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Biomechanical Properties of Posterior to Anterior Lag Screw Insertion in Fibular Supination-External Rotation Fractures and Effect of Engaged Cortical Thickness

A Thesis Submitted to the

Yale University School of Medicine

in Partial Fulfillment of the Requirements for the

Degree of Doctor of Medicine

by

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2022

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Abstract

The fracture pattern of supination-external rotation injury of the fibula is often reducible by lag screw fixation. This thesis is designed to evaluate biomechanical differences between lag screws inserted from an anterior to posterior direction and from a posterior to anterior direction and if the thickness of the anterior and posterior fibular cortices were similarly correlated. 5 donor-matched pairs of cadaver fibula were harvested and submitted to material testing following 3.5-mm cortical screw insertion from either an anterior to posterior direction or a posterior to anterior direction and screw insertion torque and axial pullout strength were measured. Computed tomography images of 40 patients undergoing preoperative planning for ankle injuries excluding the fibula were examined to define fibular cortical thickness. The anterior cortex of the distal fibula exhibited a radiographically greater thickness than that of the posterior cortex at the same level (p < 0.001). The axial pullout strength of lag screws inserted from posterior to anterior was significantly greater than that of lag screws inserted from anterior to posterior (p < 0.05). Screw insertion torque measurements demonstrated a similar trend although the data did not reach statistical significance (p = 0.056). For supination-external rotation fracture patterns of the distal fibula, posterior to anterior lag screw insertion exhibited superior biomechanical properties when compared to the anterior to posterior approach. These results also correlated with the cortical thickness of bone measured along the anterior fibula.

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TABLE OF CONTENTS

INTRODUCTION: Page 5

THESIS PURPOSE AND AIMS: Page 25

METHODS: Page 26

RESULTS: Page 33

DISCUSSION: Page 34

REFERENCES: Page 37

INTRODUCTION

Ankle Fractures: Epidemiology and Burden

Ankle fractures are a common injury seen in orthopedic practice accounting for 9% of fractures with a high incidence in both young men typically due to high energy impacts and in post-menopausal women due to fragility fractures associated with osteoporosis.[1] Fragility fractures alone are estimated to cost the United States more than 20 billion dollars annually.[2] A study from German insurers showed one million days off from work for every 100,000 members insured. [3] Compared to matched population norms, patients with ankle fractures requiring surgical intervention demonstrated reduced physical function and general health scores for at least 2 years, and between 17 and 24% of these patients may have less-than-satisfactory long-term outcomes. [4] The annual incidence of ankle fractures has increased to 150 out of 100,000 annually from 57 out of 100,000 in in 1970 and has been projected to reach as high as 270 out of 100,00 as early as 2030. This increase is explained in part by the rise in the average age of the population as well as risk factors such as osteoporosis and diabetes rising correspondingly. [5, 6] The magnitude of the incidence of ankle fractures compounded by the burden of disability expanded when recovery is prolonged drive the need for continued study and refinement of therapeutic techniques.

Relevant Ankle Anatomy

The articulation of the distal end of the tibia, consisting of the tibial plafond and medial malleolus; the distal portion of the fibula, consisting of the lateral malleolus; and the superior aspect of the talus form the talocrural or ankle joint. The talocrural joint primarily allows for dorsiflexion and plantar flexion while the subtalar joint (consisting of the articulations of the inferior aspect of the talus with the calcaneus) allows for supination, pronation, adduction, and abduction. [7] The "true" ankle joint only consists of the tibia, fibula, and talus but functions in coordination with the subtalar joint to provide the multiaxial range of motion of the foot. The lateral malleolus is the most frequently fractured area within the ankle joint, and isolated distal fibula fractures account for up to 55% of all cases.[8, 9] The medial aspect of the talocrural joint consists of the medial malleolus and a complex of intraarticular and extraarticular ligaments known as the deltoid ligaments and plays a more significant role in overall talocrural stability than the lateral aspects. [10]

The fibula is held tightly to the tibia and more loosely to the talus and calcaneus through multiple ligaments. The interosseous membrane extends between the tibia and fibula along the majority of the length of lower leg stopping approximately 7 to 3.5cm superior to the tip of the lateral malleolus.[11] When the interosseous membrane ends the tibial and fibular crests to which it inserts form the syndesmosis as they bifurcate and form triangular facets creating the superior aspect of the talocrural joint. The syndesmosis is only a true synovial joint with cartilaginous surfaces in a narrow anterior segment while the remainder is secured tightly by synovial plica. The anterior-inferior tibiofibular ligament (AITFL) and posterior-inferior tibiofibular ligament (PITFL) originate from the lateral malleolus of the fibula and extend medially and superiorly to insert on the anterior and posterior aspects of the tibia respectively and are commonly injured during ankle fracture events. [11, 12] The distal fibula is further secured by the anterior talofibular ligament (ATFL) and posterior talofibular ligament (PTFL) to the talus and by the calcaneofibular ligament (CFL) to the calcaneus. Only the AITFL, PITFL, and the medial deltoid ligaments of the tibia provide direct structural stability to the ankle joint. [11] An additional structure of note is the peroneal tendon which runs along the peroneal grove posterior to the distal fibula before moving anteriorly and inserting on the 5th metatarsal. Screws placed too deeply into the posterior cortex of the lateral malleolus have been associated with peroneal tendon irritation. [13]

Ankle Fracture Mechanisms and Classification

Ankle fractures are categorized based on biomechanics of the injury event as well as by which components of the ankle joint are injured and the extent of the injury. Initial attempts at systematically classifying ankle fractures used which malleoli were fractured due to relatively easy ascertainment of category and reliable reproducibility. [14] This system lacked clinical utility, however, as it failed to differentiate stable from unstable ankle fractures reliably. Since the 1950s the biomechanical studies of Niel Lauge-Hansen and the Lauge-Hansen classification system for ankle fractures has been a widely used tool for understanding and managing ankle fractures.[12] Danis-Weber classification delineates fractures according to their relationship to the syndesmosis where Type A is above, B is at, and C is below the level of the syndesmosis. Type B and C are far more common and more likely to result in joint instability requiring surgical intervention as the syndesmosis and the tibia and fibula inferior to the syndesmosis play important roles in stabilizing the talocrural joint.[3] Weber Type B fractures have been found to account for up to 60% of all lateral malleolar fractures.[15] The AO/OTA guidelines are another popular classification system that classifies fractures according to their relation to the syndesmosis as in Danis-Weber classification but further subdivides the fractures according to the nature and severity of structures injured in a manner that correlates to the Lauge-Hansen system. [15]

Lauge-Hansen assessed the fracture patterns seen in freshly amputated limbs when forces on various axes are applied while the foot is in pronation or supination in an attempt to reproduce the fracture mechanisms assumed in vivo.[12] The various combinations of forces and foot position produced reliably consistent patterns from which he created four categories based on mechanism and further subdivided into 13 subgroups by degree of injury.

The most frequent mechanism leading to ankle fractures is Supination-external rotation (SER) accounting for up to 40-70% of ankle fractures. SER fracture mechanics mirror the colloquial concept of rolling one's ankle. SER fractures often occur as the result a sudden lateral stop using an unstably supported foot or landing on an uneven surface, resulting in instead of the axial load of the tibia and fibula being translated relatively perpendicular to the plane of the talus, it is shifted laterally resulting in varus buckling of the ankle joint (supination) and due to the topology of the talar aspect of the talocrural joint, external rotation of the long axis of the tibia and fibula relative to the bones of the ankle and foot. [16]

The SER mechanism opens the lateral aspect of the ankle joint putting increasing strain on lateral ligaments and bony structures with increasing energy of impact and substrate instability contributing to risk of injury to the lateral structures of the talocrural joint. As the intensity of the injury mechanism progresses and degree of SER expands, damage occurs to talocrural joint structures progressively from anterior to lateral to posterior until ultimately causing damage to medial ankle structures due to compressive and shearing forces developing on the now compressed medial aspect of the ankle joint. Lauge-Hansen classification for SER ankle injuries subdivides them into four generally types increasing in severity based on which structures were damaged and the extent of the damage, providing a commonly used tool for guiding treatment decisions. In stage 1 (SER-I) injuries are seen exclusively to the AITFL. As force increases in SER-II, oblique/spiral fractures occur in the distal fibula. These fractures generally start at the level of the ankle joint and move obliquely anterior to posterior and inferior to superior at the level of the syndesmosis. [12] In SER-III as injury patterns move posteriorly, either injury to PITFL or fracture of the posterior malleolus occurs, and ultimately in SER-IV medial structures are damaged including the medial malleolus or deltoid ligaments.



Fig. 1. Sagittal computed tomography scan showing typical fracture planes for supination external rotation Weber B fracture. The yellow arrow shows screw orientation for anterior to posterior or posterior toanterior screw. A: anterior, P: posterior.

Surgical Management of Ankle Fractures

Surgical repair through open reduction and internal fixation (ORIF) can result in complication rates up to 20% and is therefore reserved for unstable ankle fractures for which it has demonstrated reduced post-traumatic arthritis and better clinical outcomes. [17] The ankle, similarly to the pelvis, forms a generally ring-like structure that can maintain stability as long as it is disrupted at no more than one location around the ring. Two or more disruptions result in an unstable joint allowing for misalignment, poor healing, and ultimately post-traumatic arthritis as the free moving joint surfaces interact. This is seen in SER-IV where both the lateral aspect of the ring of the ankle joint (fibula, AITFL) and the medial aspect (deltoid ligaments, medial malleolus) are disrupted, leading to SER-IV fractures commonly requiring surgical intervention. [17]

The goal of ORIF in these cases is the intuitive attempt to return the ankle to its stable pre-fracture state. The joint is first reduced to its anatomical alignment, and then the ankle's ring is effectively splinted by fixation with a variable combination of screws and plates. If effective reduction and alignment is not achieved or if fixation fails before the joint has sufficiently healed, significant contact stresses within the intraarticular space develop leading to degenerative changes and post-traumatic arthritis. [17] ORIF of the lateral malleolus is typically performed with lag screws and a neutralization plate. The screws are traditionally inserted distal-anterior to proximal-posterior perpendicular to the plain of the fracture at the syndesmotic level. The distal end of the lag screw fixes to the posterior cortex pulling the posterior fragment anteriorly while the head of the screw with or without augmentation from a neutralization plate provides a force on the anterior fragment in the posterior direction effectively providing a compressive force perpendicular to the plane of the fracture between the fractured segments of the fibula.[13] Implant failure due to failure of the screw-bone interface to reach sufficient holding strength is a complication of ORIF that can result in failure to effectively reconnect the ring of the ankle joint and resulting intraarticular malalignment, bone malunion, and arthritis.[17]

Screw placement for isolated Weber Type B fibular fractures traditionally starts with a lateral approach dissecting along the plain between the peroneus tertius muscle anteriorly and the peroneus longus and brevis muscles posteriorly exercising caution to avoid the superficial peroneal nerve found anteriorly and the short saphenous vein and sural nerve posteriorly. [13, 18] The relatively flat anterior aspect of the lateral malleolus is then exposed. Using the medial edge of the Achilles tendon as a palpable reference point for the transverse plain, and a 30-to-45-degree insertion angle relative to the plane of the anterior cortex generally produces effective compression while avoiding damage to the peroneal tendon and other soft tissues.[13] The average exit point for a lag screw inserted according to this technique is approximately 1.4cm above the ankle joint. [13] A more posterior-lateral insertion point can be safely used when inadequate reduction is achieved with the anterior insertion.

Engineering Principles of Fastener and Implant Failure

A basic understanding of material properties, stress, strain, and elasticity is essential for a rigorous assessment of bone-screw failure. A stress-strain curve can be created for any material by applying a force and measuring deformation. Stress is force per area on the material and describes the magnitude of the internal forces, crudely analogous to pressure in fluids. Related to stress is strain which is the degree of deformation of a material for a given stress.[19] Similar in function to phase diagrams in fluids used to predict the change in state from liquid to gas to solid, a stress-strain curve can be created for materials to predict structural changes. A critical difference is the changes in state in phase diagrams are always reversible, which is not necessarily the case in the structural changes observed with increasing stress and strain.

The inverse of the slope of the stress-strain curve gives the elasticity of the material. Materials with relatively high elasticity like cancellous bone or unsurprisingly elastics are more flexible while materials with low elasticity like cortical bone are brittle.

Figure 2 illustrates representative stress-strain curves for relatively brittle and ductile materials. Healthy whole long bones due to their stiff outer cortex and flexible inner cancellous bone can tolerate both high stress and strain before tissue destruction and degradation of biomechanical properties occurs.[20] The stress-strain curve for a material follows a predictable discontinuous pattern. During the first stage elastic deformation of the material occurs. Elastic deformation is reversible, and upon release of the applied force the material returns to its original configuration in a manner mathematically equivalent to a simple spring modelling Hook's law. It would not be inaccurate to model the complex interactions occurring in bone under stress itself as a series of springs.[19] These forces that resist and reverse deformation are due to forces at the molecular level as well microscopic and macroscopic architectural properties as exemplified by varying material properties of cortical and trabeculated bone. [10]



Figure 2. Idealized stress-strain curve showing the elastic regions for a stiff or brittle material compared to a ductile material.

Elastic compression is an unavoidable and beneficial phenomenon in screws. High insertional torque which has been shown to correlate with the strength of the bone-screw interface results in compression of the engaged bone, increasing its density and stress tolerance as well as potentially stimulating effective remodeling.[10] At an empirically determined threshold the second stage of the stress-strain curve begins as the material undergoes plastic deformation and the intermolecular and structural features exceed their own individual elastic limits resulting in breaking rather than stretching of bonds. This process also known as irreversible deformation is identified by a rapid increase in elasticity. Materials under compressive forces and as well as cortical bone along the longitudinal axis have a distinct third stage in which hardening occurs, and the material is able to tolerate additional stress and strain before reaching a point of ultimate failure. This stress-strain curve is a called a trilinear stress response. Brittle materials and cortical bone under transverse strain undergo a bilinear stress response in which elasticity is followed by an often very brief plastic phase followed by total failure without an appreciable strain hardening phase.[20]



Figure 3. Simplified stress-strain curve demonstrating a trilinear stress response curve. (A) represents the yield strength. (B) represents the ultimate strength before total failure.

Fasteners, including the various bolts and screws used both inside and out of the operating room, function according to predictable mechanical principles. During ideal screw insertion the surgeon applies two forces to the screw. A downward axial force is applied to increase the friction between the driver and the screwhead allowing for application of torque without the driver lifting out (camming out) of the screw head. The torque applied upon insertion is translated into tensile force along the length of the screw proportional to the compressive force along the fracture line. [21] This compressive force provides the fixation in ORIF procedures. This application of force produces several well-described forms of stress on the screw and the bone that can result in implant failure. [21] The tensile force along the axis of the screw results in tensile strain and the interaction between the threads of the screw with the bone create

a shear strain. Additionally on insertion, the axial force applied by the surgeon creates a compressive stress on the screw and unless the applied force is perfectly aligned with the long axis of the screw an additional bending sheer stress is also introduced. [21]

The shear and tensile stresses which result in material failure are well defined and consistent across identical screws; however, these limits are less-predictably lowered when they occur in combination as was previously described during insertion. The synergistic effect of multiaxial loads has also been demonstrated in cortical bone. [22] As axial tensile strain in the screw is the proportional to the desirable compressive force across the fracture, an effective and reliable screw should focus on maximizing the produced tension for a given torque, as not only does it increase the risk of implant failure, a high torque also increases the risk of the driver camming out of the screwhead and requires the surgeon to provide a greater axial force along the driver.[21] This relationship is the ratio of induced tension and applied torque and is considered the efficiency of the screw. Efficiency is lost due to friction between the cuff of the screwhead and the bone or plate as well as through cutting and friction at the interface between the threads and the bone. [21] Torque efficiency lost to thread cutting into bone has been shown to account for up to a 40% loss. This loss in efficiency increases as screw diameter increases and as pilot hole diameter decreases. [21] Lubrication has been shown to increase efficiency even with a lubricant as simple as normal saline.[21]

Insertion torque is the torque applied during screw insertion. [2] Insertion torque has been shown to reach a plateau upon full engagement of all threads and prior

to engagement of the screw head with the cortex and was found to be strongly predictive of the torque at which the bone-screw construct fails. [10] It can be measured accurately using a torque wrench although in practice surgeons are generally guided by experience and perceived torque. [2] Insertion torque has, however, not been found to correlate with the pullout strength of the screw, a commonly used technique for assessing screw engagement with bone. Pullout strength is the maximum force seen when pulling a screw out of stabilized bone along the axis of the screw and is a proxy for the overall strength of the screw-bone construct. [10]

A general goal of screw/bone stability is to maximize the insertional torque just short of that which would result in not only damage to the screw through tensile and sheer strain but also of stripping and loosening at the interface of the threads and the bone. [23] Multiple variables have been determined to have an impact on the insertional torque that will result in stripping, including screw design, thread pitch, and pilot hole choice. Regarding pilot holes, it's been shown that sheer stress in the bone is not shared equally along all surfaces of the threads but is predominantly focused in along the outer diameter of the engaged threads, producing a cylindrical core upon pullout. This means bone in the valleys of the threads of the screw plays little role in the risk of stripping, instead producing an overall negative contribution to the bone-screw stability by increasing the proportion of torque going to cutting and decreasing overall torque efficiency. Drilling pilot holes with diameters just under those of the outer diameter of the screw has been shown to improve insertional efficiency without compromising the pullout strength. [21] A study demonstrating increasingly practical application of an understanding of these thresholds has shown that an insertion torque of 70-80% of the previously determined torque that would result in implant failure resulted in compressive forces no less than those tightened with a torque greater than 80%, allowing surgeons a margin of error at which no loss of compressive efficacy occurs. [24]

Implant Failure by Screw Stripping

The variables of most significance in a lag screw's ability to withstand external loads leading to stripping of the screw-bone interface are those relating to stress on the threads of the screw as they typically have the lowest elastic limit, the point at which there is irreversible deformation of the strained material typically with rapid loss in fixation, and 65% of fastening (screws, bolts, etc.) failures in industrial testing occurs at the threads. [19] Biomechanical testing of the screw-bone interface has shown screw stripping results in reduction of greater than 90% of compressive forces and failure of reduction.[24] If stripping is noted during operation, the screw can be removed and the previous hole used as a pilot hole for a larger screw although this can be limiting when working with limited volume of bone or if the stripping was particularly destructive to the local bone. When practical, placing a second screw elsewhere across the fracture can be done, but the remaining hole from the initial screw further weakens the material properties of the remaining bone. [25]

One study, using utilization of synthetic bone void filler as a proxy for stripping, found that up to 38% of intraoperative screws used for ankle fractures in osteopenic patients may experience stripping and the value is expected to be higher as stripping missed by the surgeon as well as other means of augmentation such as additional screws are not included in that value. When at least one of the screws used required augmentation, the value rose to 88%. [26]

The torque manually applied by surgeons has been shown to be well within the range to cause screw stripping, particularly in bone with weaker mechanical properties such as is seen in osteoporosis. [24] In a study of 200 screws inserted into cadaver fibula, 9% were inadvertently stripped and an additional 12% were found to have an insertion torque within 10% of being stripped. [27] In order to minimize the risk of screw stripping, a detailed understanding of the mechanics at the interface between the screw threads and the engaged bone is essential.

The force per area felt by the screw threads is the bearing stress (σ_B).

$$\sigma_B = -\frac{2F}{\pi * n_t * p * d}$$

F is the force applied to the threads parallel to the long axis of the screw and by Newtonian principles is the inverse of the stress felt by the engaged cortex of the fibula, *d* is the average radius of the threaded portion of the screw, and *p* is the pitch (distance between adjacent threads or inverse of threads/inch). The elastic limit of the threads in most screws is multiple orders of magnitude greater than the elastic limit found in cortical bone, and because the cortex is feeling an equal and opposite force to the screw threads, the cortex is the expected point of mechanical failure in lag screw fixation. Fortunately, because the force experienced by the cortical bone is the inverse of the force on the threads the same principles for bearing stress apply. [19, 28] A large force (proportional to the more commonly measured insertional torque) is desirable to ensure secure fixation and maximum thread engagement with cortex while under physiological loads. As insertional torque is applied the threads of the screw and the bone matrix of the engaged cortex undergo reversible elastic deformation, increasing the contact area and friction between bone and screw. [19]This minimizes wobble and screw migration by maximizing thread engagement with the cortex effectively increasing the number of engaged threads; however, if insertional torque exceeds the elastic limit of either screw or cortex the tension will be lost as the screwbone interface irreversibly deforms.

This leaves only the variables in the denominator free to be increased if a decrease in bearing stress is desired. Increasing diameter is effective when not limited by size constraints and the damage of drilling increasing volumes of bone out of what may already be size-limited fragments of fibula. Additionally, increasing the pitch has been shown to increase the pullout strength in non-lag screws but is limited theoretically by a concurrent and proportionate increase in required insertional torque.[19] Maximizing the number of engaged threads is an effective option and a mechanistic explanation for the popular clinical principle of tip-apex distance used to guide lag screws used in trochanteric fractures to ensure adequate and ideally complete engagement of threads with the strongest bone as trochanteric fracture fixations acquire a significant portion of the fixation strength from engagement with relatively weak cancellous bone. [29] However, increasing the number of engaged threads for fibular lag screws is limited by the shallow cortical depth found in the fibula and the

number of engaged threads could only be increased further if portions of the fibula with thicker cortices were made the target of the distal end of the lag screw. One study on 200 screw insertions into elderly osteoporotic cadaver fibula did not support this assumption, finding that neither cortical thickness nor bone mineral density were predictive of screw stripping but did show variations in cortical density along the length of the fibula. [27]

The torque that results in stripping of the screw or stripping torque (T_{str}) can be effectively estimated by the following equation which considers losses of torque efficiency as torque is translated into tension as well as properties of the bone itself:

$$T_{str} = \frac{\pi * TYS}{\sqrt{3}} * D_p * L * r * \frac{p + 2f * r}{2r - f * p}$$

TYS = tensile yield stress, D_p = pitch diameter, L = axial length of along engaged screws, r = pitch radius of screw, p = pitch, and f = coefficient of friction between screw and bone. [24] TYS is the stress in the bone for a given insertion torque and L is analogous to number of engaged threads. This equation allows for nonempirical first approximations to assess proximity to theoretical stripping torque using insertion torque, known screw characteristics, and determinable bone characteristics.

Biomechanical Properties of Bone

Given its relative fragility in comparison to the screw itself and the increasing prevalence of fragility fractures, understanding the mechanical properties of bone is important to assessing risk and stability of the screw-bone construct. The compact cortical bone has been shown to withstand forces three times greater than the highly porous cancellous bone of the marrow but has less than one tenth the ability to handle strain and lacks the high energy impact absorption of cancellous bone as its trabeculations effectively function as energy dampeners. The biomechanical advantage of this combination of tissues is strength without brittleness in healthy bones. [28] Lag screws fastened to cancellous bone rather than the cortex are stress-limited by the much weaker cancellous bone and are prone to implant failure with one small study showing 100% of femoral lag screws placed in cancellous predominant locations resulted in lag screw cut out from the surrounding bone compared to 0% of the lag screws fixed firmly in the cortex. [30] An insertion torque of at least 3 Nm has been estimated as necessary for adequate bone-screw purchase in cancellous bone, which is well within the range of torques surgeons generate during insertion. [31]

Bone as a living tissue, presents multiple additional variables that illustrate the shortfalls of assuming consistency in principles applied to mechanical screws and living bone. The lack of homogeneity in bone tissues relative to the metals in screws can result in uneven or inconsistent loading of threads as they engage with a nonuniform cortex. This can result in focal areas with a disproportionate amount of stress failing far earlier than simple calculations would predict. Additionally, the material properties of a screw are relatively constant. The mechanical properties of bone, in contrast, change constantly and on multiple different time scales with baseline bone matrix recycling, acute inflammatory responses to injury, interruption of vascular supply, and chronic changes such as osteoporosis and aging. [28] A further layer of complexity found in

living bone is due to its microarchitecture producing anisotropic mechanical properties – meaning ability to handle stress varies between axes. In cortical long bones such as the fibula, the maximum yield strength is oriented along the longitudinal axis while the compressive force from a lag screw is at best oblique to this axis, meaning the orientation of the force from the screw is unfavorable. [20] This reemphasizes the limits of applying homogeneous material certainty to living tissues beyond a useful first approximation.

A final complicating factor in assessing lag screw strength in ORIF is the prevalence of comorbidities known to weaken the material properties of bone over time. Axial forces applied to long bones of adults with and without diabetes showed an almost 20% reduction in both stress and strain limits of osteoporotic bone. [28] Less than 10-44% of fractures with 10% of those affecting the ankle can be attributed to osteoporosis, defined as low bone mineral density (T-score <-2.5) as measured by dualenergy x-ray absorptiometry (DXA). Notably, ankle risk has been shown to be positively correlated with peripheral bone density but not central bone density providing additional support for the simple mechanistic explanation of equating lower bone density with decreasing material capacity of the bone structure itself rather than a proxy for an underlying process. [32] It has also been found that changes in bone mineral density and fracture risk do not have reliably consistent proportions in their associations, supporting the established principle of a qualitative aspect to bone strength beyond the quantitative found by DXA. [33] The prolonged healing rate found in patients with diabetes increases the risk of implant failure independently of any

effects on the mechanical properties of bone. Healing times in patients with diabetes have been reported to be 163% to 187% that of nondiabetic patients, meaning the lag screw cortical bone interface in a fibular fixation could be required to withstand nearly twice as many loading events as a nondiabetic fixation.[34]

THESIS PURPOSE AND AIMS

Given that pullout strength and insertional torque have been shown to correlate with fixation strength as well as stripping torque and both measures depend upon the quality of bone engaged by the screw's threads as well as the number of threads engaged, it follows that techniques which maximize engagement with the largest quantity of high-quality bone should produce better mechanical properties and improve outcomes following ORIF. [10, 31] The majority of ankle fractures are fragility fractures in which the strength of the bone is diminished in both quantity and quality and this proportion has been projected to continue to rise. [1, 5, 6, 35] These patients are at a higher risk of screw pullout and fixation failure requiring repeat intervention. The cortical bone of the fibula is the target for the engagement of the lag screw's distal threads given its superior yield stress, however this benefit is limited by the narrow depth of cortex often available in the posterior cortex of the fibula. [25, 27]

Few studies have evaluated cortical thickness within the fibula and none that this author is aware of have examined variations between anterior and posterior cortices. Theory would support a thicker anterior cortex given the relatively extensive ligamentous insertions with their translated strains stimulating bone growth and strengthening, although this has not been empirically validated for the cortices of the distal fibula. One study evaluating fibula characteristics and screw stripping found that density and cortical depth increased along the length of the fibula with maximal thickness at the distal end. [25] A posterior to anterior (PA) as opposed to anterior to posterior (AP) – as is traditionally performed, lag screw insertion approach has been suggested as a safe and effective technique for fibular fracture ORIF that minimizes the risk of implant irritation of soft tissues, in particular the peroneal tendon, but the study did not evaluate the biomechanical properties of screw purchase in the anterior cortex. [36] This study was designed to answer two questions: Is there consistent differences in the thickness of distal fibular anterior and posterior cortices and does PA insertion compared to AP insertion and/or cortical thickness correlate insertion torque and pullout strength in cadaver fibula.

METHODS

The author performed all steps described in the methods apart from those specifically noted to have been performed by a trained orthopedic surgeon. The author worked in collaboration for most steps, in particular the statistical analysis. The pullout testing apparatus was designed by the author but machined by Yale facilities.

Cadaveric fibulas were selected for this study as the biomechanical properties of human fresh-frozen, embalmed, or dried bones have been found to be statistically equivalent, as opposed to synthetic bone models, and appropriate for a nearest approximation to in vivo study. [37] 5 donor-matched pairs of intact cadaver fibula were harvested using a lateral approach. Osteotomy of the proximal head of the fibula and dissection of the interosseous membrane through the syndesmosis was completed, as well as dissection of the ligamentous attachments to the distal fibula and removal of remaining bulky soft tissue. The mean age of the cadavers used in this study was 87.2 years (range, 81-91 years), and there was no prior history of fibular fracture, infection, or instrumentation.

Weber Type B SER fracture patterns were reproduced in each fibula. The fracture lines were oriented from the distal anterior surface at the cranial cartilaginous portion of the talofibular articular surface and extended proximally and posteriorly at a 45degree angle to the longitudinal axis of the fibula. The proximal and distal ends of each fibula were firmly clamped, and the fracture line was cut using a hand saw. All cuts produced a clean plane through the fibula without splintering, fragmenting, or other defects noted.

The fracture was then reduced using a bone holding forceps and a small 3.5 mm fragment lag screw was then inserted according to AO standard technique by a trained orthopedic surgeon.[38] For each matched pair of fibula one had the lag screw placed in the standard AP orientation while the other was placed in the PA orientation. All other steps were the same. In order to secure a drill sleeve, the near cortex was over drilled with a 3.5 mm drill. A 2.5mm drill sleeve was then inserted into the near cortex drill hole and aligned perpendicular to the fracture obliquity before drilling the far cortex colinear with the drill sleeve.



Figure 4. Lag screw placement demonstrating the paired spacer setup and the excess screw length advanced beyond the far cortex. (A) Cadaver distal fibula showing orientation of the anterior to posterior lag screw. (B) Cadaver distal fibula showing orientation of the posterior to anterior lag screw.

To allow space for the pullout testing device attach to the screw, the screw's head could not be compressed directly against the bone surface. Several modifications were made to enable pullout testing while maintaining compressive force along the fracture. The pilot hole in the far cortex was drilled through the entire thickness of the far cortex, and lag screws were chosen with excess length to allow for a spacer setup directly below the screwhead and any residual excess length extending beyond the far cortex. Below the screwhead two steel spacers were placed with a 3.5mm central hole radius. The outer radius of the spacer just below the screwhead had a diameter double that of the screwhead and the spacer between it and the bone, providing a secure lip for pullout attachment. Each screw was then subjected to pullout and insertion torque testing

Measuring Insertion Torque

Each of the fibula had insertion torque measured as the lag screws were inserted. Following placement of pilot holes, the screws were inserted in a twostep process. In the first, the screws were manually tightened by a trained orthopedic surgeon until two criteria were met. To ensure maximal engagement of all threads with cortex screw lengths were chosen to allow at least 2mm extension beyond the far cortex and hand-tightened based on the surgeon's judgement. Then each bone was mounted onto a biaxial material testing machine (Instron 8874; Instron, Norwood, MA, USA). A rotary chuck adapted with a modified 20mm bore for bolt attachment to the Dynacell[®] actuator was fitted with 5-point Synthes[®] drive for measure of insertion torque.

An adjustable clamp setup was designed to ensure alignment of the actuator with the long axis of the screw. Both ends of the fibula were securely clamped such that the fibula rested at 45 degrees to the actuator and the screw aligned with the driver attachment of the actuator. The actuator was then lowered until it rested in the head of the screw with a load of 10N. The actuator applied a clockwise rotation of 240° at a rate of 180°/sec (i.e., 30 rpm: American Society for Testing and Materials [ASTM] F543 standard) to the tip of screw while maintaining the axial load of 10 N. During screw insertion, torque was measured. The insertion torque was defined as the maximum torque measured during insertion.



Figure 5. (A) Insertion torque measurement setup on Instron. (B) Pullout strength testing setup on Instron

Pullout Tests

Each fibula was mounted onto a biaxial testing machine (Instron 8874; Instron) using a similar adjustable clamp setup. A custom attachment for the actuator was designed to attach to the spacers below the screwhead. It consisted of a block of aluminum with a 20mm hole bored in the superior face and threaded to attach to the actuator. The inferior portion of the device consisted of a hollow central space for the screw head and the first spacer directly above a triangular gap cut into the base of the device, functioning similarly to the claws of a hammer. The screw was then rested in the device allowing the fibula to hang freely and ensure axial alignment of the actuator and the longitudinal screw axis. The clamp setup for insertional torque testing was not secure enough for the loads encountered during pullout testing, and a system of adjustable metal braces was designed to secure the proximal and distal ends of the fibula in this orientation. A tensile load was applied to the screw at a crosshead speed of 5 mm/min (ASTM F543 standard) until the screw was released from the bone. The pullout strength was defined as the maximum force recorded during screw removal from the bone.

Anterior and Posterior Cortical Thickness Measurements

Approval was obtained from the Institutional Review Board of Yale New Haven Hospital (IRB No. 2000023332). Informed consent was not necessary as pullout and insertion testing was a cadaver study, and cortical thickness measurements involved only retrospective review of imaging. Two of the authors of the original study independently analyzed computed tomography (CT) data on 40 consecutive patients with CT scans performed using a Siemens Somatom Sensation 64 during preoperative planning for ankle trauma without fracture involvement of the lateral malleolus. All CT scans were performed with 1-mm sections. The measurement of anterior and posterior cortical thickness was taken in sagittal plane CT scans. The sagittal plane with the maximum width of the fibular canal was used for measurements. The sagittal cuts on the CT scan were scrolled from anterior to posterior. The cut with maximum fibular canal diameter was used to measure the cortical thickness. This was done to ensure that the cortical thickness was measured at the same sagittal plane of the fibula in all cases. The readings were started at the distal most part of syndesmosis and measurements were performed at five different sites each 5 mm apart moving proximally in order to cover the most frequent locations for SER fractures of the lateral malleolus.[12] The measurements were taken using the Visage PACS imaging software (Visage 7.1; Visage Imaging, Berlin, Germany)



Figure 6. Anterior and posterior cortical thickness measurement on sagittal plane computed tomography. 2D: two-dimensional view.

Statistical Analysis

The difference in anterior and posterior cortical depth was measured using a paired t-test, and the percentage agreement between the observers was analyzed using Bland-Altman plots. Mann-Whitney U-test was used to analyze the difference between the pullout strength and insertion torque in both groups. Correlation and regression analyses were used to identify a correlation between insertion torque and pullout strength.

RESULTS

The anterior cortical thickness was significantly greater than the posterior thickness (p < 0.001) in the paired t-test at all points measured (Figure 7). Bland-Altman plots showed greater than 95% agreement between observers for CT assessment of fibular cortical thickness at all points measured.





The pullout strength was significantly greater in the PA lag screw insertion group as compared to the AP group (p < 0.05). Figure 8 shows the maximum pullout loads for each pair of fibulas. The insertion torque was greater in the posterior to anterior group (Mean, 4.90 N/mm) as compared to the anterior to posterior group (mean, 4.26 N/mm) but did not exhibit statistical significance (p = 0.056). There was no correlation between the insertion torque and pullout





Figure 8. Maximum load during pullout testing of paired cadaver fibulas for the posterior to anterior and anterior to posterior lag-screw approaches.

DISCUSSION

Ankle fractures are a frequently encountered injury accounting for 9% of all fractures, and of ankle fractures the majority are Weber Type B SER fractures of the lateral malleolus. [1, 8, 9, 35] The typical fibular fracture orientation in supination-external rotation injury mechanisms is from distal anterior to proximal posterior at the level of the syndesmosis. [9, 39] Following anatomic fibular reduction, a common technique is to insert a lag screw in an oblique manner, from proximal anterior to

distal posterior. [18] This alignment results in lag screw placement perpendicular to the fracture obliquity and thus it creates maximal compression at the fracture site while minimizing stress and loss of torque efficiency although the anisotropic orientation of the bone is unfavorable. [28]

Prior to this study, the differences in posterior and anterior distal fibular cortical thickness had not been examined. Based on CT data, the anterior fibular cortex was found to be significantly thicker than the posterior cortex at the level of the syndesmosis as had been hypothesized providing a mechanistic justification for this study's other hypotheses of increased insertion torque and pullout strength, as increased cortical thickness allows for an increased number of engaged threads with fibular cortex. This cadaver biomechanical analysis, determined there was a significantly greater axial pullout strength for screws inserted PA, compared with those inserted AP. The insertional torque demonstrated a similar trend; however, this trend did not reach statistical significance, likely due to limited sample size. The biomechanical findings may be explained by the conspicuous fibular osteology and fracture orientation. The far cortex for a posterior to anterior lag screw involves the thicker anterior cortex, whereas the far cortex for an anterior to posterior lag screw involves the thinner posterior cortex.

Insertion torque and pullout strength were the two parameters used to evaluate the screw strength. Pullout strength traditionally has been used for evaluating the screw bone stability; [23, 40-42] however, it has been suggested that insertion torque is more important in assessing screw bone stability than pullout strength. It is suggested that insertion torque is more closely correlated with the magnitude of fixation force generated by the screw. [31, 43] This can be explained by understanding that the compressive force across the fracture line is translated from the insertional torque through the screw. If torque efficiency is known, compression force across the fracture can be determined directly from insertion torque. Our study similarly found that insertion torque and pullout strength were unrelated.

There are multiple limitations to this study. The sample size for pullout and insertional torque testing was limited by the available cadaver fibula. Additionally, the BMD of the tested fibula was not determined, although most specimens likely exhibited some degree of osteoporosis given the advanced donor age (mean age, 87.2 years). Pullout testing is a commonly used technique for assessing fixation strength, however cyclical loading may more accurately predict failure after insertion and was not performed on these samples. Producing the fractures through SER mechanisms rather than by manual sawing would also likely produce conditions more closely approximating in vivo fractures.

In summary, the proposed PA lag screw technique in the distal fibula demonstrated greater biomechanical strength than the AP approach, and this was correlated with the increased cortical thickness found in the anterior cortex of the distal fibula relative to its posterior cortex.

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