"ROLE OF SHEAR WAVE ELASTOGRAPHY IN ASSESSING ACHILLES TENDON IN NORMAL INDIVIDUALS, DIABETIC PATIENTS WITH AND WITHOUT FOOT COMPLICATIONS"

By

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DISSERTATION SUBMITTED TO SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, KOLAR, KARNATAKA

In partial fulfilment of the requirements for the degree of

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IN

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Under the Guidance of

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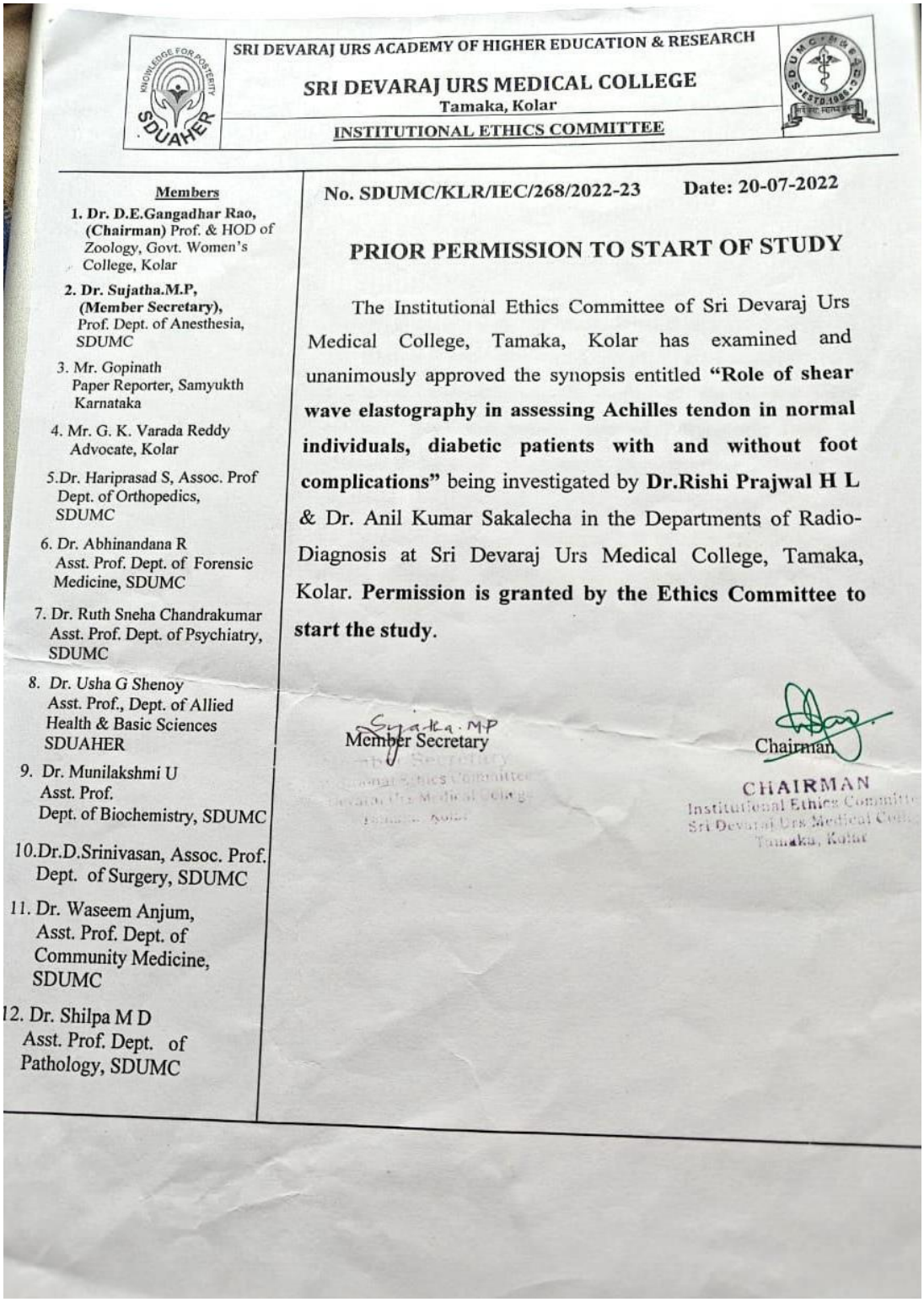

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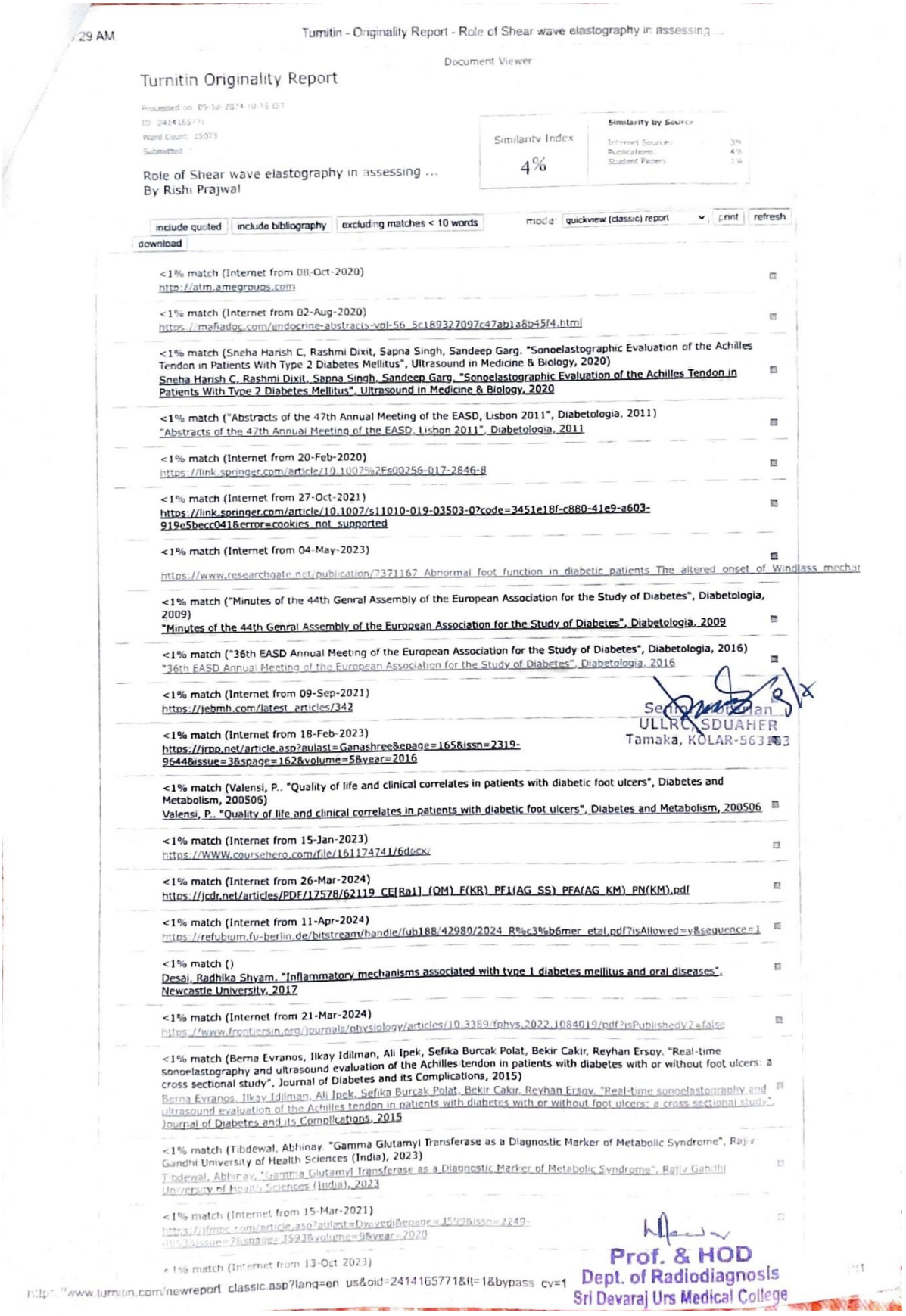

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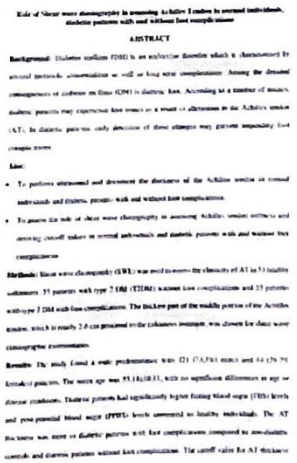

ABSTRACT

Background: Diabetes mellitus (DM) is an endocrine disorder which is characterized by elevated blood glucose concentration as well as long term complications. Among the diverse consequences of diabetes mellitus (DM) is diabetic foot. According to a number of studies, diabetic patients may experience foot issues as a result of alterations in the Achilles tendon (AT). In diabetic patients, early detection of these changes may prevent impending foot complications.

Aim:

- To perform ultrasound and determine the thickness of the Achilles tendon in normal individuals and diabetic patients with and without foot complications.
- To assess the role of shear wave elastography in assessing Achilles tendon stiffness and assessing cut-off values in normal individuals and diabetic patients with and without foot complications.

Methods: Shear wave elastography (SWE) was used to assess the elasticity of AT in 53 healthy volunteers, 55 patients with type 2 DM (T2DM) without foot complications and 25 patients with type 2 DM with foot complications. The thickest part of the middle portion of the Achilles tendon, which is nearly 2-6 cm proximal to the calcaneus insertion, was chosen for shear wave elastographic examination.

Results: The study found a male predominance with 53 (74.6%) males and 54 (76.1%) females in patients. The mean age was 55.14±10.11, with no significant differences in age or distribution conditions. Diabetic patients had significantly higher fasting blood sugar (FBS) levels and post-prandial blood sugar (PPBS) levels compared to healthy individuals. The AT thickness was more in diabetic patients with foot complications compared to non-diabetic controls and diabetic patients without foot complications. The cutoff value for AT thickness

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LIST OF ABBREVIATIONS

DM	Diabetes Mellitus
AT	Achilles tendon
US	Ultrasound
SWE	Shear wave elastography
T2DM	Type 2 Diabetes mellitus
HbA1c	Glycated hemoglobin
MTU	Musculotendinous units
ECM	Extracellular matrix
PF	Plantar fascia
CE	Compression elastography
TE	Transient elastography
VTIQ	Virtual Touch tissue imaging & quantification
ARFI	Acoustic Radiation Force Impulses
ROI	Region of interest
SWV	Shear wave velocity
USE	Ultrasound elastography
FBS	Fasting blood sugar
ATT	Achilles tendon thickness
ATS	Achilles tendon stiffness
RTSWE	Real time shear wave elastography
PPBS	Post prandial blood sugar
PN	Peripheral neuropathy

ABSTRACT

Introduction: Diabetes mellitus (DM) is an endocrine disorder which is characterized by several metabolic abnormalities as well as long-term complications. Among the dreaded consequences of diabetes mellitus (DM) is diabetic foot. According to a number of studies, diabetic patients may experience foot issues as a result of alterations in the Achilles tendon (AT). In diabetic patients, early detection of these changes may prevent impending foot complications.

Aim:

- To perform ultrasound and document the thickness of the Achilles tendon in normal individuals, diabetic patients with and without foot complications.
- To assess the role of shear wave elastography in assessing Achilles tendon stiffness and deriving cut-off values in normal individuals, diabetic patients with and without foot complications.

Methods: Shear wave elastography (SWE) was used to assess the elasticity of AT in 55 healthy volunteers, 55 patients with type 2 DM (T2DM) without foot complications and 55 patients with type 2 DM with foot complications. The thickest part of the middle portion of the Achilles tendon, which is nearly 2-6 cm proximal to the calcaneus insertion, was chosen for shear wave elastographic examinations & thickness calculation.

Results: The study found a male predominance with 121 (73.3%) males and 44 (26.7% females) patients. The mean age was 55.14±10.11, with no significant differences in age or disease conditions. Diabetic patients had significantly higher fasting blood sugar (FBS) levels and post-prandial blood sugar (PPBS) levels compared to healthy individuals. The AT thickness was more in diabetic patients with foot complications compared to non-diabetic controls and diabetic patients without foot complications. The cutoff value for AT thickness

for healthy vs T2DM without foot complications was 7.55mm, with 96.4% sensitivity and 79.4% specificity. The cutoff value for AT thickness for T2DM without vs with foot complications was 8.95mm, with 81.8% sensitivity and 78.18% specificity. The Young's modulus was significantly lower in diabetic patients with foot complications as compared to the other two groups, which implies that the elasticity of AT in patients with foot complications was significantly lower as compared to those diabetic patients without foot complications. A cut-off value of 120 kPa had a very good diagnostic accuracy (AUC = 0.879) to differentiate between the AT stiffness of diabetic patients with foot complications and diabetic patients without foot complications with a specificity of 78.18% and sensitivity of 81.5 %..

Conclusion: Modifications in the structure of AT occurs before the onset of foot complications in diabetic patients. Reduced elasticity & thickening of AT is a reliable marker of impending foot complications in diabetic patients.

Keywords: Diabetes mellitus, Diabetic foot ulcer, Achilles tendon, Shear wave elastography, Diabetic foot complications

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INTRODUCTION

INTRODUCTION

Diabetes mellitus (DM) is derived from the Latin term mellitus, which means sweet, and the Greek word diabetes, which means syphon, to pass through. A historical analysis reveals that Apollonius of Memphis first used the term "diabetes" about 250–300 BC. The term "diabetes mellitus" originated when ancient Greek, Indian, and Egyptian civilizations realised that the urine produced in this condition was pleasant. In 1889, Mering and Minkowski made the discovery that the pancreas plays a part in the pathophysiology of diabetes. Diabetes remains one of the most prevalent chronic illnesses both domestically and globally. It continues to rank as the seventh most common cause of death in the US.[1]

One of the most frequent side effects in individuals with poorly managed DM is diabetic foot ulcers. It is occurs due to inadequate foot care, peripheral vascular disease, underlying neuropathy, or poor glycemic management. It is also a prevalent cause of lower-limb amputations and osteomyelitis of the foot. Most common organism causing infection is Staphylococcus. These ulcers typically appear in the parts of the foot that are subjected to pressure points and recurrent trauma. Since the illness is usually persistent, treating it with an interdisciplinary team will yield the greatest results. Podiatrists, endocrinologists, general practitioners, vascular surgeons, and infectious disease specialists working together is very helpful.

Diabetic foot ulcers have a complex aetiology. Poor management of blood sugar, calluses, foot deformities, inappropriate foot care, ill-fitting shoes, peripheral neuropathy, poor circulation, dry skin, etc. are among the main underlying causes. People who have flat feet are more likely to develop foot ulcers because they bear an uneven amount of stress on different parts of their feet, which can cause tissue inflammation in high-risk areas. Foot ulcer affects around 60% of diabetics.

The biggest tendon in the body, the Achilles tendon (AT), is crucial for mobility in humans. When sprinting, leaping, and hopping, AT bears most stress of the body, extending up to ten times the weight of the body.[1] Structural alterations and reduced stiffness of AT in individuals with diabetes may raise the foot stress and hasten the development of diabetic foot. In clinical practise, it is simple to assess the thickness and stiffness of the AT in patients with diabetes because of its superficial nature. [2,3]

Achilles tendinopathy can be challenging to treat & rehabilitate, and the outcomes are frequently disappointing. Doctors use ultrasonography to diagnose the illness and anticipate the onset of symptoms. However, it could be challenging to detect tendon alterations if subjective qualitative conclusions based only on operator-influenced ultrasonography pictures are used. The mechanical and material characteristics of the tendon may be quantitatively investigated due to new technologies like elastography.[4]

Numerous studies have demonstrated an increase in AT thickness in diabetic patients. However, there is conflicting information about stiffness.[5] While ultrasound (US) may be used to measure the mechanical properties of soft tissue, its applicability to tendons is restricted.[6] Shear Wave Elastography (SWE) has been proposed as a viable technique to measure tissue stiffness in a number of recent research.[7] A single shear wave can be produced throughout the tissue by the US probe in SWE. When compared to quasistatic elastography, the SWE gathers velocity data while traversing soft tissue, allowing for the calculation of the elastic modulus.[8]

Limited studies have been carried out thus far to determine the usefulness of the SWE of AT. Hence our study is aimed to evaluate the SWE in assessing AT stiffness and deriving cut-off values in normal individuals and diabetic patients with and without foot complications.

AIMS & OBJECTIVES

AIMS AND OBJECTIVES

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- To assess the role of shear wave elastography in assessing Achilles tendon stiffness and deriving cut-off values in normal individuals, diabetic patients with and without foot complications.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

DM is a complex chronic disease characterised by metabolic abnormalities and long term complications. Type 2 Diabetes mellitus (T2DM) often manifests later in life, obesity in teenagers has contributed to a rise in T2DM in younger groups. Among the US population, the prevalence of type 2 diabetes is around 9% overall, but it is closer to 25% among people over 65 years of age. According to estimates from the International Diabetes Federation, 1 in 11 individuals worldwide aged 20 to 79 had DM in 2015. By 2040, experts project that 415 million people worldwide will have DM, with the majority of this growth occurring in populations moving from low to middle-income levels.[9] T2DM is 2–6 times more common among Blacks, Native Americans, Pima Indians, and Hispanic Americans than among white people in the United States, depending on the ethnic group.[10,11] Environmental variables can considerably increase the incidence of T2DM, even though ethnicity alone plays a significant role in the condition.[12]

Since several causes can frequently contribute to the condition, the pathophysiology of DM may be ambiguous. Hyperglycaemia can affect insulin secretion and pancreatic beta-cell function. As a result, it creates a vicious loop that impairs metabolic function. In this setting, blood glucose levels exceeding 180 mg/dL are frequently regarded as hyperglycaemic; however, due to the multiplicity of processes involved, a precise cut-off threshold is unknown. Higher blood glucose levels cause the nephron's glucose transporters to become saturated, which causes osmotic diuresis in patients. Serum glucose levels exceeding 250 mg/dL are likely to elicit symptoms of polyuria and polydipsia, although the impact varies.

Excess fatty acids and proinflammatory cytokines cause insulin resistance by impairing glucose transport and speeding up the breakdown of fat. The body reacts to

insufficient insulin responsiveness or synthesis by mistakenly raising glucagon levels, which exacerbates hyperglycaemia. Although insulin resistance is a part of type 2 diabetes, the disease's full impact occurs when the patient's insulin production is insufficient to offset their insulin resistance.

Chronic hyperglycaemia causes no enzymatic glycation of proteins and lipids. The glycated haemoglobin (HbA1c) test can be used to determine how much of this is present. Damage to tiny blood vessels in the kidney, retina, and peripheral nerves is caused by glucose. This harm results in the avoidable consequences of blindness, dialysis, and amputation, as well as the traditional diabetes sequelae of diabetic retinopathy, nephropathy, and neuropathy.[13]

One of the most frequent side effects for individuals with poorly managed DM is diabetic foot ulcers. There are more admissions due to diabetic foot ulcers than any other diabetes condition. In all, 5% of diabetic individuals get foot ulcers, and 1% have to have their feet amputated.[14] Between 9.1 and 26.1 million diabetic foot ulcers occur worldwide each year.[15] The frequency of diabetic foot ulcers is certain to rise in tandem with the annual rise in the number of people diagnosed with the disease.

Diabetes-related foot ulcers arise from a combination of factors. Pathophysiology can be divided into four primary branches: infection, ischemia, neuropathy, and nutritional failure. Peripheral vascular disease makes a foot less resistant to infection and ulceration than a well-perfused foot. Autonomic neuropathy in diabetics makes this problem even more difficult by decreasing the effectiveness of perfusion. This is because it lowers the recruitment of capillaries and the flow of blood through capillary beds. Neuropathy results in the loss of sweat and oil glands, which promotes dry, cracked skin and a weakened neuroinflammatory reaction to painful stimuli. Furthermore, AT stiffening puts more strain on the forefoot and can result in foot abnormalities (hammer and claw toes).[16-18]

Diabetes-related foot sores need intensive care. When danger is found, patients should be assessed for risk factors and are recommended for diabetic footwear. The most significant pathogen in diabetic foot infections is Staphylococcus aureus, but as the infection gets deeper and more severe, it becomes polymicrobial. For reversible peripheral vascular disease, surgery is recommended. Debridement of callouses and maintenance of a moist wound healing environment are necessary. Total contact casting and AT lengthening promote recovery and reduce the chance of recurrence. In cases of gangrenous ulcers, hyperbaric oxygen therapy is recommended to promote healing and avoid amputation.[19]

Anatomy and Physiology of Achilles Tendons (AT)

Tendons are a kind of soft tissues found in the human body. Their primary roles are to transfer high tensile stresses with little distortion and to release stored energy during locomotion through the process of elastic recoil.[20,21] Tendons function as biological springs that when stretched, store and release energy to aid in locomotion.[22] They account for 52–60% of the effort done during locomotion.[23]

AT is the thickest, largest and strongest tendon in the human body. The tendon is formed by the merging of fibers of the gastrocnemius and the soleus muscles (triceps surae), forming the tendon that inserts into the postero-superior aspect of the calcaneus.[24] The triceps surae muscles generate movement around the ankle joint by transmitting force to the adjacent calcaneus through the AT. Three distinct muscle compartments that integrate aponeuroses into the common AT are part of the triceps surae anatomy: the medial gastrocnemius, lateral gastrocnemius, and soleus (as described in figure 1 and 2).[25,26]

Different muscles might contribute to the pressure encountered by the free AT due to the unique architecture of the triceps surae.[25] physiological cross-sectional area of each muscle is responsible for the proportionate stress contribution from the gastrocnemii and soleus muscles. The soleus, lateral and medial gastrocnemius muscles combine to generate distinct fascicles that comprise the AT. The gastrocnemius's medial head is where the superficial fibres begin, while the lateral head is where the deep fibres begin.[27,28]

Musculotendinous Units (MTUs) generate force, store energy, and stabilise joints to permit and support movement.[29,30] Plantar flexion of the ankle results from the concentric contraction of gastrocnemius-soleus complex, applying stress to the ground to propel oneself forward.[31]

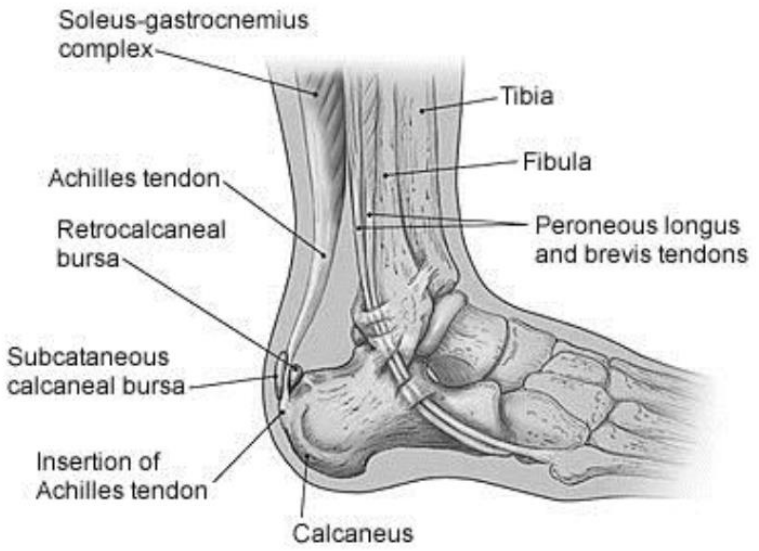

Figure 1: Image showing Achilles Tendon Anatomy

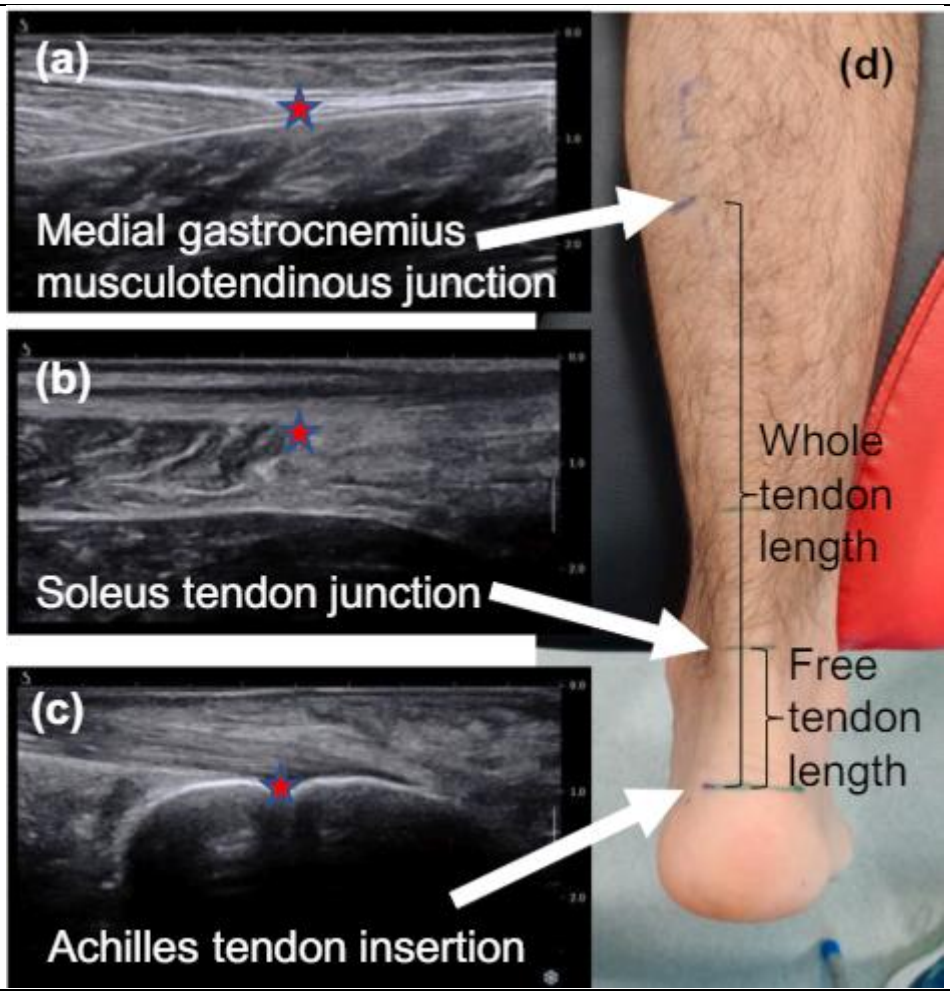

Figure 2: Longitudinal ultrasound images of the medial gastrocnemius musculotendinous junction (a), soleus tendon junction (b), and Achilles tendon insertion (c) respectively. (d) Markings on the skin of the medial gastrocnemius musculotendinous junction, soleus tendon junction, and Achilles tendon insertion for the measurement of the free tendon length and original length of the whole tendon. [26]

AT is superficially placed for most of its length, which aids in sonographic evaluation. From the point of insertion at the calcaneus to the musculotendinous junction, the tendon's depth steadily rises. The osteotendinous junction, or posterior calcaneus, is where the AT enters the bone.[32]

The free AT is the portion of the tendon that is not attached to anything else. It starts at the calcaneus insertion and finishes at the most distal section of the soleus, continuing further alongside muscle attachments. Collagen bundles are composed of many fascicles that are bundled into fibres and fascicles from a grouping of collagen macromolecules called fibrils. These collagen bundles are encircled by vascularized connective tissue and joined to produce tendons. AT is composed of densely packed collagen fibres. The vascular, lymphatic, and nerve supplies are all contained inside the thin, loose connective tissue sheath-type membrane known as the epitenon (as shown in Figure 3). More superficially, the epitenon is covered in a hard, fibrous sheath termed the paratenon, which is rich in mucopolysaccharides and has numerous layers. The epitenon and tendon travel longitudinally inside the paratenon. Since the AT lacks synovial fluid, the mucopolysaccharide layers serve as the primary lubricant to facilitate smooth movement. [33-38]

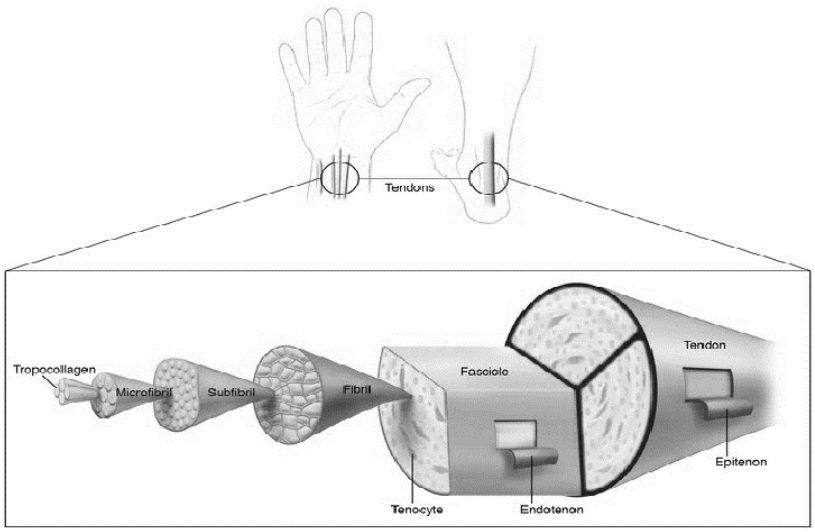

Figure 3: Achilles tendon structure and composition [38]

The type I collagen bundles found in the AT are made up of 30% collagen and 2% elastin.[39] These bundles are encased in a viscous material called ECM (Extracellular Matrix), sometimes referred to as ground substance.[40] Proteoglycans, fibroblasts, and tenocytes are among the cell-produced proteins that make up 68% of the ECM.[41] Tendon flexibility is attributed to the protein elastin, which is found in tissues that tolerate significant length changes without enduring long-term structural alterations.[42] Less than 1% of the dry weight of a tendon is made up of elastin, which is resistant to stressors and may withstand up to 200% strain before failing.[42,43] Type I collagen, which makes about 95% of total collagen and around 60% of the dry mass of tendons, is mostly found in healthy tendons. The mechanical strength and structural integrity of a tendon are determined by type I collagen, which is fibrillar and densely packed.[44]

Function of Achilles tendon:

Achilles tendon (AT) plays a crucial role in foot biomechanics. It stabilize the arch during propulsion and absorb shock and prevent the longitudinal arch of the foot from collapsing during landing. Hicks referred to this stabilizing mechanism as the "Windlass mechanism." It should occur in a healthy control at the start of the heel rise, when the AT helps to produce talus supination and tighten the plantar fascia (PF). In order to effectively accomplish the propulsion, the longitudinal arch must remain high and rigid, which is maintained by the plantar ligament being further tightened by deflection at the metatarsophalangeal joints. [45]

Tendon Imaging

The use of ultrasound (US) as a modality for tendon testing has advantages, but it also has drawbacks. As US cannot see through bone like MRI and has a lower spatial resolution than other modalities, assessing tendons that are deeply buried becomes challenging.[24] The structure of tendons has important implications for its imaging appearance. On US, the

fascicular structure is seen as multiple, closely spaced echogenic parallel lines on longitudinal scanning, whereas in the transverse plane multiple echogenic dots or lines are visible [24] (figure 4 & 5). US is a particularly operator-dependent method, where different results can be obtained depending on how the transducer is handled and how the machine is configured. Anisotropy's effect on US imaging is another possible problem. The fluctuation of qualities when measured in different orientations is referred to as anisotropy. The word refers to photos that may appear to fluctuate when inspecting tendons because of the US beam angle.[41] Fascicle within the tendon are best seen when the US beam is perpendicular to the orientation of the fascicles. If the beam is not perpendicular, the echogenic appearance is lost which may simulate disease appearance.

In human in-vivo tendon research, US and MRI have been widely used to evaluate anatomical features but not mechanical qualities. Over the past 20 years, there has been a growth in the use of US in conjunction with force measurements to determine the mechanical properties of tendon in vivo. Nevertheless, the mechanical properties reported in different studies vary significantly, which further restricts our understanding of tendon function in vivo.

Figure 4: Ultrasound of Achilles Tendon

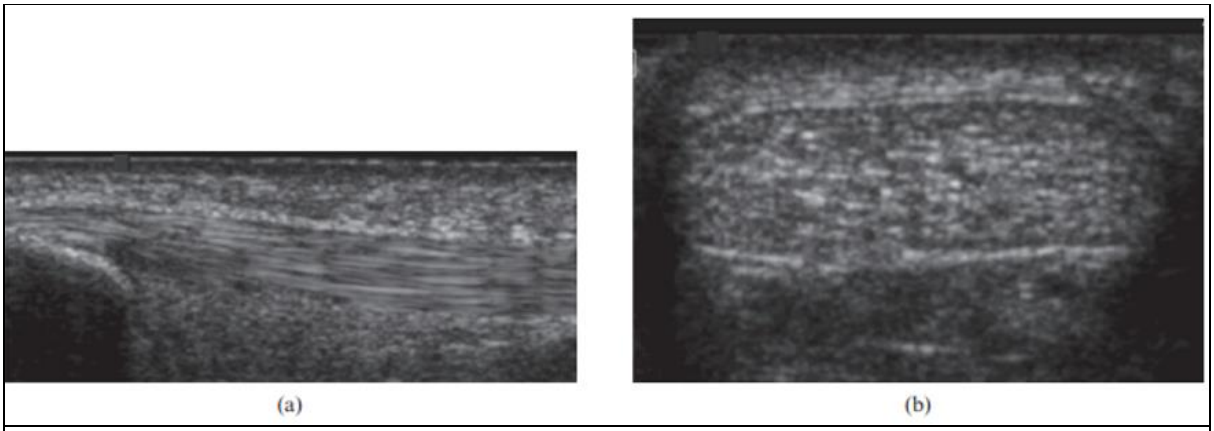

Figure 5: Ultrasound of normal Achilles tendon. Longitudinal (a) and transverse (b) ultrasound images of distal tendon. The normal tendon appears echogenic with multiple, parallel echogenic lines reflecting the internal fibrillar structure.[24]

According to the study done by Seynnes et al. in 2019, various methodological constraints during US-based approach in tendon imaging were identified which included the transducer's slight movement, the overestimation of tendon elongation due to the difficulty in tracking anatomical features during muscular contraction, the incomplete scanning of tendons due to narrow fields of view, and the estimation of the force exerted by a tendon in the in vivo environment.[46] The existence of these variations makes it challenging to directly compare the findings in the literature, and the ability to precisely quantify tendon stiffness.

The Achilles tendon should be scanned from its myotendinous junction to its calcaneal insertion in transverse and longitudinal planes. The Achilles tendon thickness should be measured on transverse images, because longitudinal images may yield measurement errors if the probe is tangential to the tendon.[47] When scanning the tendon in the short axis, the probe can be tilted on each side of the tendon to assess the peritendinous envelope. During this maneuver, the medial aspect of the plantaris and the retroachilles and retrocalcaneal bursas should be assessed.[48] Given the tendon's superficial location, a high-frequency linear probe (6–18 or 4–20 MHz) should be used to acquire highest-resolution images of the tendon and adjacent structures.

Elastography

Palpation is an age-old method used by clinicians to assess soft tissue and detect abnormality based on difference in elasticity of the tissues. This is based on the fact that abnormal tissues tend to be harder than the normal tissue.[49]

Elasticity is the ability of the material to resume its original size and shape after applying a deforming force or stress. Pathological changes in the tissue lead to change in elasticity. Elastography is an imaging modality which can qualitatively and quantitatively assess the changes in elasticity of the tissue due to pathological process.

Historic background of elastography

Assessing the stiffness of tissues using ultrasound evolved from tissue motion studies which were performed in the 1980s in England. Around 1988, a system that utilized colour Doppler to track the movement of the tissue and produce tissue stiffness-based images was created by the researchers at the University of Rochester. Elastography was introduced after 1990 and came into the clinical setting in 1997. Sono-elasticity had the ability to determine the stiffness of lesions present in various organs as dark areas with a green background of moving tissue. In vibrational Doppler imaging, the lesion is seen dark against a background of tissue that's vibrating. However, with this technique, the image that is obtained is of relatively low resolution and required an inconvenient external vibratory device that induces motion within the tissue.[50] Local shear wave velocity and stiffness of the tissues can be assessed by using a newer application of a second vibration that operates at a different frequency and is seen producing a shifting interference pattern.[51] Elastography is the first successful method of imaging the elasticity of tissue reported in 1991 by Cespedes and Ophir.

Ultrasound elastography physics

Elastography evaluates tissue elasticity, which is the ability of tissue to battle distortion with a functional force, or to recommence its original shape after elimination of the force.

Assuming that a material is entirely elastic, elasticity can be described by Hooke's Law as: $\sigma=\Gamma\cdot\varepsilon$, where strain ($\varepsilon$) is expansion per unit length which is dimensionless, stress (σ) is force per unit area with units kilopascals (i.e. N/m2), and elastic modulus (Γ) relates stress to strain with units kilopascal.[52]

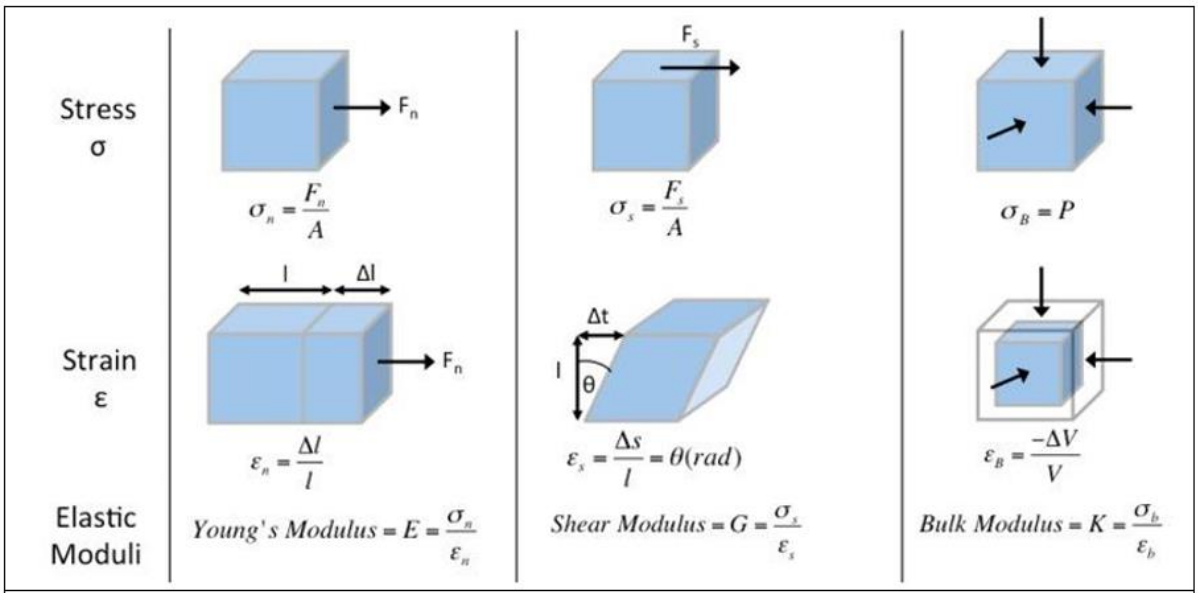

Figure 6: Ultrasound elastography physics, deformation models. Static distortions of entirely elastic materials can be described by stress σ (force per unit area, top row), strain ε (expansion per unit length, middle row) and elastic modulus Γ (stress divided by strain, bottom row). This is applied to regular (upright to the surface, first column), shear (tangential to surface, second column) and bulk (normal inward or pressure, third column) forces used in ultrasound elastography.

Ultrasound elastography techniques:

The two commercially accessible methods, which may be divided into two varieties are compression (strain) elastography (CE) and shear wave elastography (SWE).[53]

Based on the principles, the US elastography techniques are classified into (Figure 7):

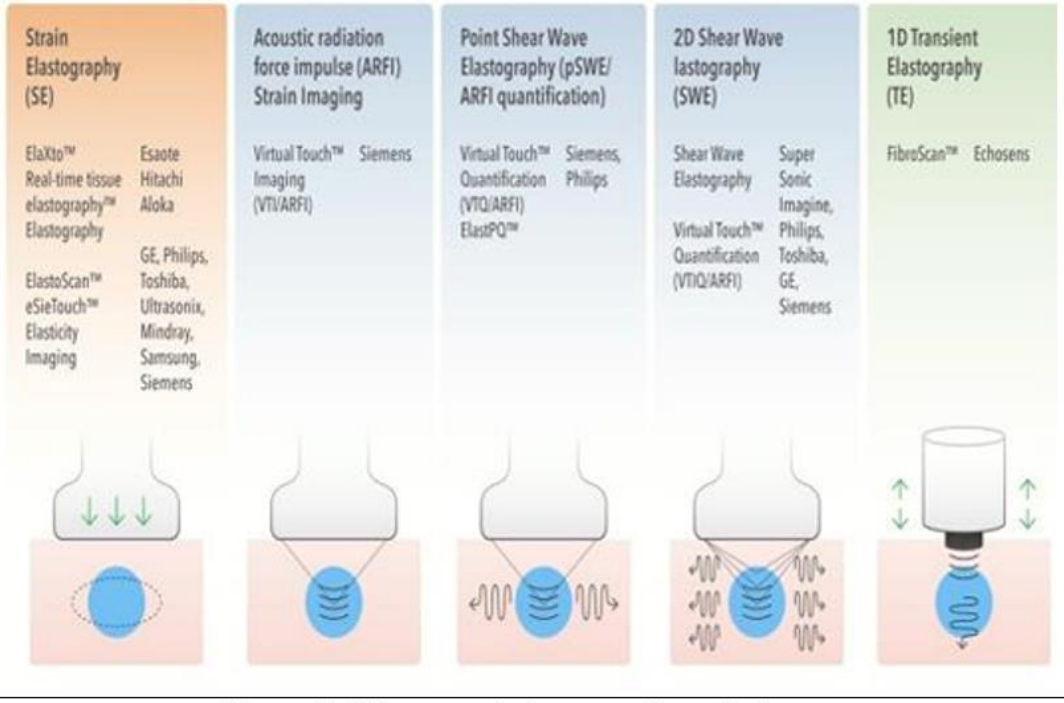

Figure 7: Ultrasound elastography techniques

1) **Strain imaging**: This method assesses the Young's modulus E qualitatively by applying a "normal stress (n)" to the tissue and measuring the "normal strain (n)".

2) Shear Wave Elastography (SWE)

Shear wave dynamic imaging is a practical and non-invasive way to evaluate tissue stiffness quantitatively in real time. Tissue is subjected to a dynamic stress by means of a vibrating mechanical device in "1D transient elastography (1D-TE)" or "an acoustic radiation force in 2-dimension shear wave elastography (2D-SWE)". SWE is credited with significantly enhancing measurement reliability by eliminating the need to rely on applied stress. Virtual Touch tissue imaging & quantification (VTIQ) technology, which employs an acquisition sequence involving reference, excitation, and tracking pulses, is also compatible with SWE technology. Because the VTIQ software generates shear waves using Acoustic Radiation Force Impulses (ARFI), it does not depend on the user applying the proper amount of pressure to the transducer. By combining data from up to 256 successive acquisition beam

lines inside the user-defined two-dimensional region of interest (ROI), the VTIQ programme generates tissue elasticity information. It can also provide a qualitative and quantitative map of Shear wave velocity (SWV) with a speed range of 0.5 to 10.0 m/s. SWE is less dependent on the operator and offers quantitative information on tissue mechanical characteristics, making it suitable for use by a variety of operators with varying degrees of expertise.[54]

In order to evaluate tissue stiffness, SWE measures the velocity of the produced shear waves as they move through the tissue. SWE was just recently introduced to imaging with the aim of addressing some of shortcomings of previously available techniques, namely its lack of repeatability and qualitative measurements. SWE, on the other hand, is operator-independent, provides quantitative, real-time measurements, is inexpensive, and is simple to use in a variety of contexts.

SWE generates shear waves inside a tissue by using an acoustic push pulse from a typical US transducer. The shear waves flow perpendicular to the push pulse through the tissue, causing it to behave similar to ripples. This allows one to imagine the push pulse as being like a stone dropped into a pond.[53]

SWV is quantified while the waves pass through the tissue, as the software can both generate and detect the shear waves using the same US transducer. Young's modulus may be estimated using SWE from SWV since stiffer or harder tissue has a quicker SWV. US pictures may be used to follow the propagation of shear waves since they move through soft tissue environments about a thousand times more slowly than longitudinal waves.[54]

Tissue stiffness is intimately correlated with the speed at which shear waves propagate through it because minute changes in stiffness result in minute variations in SWV.[55] While some commercially available US systems use SWE and report SWV in m/sec, others use Young's modulus (kPa). According to some authors, tissue elasticity of 1-300 kPa corresponds to shear wave propagation rates of 1-10 m/sec. The formula Young's modulus

(E) = 3 x density x (shear wave velocity)^2 may be used to compute Young's modulus from SWV and tissue density; however, in this example, tissue density is assumed to remain constant at 1000 kg/m^3, which may not necessarily be the case in viscoelastic tendon.

Due to the fact that varying physiological circumstances might have an impact on the precise values for tissue densities, the assumption of constant tissue density may restrict the accuracy of stiffness as measured by SWE and given in kPa. According to a research, there are no appreciable differences in the results obtained for kPa and m/sec. As a consequence, both measures may be used to distinguish between stiffness variations, and any variations in diagnostic performances have little impact in clinical practise. Moreover, prior research on skeletal muscle shows that, across a physiological stress range, SWV and Young's modulus agree well.[55]

As a result of advancements in ultrasonic technology, elastography has become a promising tool for quantitatively examining the material and mechanical properties of tendons. SWE is capable of quantifying the absolute elasticity value of soft tissue structures in addition to their morphological details. Shear waves can be generated in a number of ways, including transient elastography and US push beams (supersonic shear imaging and transient mechanical vibrations). These waves may oscillate longitudinally, with the particles moving in the direction of the wave, or transversally, with the particles moving in the opposite direction. Using several push beams directed at different depths inside the tissue, supersonic shear imaging produces shear waves over a broader range of depths and employs ultra-high-frame rate ultrasonic imaging to detect these waves as they propagate.[56-61]

Compression Elastography and SWE (Shear-Wave Elastography), two important musculoskeletal elastography techniques, were reviewed by Prado-Costa et al. in 2018. They also assessed the studies that have been published in large electronic databases using these techniques in the context of tendon pathology. Compared to SWE, CE accounts for more

research. Tendon damage can modify the mechanical characteristics of tendons, especially their stiffness. Achilles tendons, patellar tendons, quadriceps tendons, epicondylar tendons, and rotator cuff tendons and muscles have already been evaluated using CE and SWE. When compared to traditional ultrasound, ultrasound elastography (USE) has the potential to improve diagnostic accuracy and sensitivity in tendinopathy cases. It can also identify pathological alterations that conventional US imaging misses. The reviewers came to the conclusion that there are a number of acknowledged technical limitations with these procedures and that standardisation is required to guarantee reproducibility and comparability of the outcomes. Nevertheless, USE is a promising approach that is now undergoing research. It has the potential to enhance the evaluation of rehabilitation programmes, identify the risk of damage, and encourage early diagnosis.[62]

Since SWE has the potential to be utilised for several therapeutic and research-related purposes in a wide range of settings, it would be advantageous for stiffness metrics within the literature to be standardised in order to facilitate clearer results and easier comparison between studies. In conclusion, SWE has the potential to supplement US imaging since it can rapidly, simply, and non-invasively offer a real-time assessment of a tendon's mechanical characteristics.

SWE can distinguish between differing tissue stiffness, which can help in identifying minor partial rips in tendons that were previously invisible with conventional US imaging because they would have been isoechoic with the surrounding healthy tissue. In earlier studies, SWE was verified by contrasting its output with that of conventional tensile testing. This was done using a material testing apparatus on pig skeletal muscle.[55] As the whole-muscle samples used in this experiment were taken from pigs soon after their deaths, it should be underlined that the results should be cautiously generalised to the human tendon in

vivo. Additional research with human in vivo subjects supports SWE by indicating that it offers a respectable degree of reproducibility for evaluating both muscle and tendon.

When assessed using SWE in addition to conventional tensile testing, Haen et al. showed a substantial association between the stiffness values in cadaveric ATs. The usefulness of SWE in evaluating the biomechanical characteristics of human AT in vivo was shown for the first time in this work by Haen et al. [63]

Yoshitake et al. investigated the repeatability of SWE in evaluating the brachii biceps and found that SWE yields extremely consistent shear modulus measurements.[64]

When using traditional ultrasound, the angle at which the transducer is positioned in relation to the skin is critical in getting a good image. If the angle between the tendon and the transducer's emitted waves is not more than 83–88 degrees, most of the reflected waves will not be picked up, making the tendon appear hypoechoic.[56] As shear waves travel more readily along longitudinal fibres than they do across them, transducer orientation parallel to the tissue being imaged yields the most reliable readings of SWV. This means that the transducer angle is also critical for SWE accuracy.[55] Hence, in order to get the most accurate findings, transducers should be positioned longitudinally to the structure's fibres.

The amount of displacement is determined by SWE, which measures deformation in user-defined ROIs and figures out SWV at many lateral points in relation to the ROIs.[63] Since SWV is inversely correlated with tissue elasticity, more tissue stiffness is associated with higher SWV. Overlaying the B-mode picture, SWE generates a shear wave elastogram (Figure 8) that identifies regions of more rigid and tougher tissue. The midsection of a participant's right AT is depicted in Figure 8, which lacks anatomical markers. Nevertheless, the middle portion of the AT is visible between the two white lines that run along the top of the picture. The data acquired is shown in SWV (m/s), and the values marked in the red circle down the right side of Figure 8 reflect SWV at certain positions along the AT. Ten velocities

are measured at a depth of 0.5 cm, starting proximally and moving distally, following the black line that runs through the middle of the tendon. Once more, the software that created the elastogram in Figure 8 indicates softer tissue with blue and tougher tissue with red, as seen in the key located at the far left of the picture.

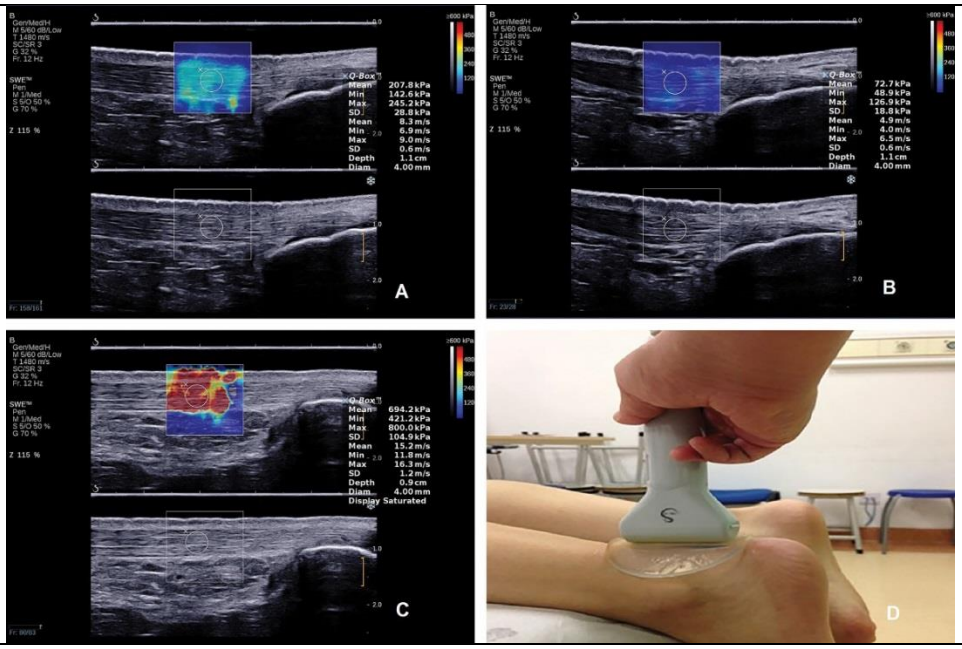

Figure 8: Shear Wave Ultrasound Elastographic evaluation of Achilles Tendon

Figure 9 shows normal SW & conventional B-mode imaging of AT. [26]

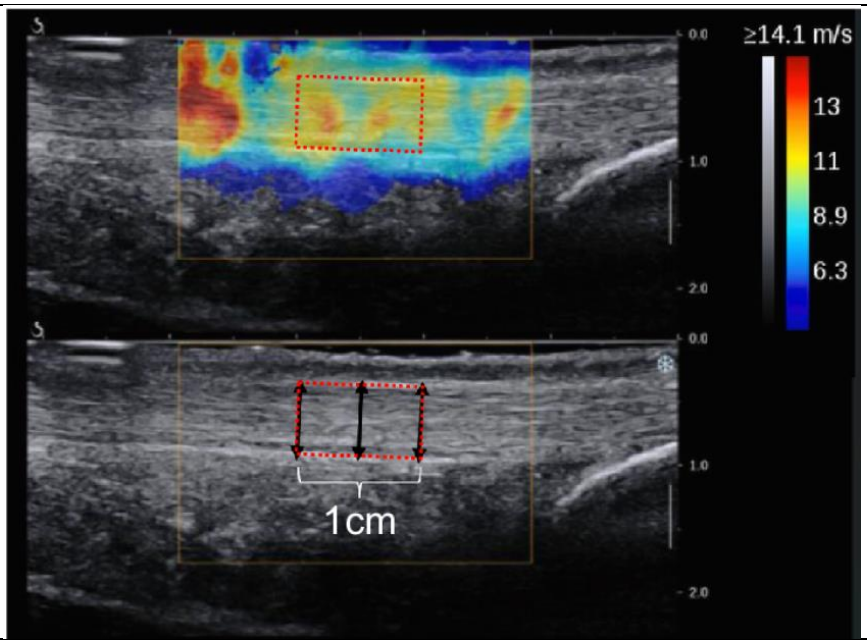

Figure 9: SW elastography (top) and conventional B-mode imaging (bottom) of the Achilles tendon. The central part of the free tendon is imaged in a longitudinal plane. The locations where thickness was measured (arrows) and the area for which SW speed was calculated (dotted box) are also indicated. [26]

In a study conducted by Evranos et al. in 2015, the effects of diabetes mellitus on the Achilles tendon were assessed. Eighty eight diabetic patients, thirty five of who had foot ulcers (Group 1) & forty three of who did not have foot ulcers (Group 2) were chosen. Thirty three healthy individuals who were age and gender matched were chosen as controls. Each subject had their Achilles tendon thickness (ATT) & Achilles tendon stiffness (ATS) measured. As a gauge of their ability to control their diabetes, each patient also had tests for FBS (Fasting blood sugar) and glycosylated haemoglobin (HbA1C). According to the findings, group I's AT was noticeably thicker than group II's and the controls'. The duration of diabetes, FBS, and HbA1C were all greater in group I. The authors found that, in group II, Achilles tendon thickness (ATT) was positively connected with peripheral arterial disease, neuropathy, retinopathy, nephropathy, and coronary arterial disease; in group I, no such association was seen. Group I saw a greater decrease in ATS (Achilles tendon stiffness) than did Group II and the control groups. Based on the study's findings, the researchers came to the conclusion that in diabetic individuals, alterations in the AT's structure could occur before foot and ankle problems. This study is the first to describe the findings of AT sonoelastosonography in diabetic individuals and to show a relationship between ATT and other long-term consequences of diabetes. [65]

In 2018, Iyidir et al. compared individuals with and without diabetic neuropathy in terms of the elastographic characteristics of the AT using an acoustic radiation force impulse. Two subgroups consisting of 45 type 2 diabetic individuals were identified based on the existence of peripheral neuropathy. Group I consisted of 22 individuals who had peripheral neuropathy, while Group II consisted of 23 patients who did not have peripheral neuropathy. Thirty healthy individuals who were matched for age, gender, and body mass index were chosen as controls. To assess the thickness and stiffness of the AT, each subject received an elastographic test using an acoustic radiation force impulse and US. The study's findings

demonstrated that each group's AT thickness was comparable ($p = 0.991$). Both patient groups' Achilles tendon thicknesses were much greater than those of the control group (group I vs. control, $p = 0.01$; group II vs. control, $p= 0.006$). Achilles tendon stiffness measurements were comparable in groups II and the control group ($p = 0.993$). Group I experienced a considerably lower SWV compared to both Group II and the control group ($p < 0.001$). They came to the conclusion that the flexibility of the Achilles tendon in diabetes patients without neuropathy is comparable to that of healthy controls, the tendon in diabetic patients with neuropathy is thicker and softer. Achilles tendon softening may identify those who are at risk for developing diabetic foot and serve as an early warning indicator.[66]

Harish et al. (2020) assessed 81 patients with type 2 diabetes and 61 healthy volunteers for AT anomalies using sonoelastography in India. Peripheral neuropathy (PN)-positive and -negative individuals were further separated within the patient population. The proximal, middle, and distal regions of the AT were assessed for thickness. Changes in the echo pattern were observed. It was discovered that the patients' tendons were thicker ($p < 0.01$) than those of the healthy participants. When comparing patients to healthy volunteers, changes in the AT's echo pattern were more frequent in the former group ($p < 0.01$). SWE imaging was used to measure the SWV in the distal one-third of the AT. According to the findings, patients' mean SWV values were lower than those of healthy volunteers ($p < 0.001$). Sonoelastographic results from the AT showed no significant difference between patients with and without PN. According to the study's findings, people with type 2 diabetes have softer, thicker AT along with changes in the echo pattern of the AT, such as hypoechogenicity, loss of fibrillar pattern, and calcification at insertion. These changes may occur before or after the onset of peripheral neuropathy.[67]

In 2023, Romer et al. assessed the sensitivity of SWE and looked at the relationship between anthropometric factors & movement unique to a certain sport along with Achilles

tendon stiffness. A standardised SWE of Achilles tendon stiffness was performed in 65 healthy professional athletes (33 females and 32 males) in the longitudinal plane and relaxed tendon position. The study looked at the impact of anthropometric parameters on Achilles tendon stiffness using SWE and examined various sports to develop approaches in preventive medicine for professional athletes. Both linear regression and descriptive analysis were carried out. Additionally, subgroup analysis was carried out for other sports, including volleyball, handball, soccer, sprinting, and hammer throwing. The research's findings demonstrated that, among the 65 participants in the study, male professional athletes had considerably higher Achilles tendon stiffness ($p < 0.001$) than female athletes (10.98 m/s (10.15–11.65) vs. 12.19 m/s (11.25–14.74)). Age or body mass index (BMI) did not significantly affect AT stiffness, according to multiple linear regression ($p > 0.05$). According to subgroup analysis based on sport, sprinters had the greatest AT stiffness values (14.02 m/s (13.50–14.63)). The author came to the conclusion that there are notable gender variations in AT stiffness among various professional athlete types. Sprinters had the highest AT stiffness scores, which should be taken into account when evaluating tendon diseases. Future research is required to examine the potential benefits of preventative or rehabilitative medicine, as well as the advantages of professional players undergoing pre- and post-season musculoskeletal SWE tests.[68]

Zhang F. et al. used high-frequency US and real time shear wave elastography (RTSWE) to assess AT in patients with diabetic foot ulcers in the year 2022. The study group consisted of patients with diabetic foot ulcers, whereas the control group consisted of patients without diabetic foot ulcers. For each of the 100 patients, high-frequency ultrasound and RTSWE were carried out on the AT. Real time shear wave elastography (RTSWE) was used to measure Young's modulus at the top, middle, and bottom of each AT. Fifty individuals suffered from diabetic foot ulcers. Compared to the control group, the research group's

patients were older, more often used insulin, and had higher cholesterol levels. Nonetheless, when comparing the two groups' AT thickness and Young's modulus using both RTSWE and high-frequency ultrasound were similar. When high-frequency ultrasound and RTSWE were used to assess AT thickness and elastic modulus, the study's findings revealed no statistically significant differences between individuals with and without diabetic foot ulcers.[69]

Shear wave elastography (SWE) has been proposed as a viable technique to measure tissue stiffness in a number of recent research. A single shear wave can be produced throughout the tissue by the US probe in SWE. Using data on velocity as it travels through soft tissue, the SWE may determine the elastic modulus.[73] To the best of our knowledge, there are very limited studies which assess the usefulness of SWE in AT imaging. The purpose of this study is to use SWE to evaluate the stiffness of AT in diabetic patients and to determine its role as a marker of impending foot complications.

MATERIALS & METHODS

MATERIALS AND METHODS

Source of Data

This is a hospital-based, prospective comparative study conducted in the department of Radio-Diagnosis, at R.L. Jalappa Hospital and Research Centre attached to Sri Devaraj Urs Medical College, Tamaka, Kolar, over a period of 18 months from September 2022 to February 2024. The study included consecutive patients with diabetic foot complications referred for ultrasound examination to the radiodiagnosis department.

Methodology

A total of 165 patients were included: 55 non-diabetic controls (Group 1), 55 patients without foot complications (Group 2) and 55 with foot complications (Group 3) referred for ultrasound examination to the department of Radio-Diagnosis at the R.L. Jalappa Hospital and Research Centre attached to Sri Devaraj Urs Medical College, Tamaka, Kolar. The study was conducted following approval from the institutional ethical committee. A written consent form was obtained from all patients fulfilling the inclusion criteria after explaining the objective, procedure, and expected outcome in detail before the start of the study. The patients were included in the study based on the inclusion and exclusion criteria mentioned as follows:

Inclusion Criteria

1. Age- and gender-matched healthy individuals will be chosen as controls aged > 35 years.
2. Diabetic patients aged > 35 years without foot complications.
3. Diabetic patients aged > 35 years with foot complications.

Exclusion Criteria

1. History of rheumatic disease, acromegaly, and trauma.
2. Achilles tendinitis.
3. Complications of varicose veins.

Informed written consent was obtained from every patient.

Sample Size

The sample size was calculated based on Berna Evrranos et al. reported the proportion with 2a or 2b grading sonoelastography of the Achillies tendon as mentioned below:[65]

Controls (without DM) = 21%

DM without foot ulcers = 32%

DM with foot ulcers = 60%

Assuming alpha error of 0.05 (95% confidence limit)

Power of 80% (beta = 0.20)

Ration of controls: DM without foot ulcer: DM with foot ulcers to be 1:1:1

The minimum required sample size to compare the difference in proportion with grade 2a/2b between controls vs DM with foot ulcers was calculate to be 29 in each group.

DM without foot ulcers vs DM with foot ulcers was calculated to be 55 in each group.

Hence the maximum sample of 55 per group were included in each of the three groups to get a final sample size of 165 subjects for inclusion in the study.

The sample size was calculated as follows:

$$n = \frac{2(Z_{\alpha/2} + Z_{1-\beta})^2 \, pq(r+1)}{r\,(p_1 - p_2)^2}$$

Where

n 2 = r n 1

n 1 = number of Group 1

n 2 = number of Group 2

Z α/2 = standard normal deviate for two-tailed test based on alpha level (relates to the confidence interval level)

Z β = standard normal deviate for one-tailed test based on beta level (relates to the power level)

r = ratio of unexposed to exposed

p1 = proportion of group 1 with outcome (2a/2b) and q1 = 1-p1

p2 = proportion of A without outcome (2a/2b) and q2 = 1-p2

Ethical considerations:

Institution's human ethics committee approved this study. All participants were provided with written informed consent, and only those willing to sign the consent were allowed to take part in the study. Before getting consent, the participants were informed about risks and advantages of study as well as voluntary nature of participation. Privacy of study participants was protected at all times.

Examination Protocol

The demographic details were taken from all patients. All ultrasound examinations were performed using the Philips EPIQ5 system equipped with shear wave point quantification, ELASTPQ, using a curvilinear broadband transducer (C5-1) and a linear transducer (L12-5).

Figure 10: Philips EPIQ5 USG machine.

All participants underwent B-mode ultrasonography and shear wave elastography of Achilles tendons. The Achilles tendon was examined in the longitudinal plane with the patient in the prone position, with the foot hanging over the examination bed in a relaxed position. The thickest part of the middle portion of the Achilles tendon, was chosen for both ultrasonographic and shear wave elastographic examinations.

The thickness of the tendon is determined by measuring the thickest anteroposterior diameter from the middle third portion (2-6 cm above the insertion of the calcaneus) of the tendon using B-mode ultrasound.

For determining the elasticity, we used shear wave elastography. This technique generates shear waves inside the tissue using a focused ultrasound beam. A fixed rectangle of size 0.5 x 0.5 cm is chosen as the region of interest and is placed in the middle third portion of the Achilles tendon. After image stabilization, the probe is held steady for 3–5 seconds for framing.

Tendons are examined in the longitudinal plane to avoid anisotropy. During elastography, the probe is placed in contact with the skin without pressure. Four

measurements were taken for each tendon, and the mean value was calculated and used for statistical analyses.

Statistical Analysis

The present study incorporates both qualitative and quantitative data analysis methodologies. Qualitative data is presented via a frequency table accompanied by percentages. The association between two qualitative variables was examined using the chi-square test

For quantitative data, the normality assumption was assessed utilizing the Kolmogorov-Smirnov test, revealing that none of the quantitative variables followed a normal distribution (P value <0.001). Consequently, the median (Interquartile Range - IQR) was employed as a summary measure for non-normally distributed quantitative data.

To compare levels of FBS (Fasting Blood Sugar), PPBS (Post-Prandial Blood Sugar), Thickness, and Young modulus among the Normal, DM (Diabetes Mellitus) without foot complications, and DM with foot complications groups, the Kruskal-Wallis test was conducted. Levene's test was utilized to assess the equality of variance (P<0.001) across all variables

Post hoc (Dunn`s test) was applied for nonnormal unequal variance variables for comparison of normal Vs DM without foot complications, Normal Vs DM with foot complications and DM without foot complications Vs DM with foot complications. The level of significance was considered 95% for all statistical tests.

A bar chart with an error bar represented the mean value along with ± SD value and a box plot was used to reveal the distribution of numeric data value of variables, especially to compare them between multiple groups.

ROC applied to predict the cutoff value of Thickness and Young Modulus to differentiate between the three groups.

RESULTS

RESULTS

Table.1 Gender wise Distribution (N=165)

Gender	Frequency	Percent
F	44	26.7%
M	121	73.3%
Total	165	100.0

The data shows that out of 165 individuals, 26.7% (44) are female and 73.3% (121) are male.

This indicates a higher proportion of males compared to females in the sample.

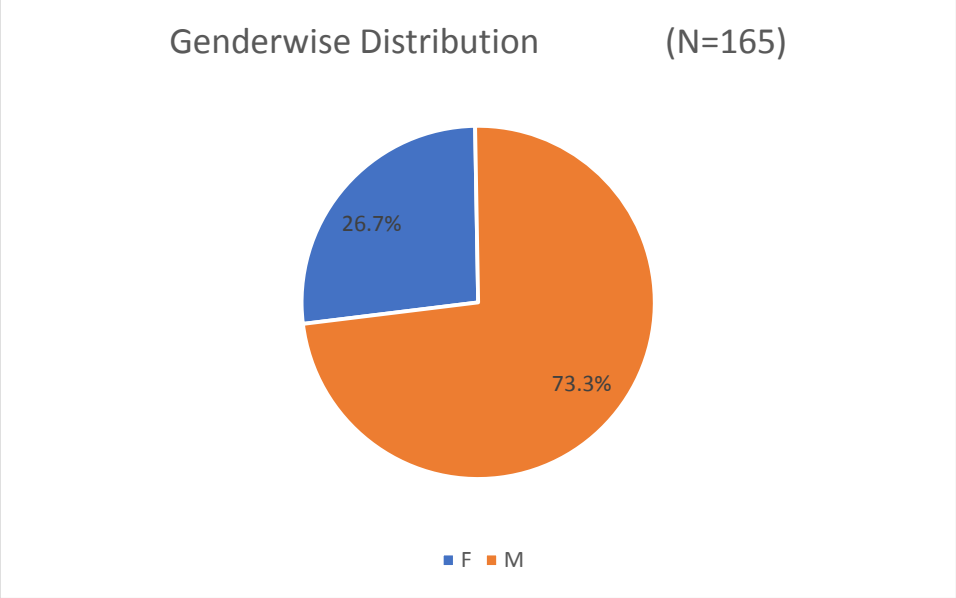

Figure 11. Pie chart showing Genderwise distribution of subjects (N=165)

Table.2 Age wise Distribution (N=165)

Age	N	%
<55 years	76	46.1%
>55 years	89	53.9%
Mean SD	55 .14± 10.11	
Median(IQR)	55(47-61)	
Min-Max	38-86	

The data summarizes the age distribution of a sample population. Of the 165 individuals, 46.1% (76) were under 55 years and 53.9% (89) are over 55 years old. The mean age is approximately 55.14 years with a standard deviation of 10.11 years, indicating some variability around the mean. The median age is 55 years, with an interquartile range (IQR) of 47 to 61 years, suggesting that the middle 50% of the sample falls within this age range. The ages span from a minimum of 38 years to a maximum of 86 years, showing a broad age distribution

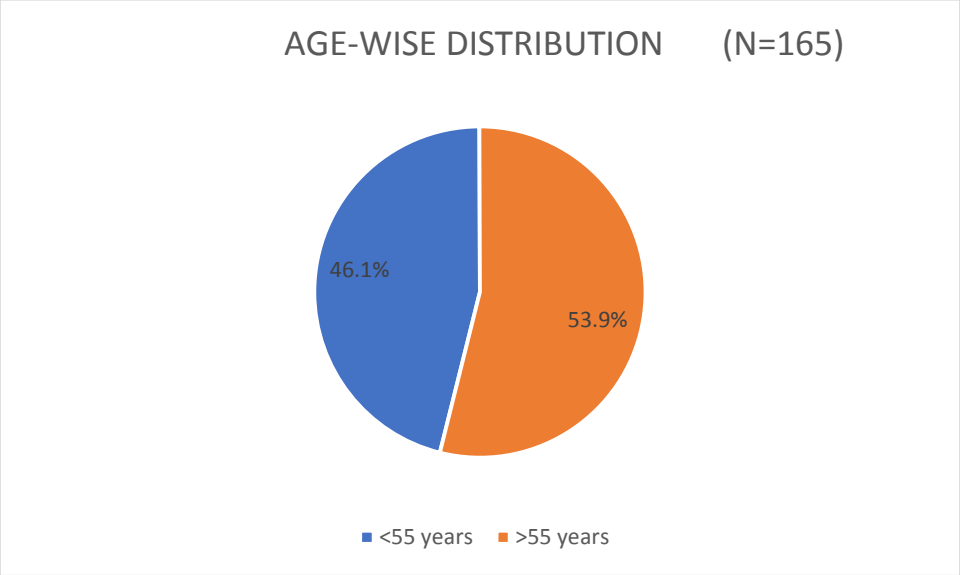

Figure 12. Pie chart showing age-wise distribution of study group (N=165).

Table.3 Association between Gender and disease (N=165)

Classification of Patients				
Gender	DM Without Foot Complications	DM With Foot Complications	Normal	Total
F	16	10	18	44
	29.1%	18.2%	32.7%	26.7%
M	39	45	37	121
	70.9%	81.8%	67.3%	73.3%
Total	55	55	55	165
	100.0%	100.0%	100.0%	100.0%

Chi-Square -3.223, P-Value -0.200 (No significant)

The table presents the classification of patients by gender and health status (DM without foot complications, DM with foot complications and normal). Among females (44 total), 29.1% have DM without foot complications, 18.2% have DM with foot complications, and 32.7% are normal. Among males (121 total), 70.9% have DM without foot complications, 81.8% have DM with foot complications, and 67.3% are normal. Each category has an equal total of 55 patients. A P-value of 0.200, indicating no statistically significant difference in the distribution of health status between gender.

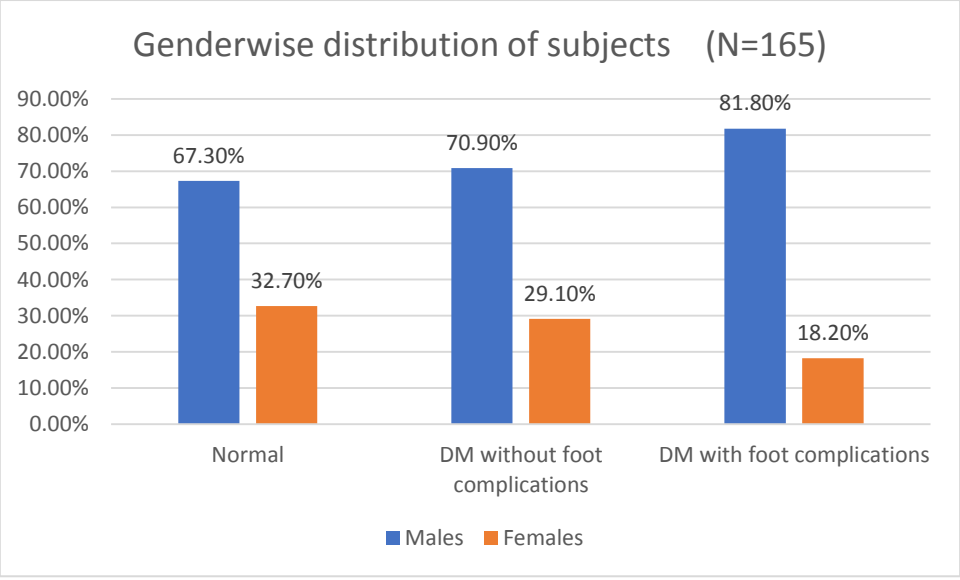

Figure 13. Bar chart showing the Association between Gender and disease

Table.4 Association between age and disease (N=165)

Gender	DM Without Foot Complications	DM With Foot Complications	Normal	Total
<55 years	26	19	31	76
	47.3%	34.5%	56.4%	46.1%
> 55 years	29	36	24	89
	52.7%	65.5%	43.6%	53.9%
Total	55	55	55	165
	100.0%	100.0%	100.0%	100.0%

*Chi square test(P- Value -0.07)

The table classifies patients by age group (<55 years and >55 years) and health status (DM, DM with ulcers, and normal). Of those under 55 years, 34.5% have DM with foot complications, 47.3% have DM without foot complications, and 56.4% are normal. Of those over 55 years, 65.5% have DM with foot complications, 52.7% have DM without foot complications, and 43.6% are normal. Each category has an equal total of 55 patients. A P-value 0.07 suggests no statistically significant difference in the distribution of health status between the two age groups.

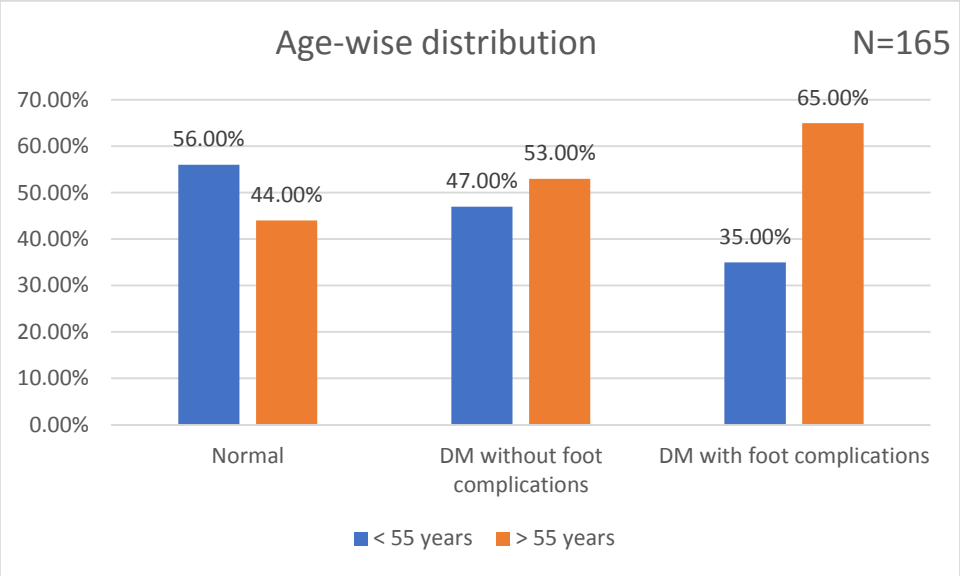

Figure.14 Bar diagram shows the association between age and disease

Table .5 Comparison of FBS (in mg/dL) among the control and disease group

Variable	Group	N	Mean ± SD	95% CI	Median (IQR)	P- value
FBS (in mg/dL)	Normal	55	88.58±5.29	(87.15,90.01)	88(86-92)	P<0.001
	DM without foot complications	55	145.16±14.21	(141.32,149.01)	142(135-150)	
	Dm with foot complications	55	142.67±11.43	(139.58,145.76)	142(135-148)	
	Total	165	125.47±28.36	(121.11,129.83)		

The table compares the median fasting blood sugar (FBS) levels across three groups: Normal, DM without foot complications, and DM with foot complications. The median FBS level for the Normal group is 88 mg/dL (IQR 86-92), for the DM without foot complications group is 142 mg/dL (IQR 135-150), and for the DM with foot complications group is 142 mg/dL (IQR 135-148). The comparison shows that the median FBS level is significantly lower in the Normal group compared to the both the diabetic groups. The P-value of <0.001 indicates that these differences are statistically significant

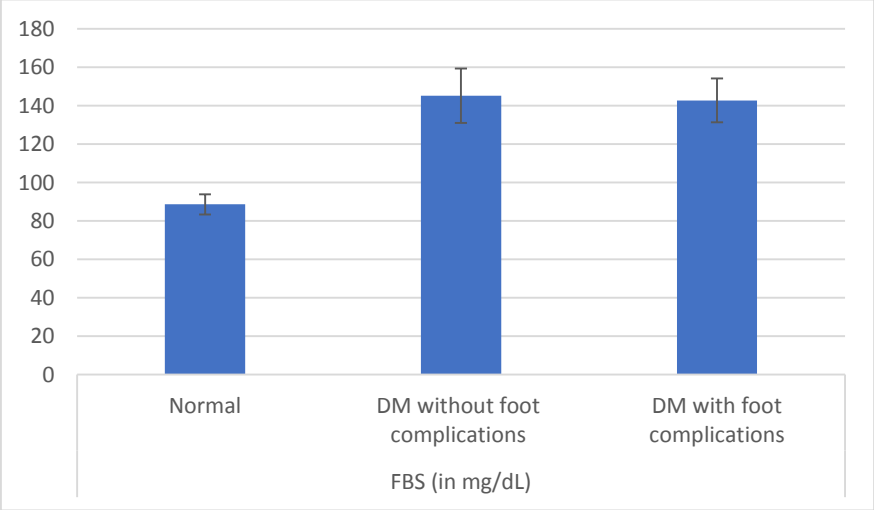

Figure 15. Bar chart showing the comparison of FBS (in mg/dL) among the control and disease group

Table.6 Comparison of PPBS (in mg/dL) among the control and disease group

Variable	Group	N	Mean ± SD	95% CI	Median (IQR)	P- value
PPBS (in mg/dL)	Normal	55	124.76±9.37	(122.23,127.3)	128(124-131)	P<0.001
	DM without foot complications	55	228.95±21.2	(223.21,234.68)	224(210-243)	
	Dm with foot complications	55	236.29±21.22	(230.55,242.03)	232(222-256)	

The table compares the median postprandial blood sugar (PPBS) levels across three groups: Normal, DM without foot complications, and DM with foot complications. The median PPBS level for the Normal group is 128 mg/dL (IQR 124-131), for the DM without foot complications group is 224 mg/dL (IQR 210-243), and for the DM with foot complications group is 232 mg/dL (IQR 222-256). The comparison shows that the median PPBS level is significantly lower in the Normal group compared to both the diabetic groups. The P-value of <0.001 indicates that these differences are statistically significant

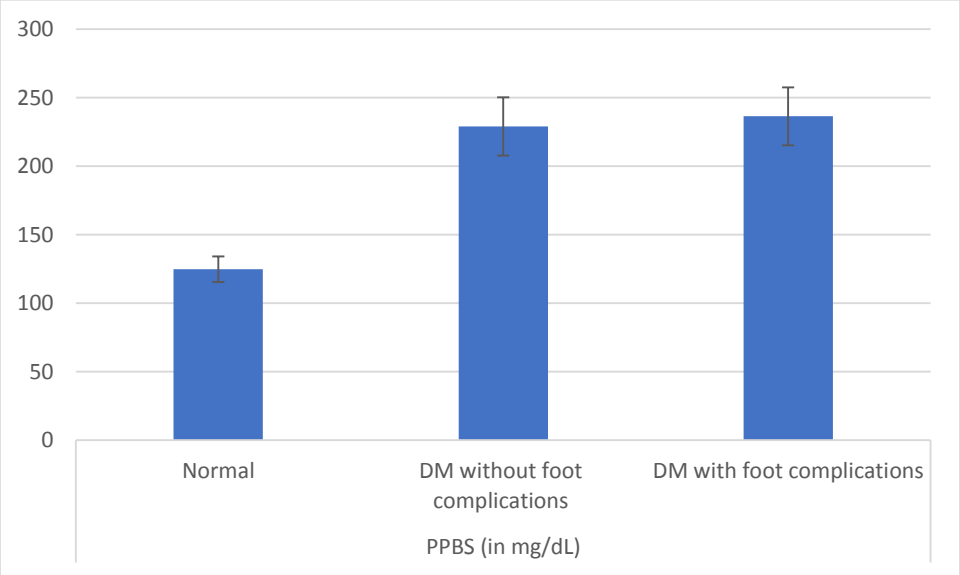

Figure 16. Bar diagram showing Comparison of PPBS (in mg/dL) among the control and disease group

Table.7 Comparison of thickness (in mm) among the control and disease group

Variable	Group	N	Mean ± SD	95% CI	Median (IQR)	P- value
THICKNESS (in mm)	Normal	55	6.71±0.69	(6.53,6.9)	6.70(6.10-7.10)	P<0.001
	DM without foot complications	55	8.73±0.36	(8.63,8.83)	8.70(8.50-8.90)	
	Dm with foot complications	55	9.49±0.5	(9.36,9.63)	9.50(9.20-10.0)	

The table compares the medan thickness across three groups: Normal, DM without foot complications, and DM with foot complications. The median thickness for the Normal group is 6.70 (IQR 6.10-7.10), for DM without foot complications group is 8.70(IQR 8.50-8.90), and for the DM with foot complications group is 9.50(IQR 9.20-10.0).The comparison shows that the median thickness was significantly lower in the Normal group compared to both the diabetic groups. The P-value of <0.001 indicates that these differences are statistically significant

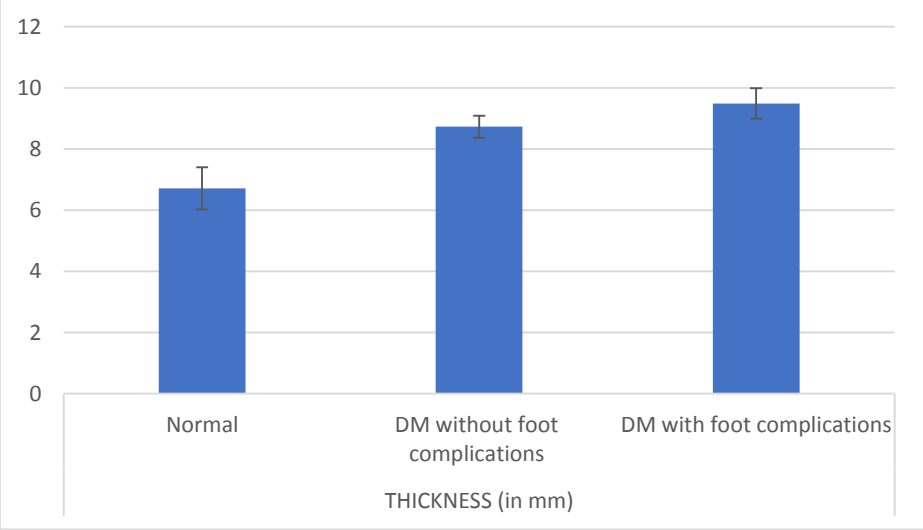

Figure 17. Bar chart showing comparison of thickness (in mm) among control and disease group.

Table .8 Comparison of Young`s Modulus (in kPa) among the control and disease group

Variable	Group	N	Mean ± SD	95% CI	Median (IQR)	P- value
YOUNG'S MODULUS (in kPa)	Normal	55	166.91±17.52	(162.17,171.65)	164(154-187)	0.919
	DM without foot complications	55	165.18±10.25	(162.41,167.95)	167(157-171)	P<0.001*
	Dm with foot complications	55	116.87±14.1	(113.06,120.69)	119(106-123)	P<0.001*

*Significance

The table compares the mean Young Modulus across three groups. The comparison shows that the mean Young modulus was significantly lower in the DM with foot complications group as compared to other two groups. There was no significant difference in the mean Young's modulus between Normal individuals and diabetic patients without foot complications (P value – 0.919). There was a significant difference in the Young's modulus of the other 2 groups.

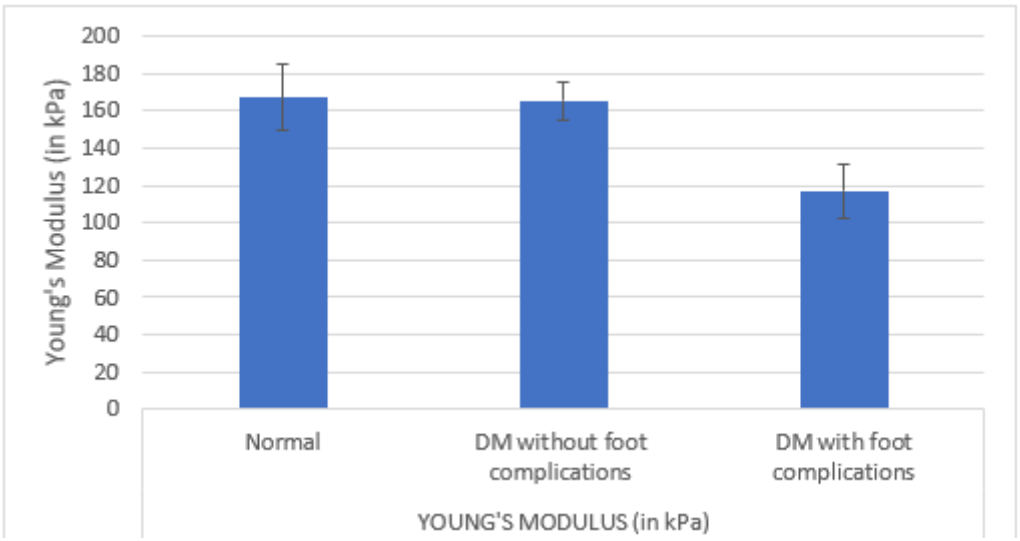

Figure 18. Bar chart comparing Young's modulus (in kPa) among the control and disease group.

Table. 9 Intragroup comparison of study variables.

Study Variables	Comparison of Groups	Mean Difference	P- Value
FBS (in mg/dL)	Normal Vs DM without foot complications	-56.58	P<0.001*
	Normal Vs DM with foot complications	-54.09	P<0.001*
	DM without Vs with foot complications	2.49091	P<0.001*
PPBS (in mg/dL)	Normal Vs DM without foot complications	-104.18	P<0.001*
	Normal Vs DM with foot complications	-111.53	P<0.001*
	DM without Vs with foot complications	-7.34545	P<0.001*
THICKNESS (in mm)	Normal Vs DM without foot complications	-2.02	P<0.001*
	Normal Vs DM with foot complications	-2.78	P<0.001*
	DM without Vs with foot complications	-0.77	P<0.001*
YOUNG'S MODULUS (in kPa)	Normal Vs DM without foot complications	1.73	0.919
	Normal Vs DM with foot complications	50.04	P<0.001*
	DM without Vs with foot complications	48.31	P<0.001*

post hoc (Dunn`s) test applied, * Significance

 FBS (Fasting Blood Sugar): Normal vs. DM without foot complications shows a mean difference of -56.58 mg/dL, and Normal vs. DM with foot complication is -54.09 mg/dL, both with P<0.001, indicating higher FBS in diabetic patients. DM without vs. with foot complications has a minor mean difference of 2.49 mg/dL (P<0.001), suggesting little change in FBS between diabetic patients with and without foot complications.

 PPBS (Postprandial Blood Sugar): Normal vs. DM without foot complications and Normal vs. DM with foot complications show mean differences of -104.18 mg/dL and -111.53 mg/dL, respectively (P<0.001), indicating significantly higher PPBS in diabetic groups. DM without vs. with foot complications has a mean difference of -7.35 mg/dL (P<0.001), showing a slight increase in PPBS with foot complications.

 THICKNESS: Normal vs. DM without foot complications shows a mean difference of -2.02 mm, and Normal vs. DM with foot complications is -2.78 mm (P<0.001), indicating increased thickness in diabetic groups. DM without vs. with foot complications has a mean difference of -0.77 mm (P<0.001), indicating increased thickness in patients with foot complications.

 YOUNG'S MODULUS: Normal vs. DM without foot complications has a mean difference of 1.73 kPa (statistically insignificant), while Normal vs. DM with foot complications shows 50.04 kPa (P<0.001). DM without vs. with foot complications has a difference of 48.31 kPa. (P<0.001), highlighting significantly reduced tissue stiffness in the patients with foot complications.

The post hoc Dunn’s test confirms significant differences across all comparisons (P<0.001).

Table 10. Cut off value of thickness between Normal Vs DM without foot complications, Normal Vs DM with complications and DM without and with foot complications with its sensitivity, specificity.

Test Result Variable(s) Thickness	AUC	P-Value	Asymptotic 95% Confidence Interval		Cut-off Value	Sensitivity	Specificity
			Lower Bound	Upper Bound			
Normal Vs DM without foot complications	0.976	P<0.001	0.947	1.00	7.55	96.4%	79.4%
Normal Vs DM with foot complications	0.982	P<0.001	0.94	1.99	8.35	100%	98.2%
DM without Vs with foot complications	0.879	P<0.001	0.816	0.942	8.95	81.8%	78.18%

Table 10 presents the details of the cut-off values for the thickness (mm) to predict foot complications in diabetic patients. ROC analysis was conducted on the thickness (mm) to determine the most appropriate cut-offs.

Normal Vs DM without foot complications : The optimal results of the cutoff value of thickness was ≥ 7.55 is highly accurate with excellent sensitivity and specificity.

Normal Vs DM with foot complications: The optimal results of the cutoff value of thickness was ≥ 8.35 is highly accurate with excellent sensitivity and specificity.

DM without Vs with foot complications: The optimal results of the cutoff value of thickness was ≥ 8.95 is highly accurate with excellent sensitivity and specificity.

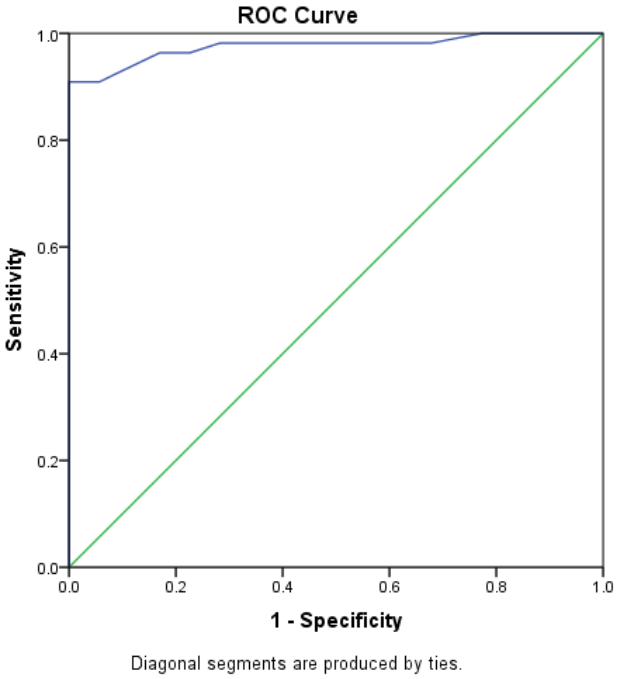

Figure 19. ROC curve comparing AT thickness between controls and Diabetic patients without foot complications

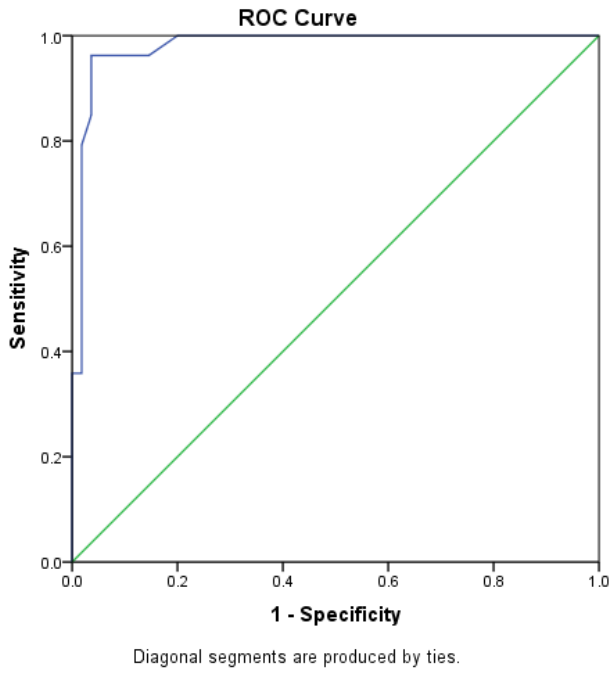

Figure 20. ROC curve comparing AT thickness between controls and Diabetic patients with foot complications

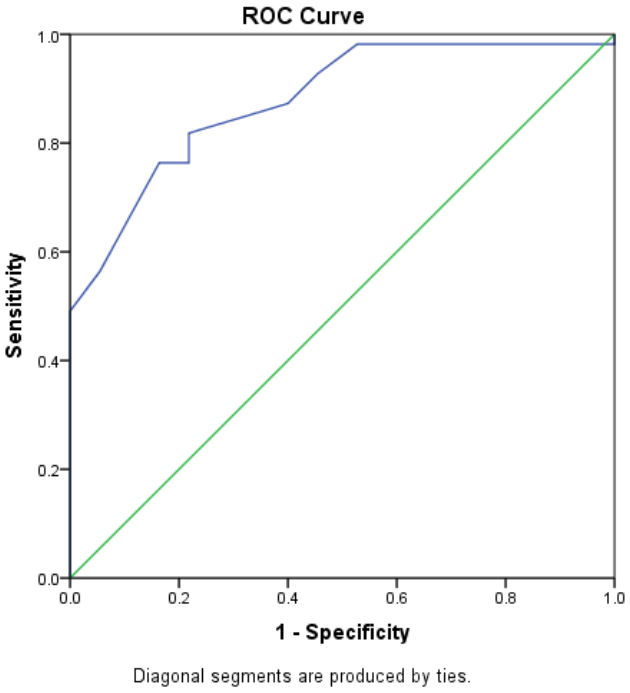

Figure 21. ROC curve comparing AT thickness between Diabetic patients without and with foot complications

Table 11. Cut off value of Young's modulus between Normal Vs DM without foot complications, Normal Vs DM with complications and DM without and with foot complications with its sensitivity, specificity.

Test Result Variable(s) Young Modulus	AUC	P-Value	Asymptotic 95% Confidence Interval		Cut-off Value	Sensitivity	Specificity
			Lower Bound	Upper Bound			
Normal Vs without foot Complications	0.494	0.919	0.380	0.609	-	-	-
Normal Vs DM with Foot Complications	0.995	P<0.001	0.987	1.00	144.5	96.2%	100%
DM without foot complications Vs DM with foot complications	0.879	P<0.001	0.816	0.942	120	81.5%	78.18%

No significant difference in the Young's modulus was found between Normal patients and diabetic patients without foot complications(AUC = 0.494, not significant).

The Young Modulus demonstrates excellent diagnostic accuracy (AUC = 0.995) with high sensitivity and perfect specificity, making it a reliable test for distinguishing between normal individuals and those with diabetes and complications with cut off value less than or equal to 144.5.

The Young Modulus demonstrates excellent diagnostic accuracy (AUC = 0.879), making it a reliable test for distinguishing between diabetic patients without and with foot complication

with cut off value less than or equal to 120.

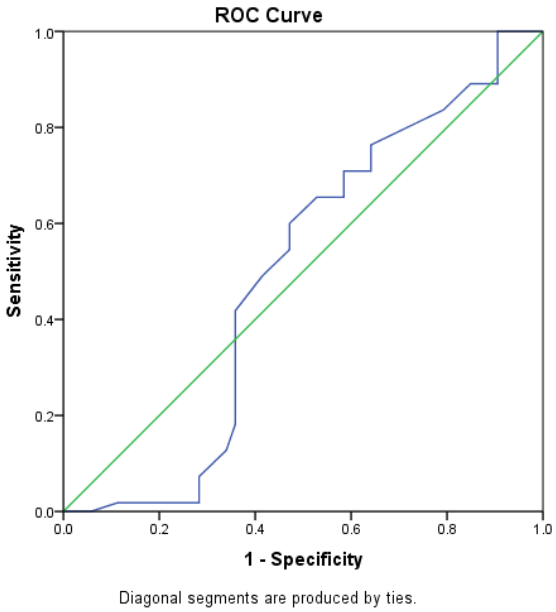

Figure 22. ROC curve comparing Young's modulus between controls and diabetic patients without foot complications

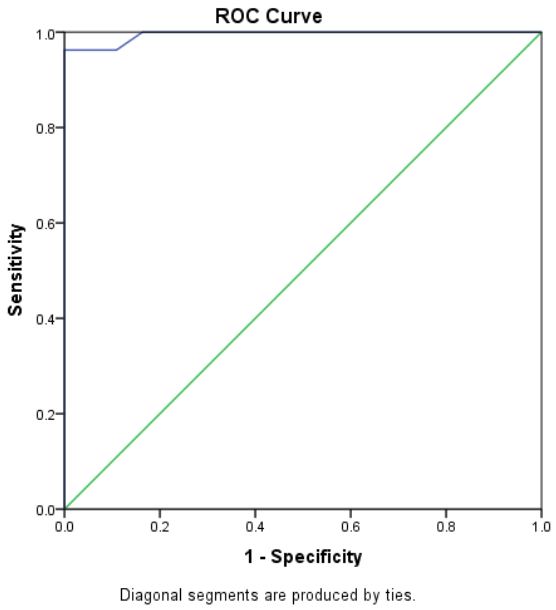

Figure 23.ROC curve comparing Young's modulus between controls and diabetic patients with foot complications

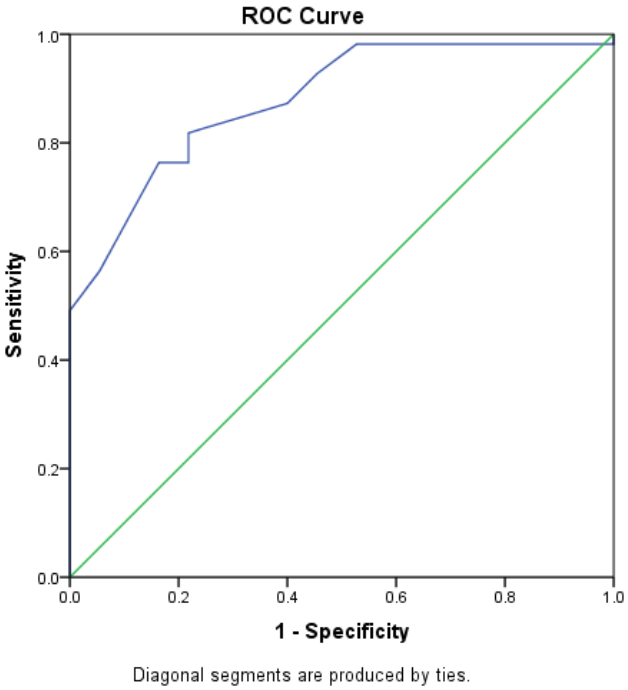

Figure 24. ROC curve comparing Young's modulus between diabetic patients without and with foot complications

IMAGES

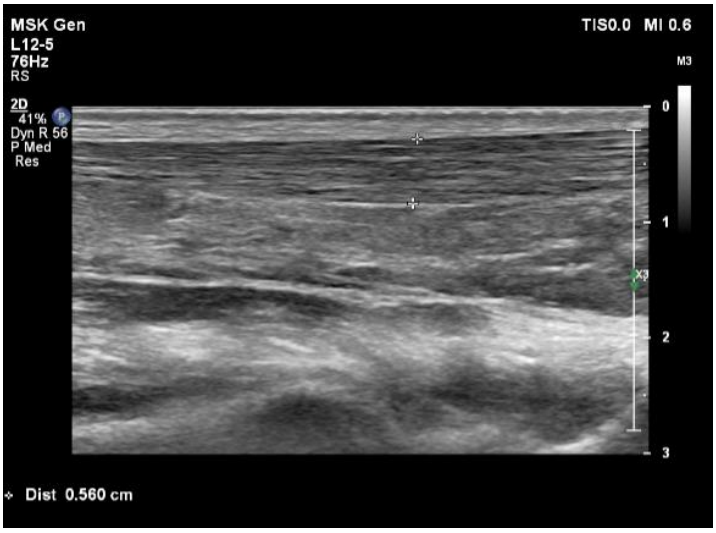

Figure 25a

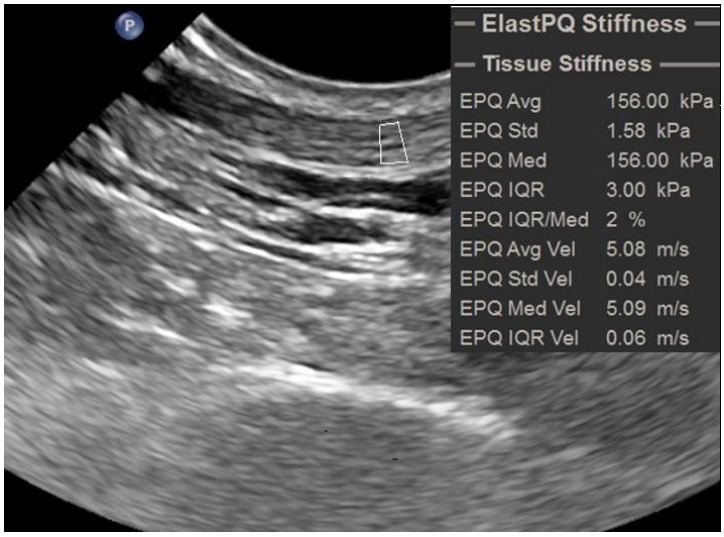

Figure 25b

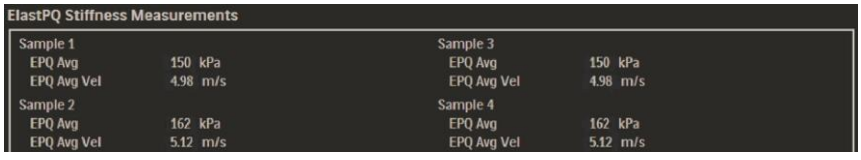

Figure 25c

Figure 25: Ultrasound grey scale images of a non-diabetic male aged 47 years showing Achilles tendon thickness of 5.8 mm (a) & mean Young's Modulus of 156 kPa (b). Figure 25c shows 4 measurements of AT stiffness (in kPa) taken in the same patient.

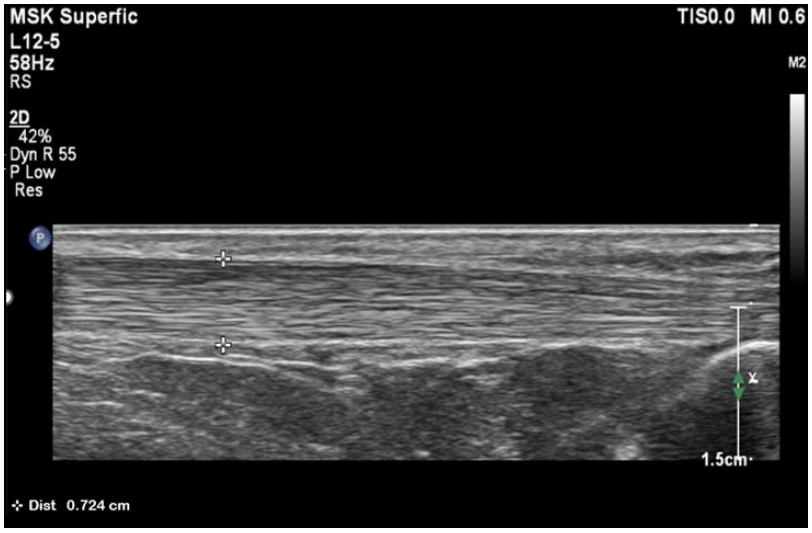

Figure 26a

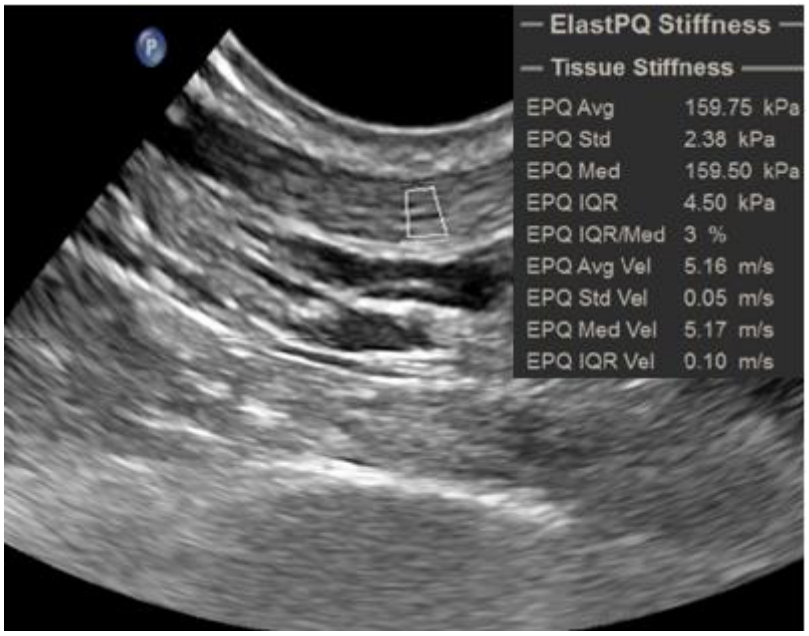

Figure 26b

Figure 26c

Figure 26. Ultrasound grey scale images of a diabetic male aged 53 years showing Achilles tendon thickness of 7.2 mm (a) & mean Young's Modulus of 158.75 kPa (b). Figure 26c shows 4 measurements of AT stiffness (in kPa) taken in the same patient.

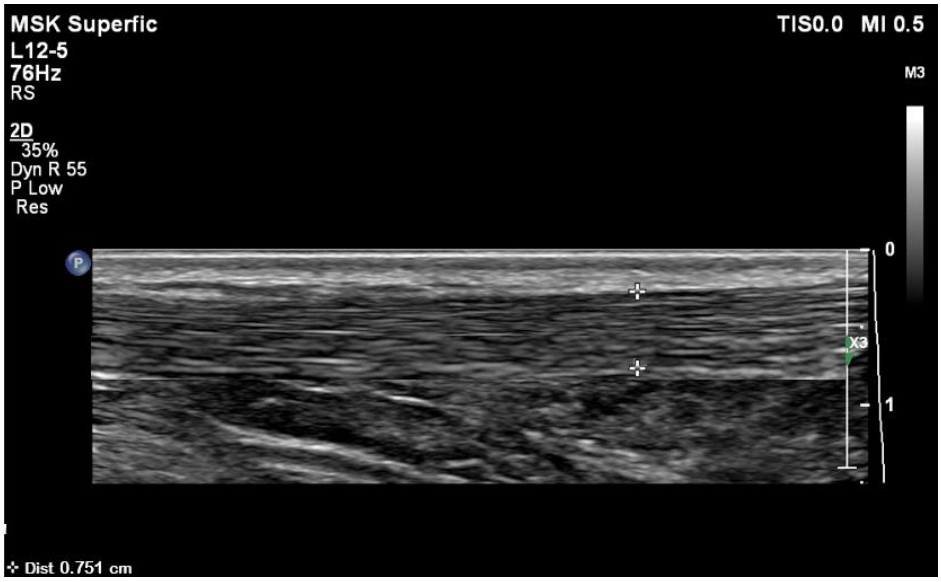

Figure 27a

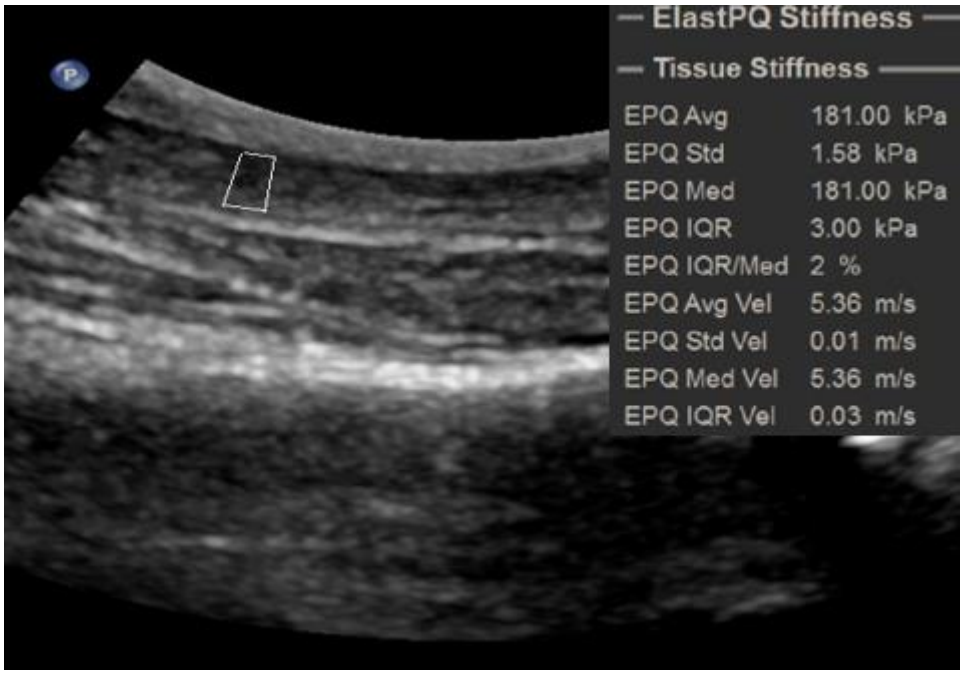

Figure 27b

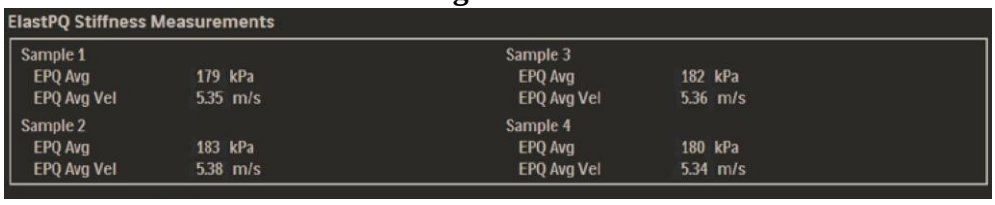

Figure 27c

Figure 27. Ultrasound grey scale images of a diabetic female aged years 57 showing Achilles tendon thickness of 7.5 mm (a) & mean Young's Modulus of 181 kPa (b). Figure 27c shows 4 measurements of AT stiffness (in kPa) taken in the same patient.

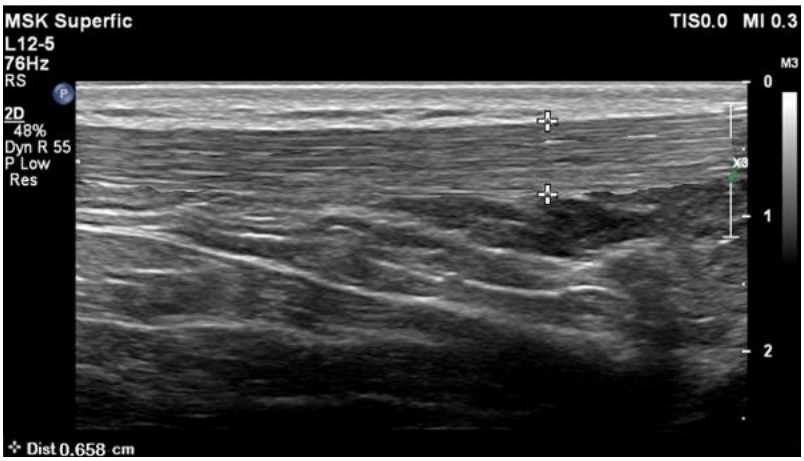

Figure 28a

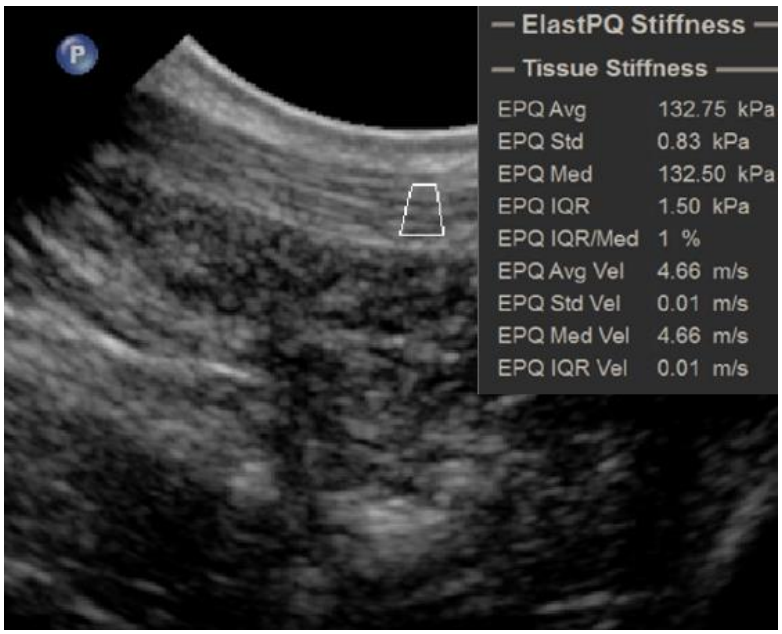

Figure 28b

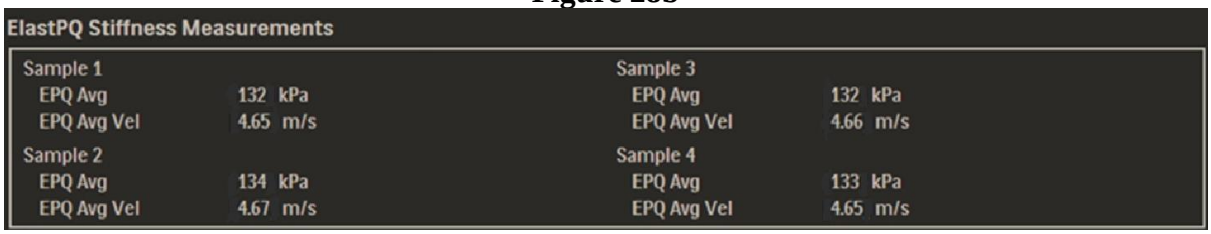

Figure 28c

Figure 28. Ultrasound grey scale images of a diabetic female showing Achilles tendon thickness of 6.5 mm (a) & mean Young's Modulus of 132 kPa (b). Figure 28c shows 4 measurements of AT stiffness (in kPa) taken in the same patient. The mean Young's Modulus of this patient's AT is borderline, suggestive of high risk for foot complications.

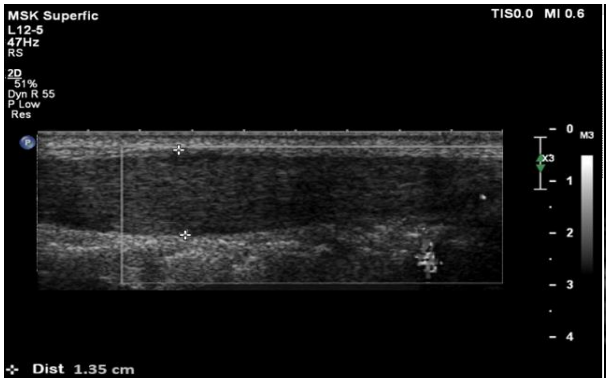

Figure 29a

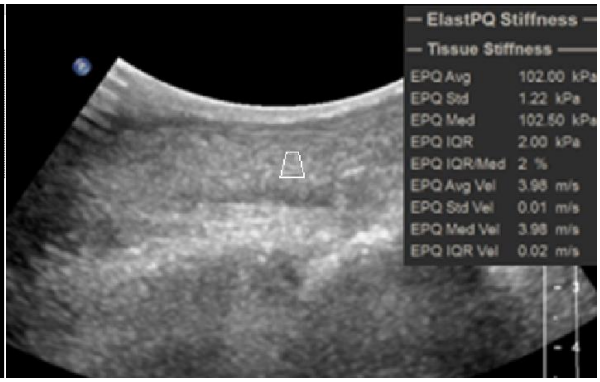

Figure 29b

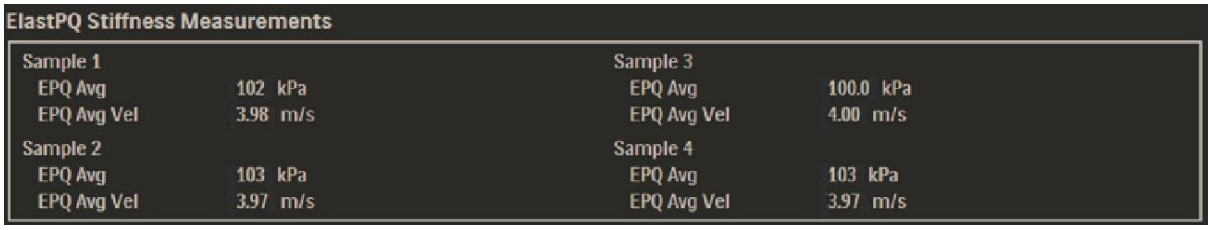

Figure 29c

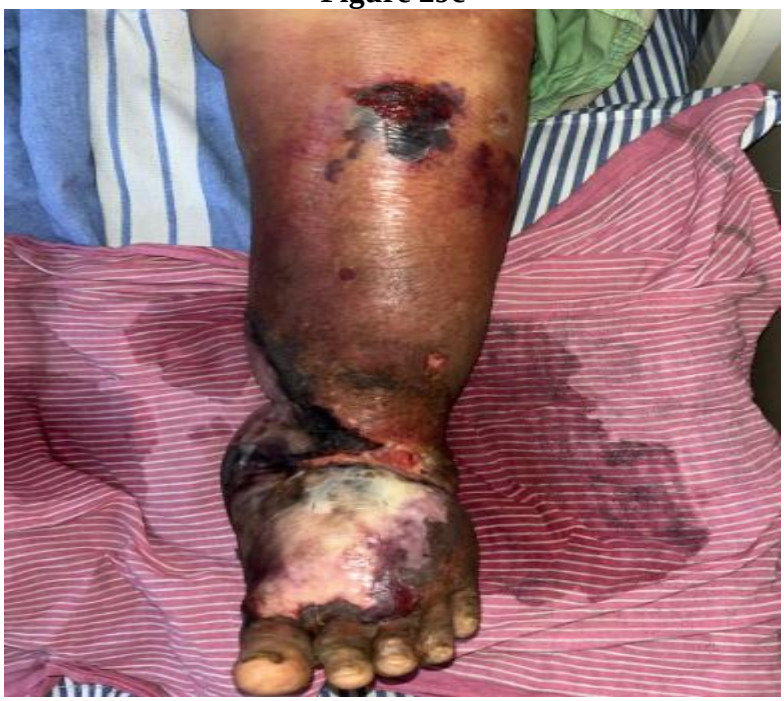

Figure 29d

Figure 29. Ultrasound grey scale images of a diabetic female aged 57 years with foot ulcers showing Achilles tendon thickness of 13.5 mm (a) & mean Young's Modulus of 102 kPa (b). Figure 29c shows 4 measurements of AT stiffness (in kPa) taken in the same patient. Figure 29d shows ulcers over the dorsal aspect of the foot in the same patient.

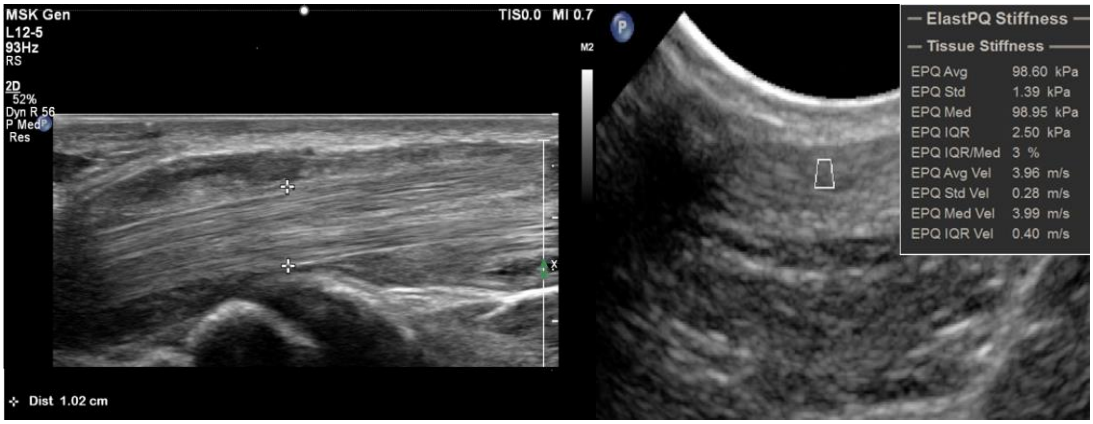

Figure 30a **Figure 30b**

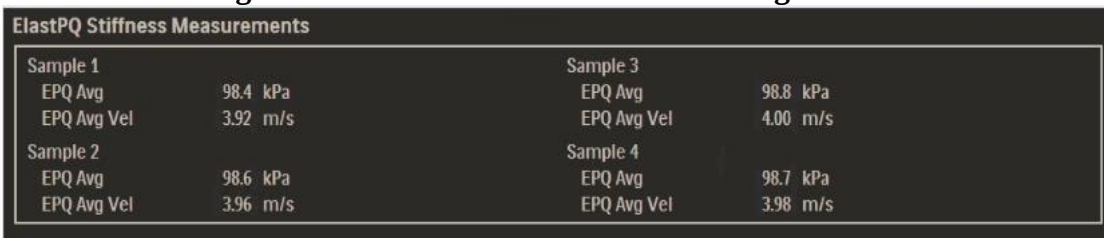

Figure 30c

Figure 30d

Figure 30. Ultrasound grey scale images of a diabetic male aged 65 years with foot ulcers showing Achilles tendon thickness of 10.2 mm (a) & mean Young's Modulus of 98.6 kPa (b). Figure 30c shows 4 measurements of AT stiffness (in kPa) taken in the same patient. Figure 30d shows ulcer over the lateral aspect of the leg & foot in the same patient.

DISCUSSION

DISCUSSION

Diabetes mellitus (DM) is an endocrine disorder associated with numerous long-term complications. Diabetic neuropathy has been extensively studied and has been considered the major cause of onset of foot ulcers. Other factors which might contribute to development of foot ulcers have not been sufficiently studied, as a result of which preventive measures for ulcers have been ineffective.[45,71] Some studies have proposed a relationship between tendinopathy and DM. Tendinopathy is characterized by thickening of peritendinous tissue, widespread proliferation of fibroblasts and connective tissue adhesions. These changes increase tendons' thickness, making the measurement of thickness an important indicator of tendinopathy.[72] Increased thickness of ligaments of the most distal parts of the body has long been observed in patients with DM. This study was programmed to assess the thickness and stiffness of Achilles tendons (AT) in diabetic patients with & without foot ulcers.

In the current study, out of the 165 (100 %) patients, Male predominance was found showing 121 (73.3%) males and 44 (26.7% females. Similar findings of male predominance was seen in the study conducted by Haung et al. showing about 54.8 % (45 patients) males.[73]

In the current study, the mean age was 55.14 years and ranged between 38 – 86 years. Similar age characteristics were noted in the study done by Evarnos et al in 2015. [65]

In our study we found significant thickening of the AT in patients with T2-DM with foot complications (9.49mm±0.5) and T2-DM without foot complications (8.73mm±0.36), compared to healthy patients (6.71mm±0.69). Similar results have been obtained in various studies assessing the effects of diabetes on the AT.

Table 12: AT thickness range.

Category	***Thickness (in mm)***
Normal	< 7.55 mm
Borderline thickened	7.55 – 8.95 mm
Thickened	>8.95 mm

Table 12 shows the derived thickness range for AT. In our study, derived cut-off value for normal AT thickness was < 7.55mm. Diabetic patients with AT thickness of 7.55 – 8.95 mm have a risk of foot complications in future.

Giacomozzi et al. demonstrated that the AT was thicker in patients with diabetes than in controls. Thickening of the Achilles tendon became statistically significant for patients with neuropathy and with previous neuropathic ulcers compared to the control group. The results of our study were similar to this study. However, in contrast to the study by Giocomozzi et al., our patients had ongoing foot ulcers, while patients of their study had previous neuropathic ulcers. Patients with diabetes and previous history of ulceration occupy the highest category of risk for reulceration.[74] Because of the similarity between our study group with current ulcers and the group of patients with diabetes with previous neuropathic ulcers involved in Giocomozzi et al.'s study, the results may not be accidental.[45]

Cheing et al. showed that patients with diabetes with or without neuropathy had a thicker Achilles tendon than the healthy controls.[75] The results of the study done by them were similar to our study. The study by Papanas et al. also demonstrated increased thickness of the Achilles tendon. [76]

In a study conducted by D'Ambrogi et al. in 2005, they showed that thickening of Achilles tendon was more evident in the presence of neuropathy but already detectable in patients with diabetes without neuropathy.[77] Akturk et al observed that the ATT levels of

male DM patients with retinopathy or neuropathy were significantly higher than male DM patients without retinopathy or neuropathy.[78] However such a statistically significant relationship was not demonstrated between the ATT and nephropathy or carotid plaque neither for male nor female diabetic patients. [78]

Very few studies have been published regarding the elastographic properties of the AT in diabetic patients. In our study, SWE was used for evaluation of the AT & was found to be softer in diabetic patients with foot complications as compared to diabetic patients without foot complications. Mean Young's modulus in diabetic patients with foot complications was found to be 116.87 ± 14.1 kPa & in those without foot complications was found to be 165.18 ± 10.25 kPa, which means to say that AT in patients with foot complications has reduced stiffness. The Young Modulus demonstrates excellent diagnostic accuracy, making it a reliable test for predicting diabetic foot complications with cut off value of 120 with a specificity of 78.18% and sensitivity of 81.5 %.

Table 13: Achilles tendon elasticity range in kPa.

Elasticity of AT	***YOUNG'S MODULUS (in kPa)***
Normal	>144.5
Borderline	120 – 144.5
Reduced	<120

Above table 13 shows the Young's modulus values of AT that were derived in our study. Diabetic patients who had borderline values are at a risk of developing foot complications.

Evranos et al. in the year 2015 was the first to evaluate AT by elastography in patients with diabetes; they found that the stiffness in the middle and lower one-third of the AT was significantly lower in patients with foot ulcers compared with controls. This can be compared

to our study which also showed similar results.[65] In their study, the Achilles tendon was softer in patients with longer duration of diabetes, or patients using insulin instead of oral anti-diabetic medications, having foot ulcers regardless of the site, or having neuropathy or Peripheral arterial disease. Our study yielded similar results where patients with diabetic foot complications had softer AT as compared to other groups.[65]

Guney et al. evaluated biochemical parameters of diabetic and non-diabetic Achilles tendons and observed decreasing of the stiffness and elasticity of diabetic tendons. They concluded that, 'the structural and functional alterations associated with diabetes adversely affect the biomechanical properties of the Achilles tendon, potentially acting together with neuropathy and ischemia in the development of diabetic foot ulcers'.[79]

Our results were similar to the results of the study conducted by İyidir et al. in 2021. Their study included 45 patients with type 2 diabetes were divided into 2 subgroups. Those with peripheral neuropathy were defined as group I (22 patients) and those without peripheral neuropathy were defined as group II (23 patients). A total of thirty age-, gender-, and body mass index-matched healthy individuals were selected as controls. They assessed the thickness & elasticity of AT and concluded that, 'Diabetic patients with neuropathy have thicker and softer Achilles tendon while the elasticity of Achilles tendon in diabetic patients without neuropathy is similar to the healthy controls. Softening of the Achilles tendon may be an early sign of diabetic foot and reveal the patients with a risk of diabetic foot. [66]

A study was conducted by Harish et al. in 2020. 61 healthy volunteers and 81 patients with type 2 DM. The patients were further divided into those with and without peripheral neuropathy (PN). Like our study, they concluded that, 'there are alterations in AT resulting in thickening and softening of this structure in patients with T2-DM compared with healthy volunteers'.[67]

Zhang et al.'s study used a novel technique of RTSWE to measure the elastic modulus of AT previous study has validated the utility of SWE in measuring viscoelastic properties of tendons. [69] The study found that SWE was a promising way to detect the change of elastic modulus in the injury and recovery period of AT. [69] Compared with other methods for the detection of AT, RTSWE has two advantages. First, the excitation frequency may be over the upper limit of commercial systems in normal AT, but RTSWE can eliminate this weakness with the use of high frequency ultrasound. Clinicians only need to adjust the machine mode without additional work. Therefore, it is feasible to evaluate AT in patients with diabetic foot ulcers as well as health AT using the combination of RTSWE and high-frequency ultrasound. They found that there was no significant difference in either thickness or Young's modulus of AT between patients with and without diabetic foot ulcers. Our results are contrast to their study since we found both AT thickness and Young's modulus showed difference between T2Dm patients with or without foot ulcer.[69]

One of the major limitation of elastography was the inability to correlate it with histological findings. However, Klauser et al. (2013) correlated elastographic findings of AT of cadavers with histology & concluded that there is perfect correlation of the two. Hence, SWE can be a very reliable technique to assess the elasticity with high accuracy. [80]

The diabetes-induced structural changes in the foot, mainly in the AT, result in alterations in the foot loading pattern during propulsion. Changes in the walking strategy in diabetics result in abnormal cumulative stress, which could result in thickening of the tendons as an adaptive response. Reduced neoangiogenesis in diabetics with chronic tendinopathy was observed in a study, which could be one of the pathologic bases for Achilles tendinopathy in diabetics. Another possible mechanism proposed for tendon thickening is compensation for the areas of structural disorganization by thickening of the pathologic

tendons. In a study by Wang et al. it has been suggested that for thicker structures, elasticity is lower therefore the elastic modulus is lesser, assuming the strain to be constant. This could be one of the possible explanations for lower SWV values found in the AT of diabetics as thickening of the tendon results in increase in cross-sectional area and reduced stress. [81]

The results obtained in the present study support the hypothesis that DM induces changes in the AT. The altered morphology and softening of the AT may lead to altered foot mechanics and eventually may even have a role in the development of foot ulcers. A knowledge of the various diabetes-related changes evaluated using SWE helps in better prevention of foot complications in diabetic patients.

CONCLUSION

CONCLUSION

Diabetic patients with foot complications have a thicker Achilles tendon as compared to those without any foot complications. Non-diabetic controls had a relatively thinner Achilles tendon as compared to both the diabetic groups.

The diabetic patients with foot complications had a relatively low Young's modulus compared to those without foot complications, which implies that the AT in patients with foot complications are less elastic as compared to those without foot complications. However, there was no significant difference in the stiffness of AT between non-diabetic controls & diabetic patients without foot complications.

A cut-off value of < 120 kPa had a very good diagnostic accuracy to differentiate between the AT of diabetic patients with foot complications and diabetic patients without foot complications, which implies that the AT is softer in diabetic patients with foot complications.

Hence, decrease in the elasticity of AT & its thickening in diabetic patients can be an important marker of impending foot complications.

SUMMARY

SUMMARY

A hospital based, prospective comparative study was conducted in the department of Radio-Diagnosis, R.L. Jalappa Hospital and Research Centre attached to Sri Devaraj Urs Medical College, Tamaka, Kolar, to perform shear wave elastography of Achilles tendon in normal individuals, diabetic patients with and without foot complications. The study included consecutive patients with diabetic foot complications referred for ultrasound examination to Radiodiagnosis department. A total of 110 patients were included with 55 patients with foot complications (Group 1) and 55 without foot complications (Group 2) with age and gender matched 55 controls (normal individuals) referred for ultrasound elastography examination to the department of Radio-Diagnosis. Patients with history of Achilles tendinitis, trauma, varicose veins, etc were excluded from the study as they would lead to false positive results.

Male predominance was found in the study, showing 121 (73.3%) males and 44 (26.7% females. The mean age of the patients was 55.14± 10.11 years. There was no significant difference in the gender and age between the three groups.

The FBS level was significantly high in in T2DM patients compared to healthy individuals with mean values of 88.58±5.29 mg/dl in healthy participants, 145.16±14.21 mg/dl in T2DM patients without foot complications and 142.67±11.43 mg/dl in T2DM patients with foot complications.

The PPBS level was significantly high in in T2DM patients compared to healthy individuals with mean values of 124.76±9.37 mg/dl in healthy participants, 228.95±21.2 mg/dl in T2DM patients without foot complications and 236.29±21.22 mg/dl in T2DM patients with foot complications.

The AT thickness was more in T2DM patients with foot complications (mean ~ 9.49±0.5 mm) when compared to T2DM without foot complications (mean ~ 8.73±0.36 mm) and healthy participants (mean ~ 6.71±0.69 mm), with p value <0.001 which is statistically significant. This shows that the structural alterations in the AT in the form of thickening is seen in DM patients. As mentioned earlier, patients with diabetic foot complications showed a thicker AT as compared to other two groups. Hence, this proves the fact that non-enzymatic glycation of collagenous component due to hyperglycemia plays an important role in AT thickening which leads to increase in mechanical load on the foot.

The cutoff value for AT thickness for healthy vs T2DM without foot complications was found to be 7.55mm with 96.4% sensitivity and 79.4% specificity. The cutoff value for AT thickness for T2DM without vs with foot complications was found to be 8.95mm with 81.8% sensitivity and 78.18% specificity. When AT thickness approaches 8.95mm in diabetic patients, it could possibly be a sign of impending foot complications.

Shear wave elastography of AT was performed and the elasticity of AT was documented in kPa. There was no significant difference in the Young's modulus between normal individuals and DM patients without foot complications. Young's modulus was significantly lower in patients with diabetic foot complications (mean ~116.87 ± 14.1 kPa) as compared to those without foot complications (mean ~165.18 ± 10.25 kPa), which means that the elasticity of AT in patients with foot complications was significantly less. A cut-off value of < 120 kPa had a very good diagnostic accuracy (AUC = 0.879) to differentiate between the AT stiffness of diabetic patients with foot complications and diabetic patients without foot complications with a specificity of 78.18% and sensitivity of 81.5 %. This means that hyperglycemia induced non-enzymatic

glycation of collagenous tissue softens the AT which affects the normal functioning of foot arches. This causes flattening of the arches of foot, hence predisposing to foot complications.

Shear wave elastography is a non-invasive technique to evaluate the stiffness of AT. Performing SWE on DM patients can help us keep a track on the stiffness of AT which in-turn helps us in preventing foot complications that can occur.

Hence, thickening & decrease in the elasticity of AT which can be evaluated using USG & Shear wave elastography can be an important marker of impending foot complications in diabetic patients.

LIMITATIONS AND RECOMMENDATIONS

Major limitation of the study was small sample size. The results of this study are more likely to contain type II statistical errors, so our findings need to be verified by carrying out a larger, multi-centric randomized trial. As with any technology, there are limitations to the modality that need to be taken into account, even if the research seems to support the use of SWE in the field of MSK imaging. There will probably be variation in the measurements obtained from a broad spectrum of the population, and in order to support clinical decision-making and application, a database of typical stiffness ranges should be established. However, SWE of AT can be incorporated as a routine method to screen diabetic patients for impending foot complications.

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ANNEXURE

ANNEXURES

ANNEXURE I

PATIENT PROFORMA

SUBJECT EVALUATION

Date:

Time:

Demographic Variables

Hospital number:

Age :

Sex :

Phone no :

Address :

Occupation :

Brief History:

Biochemical Parameters:

Fasting blood sugar:

Post prandial blood sugar:

Disease Details:

NORMAL INDIVIDUAL ☐

DIABETIC PATIENT WITH FOOT COMPLICATIONS ☐

DIABETIC PATIENT WITHOUT FOOT COMPLICATIONS ☐

Ultrasound:

Achilles tendon thickness - mm

Shear Wave Elastography:

Elastography values Achilles tendon

in kPa (4 readings): / / /

Mean elastography value (in kPa):

ANNEXURE II- INFORMED CONSENT FORM

I Mr./Mrs. _____have been explained in my own understandable language, that I will be included in a study title, "**ROLE OF SHEAR WAVE ELASTOGRAPHY IN ASSESSING ACHILLES TENDON IN NORMAL INDIVIDUALS, DIABETIC PATIENTS WITH AND WITHOUT FOOT COMPLICATIONS"**

I have been explained that my clinical findings, investigations, will be assessed and documented for study purpose.

I have been explained my participation in this study is entirely voluntary, and I can withdraw from the study any time and this will not affect my relation with my doctor or the treatment for my ailment.

I have been explained about the interventions needed possible benefits and adversities due to interventions, in my own understandable language.

I have understood that all my details found during the study are kept confidential and while publishing or sharing of the findings, my details will be masked.

I have principal investigator mobile number for enquiries.

I in my sound mind give full consent to be added in the part of this study.

Signature of the patient:

Name:

Signature of the witness:

Name:

Relation to patient:

Date:

Place:

ANNEXURE III - PATIENT INFORMATION SHEET

STUDY TITLE: " **ROLE OF SHEAR WAVE ELASTOGRAPHY IN ASSESSING ACHILLES TENDON IN NORMAL INDIVIDUALS, DIABETIC PATIENTS WITH AND WITHOUT FOOT COMPLICATIONS**"

STUDY SITE: R.L Jalappa Hospital and Research Centre, Tamaka, Kolar.

This is to inform you that,

We are conducting this study to assess role of shear wave elastography in assessing Achilles tendon in normal individuals, diabetic patients with and without foot complications.

If you are willing to be enrolled in this study, we perform elastography and other relevant investigations needed to assess the Achilles tendon.

This will facilitate in deriving cut off values of elastography of Achilles tendon in normal individuals, diabetic patients with and without foot complications. It will also benefit other patients with diabetes mellitus undergoing medical therapy in the future. You are free to opt-out of the study at anytime if you are not satisfied or apprehensive to be a part of the study. Your treatment and care will not be compromised if you refuse to be a part of the study. The study will not add any risk or financial burden to you if you are part of the study Your identity and clinical details will be confidential. You will not receive any financial benefit for being part of the study. You are free to contact Dr. Rishi Prajwal H L or any other member of the above research team for any doubt or clarification you have.

Dr. Rishi Prajwal H L
Mobile no: 8722022228
E-mail id: iamrishi96@gmail.com

MASTER CHART

KEY TO MASTER CHART:

M- Male

F- Female

FBS- Fasting blood sugar

PPBS- Post-prandial blood sugar

ATT- Achilles tendon thickness

N- Normal

T- Thickened

BL – Borderline

NA- Not applicable

*OG- On-going foot complications

*Patients already have on-going foot complications.

SL NO	UHID	AGE	SEX	GROUP	FBS (in mg/dL)	PPBS (in mg/dL)	ATT (in mm)	THICKNESS INTERPRETATION - Normal/ Thickened	YOUNG'S MODULUS (in kPa)	ELASTICITY - Normal/ Borderline/ Reduced	RISK OF DEVELOPING FOOT COMPLICATIONS - Yes/ No/ on-going foot complications
1	654744	45	M	NORMAL	87	124	7.1	N	192	N	No
2	194617	43	M	NORMAL	90	125	6	N	187	N	No
3	127454	43	F	NORMAL	92	131	6.5	N	167	N	No
4	689145	56	M	NORMAL	86	112	6.7	N	153	N	No
5	684592	51	M	NORMAL	81	102	6.9	N	159	N	No
6	140817	70	F	NORMAL	92	125	7.9	T	179	N	No
7	194622	65	M	NORMAL	89	131	8	T	194	N	No
8	663226	42	M	NORMAL	95	129	7.2	N	164	N	No
9	699119	47	F	NORMAL	98	136	6.9	N	162	N	No
10	189170	38	M	NORMAL	86	128	6.3	N	168	N	No
11	178834	45	M	NORMAL	99	131	6	N	189	N	No
12	629313	58	F	NORMAL	84	126	5.8	N	135	N	No
13	667827	77	M	NORMAL	79	110	7.9	T	149	N	No
14	634663	86	M	NORMAL	87	111	6.9	N	187	N	No
15	168737	56	M	NORMAL	89	131	6.5	N	156	N	No
16	120954	43	M	NORMAL	91	128	6.1	N	145	N	No
17	119536	59	F	NORMAL	88	129	5.9	N	156	N	No
18	146755	42	F	NORMAL	82	137	6.1	N	154	N	No
19	699797	45	M	NORMAL	87	124	7.1	N	192	N	No
20	199599	43	M	NORMAL	90	125	6	N	187	N	No
21	623035	43	F	NORMAL	92	131	6.5	N	167	N	No
22	143935	56	M	NORMAL	86	112	6.7	N	153	N	No
23	134345	51	M	NORMAL	81	102	6.9	N	159	N	No
24	690899	70	F	NORMAL	92	125	7.9	T	179	N	No
25	622942	65	M	NORMAL	89	131	8	T	194	N	No
26	616309	42	M	NORMAL	95	129	7.2	N	164	N	No
27	630834	47	F	NORMAL	98	136	6.9	N	162	N	No
28	125755	38	M	NORMAL	86	128	6.3	N	168	N	No
29	138004	45	M	NORMAL	99	131	6	N	189	N	No
30	180262	58	F	NORMAL	84	126	5.8	N	157	N	No
31	661454	77	M	NORMAL	79	110	7.9	T	149	N	No
32	164517	86	M	NORMAL	87	111	6.9	N	187	N	No
33	189810	56	M	NORMAL	89	131	6.5	N	156	N	No

SL NO	UHID	AGE	SEX	GROUP	FBS (in mg/dL)	PPBS (in mg/dL)	ATT (in mm)	THICKNESS INTERPRETATION - Normal/ Thickened	YOUNG'S MODULUS (in kPa)	ELASTICITY - Normal/ Borderline/ Reduced	RISK OF DEVELOPING FOOT COMPLICATIONS - Yes/ No/ on-going foot complications
34	629954	43	M	NORMAL	91	128	6.1	N	145	N	No
35	119817	59	F	NORMAL	88	129	5.9	N	156	N	No
36	191844	42	F	NORMAL	82	137	6.1	N	154	N	No
37	112620	45	M	NORMAL	87	124	7.1	N	192	N	No
38	614386	43	M	NORMAL	90	125	6	N	187	N	No
39	643852	43	F	NORMAL	92	131	6.5	N	167	N	No
40	619967	56	M	NORMAL	86	112	6.7	N	153	N	No
41	170145	51	M	NORMAL	81	102	6.9	N	159	N	No
42	613980	70	F	NORMAL	92	125	7.9	T	179	N	No
43	620567	65	M	NORMAL	89	131	8	N	194	N	No
44	129361	42	M	NORMAL	95	129	7.2	N	164	N	No
45	635879	47	F	NORMAL	98	136	6.9	N	162	N	No
46	682881	38	M	NORMAL	86	128	6.3	N	168	N	No
47	112428	45	M	NORMAL	99	131	6	N	189	N	No
48	652512	58	F	NORMAL	84	126	5.8	N	147	N	No
49	684690	77	M	NORMAL	79	110	7.9	T	149	N	No
50	654548	86	M	NORMAL	87	111	6.9	N	187	N	No
51	640209	56	M	NORMAL	89	131	6.5	N	156	N	No
52	678744	43	M	NORMAL	91	128	6.1	N	145	N	No
53	664830	59	F	NORMAL	88	129	5.9	N	156	N	No
54	667162	42	F	NORMAL	82	137	6.1	N	154	N	No
55	177294	45	M	NORMAL	87	124	7.1	N	192	N	No
56	658876	43	M	DM	156	220	8.7	T	168	N	No
57	163156	55	M	DM	142	243	9.2	T	169	N	No
58	630028	63	M	DM	143	218	8.6	T	161	N	No
59	159022	53	F	DM	146	237	9.1	T	143	BL	YES
60	638952	47	M	DM	128	253	9.2	T	143	BL	YES
61	641360	38	F	DM	154	210	8.5	T	179	N	No
62	652430	67	M	DM	166	224	8.4	T	182	N	No
63	144767	65	M	DM	135	211	8.9	T	169	N	No
64	655370	45	F	DM	141	203	8.3	T	166	N	No
65	190969	79	M	DM	187	225	8.9	T	178	N	No
66	122954	56	M	DM	148	226	8.3	T	171	N	No

SL NO	UHID	AGE	SEX	GROUP	FBS (in mg/dL)	PPBS (in mg/dL)	ATT (in mm)	THICKNESS INTERPRETATION - Normal/ Thickened	YOUNG'S MODULUS (in kPa)	ELASTICITY - Normal/ Borderline/ Reduced	RISK OF DEVELOPING FOOT COMPLICATIONS - Yes/ No/ on-going foot complications
67	683792	61	F	DM	150	273	8.6	T	153	N	No
68	625554	71	M	DM	130	263	9.3	T	156	N	No
69	687744	53	M	DM	134	250	8.8	T	167	N	No
70	683292	57	F	DM	129	210	9.1	T	157	N	No
71	183055	48	M	DM	135	206	8.6	T	164	N	No
72	132452	49	M	DM	141	210	8.9	T	174	N	No
73	667110	43	M	DM	156	220	8.7	T	168	N	No
74	688961	55	M	DM	142	243	9.2	T	169	N	No
75	195716	63	M	DM	143	218	8.6	T	141	N	No
76	651458	53	F	DM	146	237	7.4	N	153	BL	YES
77	130727	47	M	DM	128	253	9.2	T	133	BL	YES
78	618856	38	F	DM	154	210	8.5	T	179	N	No
79	141439	67	M	DM	166	224	8.4	T	182	N	No
80	668267	65	M	DM	135	211	8.9	T	169	N	No
81	191542	45	F	DM	141	203	8.3	T	166	N	No
82	160653	79	M	DM	187	225	8.9	T	178	N	No
83	622417	56	M	DM	148	226	8.3	T	171	N	No
84	173821	61	F	DM	150	273	8.6	T	153	N	No
85	648622	71	M	DM	130	263	9.3	T	142	BL	YES
86	189668	53	M	DM	134	250	8.8	T	167	N	No
87	160417	57	F	DM	129	210	9.1	T	157	N	No
88	651253	48	M	DM	135	206	8.6	T	164	N	No
89	638214	49	M	DM	141	210	8.9	T	174	N	No
90	628910	43	M	DM	156	220	8.7	T	168	N	No
91	189043	55	M	DM	142	243	9.2	T	169	N	No
92	673573	63	M	DM	143	218	7.2	N	161	N	No
93	196677	53	F	DM	146	237	7.5	N	147	N	No
94	153658	47	M	DM	128	253	9.2	T	139	BL	YES
95	112218	38	F	DM	154	210	8.5	T	179	N	No
96	619478	67	M	DM	166	224	8.4	T	182	N	No
97	632288	65	M	DM	135	211	8.9	T	169	N	No
98	647357	45	F	DM	141	203	8.3	T	166	N	No
99	126630	79	M	DM	187	225	8.9	T	178	N	No

SL NO	UHID	AGE	SEX	GROUP	FBS (in mg/dL)	PPBS (in mg/dL)	ATT (in mm)	THICKNESS INTERPRETATION - Normal/ Thickened	YOUNG'S MODULUS (in kPa)	ELASTICITY - Normal/ Borderline/ Reduced	RISK OF DEVELOPING FOOT COMPLICATIONS - Yes/ No/ on-going foot complications
100	653831	56	M	DM	148	226	7.4	N	171	N	No
101	167203	61	F	DM	150	273	8.6	T	153	N	No
102	165713	71	M	DM	130	263	9.3	T	144	BL	YES
103	117345	53	M	DM	134	250	8.8	T	167	N	No
104	183265	57	F	DM	129	210	9.1	T	157	N	No
105	169267	48	M	DM	135	206	8.6	T	164	N	No
106	166414	49	M	DM	141	210	8.9	T	174	N	No
107	137278	49	M	DM	141	210	8.9	T	174	N	No
108	677164	43	M	DM	156	220	8.7	T	168	N	No
109	197623	55	M	DM	142	243	9.2	T	169	N	No
110	689422	61	F	DM	150	273	8.6	T	153	N	No
111	682214	55	M	DM WITH ULCERS	152	235	9.2	T	123	R	OG
112	183613	53	M	DM WITH ULCERS	145	256	9.6	T	121	R	OG
113	670823	67	M	DM WITH ULCERS	140	218	10	T	97	R	OG
114	610128	52	M	DM WITH ULCERS	146	238	10.2	T	135	BL	OG
115	144919	51	M	DM WITH ULCERS	128	256	9.7	T	142	BL	OG
116	659707	48	F	DM WITH ULCERS	156	210	9	T	125	BL	OG
117	127060	62	M	DM WITH ULCERS	176	232	8.8	T	117	R	OG
118	116584	59	M	DM WITH ULCERS	135	222	9.2	T	109	R	OG
119	629534	50	F	DM WITH ULCERS	142	203	9.3	T	119	R	OG
120	116782	62	M	DM WITH ULCERS	129	225	9.2	T	95	R	OG
121	672348	56	M	DM WITH ULCERS	148	265	9.7	T	119	R	OG
122	675739	55	F	DM WITH ULCERS	150	273	8.9	T	107	R	OG
123	692352	61	M	DM WITH ULCERS	135	264	8.7	T	102	R	OG
124	117964	58	M	DM WITH ULCERS	141	261	10.3	T	106	R	OG
125	197293	56	M	DM WITH ULCERS	132	223	10.1	T	123	BL	OG
126	112189	56	M	DM WITH ULCERS	131	225	10.2	T	106	R	OG
127	628913	51	M	DM WITH ULCERS	145	221	9.5	T	144	BL	OG
128	178191	55	M	DM WITH ULCERS	152	235	9.2	T	123	R	OG
129	673963	53	M	DM WITH ULCERS	145	256	9.6	T	121	R	OG
130	162868	67	M	DM WITH ULCERS	140	218	10	T	97	R	OG
131	612162	52	M	DM WITH ULCERS	146	238	10.2	T	135	R	OG
132	123169	51	M	DM WITH ULCERS	128	256	9.7	T	147	N	OG

SL NO	UHID	AGE	SEX	GROUP	FBS (in mg/dL)	PPBS (in mg/dL)	ATT (in mm)	THICKNESS INTERPRETATION - Normal/ Thickened	YOUNG'S MODULUS (in kPa)	ELASTICITY - Normal/ Borderline/ Reduced	RISK OF DEVELOPING FOOT COMPLICATIONS - Yes/ No/ on-going foot complications
133	647563	48	F	DM WITH ULCERS	156	210	9	T	125	BL	OG
134	632746	62	M	DM WITH ULCERS	176	232	8.8	T	117	R	OG
135	632710	59	M	DM WITH ULCERS	135	222	9.2	T	109	R	OG
136	678920	50	F	DM WITH ULCERS	142	203	9.3	T	123	BL	OG
137	120899	62	M	DM WITH ULCERS	129	225	9.2	T	95	R	OG
138	120966	56	M	DM WITH ULCERS	148	265	9.7	T	119	R	OG
139	137398	55	F	DM WITH ULCERS	150	273	8.9	T	107	R	OG
140	110066	61	M	DM WITH ULCERS	135	264	8.7	T	102	R	OG
141	656847	58	M	DM WITH ULCERS	141	261	10.3	T	106	R	OG
142	665803	56	M	DM WITH ULCERS	132	223	10.1	T	119	R	OG
143	610218	56	M	DM WITH ULCERS	131	225	10.2	T	106	R	OG
144	699267	51	M	DM WITH ULCERS	145	221	9.5	T	144	BL	OG
145	164292	55	M	DM WITH ULCERS	152	235	9.2	T	123	BL	OG
146	624285	53	M	DM WITH ULCERS	145	256	9.6	T	119	R	OG
147	671866	67	M	DM WITH ULCERS	140	218	10	T	97	R	OG
148	194711	52	M	DM WITH ULCERS	146	238	10.2	T	135	BL	OG
149	662691	51	M	DM WITH ULCERS	128	256	9.7	T	142	BL	OG
150	115740	48	F	DM WITH ULCERS	156	210	9	T	125	BL	OG
151	692874	62	M	DM WITH ULCERS	176	232	8.8	T	117	R	OG
152	118144	59	M	DM WITH ULCERS	135	222	9.2	T	109	R	OG
153	661150	50	F	DM WITH ULCERS	142	203	9.3	T	118	R	OG
154	113701	62	M	DM WITH ULCERS	129	225	9.2	T	95	R	OG
155	156962	56	M	DM WITH ULCERS	148	265	9.7	T	119	R	OG
156	636402	55	F	DM WITH ULCERS	150	273	8.9	T	107	R	OG
157	617988	61	M	DM WITH ULCERS	135	264	8.7	T	102	R	OG
158	124131	58	M	DM WITH ULCERS	141	261	10.3	T	106	R	OG
159	130275	56	M	DM WITH ULCERS	132	223	10.1	T	123	BL	OG
160	618065	56	M	DM WITH ULCERS	131	225	10.2	T	106	R	OG
161	641248	51	M	DM WITH ULCERS	145	221	9.5	T	144	BL	OG
162	674414	59	M	DM WITH ULCERS	135	222	9.2	T	109	R	OG
163	695188	50	F	DM WITH ULCERS	142	203	9.3	T	116	R	OG
164	119549	62	M	DM WITH ULCERS	129	225	9.2	T	95	R	OG
165	127880	56	M	DM WITH ULCERS	148	265	9.7	T	119	R	OG