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# **Manual Soft Tissue Therapy to Decrease Abdominopelvic Adhesions**

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## **A Study of Increased Function Evidenced by Female Infertility Reversal**

**Gerald Wiechmann, Ph.D.**

*Research Director, Former Senior Health Research Advisor,  
National Institutes of Health*

**Belinda Wurn, P.T.**

*Clinical Director, Clear Passage Therapies*

**Larry Wurn, L.M.T.**

*Clinical Director, Clear Passage Therapies*



## Abstract

■ **Objective:** To assess the effectiveness of a specific manual soft tissue therapy protocol in reducing adhesions and improving function by measuring any infertility reversal in eight infertile women with histories indicating adhesions or scarring.

■ **Design:** Multiple case study. Patients were treated in two successive pilot studies (n=4 each).

**Study #1, retrospective study:** patients had bilateral tubal occlusion (n=2), adhesion-induced (n=1), or idiopathic infertility (n=1).

**Study #2, prospective study:** patients had bilateral tubal occlusion (n=4), attempted to scientifically replicate and quantify results observed clinically in Study #1.

■ **Setting:** Private practice physical therapy clinic.

■ **Patients:** Eight premenopausal infertile women, 27 to 40 years old, with bilateral tubal occlusion (n=6), adhesion-induced or idiopathic infertility (n=2). Medical histories indicating adhesions or scarring were evident in 8/8 patients. In 7/8 patients, tubal occlusion, adhesions or scarring were verified by pre-treatment laparoscopy or hysterosalpingogram (HSG).

■ **Intervention:** Physician-prescribed manual soft tissue therapy designed to address biomechanical dysfunction, adhesions and micro-adhesions. Manual protocol applied principles of physiology of connective tissue, and tissue response to sustained manually applied forces to adhesions and collagen cross-links.

■ **Main Outcome Measures:** Pregnancy and/or fallopian tube patency as diagnosed by HSG. Decreased subjective complaints.

■ **Results:** 4/8 patients became pregnant post treatment. Of the four, two had bilateral tubal occlusions prior to therapy, one had pelvic adhesions, and one had idiopathic infertility. Of the remaining four, two presenting with bilateral tubal occlusions demonstrated unilateral patency following therapy. The tubes of two women remained occluded after six months.

■ **Conclusion:** The positive retrospective outcome in 75% of cases (four full-term pregnancies and two patients with post-treatment unilateral tubal patency) warrants a prospective clinical trial. A prospective case study is presently in progress.

## Introduction

Adhesions have been implicated as causing infertility, intestinal obstruction, and chronic pelvic pain. Data suggests that 67% to 93% of patients will develop adhesions following abdominal surgery and 55% to 100% of patients will develop adhesions following gynecologic surgery.<sup>1, 2, 3, 4</sup>

Approximately 40% of female infertility is related to tubal obstruction attributed to scarring or pelvic adhesions resulting from previous abdominal or pelvic surgery, previous

endometriosis or pelvic inflammatory disease, postinfectious tubal damage, a ruptured appendix, ruptured ovarian cysts, bowel or bladder disease, or foreign body reaction.<sup>5, 6</sup> Scarring outside the tube can restrict the tentacle-like grasping of the egg by the fimbria. The fallopian tube must have complete freedom of movement to ensure that the properly prepared egg is not just wasted in the abdominal cavity.<sup>7</sup>

Due to the age structure of the U. S. female population over the next 20 years, Stephen<sup>8</sup> has projected the number of women with impaired fecundity to be 5.134 million in 2000, 4.985 million in 2010, 4.7 million in 2015. This population is expected to increase in 2015 and reach an all-time high of 5.241 million by 2020. Extrapolating, more than 2 million women in the U.S. will be infertile due to tubal obstruction, scarring or adhesions by the year 2000.

Many women with infertility due to adhesions are referred for medical and surgical treatment. The purpose of this report is to review the results of a focused manual soft tissue therapy protocol we developed to determine if it might be an effective treatment modality for patients with a diagnosis of abdominopelvic adhesions. Using infertile women as subjects allowed us a degree of measurable results. Positive endpoints were defined as reversal of tubal occlusion as per HSG. Positive outcomes were defined as full-term pregnancies.

## Methodology and

The case study research design was selected because some of the clinical patient data was retrospective, and because the multiple-case study strategy provided multiple units of analysis for this type of data.<sup>22</sup> Hysterosalpingography was considered as "the gold standard" for fallopian tube occlusion diagnosis in radiology.<sup>23, 24</sup>

### *For this study, we used the following operational definitions and measures.*

**Adhesions:** Deposits of fibrous tissue that occur within body cavities such as the peritoneum, pericardium, or pleura which are the pathologic result of trauma to the lining membrane of such cavities<sup>1</sup> caused by either operative procedures, endometriosis and/or inflammatory causes or infections.<sup>13</sup>

**Physical Therapy:** the specific manual physical and massage therapy protocol used as an investigational infertility intervention.

**Treatment Endpoint:** HSG demonstrating tubal occlusion reversal as indicated by free spillage of contrast post-treatment into the peritoneal cavity, or no "improvement" (no spillage of contrast into the peritoneal cavity).

**Treatment Outcome:** intrauterine pregnancy, full-term pregnancy with or without live birth, ectopic pregnancy, or no pregnancy to date.

### This study had four objectives:

1. to create a theoretical framework for using manual soft tissue therapy to address abdominopelvic adhesions;
2. to report the treatment endpoints and outcomes of eight patients, physician diagnosed as infertile;
3. to identify a possible relationship between the treatment provided and an increase in fallopian tube function, as demonstrated by diagnostic test (HSG) or pregnancy; and
4. to determine the value of using focused manual soft tissue therapy to treat the adhesions affecting infertility.

## Case Descriptions

Over a five-year period, we observed a phenomenon among eight infertile female patients that seemed to occur coincidental with a certain protocol of manual physical and massage therapy treatment. The soft tissue techniques (myofascial release and visceral manipulation) were chosen in an attempt to address myofascial and biomechanical dysfunction, adhesions and micro-adhesions by applying principles of physiology of connective tissue and tissue response to sustained manually applied forces to adhesions and collagen cross-links. Noticing

## Definition of Key Terms

**Infertility:** the involuntary inability to conceive after engaging in sexual relations without contraception for twelve to eighteen months.<sup>25</sup>

**Primary Infertility:** the diagnosis for inability to conceive (due to anatomic, physiologic, endocrine, iatrogenic obstructions or deformations) with a history of no prior pregnancies.

**Secondary Infertility:** present inability to conceive (due to anatomic, physiologic, endocrine, and psychogenic reasons) with a documented history of pregnancy, including spontaneous abortion or ectopic pregnancy.

**Idiopathic Infertility:** the inability to conceive of unknown cause after (a) all diagnostic tests have excluded intrinsic reproductive system abnormalities and (b) no clear-cut biophysical reason is identifiable.<sup>26</sup>

**Infertility Reversal:** effective deformation, removal, relocation, or measurable reduction of fallopian tube and pelvic adhesions/ obstructions sufficient to allow free spillage of contrast medium into the peritoneal cavity, as a treatment endpoint at HSG.

**Fallopian tube occlusion "Improvement"** refers to any measurable change in the degree of migration of contrast dye into either fallopian tube.

Table 1: MANUAL INFERTILITY TREATMENT

Case #	Age at Tx.	Pre-Treatment P.T. Diagnosis	Pre-Treatment Gynecologist Diagnosis
<b>PILOT STUDY #1</b>			
1	27	Myofascial Pain Syndrome	Bilateral Occlusion
2	37	Low Back Pain, Plantar Fasciitis	Adhesions
3	41	Painful Abdominal Scar, Low Back Pain	Bilateral Occlusion, Adhesions, Scarring, Endometriosis
4	36	Myofascial Pain, R Hip Capsulitis	Scarring, Endometriosis, Idiopathic Infertility
<b>PILOT STUDY #2</b>			
5	33	Urogenital Dysfunction, Abdominal Pain	Bilateral Occlusion, Endometriosis, Adhesions
6	33	Abdominal Scar, Adhesions	Bilateral Occlusion, Adhesions, Scarring
7	40	Pelvic Adhesions, Pelvic Pain, Infertility	Bilateral Occlusion, Adhesions, Scarring
8	34	Myofascial Pain Syndrome	Bilateral Occlusion, Severe Adhesions, Infertility

\*N/A: No post-treatment testing was done due to pregnancy.

an apparent relationship between specific therapeutic protocols and infertility resolution, a cohort of infertility cases who had received this treatment was selected for retrospective review. The case histories are presented in this paper.

We have profiled the clinical case histories of the eight physical therapy patients below and summarized them in Table 1. Medical histories indicating adhesions or scarring were evident in all eight patients. Because of the nature of the referral and confidentiality of medical records, gynecological information was limited in some cases.

A co-therapy team provided the manual physical and massage therapy treatment protocol, the patient's role being passive. The total number of myofascial and visceral manipulation treatments of the eight cases ranged from seven to thirty-one over a period of one to eighteen treatment weeks. Mean duration of treatment was 40 minutes.

Cases one through four constituted Pilot Study #1. PS #1 was documented through clinical observation, patient reports and gynecological records, where available. Cases five through eight constituted Pilot Study #2. PS #2



## TCOME SUMMARY

Pre-Tx. HSG, Lap. and/or Chromotubation	Post Tx. HSG	Post Tx. End-point (TxE)	Post Tx. Outcome(TxO)
<b>(Retrospective)</b>			
HSG, 2 Laparoscopies	N/A*	Assumed Patent	Pregnancy, Live Birth
none	N/A*	Assumed Patent	Pregnancy, Live Birth (Twins)
Laparoscopy & Hysteroscopy w/ Chromotubation	N/A*	Assumed Patent	Pregnancy, Live Birth
Laparoscopy w/ Chromotubation, HSG	N/A*	Assumed Patent	Pregnancy, 2 Live Births
<b>2 (Prospective)</b>			
HSG, Laparoscopy w/ Chromotubation	Yes	Still Occluded, No Change	Not Pregnant after 6 Months
2 HSGs, 2 Laparoscopies w/ Chromotubation	Yes	1 Patent Tube, 1 Improved Tube	Not Pregnant after 6 Months (marital discord)
HSG, Laparoscopy & Hysteroscopy w/ Chromotubation	Yes	Still occluded, no change	Not Pregnant after 6 Months
HSG, Laparoscopy & Hysteroscopy w/ Chromotubation	Yes	1 patent tube	Not Pregnant after 6 Months

required bilateral occlusion, diagnosed by pre- and post-treatment HSG or laparoscopy, in an attempt to scientifically replicate the results observed in Pilot Study #1.

We limited the eight cases to three causes of infertility: (a) fallopian tubal occlusion, (b) pelvic adhesions, and (c) idiopathic, with history indicative of adhesions. Where available, diagnosis was by HSG and laparoscopy. Of the eight referrals for physical therapy, seven were made on an infertility diagnostic basis, and one inadvertently "treated" for infertility secondary to diagnosis of musculoskeletal trauma. Five of the eight cases were diagnosed with primary infertility, two with secondary infertility (Cases #2 and #7), and one case with marginal secondary infertility (Case #3 had a miscarriage at eight weeks' gestation).

Figures 1 and 2 indicate pre and post treatment hysterosalpingograms (HSG) for one patient (patient #6). This subject was referred to physical therapy with a history of bilateral occlusion with hydrosalpinx as diagnosed by chromotubation during laparoscopy. Further diagnosis was provided by two separate HSG studies approximately one year apart. Both HSG studies also demonstrated bilateral occlusion with hydrosalpinx. Following treatment, one tube demonstrated free spillage of contrast per HSG. Additionally, contrast medium filled more of the ampullary portion of the contralateral tube. Table 1 summarizes pertinent data from these multiple cases including treatment endpoints and outcomes, and is the basis for the observations that follow.

## Results

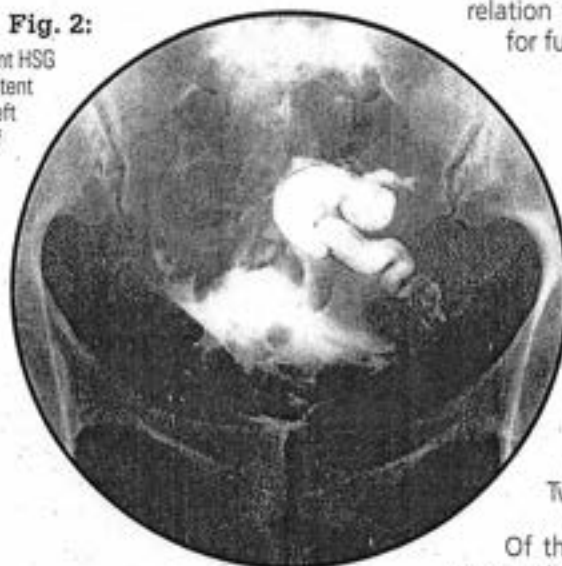
The purpose of these outcome observations is to evaluate the relationship between the endpoint and outcome in relation to the treatment as a basis for clarifying the need for further treatment research and development.

The eight cases ranged in age from twenty-eight to forty-two years old. Duration of infertility ranged from two to twelve years, a time span that extends well beyond the conception profile described in the literature.<sup>25, 27</sup> Six of the eight cases were diagnosed with bilateral tubal occlusions and adhesions/ scarring, one with pelvic adhesions, and one with idiopathic infertility and pelvic scarring. Pre-treatment gynecologic diagnoses were either by HSG, laparoscopy with chromotubation, or both. Post-treatment endpoints reflect dysfunction reversal in six of the eight cases (75%), a positive treatment endpoint pattern. Two of the eight cases (25%) showed no change.

Of the six cases with positive endpoints, four exhibited assumed resolution of unilateral tubal occlusions, adhesions or scarring due to successful pregnancy. The other two showed unilateral tubal patency with free spillage of contrast into the peritoneal cavity. Intrauterine pregnancy, the post-treatment outcome criterion, occurred in four of eight patients (50%), another positive outcome pattern. Pregnancy was full-term in each case. One patient had twins, and another has had two children.

**Fig. 2:**

Post-treatment HSG of patient #6: persistent hydrosalpinx on the left but free spillage of contrast via the right tube (late film).



**Fig. 1:**

Pre-treatment HSG of patient #6: bilateral tubal occlusion with left hydrosalpinx. These findings are consistent with two earlier diagnostic procedures, 1) laparoscopy with chromotubation and 2) hysterosalpingogram.



## Theoretical Framework

A literature search identified no studies that applied manual soft tissue mobilization techniques to treat infertility due to adhesions or other biomechanical causes. However, the ability of manual therapy to affect connective tissue adhesions has support in the basic literature on mechanical tissue testing and connective tissue physiology and remodeling.

The intent of manual soft tissue therapy is to increase mobility and decrease pain by creating microfailure in collagenous cross-links, the "building blocks" of adhesions.<sup>9</sup> Specific sustained physical forces applied will alter connective tissue mobility and length.<sup>20</sup> Myofascial manipulation consists of using the hands to apply a specific force for a sustained period of time until a mechanical (histological) change is observed, resulting in permanent elongation and improved mobility of the soft tissues. The primary goal of manual therapy is restoration of motion. Since manual therapy affects connective tissues, understanding the histology and biomechanical characteristics of connective tissue is an important foundation in order to establish a theoretical basis for treatment.

Connective tissue is a complex 3-dimensional web of fascia which provides stability to the body's structure while allowing flexibility and mobility. The fascia permits the body to retain its shape and maintain the vital organs in their correct positions. It also allows the body to resist mechanical stresses, both internally and externally. Fascia surrounds, supports and separates the muscles, bones, organs, nerves, and vessels down to the cellular level.<sup>11</sup>

Histologically, connective tissue is composed of cells (fibrocytes and fibroblasts) and extracellular matrix. The matrix consists of connective tissue fibers and a polysaccharide ground substance. Fibroblast cells synthesize all components of connective tissue including collagen, elastin, reticulin and ground substance.<sup>12</sup> The tensile collagen fibers provide strength and stiffness to the tissues and the elastic fibers furnish extensibility. The reticulin has elastic characteristics and is found in the delicate meshwork supporting the internal organs and glands. The viscous ground substance provides a mechanical barrier against microorganisms, diffuses nutrients and waste products to and from vascular areas, and maintains critical inter-fiber distance. This distance allows collagen fibers to glide smoothly and prevent microadhesions (cross-links) between fibers.

Adhesion formation occurs after trauma to the visceral or parietal peritoneum, and is caused by an inflammatory response due to tissue damage. This trauma is caused by either an operative procedure, drying due to exposure, tissue ischemia, endometriosis, or an infection.<sup>13</sup> Immobilization of connective tissue also leads to the formation of microscopic collagenous cross-links.<sup>14, 15, 16</sup> Macrophages are activated to debride and clean the area. Vascularity increases and fibroblasts begin to replace lost collagen, producing a fibrinous exudate. Myofibroblasts then appear, anchor to adjacent collagen fibers and contract, shrinking the tissue. The collagen is laid down in a haphazard manner, and cross-linking begins. As a result of

this, adjacent serosal surfaces adhere, forming a fibrinous adhesion. The tissue shrinkage results in dysfunctional movement of the area, which, in turn, creates more mechanical irritation, perpetuating the cycle.<sup>17, 18, 19, 20</sup> Mechanical components have been proposed to be the underlying mechanism of pain sensation in relation to adhesions. The pain is caused due to adhesion formation and the ensuing restricted mobility of the organs.<sup>21</sup>

Mobilization of the tissues using myofascial manipulation appears to reverse these effects. Biomechanically, connective tissue is viscoelastic in nature and has unique deformation characteristics. The presence of waviness in normal collagen represents a variable amount of slack. In myofascial manipulation, this slack is taken out by a tensile force applied to anatomic structures with the intent of permanently changing the resting length of the connective tissues. Connective tissue has the greatest resistance to stress when tensioned parallel to the direction of its collagen fibers. Fiber orientations and cross-links (adhesions) are strongly dependent on the applied loads. When all the slack has been tensioned and the force is maintained, microfailure or breakage of cross-links eventually occurs. This results in a permanent deformation and elongation of the connective tissues. Mobility may also be improved by restoring the interstitial fluid content of connective tissue structures to normal levels.<sup>9</sup>

## Discussion

Of immediate interest are those characteristics from the individual medical case histories reported prior to administration of the investigational therapeutic treatment that could influence treatment endpoints and outcomes. Several prominent characteristics emerge from the medical records: (a) unsuccessful pregnancy attempts ranged from two to twelve years; (b) each of the eight women had a history of some abdominal or pelvic surgery as well as moderate to severe musculoskeletal trauma; (c) six of the eight patients had experienced a wide range of unsuccessful infertility treatment interventions, implying that the physical therapy treatment may have been a procedure of "last resort" worth trying; and (d) seven of the eight patients had discontinued all infertility treatment modalities prior to receiving the investigational manual therapy treatment.

Based on these observations, and the best but limited information available to the research team, this suggests that possible confounding effects due to prior infertility care appear to be minimal. The above observation does not imply that the residual effects of prior infertility care may not have contributed to the physical therapy procedure's outcome, or that the manual physical therapy did or did not facilitate previous infertility treatment. Nor can we conclude that the positive results are attributable primarily or exclusively to the manual physical therapy procedure. However, the chain of evidence and positive endpoint/outcome patterns are suggestive enough of the possibility to warrant further research based on this observation as a hypothesis.

Equally important is another key observation: we cannot say that the manual physical therapy treatments did not contribute directly in a cause-and-effect way to the positive results. The evidence on this observation point is insufficient to be explicit. Definitive cause-and-effect claims other than inferences are unwarranted because of data limitations and the retrospective nature of this multiple case study.

In addition to the endpoint/outcome effectiveness data (the dependent variables in this study), the treatment data is also of analytic interest. We are beginning to define the manual therapy procedures and referral criteria as a clinical pathway. Treatment data analysis is not included in this report, but will be included in subsequent clinical trial analyses, if results warrant inclusion. As of this study, articulation of the manual physical therapy process is incomplete and the protocol remains in continuing research and development. We anticipate a

prospective pilot clinical research study using a larger number of cases and systematic research design in the future. If the results of the follow-up pilot study establish further clinical, scientific, and technical merit, we also anticipate a larger clinical trial demonstration project.

Although this study is primarily exploratory and descriptive, and the data is preliminary, overall the multiple-case chain of evidence appears to suggest a possible cause-and-effect relationship. In some cases, tubal obstruction and dysfunction secondary to pelvic adhesions appears to be reversible by a specific protocol of myofascial and visceral manipulation, with pregnancy the eventual outcome. The positive retrospective outcome in 75% of cases (four full-term pregnancies and two patients with post-treatment unilateral tubal patency) warrants a prospective clinical trial. A prospective case study is presently in progress.

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4130 Salisbury Rd. N., Suite 1600 • Jacksonville, FL 32216 • (904) 332-8000 • Fax (904) 332-8004

1240 N.W. 11th Avenue • Gainesville, FL 32601 • (352) 336-1433 • Fax (352) 336-9980

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