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Title: Serial Ultrasonographic Findings of Plantar Fasciitis after Treatment with Botulinum Toxin A: A Case Study

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Abstract: Plantar fasciitis is a common cause of heel pain and is the result of a degenerative process of the plantar fascia at its calcaneal attachment. In this paper, a case study of preliminary experience on the treatment of chronic plantar fasciitis in a 43-year-old female with local injection Botulinum Toxin A (BTX-A) is presented. We injected the patient with 70 units of BTX-A (0.7 ml) in two divided doses: 40 units (0.4 ml) in the tender region of the heel and 30 units (0.3 ml) in the most tender point of the foot arch. Visual Analog Scale (VAS) and Pressure Pain Threshold (PPT) were measured to evaluate the efficacy of BTX-A injection. Real-time high-resolution ultrasonographic finding of the plantar fascia after BTX-A injection was also used for serial follow-ups. Following BTX-A injection, decreased VAS values was reported, and increased PPT was observed. In ultrasonographic study, the thickness of the plantar fascia and the hypoechogenicity of the fascia were reduced. Decreased plantar fascia thickness was observed on the first and third week after BTX-A injection. The findings were compatible with the changes in pain assessed by VAS and PPT. Ultrasonographic findings also indicated a progressive decrease in the thickness of underlying muscle belly. Ultrasonography seems to be a valuable, noninvasive diagnostic tool for the evaluation of plantar fasciitis treated with BTX-A injection. It can offer objective measurements of therapeutic effects and is feasible for serial follow-ups.

August 4, 2010

Robert A. Werner, MD
Section Editor
Archives of Physical Medicine and Rehabilitation

RE: ARCHIVES-PMR-D-10-00326 (resubmission)

Dear Editor:

Enclosed please find the clean copy of manuscript entitled **"Serial Ultrasonographic Findings of Plantar Fasciitis after Treatment with Botulinum Toxin A: A Case Study"**, the marked copy of manuscript, my response to the reviewers (with color marks and highlighted), and 3 figures. This is a revised and resubmitted manuscript with a previous submission number of "ARCHIVES-PMR-D-10-00326 ". It has not been and will not be submitted for publication elsewhere until a decision has been made to its acceptability for *Archives of Physical Medicine and Rehabilitation***.**

Please forward all correspondence to:

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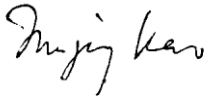
Thank you for your attention in this matter. I am looking forward to your reply.

Sincerely,



Mu-Jung Kao, M.D

*Detailed Response to Reviewers

TO:
Robert A. Werner, MD
Section Editor
Archives of Physical Medicine and Rehabilitation

August 2010
Dear Section Editor and Reviewers:

We deeply appreciate your valuable comments those critically pointed out the misleading and inadequate description in our manuscript. The reviewers' comments (highlighted in yellow) and our responses (marked in red and highlighted in green) are listed below. Thank you very much for your re-reviewing.

Mu-Jung Kao, M.D.
The correspondence author

Ms. Ref. No.: ARCHIVES-PMR-D-10-00326
Title: Serial Ultrasonographic Findings of Plantar Fasciitis after Treated with Botulinum Toxin A: A Case Study
Archives of Physical Medicine and Rehabilitation

Dear Dr. Kao,

Your manuscript entitled "Serial Ultrasonographic Findings of Plantar Fasciitis after Treated with Botulinum Toxin A: A Case Study" has been reviewed. Based on this evaluation, the Editorial Board sees merit in your manuscript but seeks revision before determining whether it might be suitable for publication. We feel that this manuscript needs major revision but the problems found during review might be correctable.

At the end of this letter, you will find all the pertinent comments obtained during the peer review. The areas in need of major clarification are highlight below:

Comments by the Section Editor

1. There are many grammatical errors. The manuscript needs to be reviewed by someone who uses English as a primary language. The editorial office can recommned people if you do not have other options. [We had sent this paper for English edition before re-submit this revised manuscript.]

We also direct you to our Supplementary Guide on Stylistic Preparation of Manuscript, available on our website (www.archives-pmr.org): we require that you review this document while preparing your revision, if you have not already done so. [We have revised this paper following the above guide.]

A Disclosure Statements and Copyright Assignment form will be emailed to you shortly. We require ALL

coauthors to complete, sign, and submit the form at this time. These forms replace those provided at original submission. Please return the forms by fax or overnight mail. Editors must have these documents in hand for each member of the author group before proceeding with manuscript evaluation. Again, if you submitted these forms online, you must resubmit them to the Editorial Office now. **[We have completed and signed the Disclosure Statements and Copyright Assignment.]**

When you submit the revised manuscript, please include, in a file separate from your cover letter, an itemized response to each of the suggested revisions and any other changes made. Cite page and line number for each revision. In addition, highlight each change in the revised manuscript. You must return the revised manuscript within by Aug 11 2010 12:00AM.

We appreciate your time and consideration in effecting these revisions.

Sincerely yours,

Robert A. Werner, MD
Section Editor
Archives of Physical Medicine and Rehabilitation

Reviewers' comments:

Reviewer #1:

1. Well conceived case study with significantly better case followup and documentation than with most case studies. This study also is timely given the surging nature of musculoskeletal/peripheral nerve ultrasounds.

2. The main issue I have with this study is there are fairly extensive typographical/syntax errors throughout. To list a few, a) The title sounds awkward with the word "treated" and should likely be changed to "treatment" **[We have changed it according to your suggestion.]**, b) page 5, line 1 "is to choose the ultrasound as a tool" is confusing **[We have rewritten this sentence.]**, c) page 6, lines 13, 18, and 19 all contain awkward phrasing or typographical errors**[We have rewritten these sentences.]**, d) page 7, line 1 The first sentence sounds as if things are going to be listed with the use of a semicolon and should be rewritten.**[We have rewritten this sentence.]** e) page 8, line 7 The last sentence has incorrect syntax and perhaps "after the site of the inflammatory lesion was confirmed with ultrasound" would be less confusing. .**[We have rewritten this sentence.]** f) page 8, last line "was" should be deleted,**["was" has been deleted.]** g) page 11, line 13 "is their unit" is confusing and I am not sure what is meant exactly. **["is their unit" was deleted.]** There are others in the paper and a careful review and editing is suggested to maximize the message of the article. If english is not the authors primary language, outside review is suggest. **[We had sent the paper for English edition before re-submit this revised manuscript.]**

3. In the discussion section, I would suggest some correlation with the observation made on ultrasound with those found in MRI with resolving/improving plantar fasciitis. This has been well-documented in MRI and

would lend strength to the author's observation. A contrast between ultrasound and MRI could then be easily made in terms of the usefulness of ultrasound for serial followup by the clinician, the relative cost, etc. **[We had added the MRI imaging finding of plantar fasciitis in the 1st paragraph of the discussion section and compared the advantages between MRI and US Imaging. Unfortunately, no paper mentioned the correlation between MRI and US, and we did not perform the MRI study for comparison, too. We will add this issue into the limitation of this study in the last paragraph.]**

4. Finally, I would expand the last paragraph about the limits of this study. I would include the fact that the songrapher was not blinded between the two feet which I think is important for future study. Many of these measurements (including the ones in your study) can be altered by slight movements of the cursor on the ultrasound images and in future studies, blinding would add significant strength. **[We had added this issue into the limitation of this study. Thank you very much for this important suggestion.]**

Reviewer #3:

This article should be rewritten.

1.In this article, "Ultrasonographic Findings" are not discussed in detail. For this reason, "title" should be rewritten. **[Ultrasounographic findings were described in the last two paragraphs of "Case Description", and discussed in 3rd, 4th, 5th paragraphs of "Discussion".]**

2.The aim of the study and the data base is inadequate.**[The last paragraph for aim of the study had been modified.]**

3.In discussion, "purpose and effect" relationship has not been discussed. **[We have already address this issue in the "Discussiion": in 2nd paragraph of "Discussiion": "**In our case, we found a significant progressive decrease in the thickness of symptomatic plantar fascias after BTX-A injection", and in **4th paragraph of "Discussiion": "**This could be underlined by our finding regarding the pain estimation and ultrasonographic study after the BTX-A injection. There was a high correlation between the symptomatic relief (assessed with VAS and PPT) and the ultrasonographic findings (significantly thinner plantar fascias) in the serial follow-up assessments after BTX-A injection."

4.In the text and references, typographical errors should be corrected.

5.There are many minor errors in the article. For example; "good shoes"" should be changed as "shoes modification".**[We had sent this paper to an American for English edition and correction of the typographical errors before re-submit this revised manuscript.]**

Cover Page

Serial Ultrasonographic Findings of Plantar Fasciitis after Treatment with Botulinum Toxin A: A Case Study

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Running Head: Ultrasonography of BTX-A for Plantar Fasciitis

No commercial party having a direct financial interest in the results of the research supporting this article has or will confer a benefit upon the authors or upon any organization with which the authors are associated.

Cover Page

Serial Ultrasonographic Findings of Plantar Fasciitis after ~~Treated~~ Treatment with Botulinum Toxin A: A Case Study

Running Head: Ultrasonography of BTX-A for Plantar Fasciitis

No commercial party having a direct financial interest in the results of the research supporting this article has or will confer a benefit upon the authors or upon any organization with which the authors are associated.

ABSTRACT

Plantar fasciitis is a common cause of heel pain and is the result of a degenerative process of the plantar fascia at its calcaneal attachment. In this paper, a case study of preliminary experience on the treatment of chronic plantar fasciitis in a 43-year-old female with local injection Botulinum Toxin A (BTX-A) is presented. We injected the patient with 70 units of BTX-A (0.7 ml) in two divided doses: 40 units (0.4 ml) in the tender region of the heel and 30 units (0.3 ml) in the most tender point of the foot arch. Visual Analog Scale (VAS) and Pressure Pain Threshold (PPT) were measured to evaluate the efficacy of BTX-A injection. Real-time high-resolution ultrasonographic finding of the plantar fascia after BTX-A injection was also used for serial follow-ups. Following BTX-A injection, decreased VAS values was reported, and increased PPT was observed. In ultrasonographic study, the thickness of the plantar fascia and the hypoechogenicity of the fascia were reduced. Decreased plantar fascia thickness was observed on the first and third week after BTX-A injection. The findings were compatible with the changes in pain assessed by VAS and PPT. Ultrasonographic findings also indicated a progressive decrease in the thickness of underlying muscle belly. Ultrasonography seems to be a valuable, noninvasive diagnostic tool for the evaluation of plantar fasciitis treated with BTX-A injection. It can offer objective measurements of therapeutic effects and is feasible for serial follow-ups.

Key words: Botulinum Toxin A, Plantar fasciitis, Pain, Ultrasonography

INTRODUCTION

Plantar fasciitis[1-4] is a common cause of heel pain and is the result of a degenerative process of the plantar fascia at its calcaneal attachment. Age, obesity, excessive weight bearing, and tight Achilles tendon are the common predisposing factors.[2, 5] Plantar fasciitis presents in a most characteristic manner, including gradual onset and worsening over a period of time, pain in the morning upon rising from rest, and localization over the medial slip of the origin of the fascia.[6] Methods for treatment are insoles[7], ~~good shoes~~shoes modification[8], stretching[9], physiotherapy, ice/cold, nonsteroidal anti-inflammatory drugs (NSAIDs)[10], analgesics, night splints[11-13], local steroid injections[14], extracorporeal shock wave therapy[15, 16], and immobilization[17].

The guidelines of the American College of Physicians summarize that there is level 1B evidence for the use of Botulinum toxin A (BTX-A) in the treatment of plantar fasciitis.[18] Babcock et al.[19] presented a randomized, double-blinded, placebo-controlled study and concluded BTX-A injection for plantar fasciitis yields significant improvements in pain relief and overall foot function at both three and eight weeks after treatment. This evidence has subsequently been reinforced by the preliminary results of a further study[20]. Outcome assessments including subjective pain intensity, Maryland Foot Score, and Pain Relief Visual Analog Scale were selected in previous studies, but no objective measurements were used to evaluate the efficacy of BTX-A injection on plantar fasciitis.

Ultrasonography is a valuable, noninvasive diagnostic tool for the evaluation of plantar fasciitis[21-23]. For symptomatic feet, increased thickness of the fascia and reduced echogenicity were constant ultrasonographic findings.[24-26] ~~The purpose of this case-~~

~~study is to choose the ultrasound as a tool to evaluate the efficacy of BTX-A injection for plantar fasciitis objectively and to assess the ultrasonographic findings of the plantar fascia after BTX-A injection for serial follow-ups.~~ To our knowledge, no ultrasonographic findings of the responses associated with BTX-A injection for plantar fasciitis have been evaluated and reported to date. Thus, the purpose of this case study was to prospectively evaluate with ultrasonographic findings of the plantar fascia after BTX-A injection with serial follow-ups.

CASE DESCRIPTION

The patient was a 43-year-old housewife who presented to our clinic with a chief complaint of limited standing and walking tolerance, and secondary to right subcalcaneal heel pain. The onset of pain was insidious approximately eight months prior to her initial visit. At the time of the first evaluation, the patient was unable to stand for more than 1 hour or walk for more than 15 minutes without heel pain. She reported a sharp shooting pain and tightness in her right heel and medial arch during weight bearing. The patient verbally rated this pain as 8 on a scale of 0 to 10 (8/10), with 0 representing no pain and 10 representing the worst pain imaginable. Pain usually occurred first thing in the morning when rising from bed and stepping on the floor, with the pain intensity rising up to 10/10 after standing for 1 hour or walking for 15 minutes. The pain intensity would decrease to 6/10 after 20 minutes of non-weight bearing activity and then partially resolve to 5/10 after 2 hours of non-weight-bearing rest. She also reported night heel pain, difficulty sleeping, and occasional sensitivity to cold. She had received multiple therapies prior to this visit, including medications (analgesic), physical therapy modalities (ultrasound, transcutaneous electrical nerve stimulation, and laser), and stretching exercise. After each therapy, the symptoms would decrease initially, but would relapse shortly after treatment. The patient was not taking any medications at the time of the evaluation. A plain film X-ray of her right foot and ankle was taken and carefully reviewed. No evidence of calcaneal spurs, avulsion fractures, or tumors was found. Prior laboratory studies and the patient's past medical history screening for systemic diseases related to heel pain were unremarkable. The patient reported no prior history of foot or ankle dysfunction.

Objective ~~parameters identified during the~~ physical examination ~~included the following findings~~ was performed in the initial visit. Palpation at the medial tubercle of the calcaneus reproduced the patient's right heel pain. There was also tenderness on palpation of the medial head of the gastrocnemius and of the medial belly of the soleus (which may be related to compensatory gait posture with right leg muscles overuse, as the heel pain was not the refer pain of the gastrocnemius and soleus muscles). Passive ankle dorsiflexion with the knee extended induced the same right subcalcaneous heel pain. With the addition of dorsiflexion and eversion of the foot, sharp shooting pain in the right heel and tightness in the right heel and calf were reproduced. The range of motion of the right knee and ankle, compared with the asymptomatic left side, was within normal limits. Sensation and lower extremity reflex testing were unremarkable. Manual muscle test revealed fair-good (3-4/5) strength in the right ankle plantar flexors due to pain in the heel. Observational gait analysis revealed decreased stance times on the right leg, excessive midfoot pronation during midstance, lack of resupination during terminal stance, and an early heel rise at the right side. During single-leg balance testing, the patient was able to stand on the left leg for 25 seconds but was only 11 seconds on the right leg. Based on subjective information and objective findings, a diagnosis of right plantar fasciitis was made.

Series treatments for the patient's condition included a four-week prescription of NSAIDs, two months wearing of orthotics, two cortisone injections into the plantar fascia at its insertion site on the calcaneus, and a four-week exercise program of calf stretching and toe curls for arch strengthening. Over the course of four months, these treatments were unsuccessful in decreasing her level of disability, so BTX-A injection was performed for further treatment of her right subcalcaneous heel pain.

The BTX-A solution was prepared by mixing 100 units with 1 ml normal saline. We injected the patient with 70 units of BTX-A (0.7 ml) in two divided doses: 40 units (0.4 ml) in the tender region of the heel medial to the base of the plantar fascia insertion and 30 units (0.3 ml) in the most tender point of the foot arch (between a point about one inch anterior to the heel and another point at the middle of the foot) following the protocol of Babcock[19]. A 27-gauge, 0.75-inch needle was used for injections. The needle was inserted directly into the heel after ~~confirmed~~ the site of the inflammatory lesion ~~with Ultrasonography~~ was confirmed with ultrasound.

Ultrasonographic examination was performed by a 10-MHz linear array transducer (GE LOGIQ 5 Pro). Evaluation was made bilaterally when the patient was in a prone position with her feet hanging over the edge of the examination table. Longitudinal sonograms of the plantar heel and underlying muscle belly on the mid-portion of the plantar fascia were obtained and the thickness was measured (Figure 1). Qualitative changes in local or diffuse hypoechogenicity at the calcaneal insertion of the plantar fascia were assessed. The same physiatrist performed the examination before and after BTX-A injection. The patient's subjective visual analog scale, the pressure pain threshold measured with a pressure algometer, and ultrasonographic study were assessed before and 1, 3, 5, and 7 weeks after treatment with BTX-A injection to determine its effectiveness.

Our results revealed remarkable decrease of visual analog scale from 8 to 2.2 on the first week, which decreased to 1.5 on the third week. Pressure pain threshold increased from 8.1 to 10.4 on the third week (Figure 2). Unfortunately, the pain symptom recurrent with the pressure pain threshold decreased slowly since the seventh week but was still higher than the baseline value. The thickness of bilateral plantar

fascia ~~was~~ decreased progressively during the whole follow up course after BTX-A injection. The thickness ratio of the plantar fascia and the arch was defined as the thickness of the right one (lesion side) divided by left one. We also found the ratio of plantar fascia decreased progressively on the first and third week after BTX-A injection, which was also compatible with the improvement of clinical symptoms. (Figure 3)

DISCUSSION

In the setting of diagnostic imaging, both ultrasonography and magnetic resonance imaging (MRI) have high levels of accuracy in identifying alterations of the plantar fascia. MRI findings, including plantar fascial thickening, increased signal intensity on T2-weighted images within the plantar fascia and adjacent subcutaneous tissue, and increased signal intensity on TI-weighted images within the plantar fascia, have been found to be characterized and useful for the diagnosis of plantar fasciitis[27-29]. Ultrasonography does not have the same sensitivity as MRI because the latter can provide an overall structural and morphological evaluation of the foot and ankle. However, ultrasonography has the undeniable advantage for serial follow-ups by the clinician because it is a relatively convenient, inexpensive, real-time, and flexible method for capturing soft-tissue images.

Several authors discussed the morphological findings of plantar fasciitis in ultrasonographic studies[21-26]. In all these studies, plantar fascia thickness was significantly greater on the symptomatic side compared with the asymptomatic side. We demonstrated similar ultrasonographic findings in this case study. To our knowledge, ultrasonographic appearance of the plantar fascia after BTX-A injection has not yet been described. In our case, we found a significant progressive decrease in the thickness of symptomatic plantar fascias after BTX-A injection.

Kamel et al.[22] described the same finding in symptomatic plantar fascias following a corticoid injection. Buchbinder et al.[30] also found the same changes after shock wave therapy for plantar fasciitis. The real-time high-resolution ultrasonography conducted by Tsai W-C et al.[31] concluded was an ideal diagnostic imaging modality for the evaluation

of plantar fasciitis because it could offer objective evidence of inflammation and is feasible for serial follow-ups. Accurate steroid injection under ultrasound guidance could effectively treat proximal plantar fasciitis without significant deterioration of the mechanical properties of the heel pads. We also applied ultrasound guidance for BTX-A injection in this case study.

Plantar fascia thickness seems to be related to the response to treatment. This could be underlined by our finding regarding the pain estimation and ultrasonographic study after the BTX-A injection. There was high correlation between the symptomatic relief (assessed with VAS and PPT) and the ultrasonographic findings (significantly thinner plantar fascias) in the serial follow-up assessments after BTX-A injection.

Plantar fascia is a strong band of fibers that maintain the medial longitudinal arch. This arch can stretch the fascia, absorb part of the shock during heel strike, and allows the foot to accommodate irregularities in the walking surface. Many theories have been presented concerning the natural history of the inflammation in the plantar fascia[1, 2, 6, 32]. After a predisposing factor, such as microtrauma or overexertion, the plantar fascia degenerates, its elasticity decreases, and the strain- and thus traction- of the insertion increases. As the tension at the insertion increases, this site is likely to become irritated, resulting in inflammation. Periosteal inflammation and bursitis have been presented as alternative causes of heel pain. Michelsson and his colleagues presented three different modes of treatment: (1) anti-inflammatory and analgesic treatment for reducing pain and inflammation, (2) rest and diminution of the strain at the insertion for reducing the stress of soft tissue, and (3) maintenance of the tension and flexibility of the soft tissues. A simple four-step treatment plan algorithm, based on symptoms, their duration, and response to treatment was suggested~~is their uni~~[17].

BTX-A has been successfully used in the treatment of spasticity, dystonia and spasmodic torticollis. There is conflicting evidence relating to the use of BTX-A in the treatment of myofascial pain, but the weight of evidence is in favor of BTX-A as a treatment in plantar fasciitis[18]. The role of BTX-A in pain management of chronic pain syndromes such as myofascial pain and refractory headaches was via blockade of acetylecholine (Ach) release from presynaptic vesicles to relieve of muscle spasms and pain. This followed the anti-inflammatory action against locally accumulated stimulant neurotransmitters (glutamate, substance P). Babcock and his colleagues[19] brought up probable mechanisms of BTX-A for the treatment of plantar fasciitis. Introduction of BTX-A into a muscle may result in transient loss of muscle volume via induction of muscle atrophy. It is possible that the subsequent size reduction of intrinsic foot muscles results in the relief of pressure on the neurovascular structures trapped under a tight and enlarged plantar fascia. In this case, we found progressive decrease in the thickness of the underlying muscle belly in follow-up ultrasonographic findings.

Important ~~The~~ limitations in this case study ~~were~~ include only one case study with no placebo injection to compare with BTX-A injection, ~~and the~~ lack of long-term follow up, lack of blindness regarding the side of the foot with plantar fasciitis during assessment of the ultrasonographic imaging, and no MRI study for comparison. In the future, a similar study on a large sample with placebo control, blind outcome assessments, and accompanying MRI study for long-term follow-up is strongly suggested.

CONCLUSIONS

Ultrasonography seems to be a valuable, noninvasive diagnostic tool for the evaluation of plantar fasciitis treated with BTX-A. Instead of relying on subjective VAS and PTT, it offers objective measurements of the therapeutic effects, including decreased thickness and disappearing of hypoechogenicity in the plantar fascia.

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FIGURE LEGENDS

Figure 1. Longitudinal ultrasonography of the plantar heel (A) and underlying muscle belly on the mid-portion of the plantar fascia (B) was obtained before BTX-A injection and the thickness was measured.

Figure 2. Serial changes of Visual Analog Scale and Pressure Pain Threshold.

Figure 3. Serial follow-up of ultrasonographic finding on the thickness of the bilateral plantar fascia and the foot arch.

Cover Page

Serial Ultrasonographic Findings of Plantar Fasciitis after Treatment with Botulinum Toxin A: A Case Study

Running Head: Ultrasonography of BTX-A for Plantar Fasciitis

No commercial party having a direct financial interest in the results of the research supporting this article has or will confer a benefit upon the authors or upon any organization with which the authors are associated.

ABSTRACT

Plantar fasciitis is a common cause of heel pain and is the result of a degenerative process of the plantar fascia at its calcaneal attachment. In this paper, a case study of preliminary experience on the treatment of chronic plantar fasciitis in a 43-year-old female with local injection Botulinum Toxin A (BTX-A) is presented. We injected the patient with 70 units of BTX-A (0.7 ml) in two divided doses: 40 units (0.4 ml) in the tender region of the heel and 30 units (0.3 ml) in the most tender point of the foot arch. Visual Analog Scale (VAS) and Pressure Pain Threshold (PPT) were measured to evaluate the efficacy of BTX-A injection. Real-time high-resolution ultrasonographic finding of the plantar fascia after BTX-A injection was also used for serial follow-ups. Following BTX-A injection, decreased VAS values was reported, and increased PPT was observed. In ultrasonographic study, the thickness of the plantar fascia and the hypoechogenicity of the fascia were reduced. Decreased plantar fascia thickness was observed on the first and third week after BTX-A injection. The findings were compatible with the changes in pain assessed by VAS and PPT. Ultrasonographic findings also indicated a progressive decrease in the thickness of underlying muscle belly. Ultrasonography seems to be a valuable, noninvasive diagnostic tool for the evaluation of plantar fasciitis treated with BTX-A injection. It can offer objective measurements of therapeutic effects and is feasible for serial follow-ups.

Key words: Botulinum Toxin A, Plantar fasciitis, Pain, Ultrasonography

INTRODUCTION

Plantar fasciitis[1-4] is a common cause of heel pain and is the result of a degenerative process of the plantar fascia at its calcaneal attachment. Age, obesity, excessive weight bearing, and tight Achilles tendon are the common predisposing factors.[2, 5] Plantar fasciitis presents in a most characteristic manner, including gradual onset and worsening over a period of time, pain in the morning upon rising from rest, and localization over the medial slip of the origin of the fascia.[6] Methods for treatment are insoles[7], shoes modification[8], stretching[9], physiotherapy, ice/cold, nonsteroidal anti-inflammatory drugs (NSAIDs)[10], analgesics, night splints[11-13], local steroid injections[14], extracorporeal shock wave therapy[15, 16], and immobilization[17].

The guidelines of the American College of Physicians summarize that there is level 1B evidence for the use of Botulinum toxin A (BTX-A) in the treatment of plantar fasciitis.[18] Babcock et al.[19] presented a randomized, double-blinded, placebo-controlled study and concluded BTX-A injection for plantar fasciitis yields significant improvements in pain relief and overall foot function at both three and eight weeks after treatment. This evidence has subsequently been reinforced by the preliminary results of a further study[20]. Outcome assessments including subjective pain intensity, Maryland Foot Score, and Pain Relief Visual Analog Scale were selected in previous studies, but no objective measurements were used to evaluate the efficacy of BTX-A injection on plantar fasciitis.

Ultrasonography is a valuable, noninvasive diagnostic tool for the evaluation of plantar fasciitis[21-23]. For symptomatic feet, increased thickness of the fascia and reduced echogenicity were constant ultrasonographic findings.[24-26] To our knowledge, no

ultrasonographic findings of the responses associated with BTX-A injection for plantar fasciitis have been evaluated and reported to date. Thus, the purpose of this case study was to prospectively evaluate with ultrasonographic findings of the plantar fascia after BTX-A injection with serial follow-ups.

CASE DESCRIPTION

The patient was a 43-year-old housewife who presented to our clinic with a chief complaint of limited standing and walking tolerance, and secondary to right subcalcaneal heel pain. The onset of pain was insidious approximately eight months prior to her initial visit. At the time of the first evaluation, the patient was unable to stand for more than 1 hour or walk for more than 15 minutes without heel pain. She reported a sharp shooting pain and tightness in her right heel and medial arch during weight bearing. The patient verbally rated this pain as 8 on a scale of 0 to 10 (8/10), with 0 representing no pain and 10 representing the worst pain imaginable. Pain usually occurred first thing in the morning when rising from bed and stepping on the floor, with the pain intensity rising up to 10/10 after standing for 1 hour or walking for 15 minutes. The pain intensity would decrease to 6/10 after 20 minutes of non-weight bearing activity and then partially resolve to 5/10 after 2 hours of non-weight-bearing rest. She also reported night heel pain, difficulty sleeping, and occasional sensitivity to cold. She had received multiple therapies prior to this visit, including medications (analgesic), physical therapy modalities (ultrasound, transcutaneous electrical nerve stimulation, and laser), and stretching exercise. After each therapy, the symptoms would decrease initially, but would relapse shortly after treatment. The patient was not taking any medications at the time of the evaluation. A plain film X-ray of her right foot and ankle was taken and carefully reviewed. No evidence of calcaneal spurs, avulsion fractures, or tumors was found. Prior laboratory studies and the patient's past medical history screening for systemic diseases related to heel pain were unremarkable. The patient reported no prior history of foot or ankle dysfunction.

Objective physical examination was performed in the initial visit. Palpation at the medial tubercle of the calcaneus reproduced the patient's right heel pain. There was also tenderness on palpation of the medial head of the gastrocnemius and of the medial belly of the soleus (which may be related to compensatory gait posture with right leg muscles overuse, as the heel pain was not the refer pain of the gastrocnemius and soleus muscles). Passive ankle dorsiflexion with the knee extended induced the same right subcalcaneous heel pain. With the addition of dorsiflexion and eversion of the foot, sharp shooting pain in the right heel and tightness in the right heel and calf were reproduced. The range of motion of the right knee and ankle, compared with the asymptomatic left side, was within normal limits. Sensation and lower extremity reflex testing were unremarkable. Manual muscle test revealed fair-good (3-4/5) strength in the right ankle plantar flexors due to pain in the heel. Observational gait analysis revealed decreased stance times on the right leg, excessive midfoot pronation during midstance, lack of resupination during terminal stance, and an early heel rise at the right side. During single-leg balance testing, the patient was able to stand on the left leg for 25 seconds but was only 11 seconds on the right leg. Based on subjective information and objective findings, a diagnosis of right plantar fasciitis was made.

Series treatments for the patient's condition included a four-week prescription of NSAIDs, two months wearing of orthotics, two cortisone injections into the plantar fascia at its insertion site on the calcaneus, and a four-week exercise program of calf stretching and toe curls for arch strengthening. Over the course of four months, these treatments were unsuccessful in decreasing her level of disability, so BTX-A injection was performed for further treatment of her right subcalcaneous heel pain.

The BTX-A solution was prepared by mixing 100 units with 1 ml normal saline.

We injected the patient with 70 units of BTX-A (0.7 ml) in two divided doses: 40 units (0.4 ml) in the tender region of the heel medial to the base of the plantar fascia insertion and 30 units (0.3 ml) in the most tender point of the foot arch (between a point about one inch anterior to the heel and another point at the middle of the foot) following the protocol of Babcock[19]. A 27-gauge, 0.75-inch needle was used for injections. The needle was inserted directly into the heel after the site of the inflammatory lesion was confirmed with ultrasound.

Ultrasonographic examination was performed by a 10-MHz linear array transducer (GE LOGIQ 5 Pro). Evaluation was made bilaterally when the patient was in a prone position with her feet hanging over the edge of the examination table. Longitudinal sonograms of the plantar heel and underlying muscle belly on the mid-portion of the plantar fascia were obtained and the thickness was measured (Figure 1). Qualitative changes in local or diffuse hypoechogenicity at the calcaneal insertion of the plantar fascia were assessed. The same physiatrist performed the examination before and after BTX-A injection. The patient's subjective visual analog scale, the pressure pain threshold measured with a pressure algometer, and ultrasonographic study were assessed before and 1, 3, 5, and 7 weeks after treatment with BTX-A injection to determine its effectiveness.

Our results revealed remarkable decrease of visual analog scale from 8 to 2.2 on the first week, which decreased to 1.5 on the third week. Pressure pain threshold increased from 8.1 to 10.4 on the third week (Figure 2). Unfortunately, the pain symptom recurrent with the pressure pain threshold decreased slowly since the seventh week but was still higher than the baseline value. The thickness of bilateral plantar fascia decreased progressively during the whole follow up course after BTX-A injection.

The thickness ratio of the plantar fascia and the arch was defined as the thickness of the right one (lesion side) divided by left one. We also found the ratio of plantar fascia decreased progressively on the first and third week after BTX-A injection, which was also compatible with the improvement of clinical symptoms. (Figure 3)

DISCUSSION

In the setting of diagnostic imaging, both ultrasonography and magnetic resonance imaging (MRI) have high levels of accuracy in identifying alterations of the plantar fascia. MRI findings, including plantar fascial thickening, increased signal intensity on T2-weighted images within the plantar fascia and adjacent subcutaneous tissue, and increased signal intensity on TI-weighted images within the plantar fascia, have been found to be characterized and useful for the diagnosis of plantar fasciitis[27-29]. Ultrasonography does not have the same sensitivity as MRI because the latter can provide an overall structural and morphological evaluation of the foot and ankle. However, ultrasonography has the undeniable advantage for serial follow-ups by the clinician because it is a relatively convenient, inexpensive, real-time, and flexible method for capturing soft-tissue images.

Several authors discussed the morphological findings of plantar fasciitis in ultrasonographic studies[21-26]. In all these studies, plantar fascia thickness was significantly greater on the symptomatic side compared with the asymptomatic side. We demonstrated similar ultrasonographic findings in this case study. To our knowledge, ultrasonographic appearance of the plantar fascia after BTX-A injection has not yet been described. In our case, we found a significant progressive decrease in the thickness of symptomatic plantar fascias after BTX-A injection.

Kamel et al.[22] described the same finding in symptomatic plantar fascias following a corticoid injection. Buchbinder et al.[30] also found the same changes after shock wave therapy for plantar fasciitis. The real-time high-resolution ultrasonography conducted by Tsai W-C et al.[31] concluded was an ideal diagnostic imaging modality for the evaluation

of plantar fasciitis because it could offer objective evidence of inflammation and is feasible for serial follow-ups. Accurate steroid injection under ultrasound guidance could effectively treat proximal plantar fasciitis without significant deterioration of the mechanical properties of the heel pads. We also applied ultrasound guidance for BTX-A injection in this case study.

Plantar fascia thickness seems to be related to the response to treatment. This could be underlined by our finding regarding the pain estimation and ultrasonographic study after the BTX-A injection. There was high correlation between the symptomatic relief (assessed with VAS and PPT) and the ultrasonographic findings (significantly thinner plantar fascias) in the serial follow-up assessments after BTX-A injection.

Plantar fascia is a strong band of fibers that maintain the medial longitudinal arch. This arch can stretch the fascia, absorb part of the shock during heel strike, and allows the foot to accommodate irregularities in the walking surface. Many theories have been presented concerning the natural history of the inflammation in the plantar fascia[1, 2, 6, 32]. After a predisposing factor, such as microtrauma or overexertion, the plantar fascia degenerates, its elasticity decreases, and the strain- and thus traction- of the insertion increases. As the tension at the insertion increases, this site is likely to become irritated, resulting in inflammation. Periosteal inflammation and bursitis have been presented as alternative causes of heel pain. Michelsson and his colleagues presented three different modes of treatment: (1) anti-inflammatory and analgesic treatment for reducing pain and inflammation, (2) rest and diminution of the strain at the insertion for reducing the stress of soft tissue, and (3) maintenance of the tension and flexibility of the soft tissues. A simple four-step treatment plan algorithm, based on symptoms, their duration, and response to treatment was suggested[17].

BTX-A has been successfully used in the treatment of spasticity, dystonia and spasmodic torticollis. There is conflicting evidence relating to the use of BTX-A in the treatment of myofascial pain, but the weight of evidence is in favor of BTX-A as a treatment in plantar fasciitis[18]. The role of BTX-A in pain management of chronic pain syndromes such as myofascial pain and refractory headaches was via blockade of acetylecholine (Ach) release from presynaptic vesicles to relieve of muscle spasms and pain. This followed the anti-inflammatory action against locally accumulated stimulant neurotransmitters (glutamate, substance P). Babcock and his colleagues[19] brought up probable mechanisms of BTX-A for the treatment of plantar fasciitis. Introduction of BTX-A into a muscle may result in transient loss of muscle volume via induction of muscle atrophy. It is possible that the subsequent size reduction of intrinsic foot muscles results in the relief of pressure on the neurovascular structures trapped under a tight and enlarged plantar fascia. In this case, we found progressive decrease in the thickness of the underlying muscle belly in follow-up ultrasonographic findings.

Important limitations in this case study include only one case study with no placebo injection to compare with BTX-A injection, lack of long-term follow up, lack of blindness regarding the side of the foot with plantar fasciitis during assessment of the ultrasonographic imaging, and no MRI study for comparison. In the future, a similar study on a large sample with placebo control, blind outcome assessments, and accompanying MRI study for long-term follow-up is strongly suggested.

CONCLUSIONS

Ultrasonography seems to be a valuable, noninvasive diagnostic tool for the evaluation of plantar fasciitis treated with BTX-A. Instead of relying on subjective VAS and PTT, it offers objective measurements of the therapeutic effects, including decreased thickness and disappearing of hypoechogenicity in the plantar fascia.

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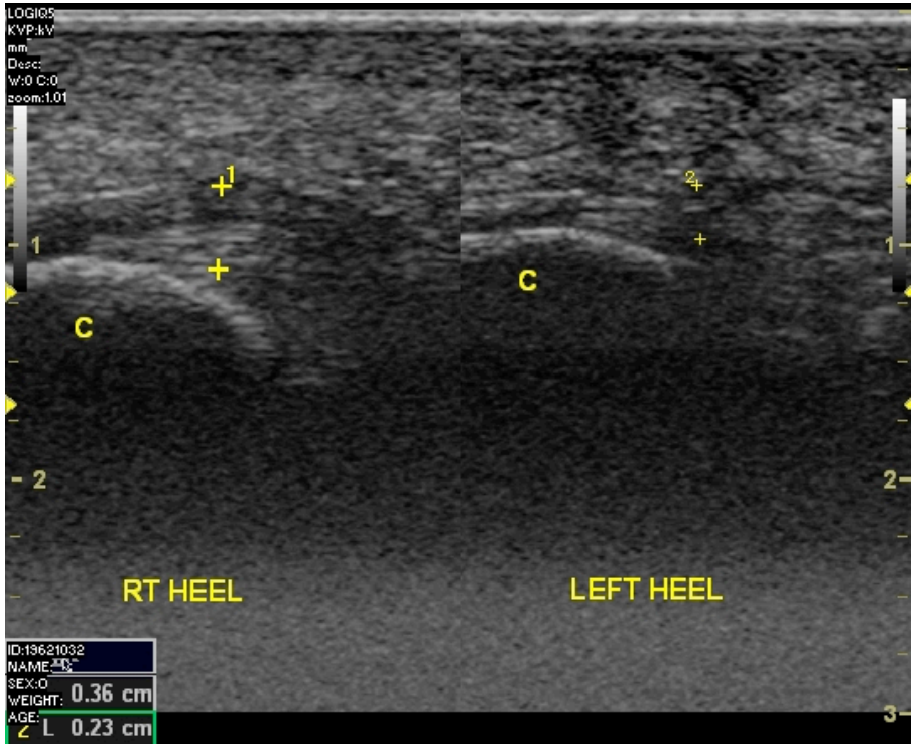
FIGURE LEGENDS

Figure 1. Longitudinal ultrasonography of the plantar heel (A) and underlying muscle belly on the mid-portion of the plantar fascia (B) was obtained before BTX-A injection and the thickness was measured.

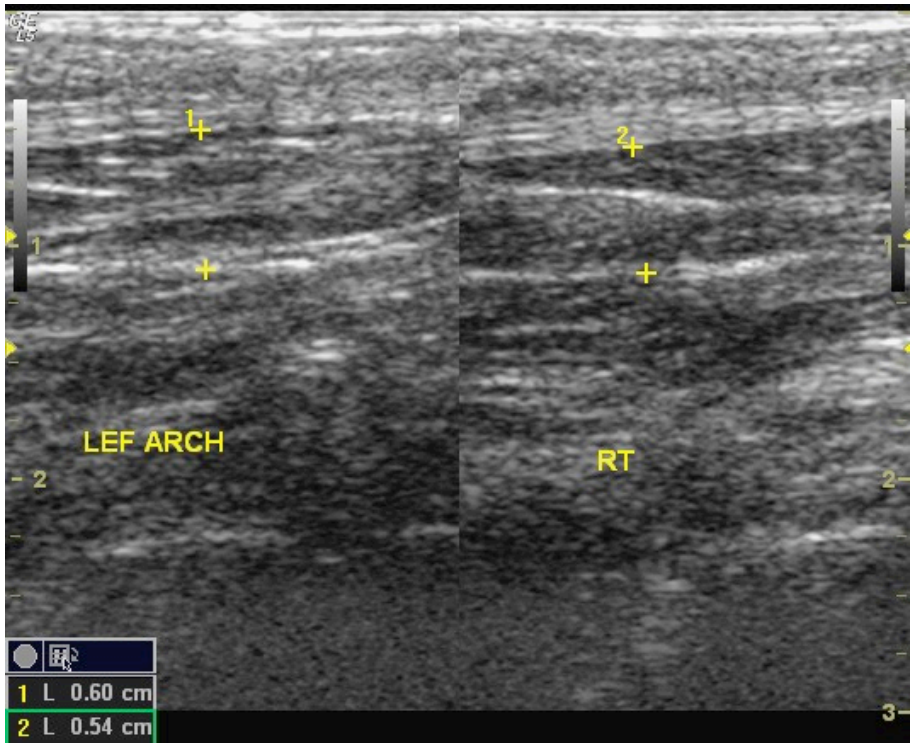
Figure 2. Serial changes of Visual Analog Scale and Pressure Pain Threshold.

Figure 3. Serial follow-up of ultrasonographic finding on the thickness of the bilateral plantar fascia and the foot arch.

Figure 1



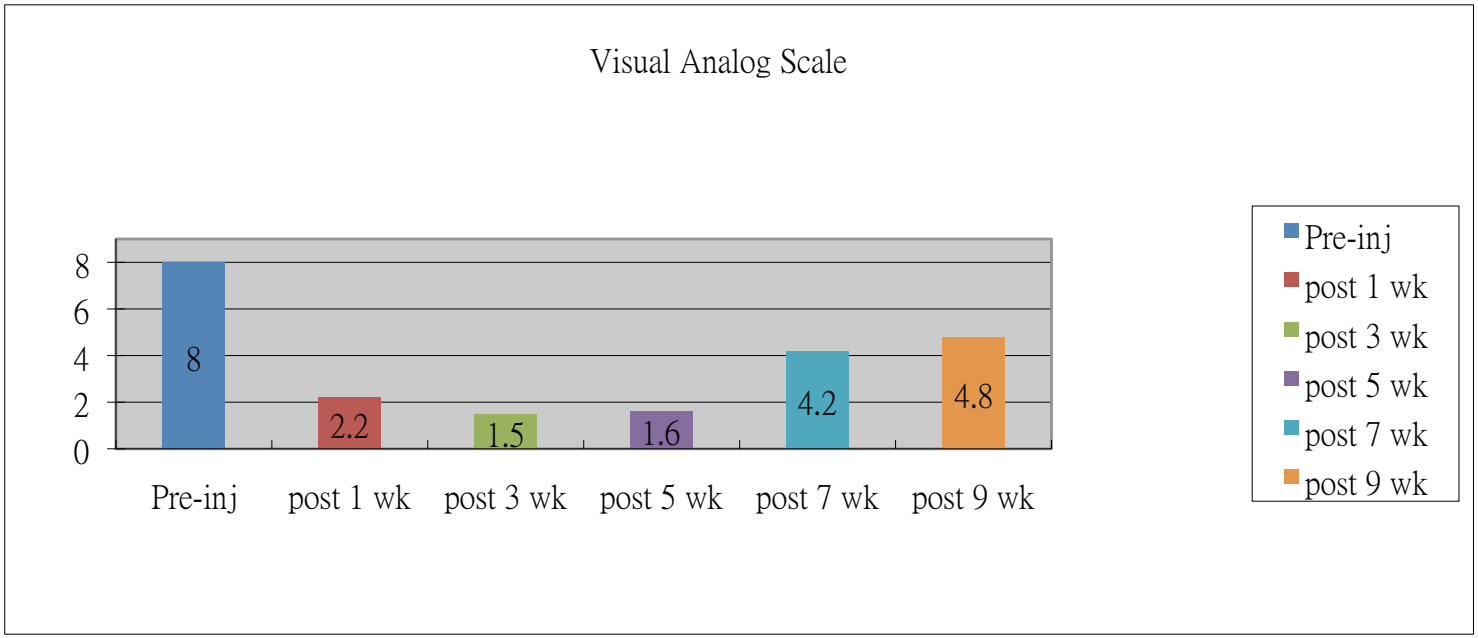
(A) Plantar fascia (PF)



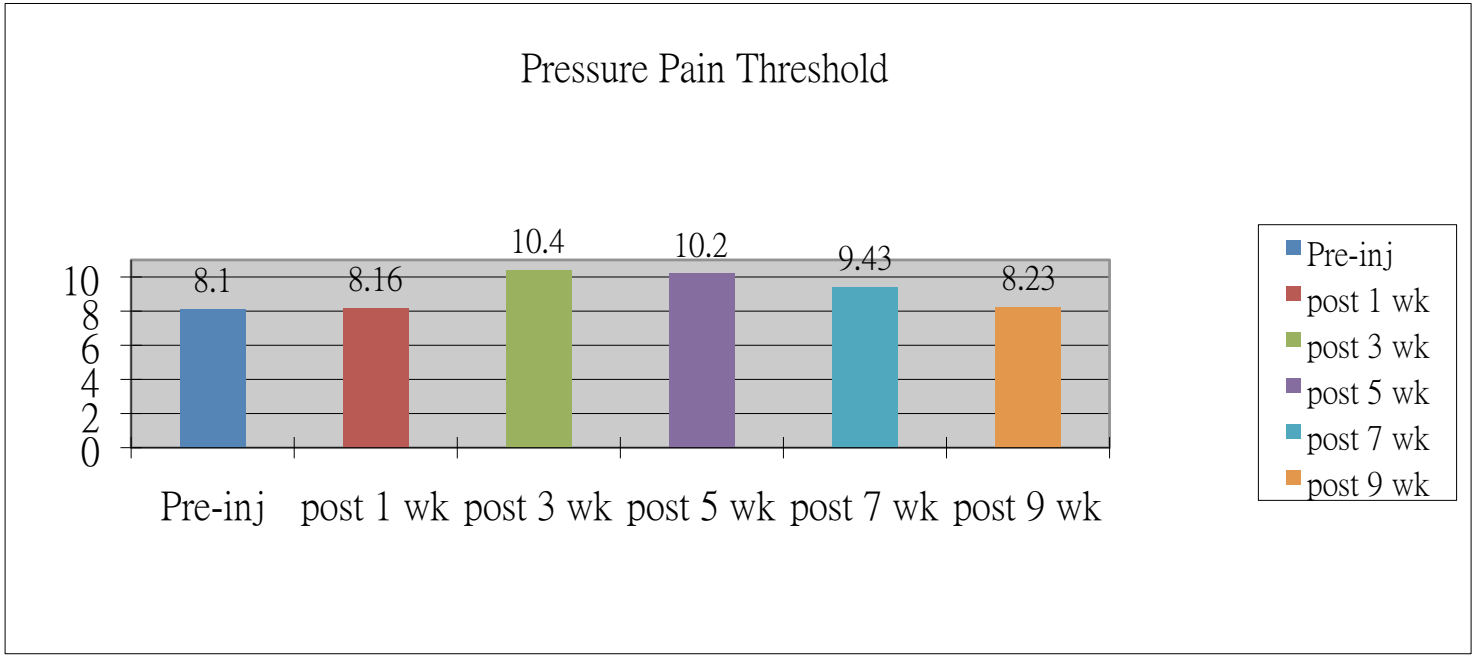
(B) Underlining muscle belly (Arch)

Figure 2

A


Visual Analog Scale
8
6
4
2
0
8
2.2
1.5
1.6
4.2
4.8
Pre-inj
post 1 wk
post 3 wk
post 5 wk
post 7 wk
post 9 wk
Pre-inj
post 1 wk
post 3 wk
post 5 wk
post 7 wk
post 9 wk

B


Pressure Pain Threshold
10
8
6
4
2
0
8.1
8.16
10.4
10.2
9.43
8.23
Pre-inj
post 1 wk
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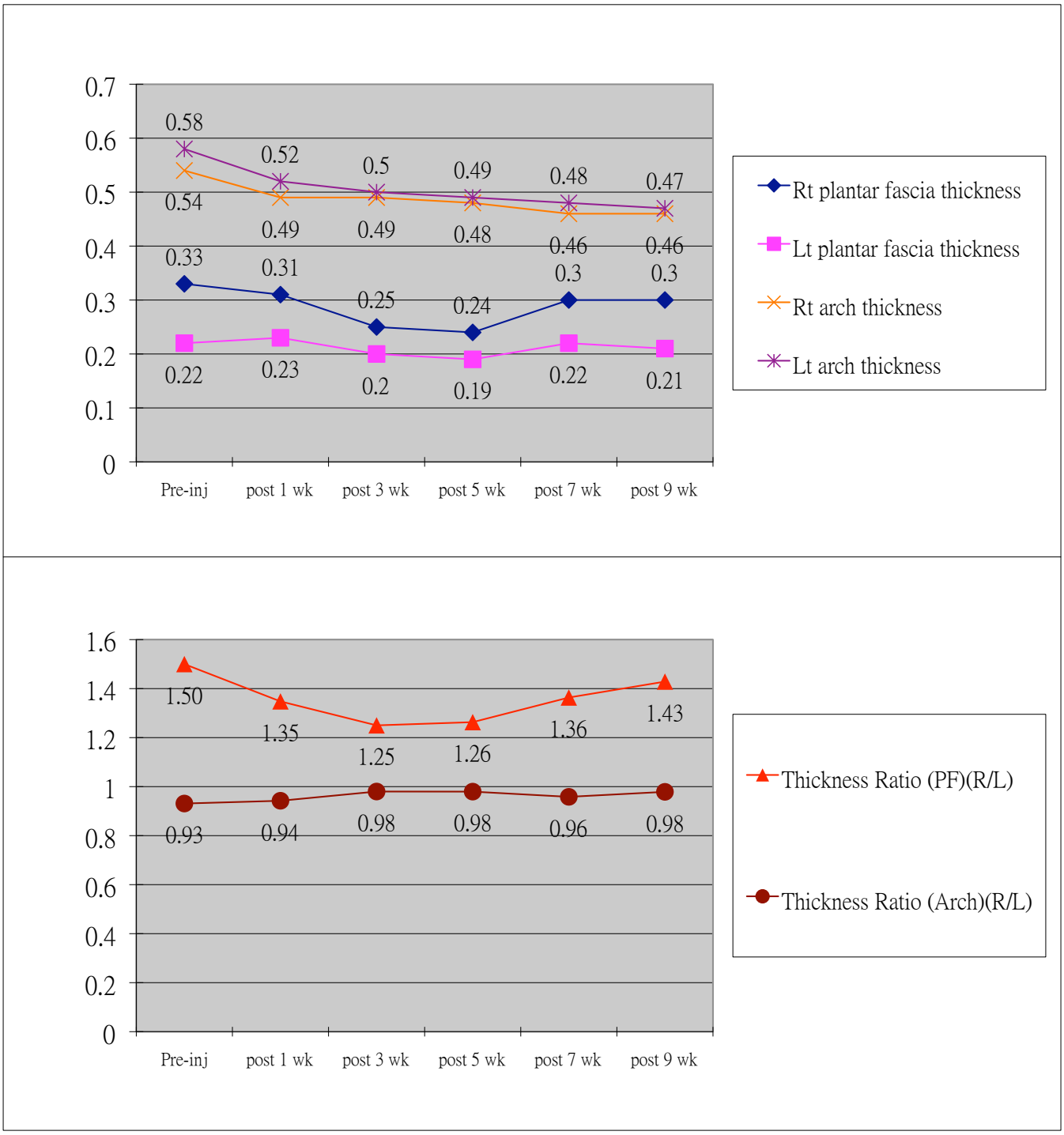
post 7 wk
post 9 wk
Pre-inj
post 1 wk
post 3 wk
post 5 wk
post 7 wk
post 9 wk

Figure 3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0.5
0.4
0.3
0.2
0.1
0
0.58
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0.49
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0.47
0.54
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0.49
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0.46
0.33
0.31
0.25
0.24
0.3
0.3
0.22
0.23
0.2
0.19
0.22
0.21
Pre-inj
post 1 wk
post 3 wk
post 5 wk
post 7 wk
post 9 wk
Rt plantar fascia thickness
Lt plantar fascia thickness
Rt arch thickness
Lt arch thickness
1.6
1.4
1.2
1
0.8
0.6
0.4
0.2
0
1.50
1.35
1.25
1.26
1.36
1.43
0.93
0.94
0.98
0.98
0.96
0.98
Pre-inj
post 1 wk
post 3 wk
post 5 wk
post 7 wk
post 9 wk
Thickness Ratio (PF)(R/L)
Thickness Ratio (Arch)(R/L)

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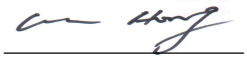
Signature: 

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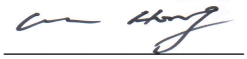
Signature: 

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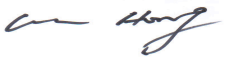

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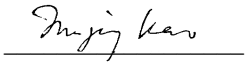
Signature: 

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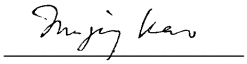
Signature: 

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