413-20.

Liem T. Kraniosakrale Osteopathie. Hippokrates, 1998

Nakagawa K, Ozawa N, Takamatsu K, Takahashi Y, Irahara M, Yoshimura Y, Saito H. A Reduction in intraovarian arterial blood flow resistance after ovulation is necessary to achieve pregnancy in natural cycle. *Journal of assisted reproduction and genetics*. 2005; 22(1):9-14

Netter FH. Atlas der Anatomie des Menschen. Ciba-Geig, 1994

Pandian Z, Bhattacharya S, Nikolaou D, Vale L, Tempelton A. In vitro fertilisation for unexplained subfertility. *Cochrane Database Syst Review*. 2002; (2):CD003357.

Randolph JF, Ginsburg KA, Leach RE, Blacker CM, Moghissi KS, Diamond MP, Reame NE. Elevated early follicular gonadotropin levels in women with unexplained infertility do not provide evidence for disordered gonadotropin-releasing hormone secretion as assessed by luteinizing hormone pulse characteristics. *Fertil Steril*. 2003; 80(2):320-7.

Riepler-Reisecker I. Influence of osteopathic treatment on congestive menstrual disorders and premenstrual syndrome. Donau-Uni Krems, 2006.

Roberts P, Braude P. Variations in ambient temperature can lead to incorrect prediction of the luteinizing hormone surge using urinary dipsticks (OvuStick). *BR J Obstet Gynaecol*. 1987; 94(5):486-7.

Stamm HE, Stamm H. Leitfaden der praktischen Gynäkologie. Ecomed, 1987

Steer CV, Tan SL, Mason BA, Campbell S. Midluteal-phase vaginal color Doppler assessment of uterine artery impedance in a subfertile population. *Fertil Steril*. 1994;61(1):53-8.

Steures P, van der Steeg LW, Hompes PG, Habbema JD, Eijkemans MJ, Broekmans FJ, Verhoeve HR, Bossuyt PM, Van der Veen F, Mol BW. Collaborative Effort on the Clinical

Evaluation in Reproductive Medicine. Interuterine insemination with controlled ovarian hyperstimulation versus expectant management for couples with unexplained subfertility and an intermediate prognosis: a randomised clinical trial. *Lancet*. 2006; 368(9531):216-21.

Subramanian MG, Kowalczyk CL, Leach RE, Lawson DM, Blacker CM, Ginsburg KA, Randolph JF Jr, Diamond MP, Moghissi KS. Midcycle increase of prolactin seen in normal women is absent in subjects with unexplained infertility. *Fertil Steril*.1997;67(4):644-7.

Tempelhof S. Osteopathie. Gräfe und Unzer, 2001

Tan SL, Zaidi J, Campel S, Doyle P, Collins W. Blood flow changes in the ovarian and uterine arteries during the normal cycle. *Am J Obstet Gynaecol*. 1996; 175:625-31.

Vesmesh M, Kletzky OA, Davajan V, Israel R. Monitoring techniques to predict and detect ovulation. *Fertil Steril*.1987;47(2):259-64.

Wilcox AJ, Weinberg CR, Blair DD. Timing of Sexual Intercourse in Relation to Ovulation-Effects on the Probability of Conception, Survival of the Pregnancy, and Sex of the Baby. *N. Engl. J.of Medicine*. 1995, 333(23):1517-21.

Yokota A, Nakai A, Oya A, Koshino T, Araki T. Changes in uterine and ovarian arterial impedance during the periovulatory period in conception and nonconception cycles. *Obstet Gynaecol Res*. 2000;26(6):435-40.

## **9. List of Illustrations**

Illustration 1 Pelvis with Intestines and Female Genital

Netter FH. Atlas der Anatomie des Menschen. Ciba-Geig, 1994, p. 341

Illustration 2 Lesser Pelvis, Cranial View

Netter FH. Atlas der Anatomie des Menschen. Ciba-Geig, 1994, p. 348

Illustration 3 Uterus and Uterine Tube

Netter FH. Atlas der Anatomie des Menschen. Ciba-Geig, 1994, p. 350

Illustration 4 Feedback-Mechanism

Benninghoff A. Makroskopische Anatomie, Embryologie und Histologie des Menschen.  
Urban&Schwarzenberg, 1993, p. 147

## 10. Abstract

Topic: Unexplained Subfertility and Osteopathic Treatment

Author: Astrid Kapper

Background: Infertility or subfertility affects 10 to 15% of couples trying to conceive for one year. After one year severe subfertility has to be assumed although among these untreated couples the live birth rate reaches 55% after three years.

The purpose of this investigation is to support the hypothesis that osteopathic treatment might raise the pregnancy rate in women with unexplained subfertility as the study of Kirchmayr concludes that a woman with the problem of infertility receiving osteopathic treatment has an increased chance of becoming pregnant.

Design: A 'within subject design' is used as a special form of the repeated measure design.

Methods: Ten women with unexplained subfertility for at least twenty-four months receive osteopathic treatment for a period of six months. The women aged between 31 and 40 years are treated by four different osteopaths maximally of eight times. Questionnaires at the beginning and the end of the treatment period are collected and analysed in comparison.

Result: One woman conceives after six months and nine do not conceive. The women profit in regard of their period pain.

Discussion: The result which differs widely from the study result of Kirchmayr does not support the hypothesis that osteopathic treatment rises the pregnancy rate, but it demands further investigation to clear the role of osteopathy in the field of unexplained subfertility. The different results seem to be caused by different characteristics of the two study groups concerning age and especially the period of unwanted non-conception.

In further research it seems more responsible to look for participants who have a shorter period of non-conception than in this study.

Key words: unexplained subfertility, female infertility, osteopathic treatment