Effect of Acetic Acid Shockwave Phonophoresis on Calcaneal spur patients: A Randomized Controlled Trial

By

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CHAPTER I
INTRODUCTION

Epidemiological data shows that 46 % of adults suffer from various foot conditions that result in abnormal mechanics of standing and walking. Chronic heal pain might impair walking and cause spinal pain. Plantar heel pain is one of the most common musculoskeletal disorders of the lower extremity that affects about 10% of the general population, associated with limitation on activity, depression, and reduced health related quality of life **(Krukowska et al., 2016)(Cotchett et al., 2016).**

A calcaneal spur is an abnormal undesired calcium deposits on the heel bone, this process usually chronic process that continues for many months. The treatment of calcaneal spur is primarily conservative. However, Surgery and corticosteroid therapy is a line of treatment in severe cases. **(Lizis et al., 2017).**

Conservative treatment includes non-steroidal anti-inflammatory drugs (NSAIDs), physiotherapy modalities such as electrotherapy (microwaves, extracorporeal Shockwave (ESWT), Ultrasounds, Transcutaneous electrical nerve stimulation (TENS), short waves, Iontophoresis, phonophoresis, interferential and pulsed electromagnetic therapy) **(Cuadros, 2016).**

Extracorporeal shockwave therapy (ESWT) is now extensively used in the treatment of musculoskeletal disrobes, For example, chronic diabetic and non-diabetic ulcers ,calcifying tendinitis of shoulder, planter fasciitis and lateral epicondylitis, from approximately 20 years with successful rate ranged from 65% to 91% **(Frairia & Berta, 2011) (Wang, 2012).**

Many researchers investigated the effect of shockwave therapy in the management of proximal plantar fasciitis and conveyed a success rate ranging from 34% to 88%. **(Wang, 2012).**

The interaction of shockwave with biological cells is a new area of research. For example, water purification, desalination, and bacterial decontamination. Shockwave also have great potential for biomedical use, since they can also permeabilize cell membranes thereby allowing for the transport of various macromolecules, drugs and genetic material into cells. in addition to that extracorporeal Shockwave lithotripsy (ESWL) used to treat kidney stones below 20 mm in size, or destruction of cancer cells **(Hu et al., 2019).**

Marcos et al., conducted a research about the effect of 5% Acetic Acid Iontophoresis and Ultrasound over calcified Achilles Tendon. The result showed that Iontophoresis with 5% Acetic Acid and Ultrasound is a safe, simple and inexpensive modality able to reduce significantly pain and size of calcification on the ankle **(Marcos et al., 2019).**

Acetic acid is one of the most important substance used in physical therapy to treat abnormal calcification via introducing it by phonophoresis or iontophoresis because it promotes a chemical reaction capable of forming a compound more soluble, which facilitates the calcium absorption. Pamplona E et al., report a case study in which he apply (5% acetic acid) phonophoresis for calcified shoulder joint was effective in the treatment of calcific tendinitis of supraspinatus muscles , improving the ROM, muscle strength and functional capacity, in addition to eliminating the pain of the affected shoulder **(Pamplona et al., 2017).**

➢ <u>Statement of the Problems:</u>

There is a gap in literature on the effect of Shockwave in combination with substance like acetic acid gel on treatment of calcaneal spur patients. So, this study conducted to answer the following question:

- Dose the extracorporeal acetic acid shockwave phonophoresis has any effect on length of calcaneal spur, pain pressure threshold, pain level and physical function in patients with calcaneal spur?
- Dose the extracorporeal shockwave has any effect on length of calcaneal spur, pain pressure threshold, pain level and physical function in patients with calcaneal spur?
- Is there a statically significant difference between extracorporeal shockwave and extracorporeal acetic acid shockwave phonophoresis on length of calcaneal spur, pain pressure threshold, pain level and physical function in patients with calcaneal spur?

➢ <u>Purposes of study:</u>

The aims of this study is:

- To investigate the effect of extracorporeal acetic acid shockwave phonophoresis on length of calcaneal spur, pain pressure threshold, pain level and physical function in patients with calcaneal spur.

- To investigate the effect of extracorporeal shockwave on length of calcaneal spur, pain pressure threshold, pain level and physical function in patients with calcaneal spur.
- To investigate and compare the efficacy of extracorporeal shockwave versus extracorporeal shockwave acetic acid phonophoresis in patients with calcaneal spur.

➤ **Significance of the study:**

The painful heel is a common musculoskeletal problem that affects the general population in their lifetime especially runners **(Perez et al., 2003).** Local application of the drug is faster, increased comfort of the patient, improve the effectiveness of the treatment, and decreases the hazards of systematic side effect of the Like gastrointestinal tract problems and decrease the efficacy of the treatment.

Iontophoresis with 5%Acetic Acid and Ultrasound is a safe, simple and inexpensive technique and effective treatment capable to reduce pain and calcification on the shoulder, elbow, wrist, hip, knee and ankle **(Cuadros, 2016).**

The biochemical theory of the process has been described in detail where the use of acetic acid iontophoresis converts insoluble calcium carbonate in chronically inflamed tissue to calcium acetate, which is soluble in blood. Pulsed ultrasound was used to reduce inflammation, improve local blood flow that facilitate the removal of the newly formed calcium acetate into the blood, and thereby remove it from the localized area of heel pain **(Costa & Dyson, 2007).**

The effect of shockwave and the ultrasound has been compared on feet pain and quality of life in the patients with calcaneal spur. There was a significant improvement in the feet pain and quality of life. However, the patients treated with shockwave had significantly greater pain decrease and life quality improvement, and those benefits were still present three months after the treatment **(Lizis & Hudáková, 2016).**

Shockwave could be used as a pretreatment of cell membranes for electroporation. The Shockwave possible role of multiple Nano bubbles was examined. It has also been shown that not only would the multiple Nano bubbles make it possible to create larger pores, but also increase the pore density on the surface. The multi-pore scenario would be useful practically in enhancing material throughout into cells. **(Hu et al., 2019).**

Direct and indirect Shockwave effects described concerning stone disintegration could also contribute to transient increase membrane permeability on application of low energy shockwave to eukaryotic cell membranes. Low energy shockwave can deliver macromolecules of up to 2,000,000 molecular weight into the cytoplasm of cells. **(Tyagi & Chuang, 2018).**

Low energy shockwave has a significant effect on the permeability of tissue. Consequently, it might be used to deliver substance such as Acetic acid. Accordingly, Shockwave might help to improve the outcomes with calcaneal spur patients. Therefore, the present study might help in treatment of calcaneal spur patient and might improve the quality of life in fast and efficient way.

➢ Delimitations:

This study will be delimited to calcaneal spur patients, selected from outpatient clinics at faculty of physical therapy on Beni-Suef University on the following criteria:

1. The patient's age ranged from 30 to 65 years
2. Patients with calcaneal spur.
3. Patients with intact sensory perception.
4. At least 6 weeks from last corticosteroid injection; 4 weeks from the last local anesthetic injection, iontophoresis, ultrasound, and electrotherapy **(Gerdesmeyer et al., 2008)**
5. X-Ray will be used to measure the length of calcaneal spur.
6. Algometry will be used to measure Pain pressure threshold.
7. Visual Analogue scale will be used to measure Pain intensity level.
8. Foot and Ankle Ability Measure (FAAM) questionnaire will be used to measure physical function.

➢ Basic Assumptions:

The following assumptions are necessarily for the development of the study:

- The instructions that will give to all patients for assessment should be accurately, clearly, and faithfully followed.
- All patients will be cooperative during the assessment and treatment procedures.

➢ Hypothesis:

The null hypotheses of this study stated as the following:

- H_0 : there is no statistical significant effect of the use of extracorporeal acetic acid shockwave phonophoresis on length of calcaneal spur, pain pressure threshold, pain intensity level and physical function in patients with calcaneal spur.
- H_0: there is no statistically significant effect of the use of extracorporeal Shockwave on length of calcaneal spur, pain pressure threshold, pain intensity level and physical function in patients with calcaneal spur.
- $H_{0:}$ there is no statistically significant difference between extracorporeal shockwave versus acetic acid shockwave phonophoresis on length of calcaneal spur, pain pressure threshold, pain intensity level and physical function in patients with calcaneal spur.

➤ Definition of terms:

The following terms defined for clear understanding of the terminology used in the presented study:

Calcaneal spur: is an osteophyte outgrowth just medial process of calcaneal tuberosity.

Shockwave: is an acoustic wave characterized by high positive pressures of more than 1000 bar (100 MPa), which can be developed within an extremely short rise time (10^{-9} seconds) and followed by a low-pressure phase of tensile stress equivalent to 100 bar (10 MPa).

Energy flux density: is a term used to reflect the amount of energy delivered to a specific area of tissue. measured in (Mj/mm2) **(Speed C , 2014)**

Enthesis is the site of attachment of tendon, ligament, fascia, or capsule to bone.

CHAPTER II
REVIEW OF LITERATURE

This study conducted to investigate the efficacy of Shockwave phonophoresis on calcaneal spur patients.

In this part of the current study, the review of the related researches and studies of the main concepts presented under the following headings:

- Foot anatomy and calcaneal spur.
- Shockwave.
- Acetic acid and abnormal calcifications.

1. Foot anatomy and calcaneal spur:

a. Foot anatomy:

The foot consists of 26 bones, more than 30 articulations, more than 100 ligaments and 30 muscles act in foot segment. All of these joints must interact harmoniously and in combination to achieve a smooth motion. The foot moves in three planes, with most of the motion occurring in the rear foot; this will enabling three fundamental functions: supporting, shock absorbing, and weight bearing **(Woźniacka et al., 2013)**

The foot divided into three regions:

- The rear foot: consisting of the talus and the calcaneus.
- The mid foot: including the navicular, cuneiforms, and the cuboid.
- The forefoot : containing the metatarsals and the phalanges **(Standring, 2016)**

The tarsal bones arranged in a proximal and distal row, similar to the carpal bones in the wrist. The talus and calcaneus make up the proximal row in the foot, while the medial, intermediate, and lateral cuneiforms and the cuboid comprise the distal row. The navicular bone is interspersed between the talus and the cuneiform. The bones of the toes are very similar to the hand with the second through fifth toes consisting of metatarsal, proximal, middle, and distal phalanges. The first toe – similar to the thumb – does not contain a middle phalanx.

b. Foot musculature:

The foot and ankle are worked by both extrinsic and intrinsic musculature. The extrinsic muscles all originate from proximal to the foot. The intrinsic muscles of the foot originate and insert within the foot and act primarily on the toes. Their secondary function is to maintain postural balance through stabilization of the osteocartilaginous architecture of the foot.

The plantar muscles of the foot can be thought of as organized by layers from sole of the foot progressing deep to the bony structures .The first layer consists of muscles found just beneath the plantar aponeurosis – the flexor digitorum brevis, the abductor hallucis, and the abductor digiti minimi. These muscles extend from calcaneus to toes and create a functional group that assists in maintaining foot concavity. All three have been described as local pedicles muscle flaps, and all have type I vascular supply. The flexor digitorum brevis is supplied by branches of the posterior tibial artery via the medial and lateral plantar arteries on its proximal deep surface. The abductor hallucis is supplied by a dominant pedicle on its deep surface and by a branch of the medial plantar artery in the proximal foot. The abductor digiti minimi muscle receives its dominant pedicle from a lateral branch of the proximal lateral plantar artery.

The first layer for the plantar foot is separated from the second layer by the tendons of the extrinsic muscles of the flexor digitorum longus and the flexor hallucis longus. Also, the medial and lateral plantar artery and nerve course in this intermediary plane **(see Fig 1). (Paulsen, 2019)**

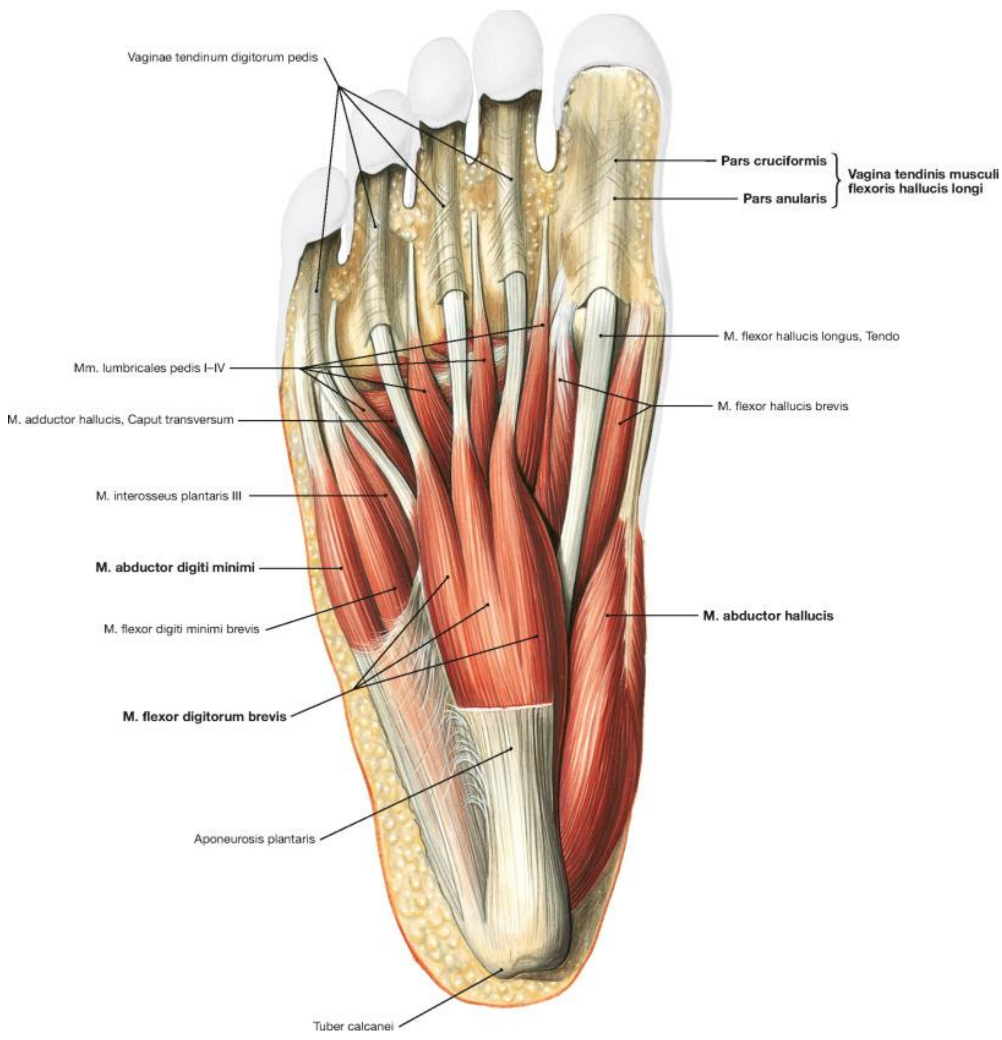

***Figure 1*: the first layer of foot muscles (the outer layer) adapted from(Paulsen, 2019)**

The second layer consists of the quadratus plantae muscle and the lumbricals muscles of the foot. The quadratus plantae is one of the few muscles of the foot that does not have an similar structure in the hand. It has two heads extending from the medial and lateral border of the calcaneus, inserts into the tendon of the flexor digitorum longus, and aids in plantarflexion of the second to fifth toes. The lumbricals of the foot mirror those of the hand in their unique attribute of both originating and inserting on tendons. These four muscles arise from the medial side of the flexor digitorum longus and insert on the extensor system of the second through fifth phalanges .The foot lumbricals follow the same course as those of the hand and flex the metatarsophalangeal joints and extend the interphalangeal joints **(see Fig 2).**

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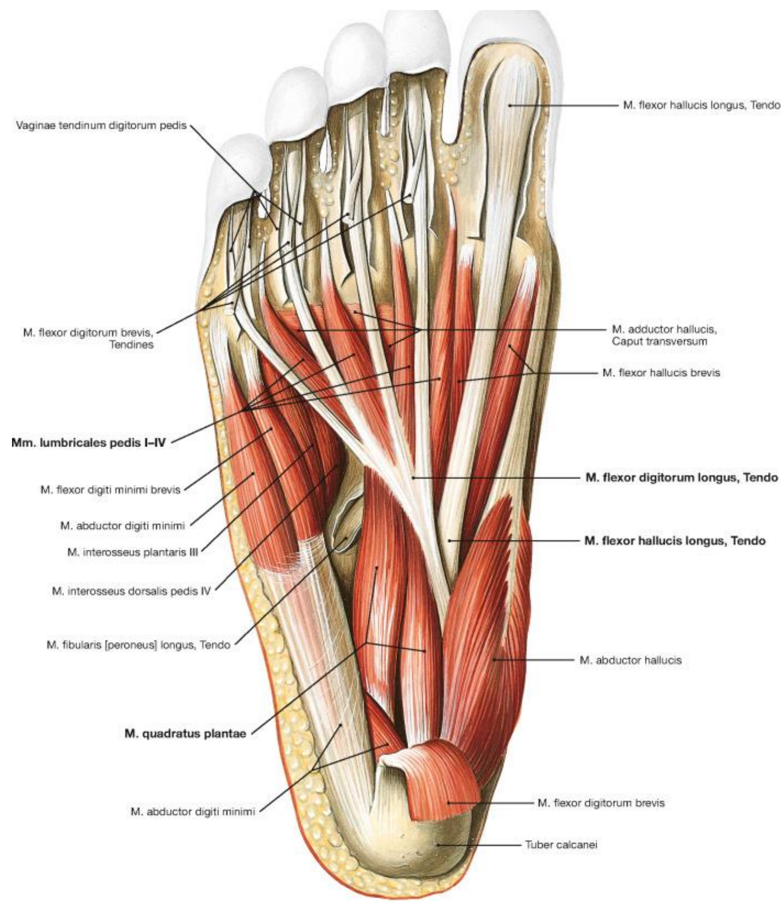

Figure 2: the second layer of foot muscles (the middle layer) adapted from**(Paulsen, 2019)**

The third layer consists of the flexor hallucis brevis, the adductor hallucis, and flexor digiti minimi brevis. These form a small, deep intrinsic musculature that contributes in the maintenance of the longitudinal plantar arch and participates in the stabilization of intrinsic foot osteoligamentous intercalation and balance **(see Fig 3).**

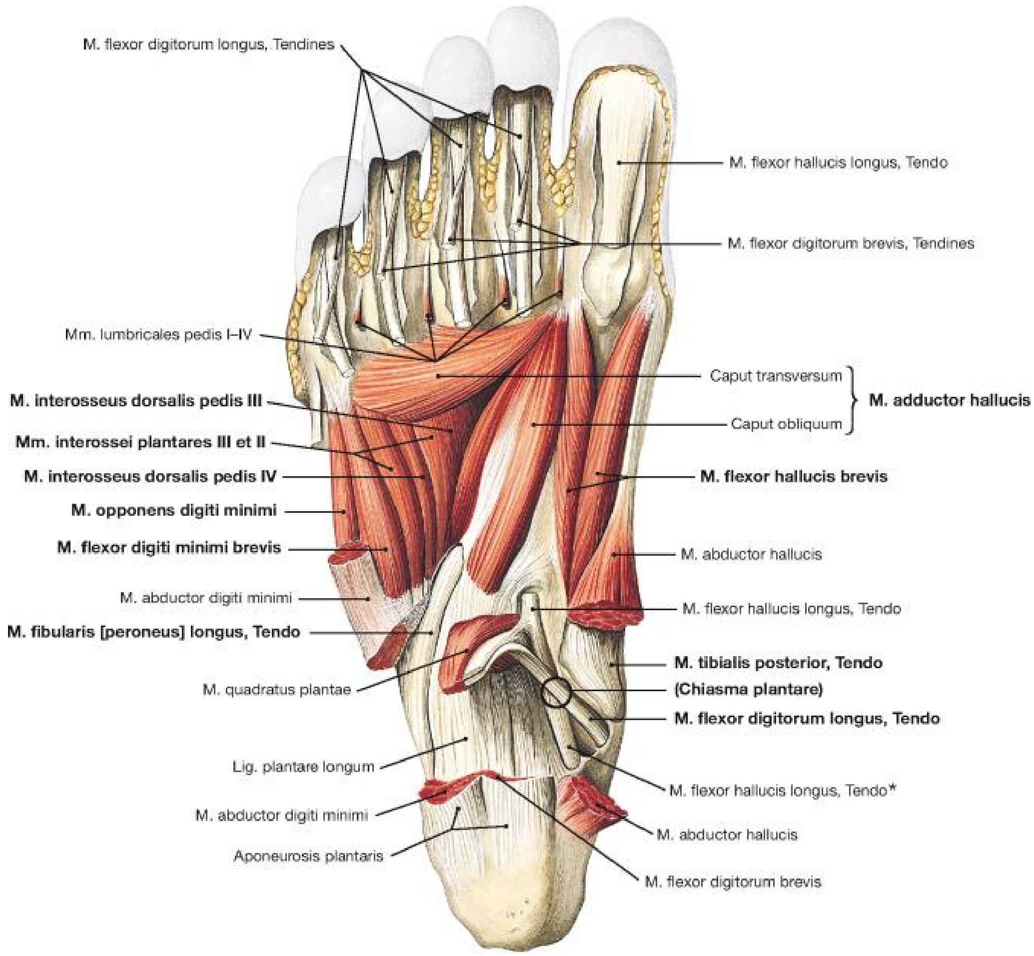

Figure 3: the third layer of foot muscles adapted from**(Paulsen, 2019)**

The fourth layer is the interosseous compartment that contains both the plantar and the dorsal interossei. The three plantar interosseous muscles adduct the toes. The four dorsal interosseous muscles abduct the toes. The adduction–abduction activity of the interossei is based through the axis of the second toe, making this toe the least mobile at the metatarsophalangeal joints. Tendons of the tibialis posterior and the peroneus longus are considered part of the fourth layer **(see Fig 4).**

a

b

Figure 4: the fourth layer of foot muscles adapted from**(Paulsen, 2019)**

The dorsum of the foot contains two muscles – the extensor digitorum brevis and extensor hallucis brevis. These muscles perform accessory toe extension function to the extrinsic toe extensors. The loss of these muscles does not significantly affect toe extension or impede ambulation. The extensor digitorum brevis extends the second through fifth toes while the extensor hallucis brevis extends the great toe. The extensor digitorum brevis receives its blood supply from the lateral tarsal artery, a branch off the dorsalis pedis. The extensor digitorum brevis is a useful muscle flap for small skin defects of the proximal foot and ankle. It can also be used as joint interposition to prevent fusion in nearby tarsal joints (e.g., calcaneonavicular bar)**(Kleiber, 2018)**

c. Planter fascia anatomy and histology:

Planter fascia (plantar aponeurosis) is a strong connective tissue structure that helps maintain the longitudinal arch of the foot besides absorbing forces placed on the foot across the mid-tarsal joints. Planter fascia consists of three bundles:

1) **Central bundles (CP):** (thickest bundle) and it thickness more proximally than distally. It originate from the medial tubercle of the calcaneus and extends distally becoming wider and covering the plantar surface of the flexor digitorum brevis muscle. Distally, it divides into five digitations that insert into the five metatarsophalangeal joints
2) **Medial bundles (MP):** (thinnest one). It arises from the middle of the central bundle and covering the plantar surface of the abductor hallucis muscle and inserts into the capsule of the first metatarsal joint
3) **Lateral bundles (LP):** also it thickness more proximally than distally. It originate from the lateral margin of the medial calcaneal tubercle and covering the plantar surface of the abductor digiti minimi muscle and inserts into the capsule of the fifth metatarsal joint **(see Fig 5)(Stecco et al., 2013)(Draghi et al., 2017)(Chen et al., 2014)**

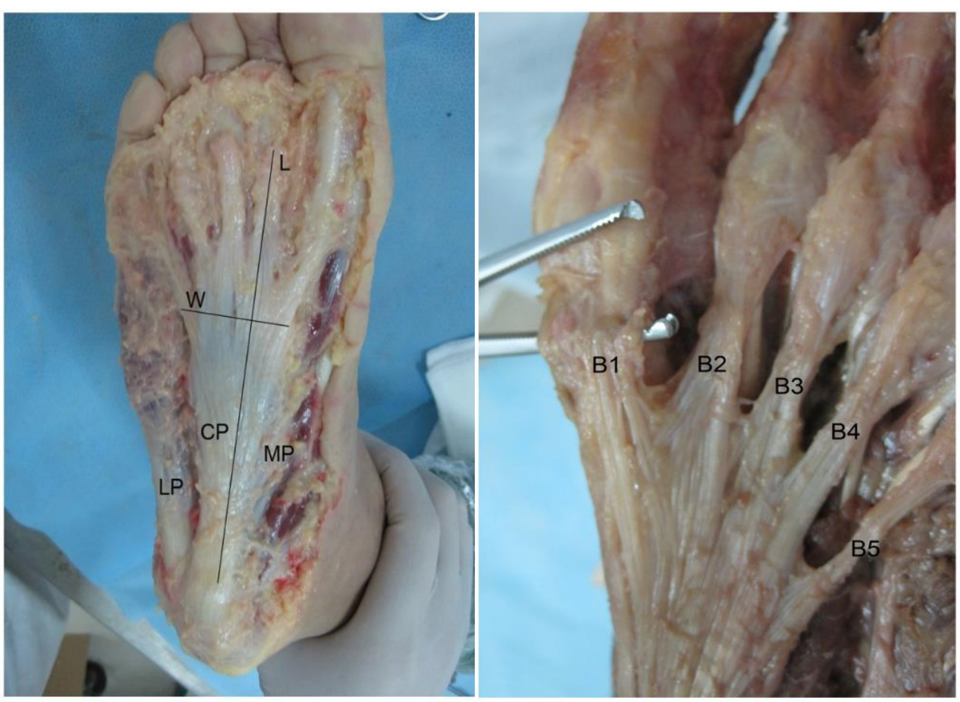

Figure 5 *:* on left Axial view of the plantar aponeurosis. LP, lateral part; CP, central part; MP, medial part; L, length; W, width. On right five central part central bundle adapted from **(Chen et al., 2014)**

Stecco et al., Claim very important facts about the histological and anatomical future about planter fascia. The planter fascia was:

1. Planter fascia closely connected with paratenon of Achilles tendon than to the Achilles tendon; through the periosteum of the calcaneus confirm the idea that the calf muscle problems can participate in planter fascia pathology **(See Fig 6).**
2. Planter fascia has important role the foot sense of proprioception and that because it is rich in nerve endings and Pacini and Ruffini corpuscles were present, particularly in the medial and lateral portions, and on the surface of the muscles.
3. Planter fasciitis can be treated by injection of hyaluronic acid (hyaluronan) because the normal planter fascia rich in Hyaluronic acid, probably produced by fibroblastic-like cells described as 'fasciacytes'. **(Stecco et al., 2013).**

Figure 6: continuity of Achilles tendon paratenon with planter fascia.
Adapted from **(Stecco et al., 2013).**

d. Calcaneal spur and planter fasciitis:

A Calcaneal Spur is an osteophyte outgrowth just medial process of calcaneal tuberosity. Calcaneal Spur affects the resting & activity pain and ankle muscle strength of patients suffering from this condition **(Büyükturan, 2017).**Moreover, some authors define it as projections of more than 1 or 2 mm, while others use microscopy or subjective assessment **(Kirkpatrick et al., 2017)**

The prevalence of calcaneal spur among difference ethnicities approximately the same; in the young to middle-aged population calcaneal Spur occurrence is 11–21%. However, this rate increases with age to 55% in those over 62, to 59–78% in those with current or previous heel pain, and up to 81% in those with osteoarthritis **(Kirkpatrick et al., 2017)**

Calcaneal Spur developed on calcaneal tuberosity that located on the posterior plantar surface of the calcaneus. The majority of PCS arise from the medial process of the tuberosity, but they can also originate from the lateral processes and the sulcus **(see Fig. 7)(Kirkpatrick et al., 2017)**

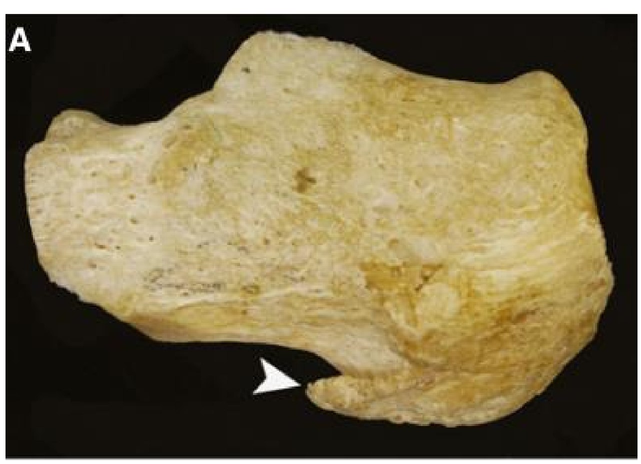

*Figure 7:*calcaneal spur in real bone adapted from **(Kirkpatrick et al., 2017)**

Calcaneal spurs have been recorded in 45% to 85% of patients with plantar fasciitis but also in 10% to 63% of asymptomatic controls. Moroney et al., reported that plantar calcaneal spurs affects more women, higher BMI ,abnormal foot biomechanics. and elderly. In addition to that, they susceptible four times higher than peers for diabetes mellitus and ten time higher for osteoarthritis **(Moroney et al., 2014).**

However, Plantar fasciitis is an abnormal degenerative inflammatory condition in which plantar fascia became shortening by changes in the collagen matrix of the plantar fascia, which progresses to accompanied by pain and functional changes of gait **(D'Andréa et al., 2009)**

The cause of plantar fasciitis is multifactorial. Biomechanical risk factors include those causing repetitive stress on the planter fascia, such as foot abnormalities, inappropriate footwear, and obesity, activities that involve prolonged standing, walking or running **(Draghi et al., 2017).**

Menz et al., investigate the correlation between calcaneal spur and fascial thickening and found that it is commonly to be coexisted in about (30%) of cases. while calcaneal spurs without fascial thickening were found only on (4%) cases. In fact, The histological studies suggest that fascial thickening may trigger the development of the spur, and that spur formation may be a protective mechanism to reinforce the enthesis against further damage from compressive loads **(Menz et al., 2019).**

However, some author contradict that and mention that the majority of calcaneal spurs founded deep to the planter fascia and surrounded by fibrocartilage. They postulated to function as an adaptive response to redistribute the forces away from the calcaneal insertion site to the surrounding tissues via a reinforcement effect. The calcaneal spur trabecular pattern is consistent with a vertically oriented ground force vector and is in agreement with key associations listed above, i.e., obesity, age, and alterations in foot structure, all factors that control the heel pressure **(Kirkpatrick et al., 2017)**

Moreover, Moroney et al., concluded that the calcaneal spur and planter facilities are separated phenomena and planter heal pain patient can be complain from spur, fasciitis or both. In addition, Li and Muehleman have documented that the trabeculae within these calcaneal spurs are not oriented in the direction of soft-tissue traction but rather in a vertical orientation **(Moroney et al., 2014).**

Li & Muehleman et al., the calcaneal Spur may be closely associated with any intrinsic muscle on the first layer of the foot which consists of the abductor hallucis (AH), flexor digitorum brevis (FDB) and abductor digiti minimi (ADM); The second layer consists of quadratus plantae and it attaches deep to the calcaneal Spur. Tanz (1963) was one of the earliest authors to show that calcaneal Spur can arise from muscle rather than from the planter fascia itself. The FDB attaches to the medial process of the calcaneal tuberosity or the apex of the calcaneal Spur if present, anterior and superior to the attachment of the planter fascia (Forman & Green, 1990). The FDB inserts into the periosteum of the calcaneal Spur along with the planter fascia in (22%) of cases, most commonly at the spurs distal tip and inferior aspects (14%), but also at the superior aspect 8% **(Li & Muehleman ., 2007)**

The calcaneal Spur is oriented along the axis of the planter fascia and FDB approximately half of the time Abreu et al., The ADM also attaches directly to the calcaneal Spur, although not as extensively as the FDB does; the calcaneal Spur is aligned with the ADM 20–50% of the time (Smith et al. 2007). The AH arises just medial to the FDB origin and has been hypothesized to contribute to calcaneal Spur formation (Forman & Green, 1990). calcaneal Spur have also been shown to arise from around the calcaneal insertion point of the long plantar ligament **(Smith et al., 2007) (Abreu et al., 2003) (Kirkpatrick et al., 2017)**

Factors which may be important in determining whether a given calcaneal spur will cause an individual heel pain include the size of the spur, whether there is compression of the inferior calcaneal nerve, spur factures, concurrent inflammation, fat pad abnormalities or degeneration, and the individual's occupational environment **(Kirkpatrick et al., 2017).**

Irving, et al. researched the risk factors associated with chronic heel pain in a systematic review. They included 16 papers and found that the age and Body mass index (BMI) were correlated to the incidence of calcaneal Spur **(Büyükturan, 2017).**

There is also evidence that certain individuals have a genetic predisposition to generate new bone and undergo osteogenesis at levels of mechanical stress, which are not sufficient to initiate bone growth in others. This more supported by association between increase incidences of osteoarthritis ten folds in calcaneal spur patients **(Kirkpatrick et al., 2017).**

2. Extracorporeal Shockwave therapy (ESWT):

Valchanou and Michailov were the first to use the (ESWT) to treat musculoskeletal conditions in 1991. (ESWT) is an acoustic wave characterized by high positive pressures of more than 1000 bar (100 MPa), which can be developed within an extremely short rise time (10^{-9} seconds) and followed by a low-pressure phase of tensile stress equivalent to 100 bar (10 MPa). Because the pulse duration of the Shockwave is extremely short (**3 to 5 µs**) and is generated at low frequencies, it is minimally absorbed by the tissues and therefore no thermal effect is generated **(Bonder et al., 2003).**

Sound waves (or Pressure waves) are oscillating mechanical waves that can travel through gas, liquids and solids. A Shockwave is a non-linear special type of pressure wave, characterized by a short rise time. The total duration of a Shockwave is around **10** µs. Shockwave has positive and negative phase. During the positive phase (pressure phase) , Shockwave with high pressure pass and gradually become absorbed. However, Shockwave may hit an interface & reflected. On other side, the negative phase (tensile phase) of the Shockwave causes cavitation at the tissue interfaces. During cavitation, air bubbles may be formed because of the negative pressure. These bubbles subsequently collapse with high speed, generating an additional wave of Shockwave or micro jets of fluid. **(van der Worp et al., 2013) (Vulpiani et al., 2015)(Tyagi & Chuang., 2018)(López-Marín et al., 2017)**

Many of the physical effects of Shockwave therapy considered dependent on the energy delivered to an area. The concentrated Shockwave energy per unit area, the energy flux density,(EFD), measured in (mJ/mm^2), is a term used to reflect the flow of Shockwave energy in a perpendicular direction to the direction of propagation and is taken as one of the most important parameters of Shockwave dosage. There remains no agreement as to the definition of 'high and 'low' energy ESWT, but as a guideline, low- energy ESWT is EFD ≤ 0.12 Mj/mm^2 (4 bar), and high energy is > 0.12 mJ/mm^2 (4 bar) (to convert between bar and Mj/mm^2 see Tab 1) **(Speed, 2014)**

However, Change K et al., claim that intensity of energy flux density divided into three category and recommend the highest intensity is more effective in pain relief:

a. Low intensity(L-FSW) (energy flux density= < 0.08mJ/mm^2)

b. Medium intensity(M-FSW) (energy flux density = 0.08 - 0.28mJ/mm^2)

c. High intensity (H-FSW) (energy flux density = ≥ 0.28mJ/mm^2)**(Chang et al., 2012)**

Moreover, another classification for energy density by wang et al.,:

1. low- (energy flux density <0.1 mJ/mm^2)
2. medium- (energy flux density: 0.1–0.2 mJ/mm^2)
3. high-energy (energy flux density ≥0.2 mJ/mm^2)**(Wang et al., 2019)**

Table 1: *conversion from bar to Mj/mm*

Bars	**Mj**	**Mj/mm^2**
2	**90**	**.09**
3	**120**	**.12**
4	**150**	**.18**
5	**180**	**.38**

The most important physical parameters of Shockwave therapy for the treatment of orthopedic disorders include the pressure distribution, energy flux density and the total acoustic energy **(Wang, 2012).**

a. Shockwave versus ultrasound:

Extracorporeal Shockwave and ultrasound waves are sound waves with different characteristics. Shockwave pattern is Uniphasic and characterized by initial rise of a high peak pressure, up to **50** MPa (**500** bar) within **10** nanoseconds, followed by low tensile amplitude, up to **10** MPa with a broad frequency spectrum in the range of **16** to **20** MHz While ultrasound waves are typically biphasic and have a peak pressure of **0.5** bar. However, the peak pressure of Shockwave is approximately **1000** times that of ultrasound wave. **(Vulpiani et al., 2015)(Wang, 2012).**

Sound waves (or Pressure waves) are oscillating mechanical waves that can travel through gas, liquids and solids. While a Shockwave is a non-linear special type of pressure wave **(see Fig. 8),** characterized by a short rise time around 10 μs. Shockwave have positive and negative phase. During the positive phase (pressure phase), Shockwave with high-pressure pass and gradually become absorbed. On other side, the negative phase (tensile phase) of the Shockwave causes cavitation at the tissue interfaces. During cavitation, air bubbles may be formed because of the negative pressure. These bubbles subsequently collapse with high speed, generating an additional wave of Shockwave or micro-jets of fluid. **(van der Worp et al., 2013)(Tyagi & Chuang, 2018).**

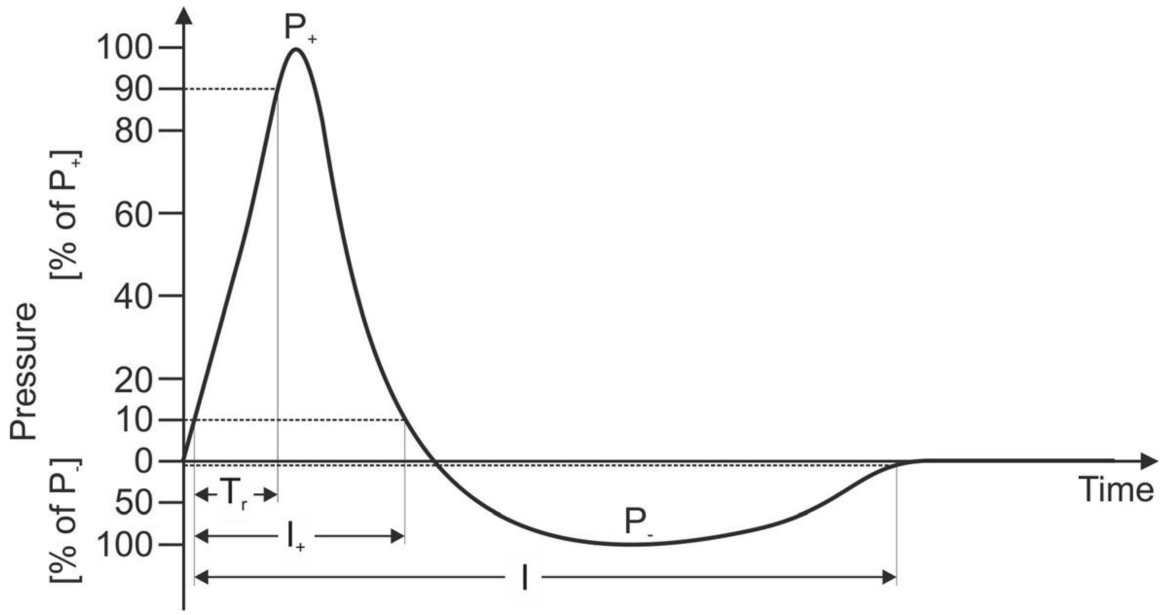

Figure 8 *:* form of shockwave adapted from **(Schmitz et al., 2013)**

b. Types of Shockwave:

1. **Focused Shockwave therapy (FSWT):** single acoustic pulses are generated with either a spark gap (electrohydraulic principle), a technology similar to a loud speaker (electromagnetic principle) or piezocrystals (piezoelectric principle).
2. **Radial Shockwave therapy (RSWT**): represent an alternative to FSWT and produced ballistically by accelerating a bullet to hit an applicator, which transforms the kinetic energy into radially expanding acoustic impulses. In another word, a projectile is fired within a guiding tube that strikes a metal applicator placed on the skin. The projectile generates stress waves in the applicator that transmit pressure waves into tissue **(see Fig 9) (Schmitz et al., 2015)(Contaldo et al., 2012)**

Moreover, if there are any disturbance at the pathway of FSWT it is will disturb the acoustic wave pathway and consequently, weakening the Shockwave energy (i.e. the energy flux density) at the target. The same disturbances would not influence the energy of radial Shockwave at the target. This is probably the cause why in muscle tissue, the energy of focused Shockwave decreased by >50% compared with measurements in water, whereas for radial Shockwave, measurements in muscle tissue and water were the same.**(Schmitz et al., 2015) (Wang, 2012)(Frairia & Berta 2011).**

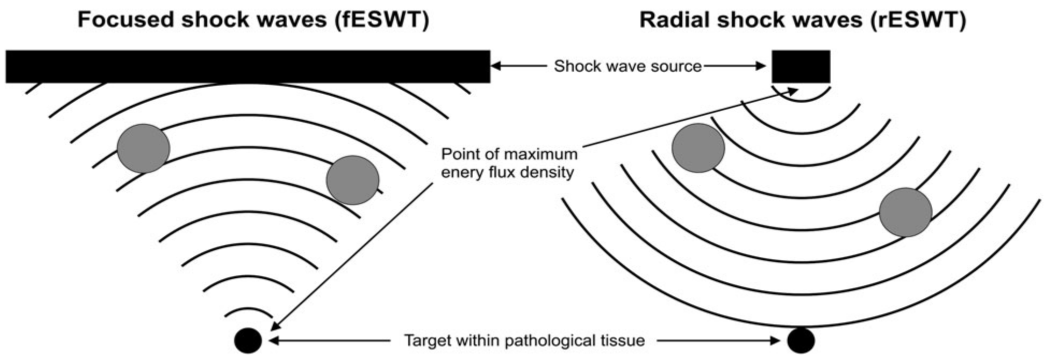

Figure 9 *Types of Shockwave, gray dotes is an obstacle like calcification in muscles. Adapted from* ***(Schmitz et al 2015)***

c. **Method of generation of Shockwave:**
   Two types of Shockwave generation:

1. **Focused Shockwave therapy (FSWT):** High- energy extracorporeal Shockwave that has been used to treat urolithiasis, the formation of stone in the bladder or urinary tract. There are three different types of energy sources classically generated:
   - **Electrohydraulic method:** in which device contains tips of two electrodes submerged in a fluid, when voltage is applied the fluid is vaporized which causes rapid expansion in the surrounding fluid which in turn lead to Shockwave propagation **(see Fig. 10A).**
   - **Electromagnetic method:** in which device contains a coil rounded around metallic membrane. Because of that, Electromagnetic filed will generated when high voltage current pass through the metallic membranes. Moreover, that lead to fluid

disturbance and corresponding Shockwave propagation **(see Fig. 10B).**

- **Piezoelectric method:** in which device contain large number of Piezo electrical plates are embedded into a bowel shaped device and submerged in a medium; when voltage is applied to the piezoelectric effect occur, expansion and contraction of plates, , which in turn induces a mechanical disturbance in the medium and resulting in Shockwave propagation **(see Fig. 10C).**

3. **Radial Shockwave therapy (RSWT)** : Low energy extracorporeal Shockwave (LESW) that had been used recently to treat a different musculoskeletal condition like, Calcaneal Spur, Shoulder impingement, Trigger point release…etc. there are two method of production by using magnetic field or compressed air (pneumatic principle) accelerating a projectile, using compressed air, through a tube on the end of which an applicator is placed. The projectile hits the applicator and the applicator transmits the generated pressure wave into the body **(see Fig. 10D). (Katzet al, 2020) (Wang, 2012)**

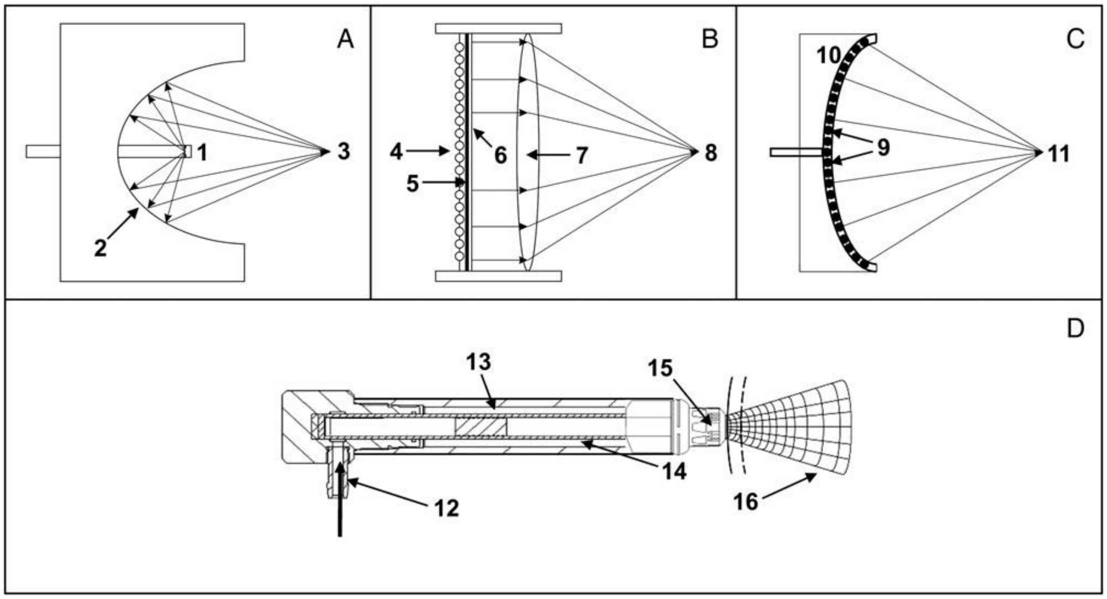

Figure 10: Schematic representation types of FSWT (A–C) and RSWT (D) generators. (A) Electrohydraulic principle: two electrode tips (spark-gap) (1) reflectors (2), convergent/focused point (3). (B) Electromagnetic principle: a coil (4). metal membrane (5), an adjacent membrane (6) an acoustic lens (7) convergent/focused point (8). (C) Piezoelectric principle: piezocrystals (9) a bowl-shaped device (10); convergent/focused point (11). (D) Ballistic principle (RSWT): compressed air (pneumatic principle; 12) a projectile (13) a guiding tube (14) a metal applicator (15) transmition pressure waves into tissue (16) Adapted from (Schmitz et al 2015)

e. Focused Shockwave therapy versus radial Shockwave therapy:

Radial Shockwave therapy more superficial than Focused Shockwave therapy but have been shown to be effective for treating musculoskeletal disorders that are more superficial, with clinical results that are similar to those of focal Shockwave **(D'Andréa et al., 2009)**

In a systemic review done by speed C in which the author investigated the evidence base for the use of these modalities. The result showed evidence for the benefit of FSWT and of RSWT or radial pulse therapy (RPT) in a number of soft tissue musculoskeletal conditions, and evidence that both treatment modalities are safe. **(Speed , 2014)**

There are two significant variances in wave characteristics between RSWT and FSWT. **First**, RSWT have a more superficial effect, compared to FSWT, which reach a maximal energy in the focus in deeper body tissues. It was shown that a RSWT device generates a pressure field extending to 40 mm in water, whereas the pressure field generated during FSWT may reach a distance that is about twofold as high. How these measures relate to biological tissue is unknown. These measures are also dependent on the device that is used and the energy setting. Overall, FSWT will travel further and have more impact on deeper body tissues. **Second**, research has shown that pressure waves generated by RSWT from a fundamental point of view cannot be called Shockwave because they lack the characteristic physical features of Shockwave such as a short rise time, a high peak pressure and nonlinearity **(van der Worp et al., 2013).**

Moreover, Radial extracorporeal Shockwave therapy (RSWT) is extensively used as a non-invasive treatment of various musculoskeletal disorders. Several studies discuss the mechanisms of RSWT on cellular and molecular level which include the mediation of cell apoptosis, enhanced angiogenesis and wound healing as well as new bone formation. The working principle of RSWT devices is illustrated in **(Fig 10D)**. For the reason that radial Shockwave are not like Shockwave in the strict physical properties, some researchers called RSWT "radial pressure wave treatment (RPWT)" **(Contaldo et al., 2012)** , "radial pulse therapy (RPT)" **(Speed, 2014)**, **"**low-energy radial- pulsed–activated (EPAT) Shockwave (sound wave)**" or "**Acoustic Wave Therapy (AWT)**" (Császár et al., 2015).**

Furthermore, conflicting reports exist in the literature as to whether at all radial extracorporeal Shockwave (RSWT) can generate cavitation, which refers to the rapid formation, expansion, and forceful collapse of vapor bubbles in liquids subject to rapid pressure changes. Cavitation exerts important therapeutic bioeffects; also produce unwanted side effects including hematomas, blood vessel rupture, and permanent injury to organs such as kidneys and lungs. In this respect an early review about ESWT published in 2003, 2006, 2015 concluded that RSWT devices were in fact capable of generating cavitation. In conclusion, FSWT & (RPWT) or (RSWT) produce cavitation activity which is limited to the area of the applicator head in RSWT applicators .**(Contaldo et al., 2012)(Császár et al., 2015).**

d. Mechanism of Shockwave therapy:

The mechanism of action of Shockwave in human still unclear. It speculated that ESWT could induce analgesics effect via excitability of the axon and destroy unmyelinated sensory fibers. However, many authors suggest that when shockwave pass human tissues. It speculated that four biological stages occurs. The first stage is the direct physical (mechanical) impact of the shockwave, which lead to extracellular cavitation, ionizes the particles and increase of membrane permeability. The second stage is the physical-chemical stage. This includes the connection of diffusible radicals with biomolecules from stimulated cells. ESWT may influence lysosomes and mitochondria, and interfere with cell metabolism. The third stage is the chemical stage, which may be accompanied by intracellular reactions and molecular changes in actual cells. A high temperature is grown locally during cavitation, which prompts the development of radicals. The fourth stage is the biological stage . Physiological responses take place in this stage when the changes from the chemical phases persist. These four stages include the most important biological effects of shockwave **(Wang et al., 2019)(Frairia & Berta, 2011)(Tyagi & Chuang, 2018).**

f. Shockwave and cell permeability:

Shockwave characterized by discontinuous changes in pressure, temperature, and density of the medium in which they applied. When Shockwave applied on lipid bilayer membranes, the high particle velocity induced by the Shockwave pulse can disrupt and displace the lipid molecules and temporarily increase the membrane permeability. Application of shockwave has been proven to increase permeability of the lipid bilayer allowing for delivery of drugs into the cell **(Kfoury et al., 2019).**

Molecular dynamics simulations demonstrated that the shockwave initially hits the membrane and followed by a Nano jet produced by the collapse of the nanobuble, which formed due to acoustic micro cavitation effect. Because the pressure acting on the bubble from the outside is generally not homogeneous, its collapse, resulting in the development of a fluid micro jet into the cell membrane along the direction of shockwave propagation. Therefore, LESW results in reversible permeabilization of cells in targeted tissue, and can deliver molecules of up to 2,000,000 molecular weight into the cytoplasm of cells. The ability to deliver macromolecules of large molecular weight by cell permeabilization **(see Fig 11)(Tyagi & Chuang, 2018)(Li et al., 2013).**

Kodama et al. suggested that Shockwave could cause shear force generated because of liquid movement relative to the cells, which temporarily affect plasma membrane permeability. The pressure impulse (which is defined as the integral of the pressure over a time interval), rather than the peak pressure of the Shockwave, plays an important role in increase permeability for delivering macromolecules into cells **(Kfouryet al., 2019)**

López-Marín et al., study show that membrane poration by Shockwave is critically dependent on the collapse of nano bubble formed due to acoustic micro cavitation effect. Two dimensional pressure maps revealed that even distribution of the shock pressure along the lateral area of the membrane is disturbed by the nanobuble, which leads to the membrane poration. The size of the pore formed depends on shockwave velocity, pressure waveform, Energy flux density and shockwave duration **(Tyagi & Chuang, 2018).**

The positive peak pressure of Shockwave is considered to affect the material based on the plasticity nature of the material and recent study on immortalized cell line and tumor derived cell line reported differences in membrane permeabilization of two cell lines. Researches used scanning electron microscopy to report that shockwave induced transient deformations at the cell membrane. Cell size decreased and hole like structures noted after shockwave application. Trypan blue dye exclusion test indicated that cell membranes were poration by shockwave application but resealed after a few seconds. Deformations of the cell membrane lasted for at least 5 min, allowing their observation in fixed cells. the mechanisms for shockwave mediated membrane permeability are still poorly understood **(López-Marín et al., 2017).**

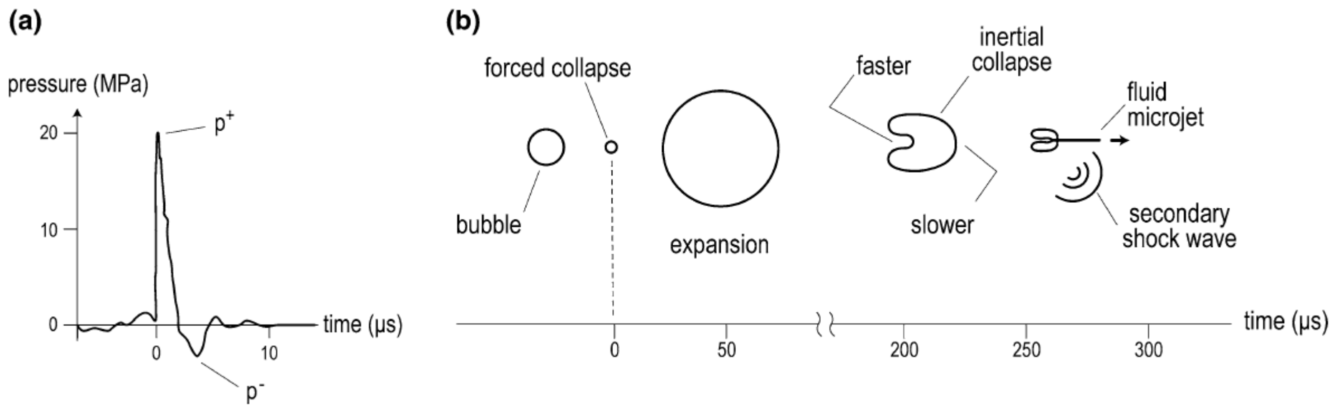

Figure 11 Typical pressure waveform of a shockwave as used in some biomedical applications (a) and schematic diagram of the dynamics of an air microbubble in fluid subjected to the passage of a shockwave (b). The positive pressure peak compresses the bubble at time= 0. Once the shockwave has passed, the bubble expands and collapses. adapted from **(López-Marín et al., 2017)**

g. Shockwave and calcaneal spur:

The primary effect is the direct mechanical forces that result in the maximal beneficial pulse energy concentrated at the treatment site. in addition to that, the secondary effect is the indirect mechanical forces by cavitation, which may cause negative effect or damage to the tissues which can help in calcaneal spur destruction **(Wang, 2012)(Frairia & Berta, 2011) (Schmitz C et al., 2013)**

Xian Li et al., conducted meta-analysis research compared the effectiveness of eight modalities for treating plantar fasciitis (Shockwave therapy), both Intracorporeal pneumatic shock therapy (IPST) and extracorporeal shock therapy (FSWT (3 groups low, medium, high energy flux density), RSWT), Low level LASER therapy, Ultrasound therapy (US), and noninvasive interactive neurostimulation (NIN) ultrasound-guided pulsed radiofrequency (UGPRF) treatment were included. The therapies compared these modalities with each other or with a sham group. Regarding the three follow up effectiveness time points, RSWT provided relatively more effective and stable pain relief compared with other modalities. Consequently, RSWT is a promising candidate for clinical applications. FSW therapies and US can also be considered treatment candidates. However, H-FSW and UGPRF not recommended **(X. Li et al., 2018).**

3. Calcaneal spur and Acetic acid:

An acetic acid gel is an important component used via ultrasound phonophoresis to treat bone calcification deposits. It is composed of calcium carbonate ($CaCO_3$) which exposed to active acetate radical and replace the carbonate forming the blood soluble calcium acetate molecule Ca(CH3COO)[2] **(Pamplona et al., 2017).**

Shtofmakher G et al., describe that the use of acetic acid as ionized solution to treat insertional Achilles tendonitis (Calcaneal exostoses of the Achilles tendon) pain. They claim that a significant improvement in pain and function as the acetic acid helps to convert exostoses composed of calcium carbonate ($CaCO_3$) to more chemically active acetate radical and replace the carbonate forming the blood soluble calcium acetate molecule ($Ca(C_3H_3O_2)_2$). In another study by Japour et al., they describe that transdermal application of acetic acid through iontophoresis was shown to be an effective conservative treatment modality for heel pain. **(Kilfoil et al.,2014).**

The use of acetic acid iontophoresis treatments for chronic heel pain has shown promising results within 3–4 weeks and over an extended follow up period of greater than 2 years. It has been hypothesized that the physiological responses to chronically inflamed tissue results in higher concentrations of insoluble calcium carbonate to an injured area which contributes to the constant pain cycle and abnormal restructuring of myofascial tissue. The acetate ion in acetic acid combines with the calcium ion in calcium carbonate to form more soluble calcium acetate, see blow chemical equation, which is then able to dissolve within local blood circulation and removed from the site of injury **(Costa & Dyson, 2007)**

$$CaCO_3 + 2H\,(C_2H_3O_2) \rightarrow Ca\,(C_2H3O_2)^2 + H_2O + CO_2$$

CHAPTER III

SUBJECTS, MATERIALS AND METHODS

The current study will conducted to investigate the efficacy of Shockwave phonophoresis on calcaneal spur, this study will conducted at outpatient clinic in faculty of physical therapy at Beni-Suef University, Beni-Suef governorate, Egypt.

1. Design of the study:

Double-blinded pretest posttest randomized control design will used.

2. Subjects:

The age of participant will range from 30 to 65 years. These patients will be allocated from the outpatient clinic in faculty of physical therapy at Beni-Suef University. The purpose, nature and potential risk of the study will be explained to all participant and they will sign a written informed consent prior to participation **(Appendix I).** Forty patients from both gender will be involved in this study and will randomly subdivided into two equal groups in number:

Group (A): (experimental group 1) this group composed of 20 subjects represented the experimental group 1. They will receive 6 sessions acetic acid shockwaves phonophoresis with Time between sessions 5-7 days plus exercise and dietary advice.

Group (B): (experimental group 2) this group composed of 20 subjects and represented the experimental group 2 who will receive 6 sessions of Shockwave plus exercise and dietary advice.

Group (C): (Control Group): This group composed of 20 subjects they will take conventional physical therapy program (Exercise)

3. Inclusion criteria:

Subjects included in this study will having all of the following criteria:

- Heel pain with calcaneal spur.
- Calcaneal spur in lateral calcaneal x-ray.
- Patient's age ranged from 30 to 65 years.
- Body mass index less than 30 Kg/M^2.
- Patients with calcaneal spur.
- Patients with intact sensory perception.
- At least 6 weeks from last corticosteroid injection; 4 weeks from the last local anesthetic injection, iontophoresis, ultrasound, and electrotherapy **(Gerdesmeyer et al., 2008).**

4. Exclusive criteria:

Subjects excluded in this study for any of the following cases:

- History of fracture or surgery of the heel or ankle.
- Presence of inflammatory joint disease.
- Marked osteoporotic patient.
- Presence of ankylosing spondylitis Heart pacemaker use.
- Patient on anticoagulant and coagulation disease.
- Skin wound or ulcers.

5. <u>Martials:</u>

The study materials will divided into two different categories:

a. Evaluative Equipment:

1. X-ray Machine: The best method of assessment of skeletal structure of foot by using radiographic techniques, which considered as the gold standard for assessment bone deformity and alignment of foot in weight bearing position**.** It will used to scan the foot and calcaneus before and after treatment; it consists of operating console of x ray machine, x ray tube, x ray cassette, digital radiography systems and desktop computer with windows operating system to measure the length and width of the calcaneal spur. **(Rajakaruna et al., 2015).**

2. Pressure pain threshold (PPT): A handheld pressure algometry will be used to measure heel tenderness threshold. The threshold is the minimum force required producing the sensation of pain. The PA is a force gauge equipped with a rubber tip and calibrated in kg/cm2 (Model FDX, Algometer, WAGNER instruments, Greenwich, CT) **(Alotaibi et al., 2015).**

3. Visual analogue scale (VAS): are used to express the severity of illness (usually pain) by patients by making a mark determining a decimal number from 0 to 100 (mm) on line with ‘no pain’ to the left and sever pain could be to the right. The subjects rated their perception of pain by making a mark on the VAS line. The distance from the left to the mark will measured and the accuracy will adjusted to one decimal place **(see appendix** III) **(Kamper, 2012).**

4. Foot and Ankle Ability Measure (FAAM): is a self-report measure that assesses physical function of individuals with lower leg, foot, and ankle musculoskeletal disorders. FAAM is assess activity of daily living ADLs (26 items) and sport activity (8 items). **(Irrgang M et al., 2005).** FAAM is a reliable, responsive, and valid measure of physical function for individuals with a broad range of musculoskeletal disorders of the lower leg, foot, and ankle **(see appendix II) (Martin et al, 2005).**

b. Therapeutic Equipment:

1. Shockwave apparatus: Gymna Shockmaster 500 device will be used in this study. This device is a radial shockwave device, pneumatically generated and composed from **(Fig12):** Device Shockmaster 500, Communicating Wire between applicator and device, Hand piece applicators that is light ergonomically well design hand piece applicator, D-Actor 20 mm applicator and Trolley Shockmaster 500. The device allow variability in the setting with Frequency range 0,5 - 21 Hz and Pressure range 0,3 - 5 bar.
2. Acetic acid gel: 5% concentration acetic acid gel form will be applied to the foot as a coupling media instead of ultrasound gel between the applicator and the body surface **(Pamplona et al., 2017).**
3. Exercise program: designed to adjust foot mechanics by stretch tight structure and strength the weak muscles.
4. Advices: Dietary advices and advices to alter calcaneal spur pain.

Figure 12: shockwave apparatus adapted from ***https://gymna.com/en/products/shockwave-therapy/gymna-shockmaster-500***

6. Methods:

A verbal explanation about the important of the study procedure, main aim and conceptual approach will explained to every patient. The procedure of this study will divided into two main procedures:

A. Measurement methods:

Before starting the study, a consent form will be taken from each participant in this study as an agreement to be included in the present study. Each participant will examined medically to exclude any abnormal medical problem, which previously mentioned. Measurement will taken pretest assessment and posttest assessment and post one month follow up as follow:

1. X-ray:

Lateral calcaneal x-ray helps to evaluate bony conditions of the foot for example, Calcaneal spur, calcaneal stress fractures may be visualized on lateral calcaneal and that help in excluding any condition not suitable with this research. Each patient should do at least two x-rays ,one before and another after, computer aided linear measurements will recorded for spur length and width in (mm) from tip to base as defined by a line determining the calcaneal border as described by many authors **(Fig. 13) (Kuyucu et al.,2015)(Büyükturan, 2017) (Gladman et al., 2014)**

Figure 13 : X-ray machine

2. **Pressure pain threshold (PPT):**

The procedure will be explained to the participant prior administration of the algometer and Measurement will be by Wagner base line algometry**.** Then the therapist will instruct the patient to recline in supine position. The investigator will palpate and mark the tender point over the medial tuberosity of the calcareous. After that, therapist will apply the algometry over the mark placed on the medial tuberosity of the calcaneus. The algometer contact head will aligned perpendicularly to the tender point, with the investigator gradually increasing the algometer force until the patient reported pain. The algometer reading will recorded in newton’s. Higher algometer scores indicate greater force tolerance and, thus, less tenderness. Lower algometer readings indicate less force tolerance and, thus, greater heel tenderness. The reliability and validity of the algometer as a subjective outcome measure of tenderness has been supported in various studies **(see Fig. 14). (Wibowo et al ., 2017) (Sangam et al., 2015)(Alotaibi et al., 2015)**

Figure 14 *WAGNER FDX 50 algometer*

3. **Pain intensity level assessment:**
   - Each patient will be instructed to mark his/her level of pain on visual analogue scale. Then, the distance will be measured by ruler in

millimeter (mm) from 0 direction and recorded in patient file. See in Appendix III **(Janusz, 2017).**

4. **Activity of daily living:**

- Foot and Ankle Ability Measure (FAAM) scale will measure disability**:** which is a self-report outcome instrument developed to assess physical function for individuals with foot and ankle related impairments. Patient will choose from (0-4) where zero mean unable to do and four mean no difficulty (see appendix II). This instrument includes two subscales:
  a. Activities of Daily Living (ADLs) subscale of 26 items
  b. Sports subscale of 8 items

B. Therapeutic methods:

1. **Shockwave therapy:**

- The shockwave will be applied for both group:
  a. Group A: Shockwave (with 5% Acetic acid gel).
  b. Group B: Shockwave (with ultrasound coupling medium gel).
  c. Group C: conventional physical therapy program (Exercise).
- Once per week for 6 weeks for Shockwave.
- The intensity of Shockwave adjusted according to highest energy flux density the patient can tolerate. To achieve the best improvement in pain relief, the energy level of ESWT will adjusted to the maximum level that patients can tolerate the pain induced by ESWT
- Application at the most painful sit on Calcaneus.
- Total Energy flow density will calculated (as the product of the number of treatment sessions, the number of impulses per treatment session and the EFD of the impulses)**(Schmitz et al., 2015).**

1. Exercise program:

a. Stretching exercise:

- Standing calf-stretching exercise: stretching gastrocnemius & Soleus and Posterior Tibialis Muscle stretch muscle: In sitting and standing position for 15-30 seconds and Repeat three times.
- Towel stretch: stretching exercise for planter fascia in sitting and standing position for 15-30 seconds (Repeat three times)
- Ice bottle applied as a home advice to stretch intrinsic foot muscles and analgesic effect.

b. Strengthening exercise:

- Some authors suggest that calcaneal length related to the dorsal and plantar flexor muscle strengths, which in turn affect the foot and lead to abnormal loading which increase the susceptibility for injury and pain **(Sonu & Aman, 2015) (Büyükturan, 2017).**
- Towel pickup exercise to strengthen intrinsic muscles of the foot
- Marble pickups exercise: patients will be instructed to collect 10 marbles from ground, by toes, and put it in a bowl and repeat it (3sets).
- Calf raises exercises
- Static and dynamic balance exercise.

2. Advices:

- Advices to alter calcaneal spur pain: rest, modified shoes, modified activity, use ice cubes regularly.
- Dietary advices to decrease gout and adjust body weight.

Data collection:

In this study, data collection will be conducted via data collection sheet and then the data will be collected in large table to form raw data that will be used as base for statistical analysis.

Statistical Analysis:

- All analysis will be carried out using the statistical package SPSS V.25.00 (IBM Corporation).
- Data will be expressed as mean and SD or median (in case of violation of normality) for continuous variables and as percentages for categorical data.
- The Shapiro-Wilks test will be used to test the normality of the data.
- 2-way mixed Design MANOVA will be used to compare the groups for normally distributed data.
- 2-way mixed Design MANOVA will be used to compare the groups for normally distributed data.
- Kruskal Wallis and Mann-Whitney tests will be used to compare the groups for non-parametric and not normally distributed data.
- Age and gender will be considers as an independent variable.
- Pairwise multiple comparisons will be performed using the Bonferroni correction test.
- All tests are two-sided, and statistical significance will be set at $p<0.05$.

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Appendix I
Consent Form

I am\ ....Freely and voluntarily consent to participate in this research study under the supervision and direction of the research\ Mostafa Ali Elwan. A thorough description of the study procedures has been explained to me, and I understand that I may withdraw my consent and discontinue participation in this study research at any time without prejudice to me. Signature of Participant: Date: \ \

Appendix II

Foot and Ankle Ability Measure (FAAM)
Activities of Daily Living Subscale

Please Answer **<u>every question</u>** with **<u>one response</u>** that most closely describes your condition within the past week.
If the activity in question is limited by something other than your foot or ankle mark "Not Applicable" (N/A).

	No Difficulty	Slight Difficulty	Moderate Difficulty	Extreme Difficulty	Unable to do	N/A
Standing	☐	☐	☐	☐	☐	☐
Walking on even Ground	☐	☐	☐	☐	☐	☐
Walking on even ground without shoes	☐	☐	☐	☐	☐	☐
Walking up hills	☐	☐	☐	☐	☐	☐
Walking down hills	☐	☐	☐	☐	☐	☐
Going up stairs	☐	☐	☐	☐	☐	☐
Going down stairs	☐	☐	☐	☐	☐	☐
Walking on uneven ground	☐	☐	☐	☐	☐	☐
Stepping up and down curbs	☐	☐	☐	☐	☐	☐
Squatting	☐	☐	☐	☐	☐	☐
Coming up on your toes	☐	☐	☐	☐	☐	☐
Walking initially	☐	☐	☐	☐	☐	☐
Walking 5 minutes or less	☐	☐	☐	☐	☐	☐
Walking approximately 10 minutes	☐	☐	☐	☐	☐	☐
Walking 15 minutes or greater	☐	☐	☐	☐	☐	☐

Foot and Ankle Ability Measure (FAAM)
Activities of Daily Living Subscale
Page 2

Because of your foot and ankle how much difficulty do you have with:

	No Difficulty at all	Slight Difficulty	Moderate Difficulty	Extreme Difficulty	Unable to do	N/A
Home responsibilities	☐	☐	☐	☐	☐	☐
Activities of daily living	☐	☐	☐	☐	☐	☐
Personal care	☐	☐	☐	☐	☐	☐
Light to moderate work (standing, walking)	☐	☐	☐	☐	☐	☐
Heavy work (push/pulling, climbing, carrying)	☐	☐	☐	☐	☐	☐
Recreational activities	☐	☐	☐	☐	☐	☐

How would you rate your current level of function during you usual activities of daily living from 0 to 100 with 100 being your level of function prior to your foot or ankle problem and 0 being the inability to perform any of your usual daily activities.

__ __ __ . 0 %

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Appendix III

Visual analogue scale: (measurement in mm 0 is no pain & 10 is maximum pain)