

FANTASTIC FINDINGS

ABSTRACT

Background Content: This case study examined the effects of a single Prolotherapy injection series on the left iliolumbar ligament. The ligament measurements were split between medial and lateral portions of the iliolumbar ligament and we hypothesized that growth would occur increasing the cross sectional area and thus provided added stability to the pelvis and lumbar spine.

Purpose: The purpose of our study was to answer two questions: 1) how do you know that the Prolotherapy injectant actually reaches the ligamentous structure you are attempting to heal; and 2) how long does it take for the ligament to recover?

Study Design: Single case study.

Methods: One subject, 32 year-old female with no history of lower back pain (LBP) participated in our study. Her job tasks as a physical therapist required her to twist turn and bend; putting pressure on her pelvis and ligamentous system. The primary author (A.A.) assessed her pelvic ligaments which lead to using a specified Prolotherapy solution for the left iliolumbar ligament. Ultrasound (US) guided imaging was used to take baseline measurements of the left iliolumbar ligament prior to Prolotherapy. Bi-weekly US measurements were up to six weeks to determine cross-sectional area (CSA) changes within the ligament.

Results: The results indicated that after the initial Prolotherapy treatment, there was growth in the left iliolumbar ligament at both the medial and lateral sites. The CSA increased by 27% for the medial measurement and 21% for the lateral measurement compared to baseline. The left iliolumbar ligament also appeared to change its characteristics and looked more uniform as a result of one Prolotherapy treatment.

Conclusion: Patients that experience lower back pain and or pelvic shifting may benefit from the usage of Prolotherapy to strengthen the ligaments surrounding their pelvis. Our study also brings out the positive effects of using US to capture changes that occur within specific tissue.

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KEYWORDS: iliolumbar ligament, Prolotherapy, sacroiliac joint, ultrasound.

Increase in Cross Sectional Area of the Iliolumbar Ligament using Prolotherapy Agents: An Ultrasonic Case Study

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Introduction

In order for information to become pertinent and cogent to a specific medical community, it needs to become valid, reliable and reproducible.¹ The complaints of lower back pain (LBP) are frequent at a physician's office² and as the body ages so do the structures that support it (i.e. disc, muscles and ligaments).³ Degenerative disc disease is still the leading lower back diagnosis in the United States.⁴ However, the lack of a specific patho-anatomic diagnosis in many cases of low back pain has led to the development of alternative diagnostic schemes. One example is the treatment-based classification system proposed by Delitto et al.⁵⁻⁶ We too suspect that diagnostic accuracy is improved by determining what structure or structures are responsible for the origin of the patient's symptoms. Auburn, et al⁷ has shown that ligamentous structures can generate pain and cause referral patterns that mimic discogenic pain patterns, as originally reported by Hackett in the 1960s and replicated by Hauser in 2004. Ligament involvement can be confirmed by the changes in symptoms following treatment by Prolotherapy.

The passive ligament system of the pelvis is very strong and will stabilize the sacrum and pelvis against unwanted motion.⁸ The ligaments that are primarily responsible for control of lumbopelvic motion are the iliolumbar ligament (IL), the long dorsal sacroiliac ligament (SI), the sacrospinous ligament (SS) and the sacrotuberous ligament (ST). (See *Figure 1*.) The iliolumbar ligament

will stabilize L4 and L5 on the ilium and sacrum and is considered a very important pelvic stabilizer.⁹⁻¹⁰ The SI, SS and the ST help stabilize the pelvis and subsequently will keep the lumbar spine in check as well.^{9,11} When there is a disruption in one of the lumbopelvic ligaments, poor control of lumbopelvic motion and muscular imbalances are the result.¹² When this disruption occurs, the clinician needs to determine which ligament is affected so that effective treatment can be applied to help restore normal stability and decrease pain.

Effective treatment for ligament strengthening via cell restoration is called Prolotherapy. This treatment dates back to the 1950s and 1960s when its pioneer Dr. G.S. Hackett discovered that by injecting a hypertonic sugar solution into a painful ligament, a patient's LBP was reduced.¹³⁻¹⁵ Two questions that arise from the cell proliferation procedure are 1) how do you know that the Prolotherapy injectant actually reaches the ligamentous structure you are attempting to heal; and 2) how long does it take for the ligament to recover? The purpose of our study is to answer these questions using the iliolumbar ligament as a model. We used Ultrasound (US) technology to inject the ligament under guidance and to quantify the changes in ligament shape and substance from week to week.

ULTRASOUND IMAGING

Ultrasound consists, simply, of very short wavelength sound waves with a frequency that is higher than 20000 Hz.¹⁶⁻¹⁸ The wavelengths are so short that these waves cannot travel through air, but require a denser coupling medium, usually a gel. Ultrasound imaging (US) has been reported in the recent literature as a reliable and useful way to look at the muscular structures in the body.^{16,19} Whitaker discusses, for example, that to accurately determine changes in the tissue structure, the clinician needs to understand the ligament's baseline appearance and how its appearance changes after Prolotherapy procedures.²⁰ US technology allows direct visualization of changes in tissue density and structure. Previous researchers have used ultrasonic techniques to identify changes in muscle and ligamentous structures. (See Figure 2.)^{18-19, 21-25} Ultrasound imaging has also been used to look specifically at multifidus muscle atrophy²⁶ after an injury to its nerve supply. US is easier and more cost effective than MRI, thus making it possible for clinicians to assess the integrity of the active (muscle) and passive (ligamentous) stability system.^{17, 27} We chose to use the

iliolumbar ligament due to its relationship with the pelvis⁸ and ease of imaging compared to the sacroiliac or the dorsal sacral iliac ligaments. With a paucity of human studies on the US imaging of the sacral ligaments and only a few using animal (Goff, 2006) we decided that being able to use the ilium as a landmark would give us good insight as to where the iliolumbar ligament was located for our imaging. In our case, the B-mode US was used to measure the cross sectional width of the iliolumbar ligament.¹⁶⁻¹⁷ Whittaker et al¹⁶ determined that the mode in which you use the US is important to determine what you will see. For example, to look at the thickness, length and diameter of a muscle or structure, the B-mode is most efficient. The M-mode which is used most of the time for visualizing internal organs is not as effective for our purpose, but recently researchers²⁸⁻³⁰ have been using the M-mode to study muscle motion during locomotion due to its ability to detect changes in structure during movement.³¹

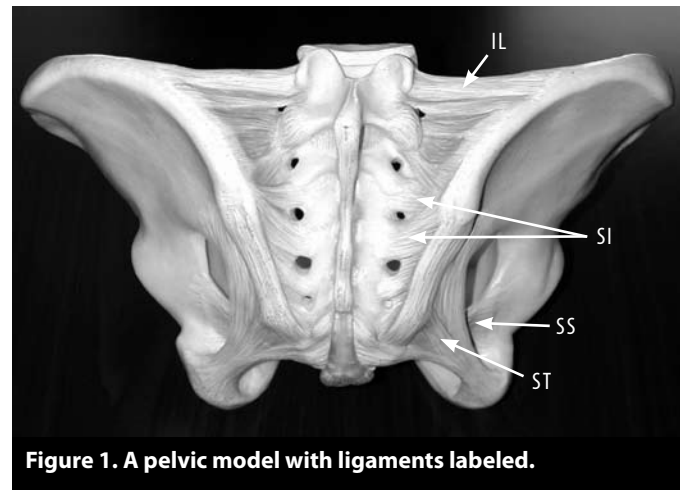


Figure 1. A pelvic model with ligaments labeled.

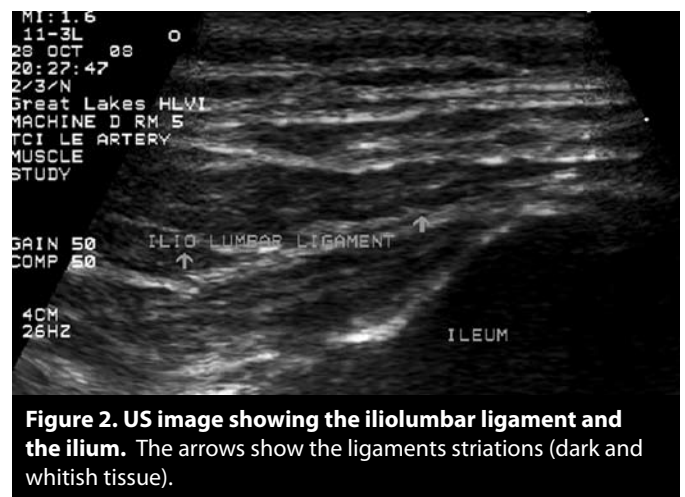


Figure 2. US image showing the iliolumbar ligament and the ilium. The arrows show the ligaments striations (dark and whitish tissue).

Methods/Materials

This study was conducted at Ingham Regional Medical Center in Lansing, Michigan and was reviewed and approved by the board at the Natural Health and Improvement Center. One female, 32 year old, 5'6, and 60 kg was included in this study. She had no history of LBP nor did she have any surgery or lower back procedures performed for pain control. She worked as a physical therapist and performed bending and twisting activities during her daily treatment of patients. She had two children but did not experience lower back pain as a result of her pregnancies.

Procedure

The patient was brought into the examination room, laid prone and the experimental procedure was explained to her. The certified US technician explained how we were going to use US not only to measure the iliolumbar ligament changes but also to guide the injection and monitor the Prolotherapy solution as it was injected in and around the ligament. (See Figure 3.) Author two (B.S.) had experience with this US technician from the previous multifidus isolation imaging studies that they conducted. The US technician has 14 years of imaging experience and author two (B.S.) has had over 400 Prolotherapy injections from the primary author (A.A.); (who has over 13 years of Prolotherapy injection experience) thus all principal investigators had the qualifications to examine the ligaments in the spine. The ultrasound technician placed the aqueous US gel onto the patient's skin as a conduction medium and then positioned the US probe (using the

B mode to see the shape and size of the ligamentous structure involved (a 3.5 MHz curved linear array probe connected to the Phillips Sonos Duplex Imager) to send the sound waves to the computer for observation and recording. (See Figure 3.) Based on the work of Loukas³² the iliolumbar ligament was identified using the US probe. The left iliolumbar ligament was used for analysis. A baseline cross section area measurement of the ligament was obtained. We used medial and lateral measurements to determine how much growth was obtained from the Prolotherapy solution. (See Figures 4a & 4b.) Whittaker³³ points out that the muscle tissue appears darker with US due to the larger amount of blood it contains, and fascia or ligamentous structures appear lighter, reflecting their increased density and lower fluid content. The iliolumbar ligament is thus referred to as hyperechoic compared to the hypoechoic muscle tissue.¹⁶⁻³⁴ In order to determine any changes within the ligament being looked at, we had to apply the above parameters as well as the following, in order to give the study some true quantitative objectives. Each time we imaged, we duplicated the exact settings on the same ultrasound equipment, the Philips Sonos 5500 using the 3.5 MHz curved linear array probe. We



Figure 3. US technician and subject with the US probe being placed on the left side of the low back.

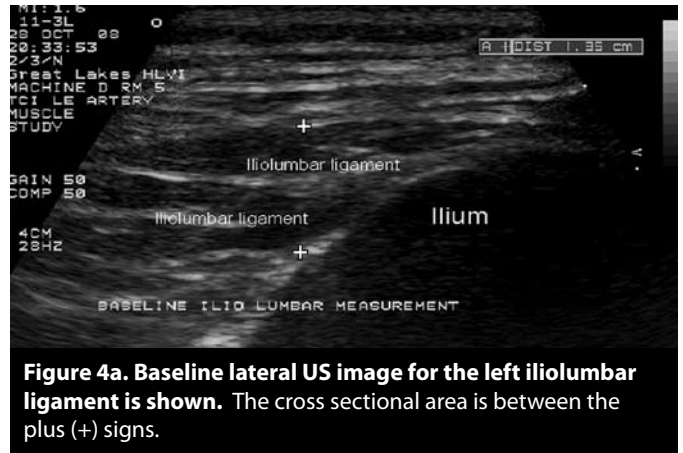


Figure 4a. Baseline lateral US image for the left iliolumbar ligament is shown. The cross sectional area is between the plus (+) signs.

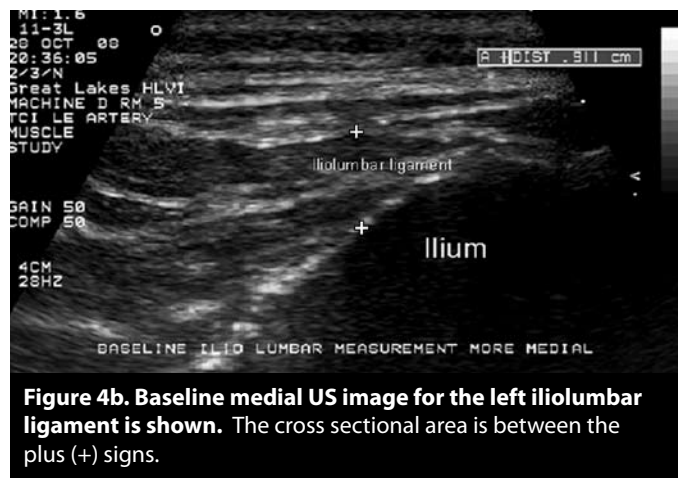


Figure 4b. Baseline medial US image for the left iliolumbar ligament is shown. The cross sectional area is between the plus (+) signs.

used the same gray scale map with B-Mode imaging, consistent depths, as well as consistent patient positioning. When evaluating the ligament for any cross sectional area measurement changes or tissue integrity we made comparable measurements from one session to the next with review of previous imaging.

PROLOTHERAPY INJECTION PROCEDURE

The left and right lower lumbar region was prepped and draped, sterile alcohol was used to clean the area of interest. The primary author (A.A.) then identified landmarks for the posterior superior iliac spine (PSIS), L5-S1 and the left ilium. The primary author (A.A.) then found the attachment site for the left iliolumbar ligament which was verified via US imaging. The US technician isolated the iliac crest and the iliolumbar ligament on the left side so that the primary author (A.A.) could identify the two sites that were used during the procedure. (See Figure 4.) Once the ligament was located, the physician inserted the needle into the affected area until bone was approximated and then the needle was drawn out prior to the solution being injected.³⁵ This procedure is supported by references 14, 15 and 35 and they concurred that the needle is injected into the skin and the bone is approximated in the affected tissues or region prior to the solution being injected. The Prolotherapy solution that was used for this patient was 4cc of procaine, 1cc of 50% dextrose, 0.5cc of PQU (2.43 ml of phenol liquefied, 5.73 GM Quinine HCL, 1.26 GM Urea USP). This material was fabricated at the Compounding Pharmacy of Wyoming Park, 2301 Lee Street SW, Wyoming, MI 49519). Using US, the primary author (A.A.) located the medial injection site on the iliolumbar ligament and injected the Prolotherapy solution. Similarly, the lateral site was identified and the procedure was repeated. (See Figures 5a & 5b)

PROGRESSIVE WEEKLY MEASUREMENTS

The US technician took measurements for the lateral and medial sections of the left iliolumbar ligaments pre-injection, after one week, then, every two weeks. There were four measurements in total for the duration of six weeks from the time of the baseline measurement.

Results

One week after a single series of Prolotherapy injections, there was cross sectional growth in the iliolumbar ligament compared to baseline, although most dramatic growth in the ligament was recorded during weeks two through four. At the six week mark, the growth leveled off for the lateral portion of the left iliolumbar ligament,

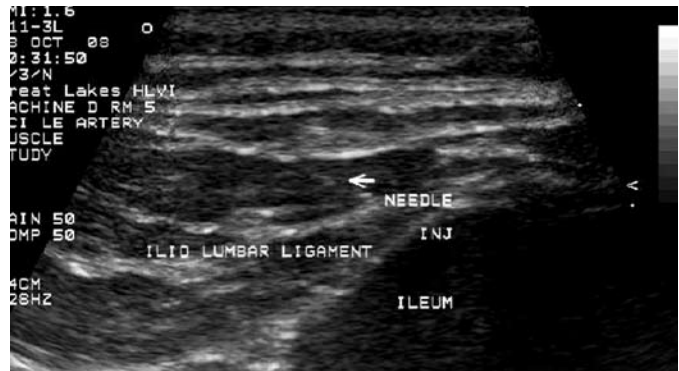


Figure 5a. US illustration showing the needle, ilium, iliolumbar ligament prior to the Prolotherapy injection material moving into the iliolumbar ligament.

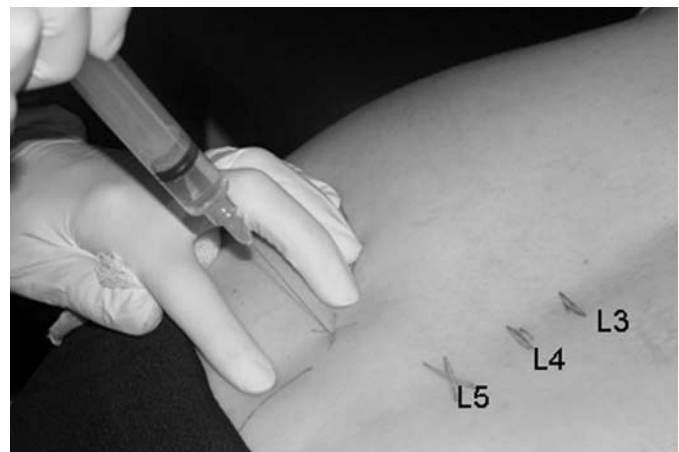


Figure 5b. Iliolumbar ligament site as indicated by the X and the needle placement.

but the medial side of the ligament still showed signs of further tissue proliferation. (See Table 1.) Total growth in the left iliolumbar ligament for the medial portion was a positive 27% from the initial measurement at six weeks post-injection. The lateral section of the ligament also grew by 21% from the initial baseline measurement. (See Table 1.) Thus the cross sectional area of the left iliolumbar ligament in this subject improved from one series of Prolotherapy injection material.

Table 1. Iliolumbar ligament measurements from baseline.

Measurements in CM	Medial	Lateral
Measurement one, baseline	0.91	1.35
Measurement two, 2 weeks	0.995	1.4
Measurement three, 4 weeks	1.25	1.7
Measurement four, 6 weeks	1.2	1.7
Total percentage of growth from baseline to 6 weeks	27%	21%

TISSUE INTEGRITY FINDING

Initially it appeared to us that the iliolumbar ligament tissue was not uniform. Some areas appeared darker and others had a more whitish appearance. We interpreted this to indicate areas of less dense ligamentous tissue and denser ligamentous tissue. As we continued to measure the left iliolumbar ligament, medial and lateral portions, the tissue began to take on an appearance that looked more uniform and hyperechoic (lighter).³⁶⁻³⁷ (See Figure 5a.)

Discussion

Low back pain (LBP) can routinely deter a person from functioning at their optimal level which can lead to poor productivity and increasing health care costs.³⁸ When a clinician determines what the cause of the LBP is one must evaluate if the problematic area is a ligament, muscle, disc or nerve root. Knowing the correct structure to target gives your evidence more credence.³⁹ US technology gives us the validity⁴⁰ and the reliability that is needed to accurately find a structure, and determine its function and or pathology.^{41-42, 43} Fullerton⁴⁴ showed that through US and MRI imaging that a partially torn patellar tendon was repaired through Prolotherapy treatments. He quantified his measurements using US and demonstrated that when using Prolotherapy, the patellar tendon tissue was thickened and healed. He also showed that using Prolotherapy could help restore meniscus tissue which was shown via MRI scans. Rehabilitative clinicians thus can be equipped with a non-invasive technology that allows visualization of deeply-placed structures to determine their state of function and/or pathology.⁴⁵

Other researchers, Young, et al⁴⁶ used US to measure the quadricep muscle comparing tape measure versus US measurement. They concluded that the US proved to be far superior to most clinical measures, specifically, allowing clinicians to visualize quadriceps muscle wasting when very little wasting was demonstrated with the tape measure method. Thus US can help a clinician understand with high sensitivity, if a certain tissue has undergone changes, and whether those changes are positive or negative.

Our findings showed the effectiveness of using Prolotherapy solution to specifically target a designated structure. Our question of whether or not the material actually made its way into the ligament was answered using US technology, since we directly visualized the bolus of injectant entering the tissue. The results showed that the cross sectional area increased in both the medial and lateral portions of the left iliolumbar ligament. The left

iliolumbar ligament was measured on a bi-weekly basis to determine if there was growth in both locations. Loukas⁴⁷ determined how to best visualize the iliolumbar ligament with US, and we employed his ideas to show the changes in the tissue structure over a six week period of time. We did not scan the deep sacroiliac ligamentous structures because of poor visualization of landmarks and inability to accurately measure cross sectional changes. Further research in this area is needed to help identify and treat the ligamentous structures around a person's pelvis that may be contributing to their pain.

Within a week after one Prolotherapy series, the ligament began to increase in cross sectional area and this continued for at least part of the ligament up to the last measurement at six weeks. We hypothesize from this that one series of Prolotherapy (using the reported materials) caused the body to ramp up cellular growth as suggested by Reeves.⁴⁸ Thus, we concluded that one series of injections is sufficient to enhance the stabilizing function of the left iliolumbar ligament and subsequently give the lumbar spine and pelvis increased support. It appears that after six weeks, to maintain ligament hypertrophy, we would need to introduce further solution.

Our finding demonstrated that the iliolumbar ligament appeared to change in how it presented from week one to week six. (See Figures 6a-f.) This finding is separate from the fact that the cross sectional area of the ligament positively increased in size from week one to week six. Our findings are encouraging from many points of view. The first positive effect was that it took only one series of injections to cause a change in a tissue structure. Secondly, we saw that the left iliolumbar ligament appeared differently (more uniform) over the six weeks that the measurements were taken. Lastly, US technology has been shown to be able to visualize the Prolotherapy solution as it is being injected, and can also aid in showing the changes that occur from the Prolotherapy solution. With the array of chemical mixtures for Prolotherapy available today, it would be interesting to see what effects those proliferents would have on various tissues using US technology to monitor cross sectional area changes and tissue growth. In our case, we were not concerned about pain, but only with what effect Prolotherapy would have on the tissues that support the lumbar spine and pelvis. Our positive findings move us one step closer to showing how, for patients with lower back pain, Prolotherapy can prove to be a good adjunct to increase stability in the lumbar spine and pelvis. ■

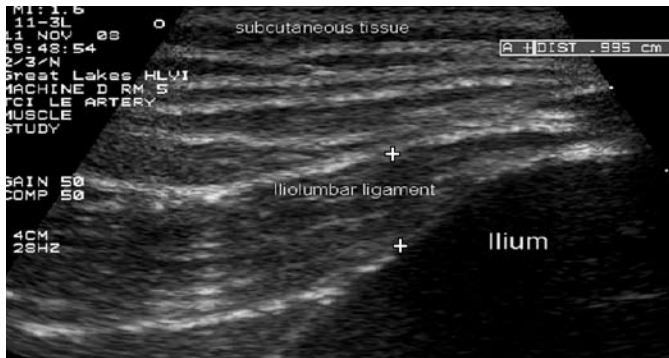


Figure 6a. US illustration of the left iliolumbar ligament, *medial portion* at 2 weeks from baseline. The cross sectional area is between the (+) signs and the striations are shown in the iliolumbar ligament.

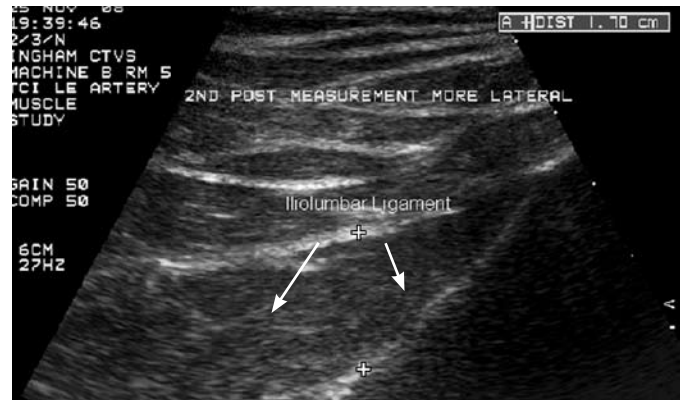


Figure 6d. US illustration of the left iliolumbar ligament, *lateral portion* at the 4 week mark from baseline. The cross sectional area is shown between the (+) signs and the striations are shown. The delineation line between the ilium and the iliolumbar ligament is shown by the white line; the ligament is becoming more hyperechoic.

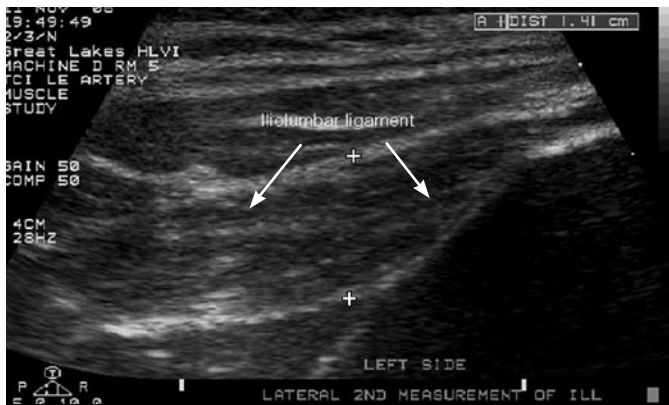


Figure 6b. US illustration of the left iliolumbar ligament, *lateral portion* at 2 weeks from baseline. The cross sectional area is between the (+) signs and the striations are shown in the iliolumbar ligament.

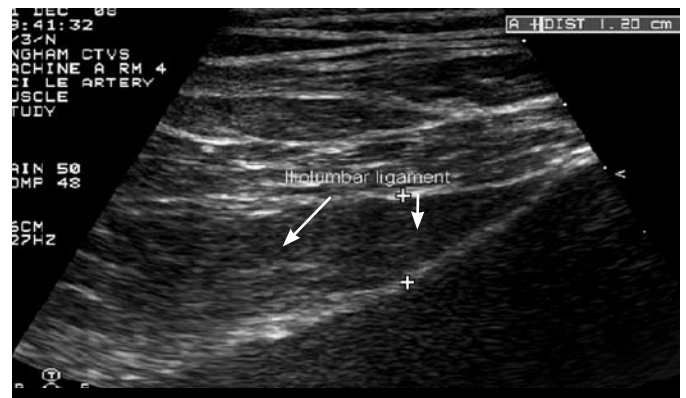


Figure 6e. US Illustration of the left iliolumbar ligament, *medial portion* at the 6 week mark from baseline. The ligament tissue as shown is more hyperechoic (lighter) and more defined compared to the previous illustrations.

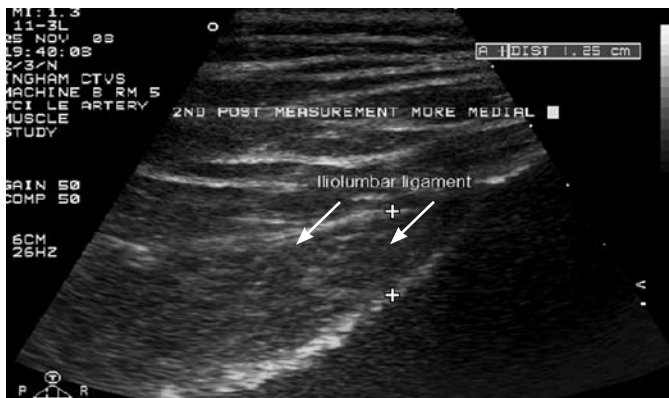


Figure 6c. US illustration of the left iliolumbar ligament, *medial portion* at the 4 week mark from baseline. The cross sectional area is shown between the (+) signs and the striations are shown. The delineation line between the ilium and the iliolumbar ligament is shown by the white line; the ligament is becoming more hyperechoic.

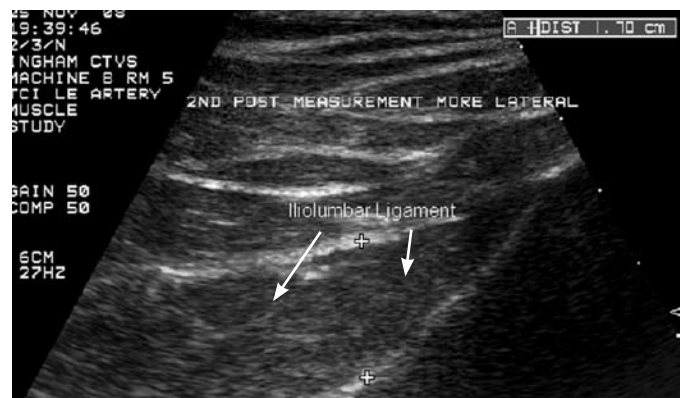


Figure 6f. US Illustration of the left iliolumbar ligament, *lateral portion* at the 6 week mark from baseline. The lateral portion is also more hyperechoic (lighter) and the delineation line between the Ilium and the ligament is much defined as shown by the white line.

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