Ex-Vivo Biomechanical Testing of a Tendon Implant Device for the Repair of Equine Flexor Tendon Lacerations

by

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Abstract

Flexor tendon lacerations are a serious injury in horses that are life threatening and often career ending. An ideal tendon repair allows rapid return to weight bearing by providing a high strength to failure, high resistance to gap formation, minimal compromise of tendon vasculature and producing minimal adhesion formation. The 3 loop pulley (3LP) is the currently recommended primary repair technique for tendon lacerations in the horse. The 3LP is limited by gap formation, vascular compromise. This project compares the in vitro strength and failure characteristics of a novel tendon implant device (SA) against the 3LP in equine superficial digital flexor tendon laceration (SDFT) repair. 8 pairs of superficial digital flexor tendons were harvested with various breeds represented including: American Quarter Horses (3), Tennessee Walking Horse (2), Thoroughbred(2) and warmblood(1). Ultimate load to failure, mode of failure, gap at failure, and load to create a 2 mm gap were compared between the two repairs. Statistical evaluation was made using a Student's T-test, with significance set at P≤0.05. The 3 LP failed at a significantly (P = 0.0001) greater load (363.5 N +/- 83.7 N) than SA (132.4 N +/- 26.8N), but the load to a 2 mm gap (3 LP = 164.9 N +/- 67.7 N, SA = 114.5 N +/- 21.5 N) was not significantly different (P = 0.09). Mode of failure was by suture pull out and anchor pull out respectively. The gap at failure was significantly larger in the 3LP, than in the SA repair (*P* = 0. 000005). Load to 2 mm gap formation is a clinically

significant test, because gaps larger than 2 mm in lacerated tendons produce a weaker tendon callous than gaps smaller than 2 mm.

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I. Introduction

Flexor tendon lacerations in horses are life-threatening injuries that can result in loss of the biomechanical function of the tendon and support of the weight bearing column.[1] The loss of function varies depending on which tendon(s) are involved and the location at which it is lacerated. Regardless, the horse's ability to properly ambulate is compromised. Complications of flexor tendon lacerations include the formation of exuberant granulation tissue, lameness from adhesions or scar tissue formation, flexural deformities, elongation and weakening of the tendon or necrotic tendonitis.[2]

Prognosis is poor for return to athletic function following flexor tendon injuries. Reports from the early 1990's showed that approximately 45% - 65% of horses treated for flexor tendon lacerations return to athletic function.[1-5] In the most recent review, performed in 2011, 55% of horses treated for flexor tendon lacerations returned to their previous level of athletic function, while 27% returned to limited athletic function at a lower level than prior to the injury.[3] These results suggest that no significant improvements in treating flexor tendon lacerations in horses have been made in the past 20 years.

Superficial digital flexor tendon repairs in horses need to support loads of up to 3600 N and strain rates of 2-4% at a walk, without external coaptation.[2,6-8] (Figure 1) The three loop pulley (3LP) has been shown to be superior in terms of strength and failure characteristics of the suture patterns currently used in clinical equine practice.[9-12] The pattern uses a single strand of suture that crosses the flexor tendon laceration six times, forming three loops (Figure 2). However, the 3LP withstands only 1/3 of the normal weight bearing load.[6,9] Therefore repairs are typically supported with some form of external coaptation for 4 to 6 weeks postoperatively to allow some tendon strength to return before subjecting the repair to full loads.[9-12] (Figure 3)

An additional drawback for the 3LP repair is the presence of exposed suture on the tendon surface remaining after the repair is performed. This excess suture could lead to adhesion formation, serve as a nidus for infection, or delay healing.[9,11] Placement of a 3LP suture has also been shown to compress the core of the repaired tendon leading to deleterious effects on the intrinsic vasculature of the tendon.[13] This compression compromises blood flow to the lacerated tissue and may be detrimental to normal healing.[13]

Current research is focused on improving tendon repair methods by improving the overall strength of the repair. Newer techniques accomplish this by using different suture patterns, bioabsorbable implants, and devices that are contained completely

within the tendon.[14-19] A 6- and 10-strand Savage suture pattern (Figures 4,5) and a bioabsorbable tendon plate (Figure 6) have been evaluated in equine tendons and were found to have a greater mean load at failure than the 3LP, indicating that they may be superior to the 3LP in their ability to restore tendon gliding function.[14,18,19] The 6- and 10-strand Savage suture patterns do not have the same constricting effect on the tendon as the 3LP, because they use a grasping pattern, which may improve the biomechanics. However, both patterns are intricate and leave exposed suture material.[18,19] No published reports on the use of these repair methods in clinical cases, or in an in-vivo trial currently exist, so the authors have chosen to compare the tendon implant we are evaluating to the 3LP.

The stainless steel suture device (SA) evaluated in this study is currently in use in human orthopedic surgery practice.[20-22] Studies in dogs and humans have shown the device is well tolerated, producing a healed tendon with minimal scarring.[21-23] The device consists of two stainless steel anchors placed within the tendon on either side of the laceration and a stainless steel suture that bridges these anchors. (Figure 7) This implant uses the anchors lodged within either end of the severed tendon to hold a stainless steel suture, so no portion of the suture is located outside of the tendon.[17,20-23] Investigations into the viability of this SA have not been reported in the horse.

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The goal of our study was to compare the tensile strength of a tenorrhaphy technique for equine tendon repair using stainless steel suture and anchors to the currently recommended 3LP pattern, in an *ex vivo* model. We hypothesized that the SA would be as strong as the 3LP to a 2 mm gap. If the SA proved comparable in strength to the 3LP, it would justify further investigations, to assess the SA's effects on the dynamics of equine tendon healing.

II. Literature Review

Prognosis

Flexor tendon lacerations in horses occur as a result of traumatic insults to the distal limb. Flexor tendon lacerations carry a poor prognosis because of the tendon's necessity for immediate weight bearing function after surgical repair. Without an adequate repair of a tendon laceration, the injury becomes life threatening. Limited numbers of retrospective studies evaluating digital flexor tendon injuries in horses have been published.[3-5] A large number of horses in two of these studies (11/35 and 22/90) were euthanized on presentation, and the final study did not report the number of horses euthanized prior to treatment but stated they were excluded from analysis. This high number of euthanasias prior to treatment may reflect the poor quality of repair options we currently have for addressing these injuries in horses, leading to a reluctance on the part of the owner to proceed with treatment attempts. Horses in each study were treated with wound debridement and closure, with or without primary suturing of the tendon involved and with or without external coaptation post-operatively. In one study by Foland, of 22 horses treated for flexor tendon lacerations, 13 were repaired using sutured tenorrhaphy and 9 were not sutured. Of the 13 sutured, 8 (62%) returned to the same or limited athletic function and 4 (31%) returned to pasture soundness.

The remaining horse was euthanized for complications incurred during treatment. Of the 9 unsutured lacerations, 5 (56%) returned to limited athletic function, 3 (33%) were found to be pasture sound and again, and the remaining horse was euthanized during the course of treatment.[5] This study was unable to find a significant reason for the increased survival rates associated with suturing the tendons. A second study, by Taylor, sutured 16 of 50 lacerations (32%) but no significant difference in prognosis was reported between sutured and un-sutured groups. This study had an 84% survival rate, with 82% of horses treated being sound enough to be used for pleasure riding, regardless of treatment group.[4] Of the sutured horses, 9/16 (56%) returned to their original use with only 1/16 (6%) being euthanized. Of the un-sutured group, 18/34 (53%) returned to use and 10/34 (29%) were euthanized for complications associated with treatment. These numbers show a trend where horses whose tendons are sutured after a laceration have fewer complications than those that are not. In the final and most recent retrospective by Jordana in 2011 involving 106 horses, tendons were sutured if the ends could be apposed (n=58). Fifty eight of the horses in this study returned to previous level of function, and 87% overall returned to some level of function.[3] No significant effect on prognosis for return to previous level of function was noted between sutured and un-sutured groups in this study. An increased risk of metacarpophalangeal or metatarsophalangeal joint hyperextension was seen in un-sutured tendons. Metacarpophalangeal or metatarsophalangeal joint

hyperextension was associated with fewer horses returning to their previous level of function.[3] Of the fifty-eight horses with tendons sutured in the study, 29 (56%) horses achieved a level of performance equal to their performance prior the injury, 16 (32%) had decreased performance and 13 (12%) were euthanized during treatment. Of horses with un-sutured tendon lacerations, 29 (63%) returned to equal performance, 13 (28%) to reduced performance and 4 (8%) were euthanized. Jordana's report does not support suturing tendon lacerations, as previous results[24,25] have, but this could be due to the high number of only partially lacerated tendons (n = 60) that were mostly left un-sutured (36/60) and would generally have a better prognosis then fully lacerated tendons.

Physiology of Tendon Repair

Tendon is a complex tissue with the mechanical function of translating muscular contraction into joint movement by transmitting forces from muscle to bone. Mature tendon matrix is made up of a hierarchically structured backbone of type I collagen fibrils interspersed with tenocytes and noncollagenous molecules, predominately comprised of water (70%).[2,26-28]

Five collagen molecules together form a collagen fibril. Fibrils are grouped into fibers that are separated and bound together by cytoplasmic extensions of tenocytes. Collagen fibers are grouped together by loose connective tissue into

fascicles.[26,27] It is the collagen fibers that are gathered in the SA repair anchor as it is twisted into place in the tendon.[20,22]

After injury to a tendon occurs, intratendinous hemorrhage ensues, disrupting the tendon matrix. A strong, and prolonged inflammatory reaction follows the hemorrhage leading to increased blood flow, edema, infiltration of neutrophils, macrophages and monocytes and proteolytic enzyme release. This stage is prolonged in horses in all body tissues, compared to other species, leading to removal of not only damaged tissue, but further damage to healthy tissues. The inflammatory stage usually lasts a few days and overlaps with the reparative phase. The reparative phase lasts for several months and involves both extrinsic and intrinsic repair. Extrinsic repair occurs through cellular infiltration from the paratendon or tendon sheath and causes angiogenesis and proliferation of fibroblastic cells. Intrinsic repair from the epitenon or endotenon within the tendon itself is very limited.[26.27] The resulting scar tissue produced in the reparative phase has a higher ratio of type III collagen to type I collagen than normal tendon. Injured tendons have a ratio of 50% type I versus type III collagen in comparison to only 10% type III collagen in normal tendon.[26] This scar tissue also has a higher hydration status and higher levels of glycosaminoglycans then normal tendon.[26,27] Overall, this equates to a weaker, less organized tendon tissue. The reparative phase of tendon healing overlaps with the remodeling and final phase. During remodeling there is a gradual but incomplete change from collagen

type III to collagen type I as the scar tissue matures. The newly formed scar tissue itself is less stiff than normal tendon tissue. However, the scar forms a larger cross sectional area leaving a functional tendon unit that is stiffer and less forgiving than it was prior to injury.[2,26,27,29] This leads to a tendon that is predisposed to injury at sites adjacent to previous injuries and one that may have reduced performance. The junction between the scar and normal tendon is a weak area because the biomechanics of the different stiffness in each section meet at that point.[2,29] Tendon repair within an intact tendon sheath is less efficient then tendon healing without a tendon sheath likely due to the lack of a peritenon contributing extrinsic repair mechanisms and the washing action of synovial fluid bathing the tendon defect.[29]

The type of scar tissue formed in a healing tendon depends on the size of the gap between the tendon ends and the ability of the horse to mobilize the injured tendon appropriately.[2,26,30] Controlled mobilization, or movement without weight bearing, of injured tendons after the initial inflammatory phase has been shown to improve the ultimate strength, gliding function and morphological properties of the repair. It is thought that the controlled mobilization stimulates fibroblast proliferation and collagen realignment by promoting the release of growth factors from the extracellular matrix.[26,30-35] Therefore, an ideal repair would have enough strength to allow passive motion exercise in the early post-operative period while preventing the tendon ends from gapping apart.[30-35]

The blood supply of normal equine flexor tendons has been shown to be primarily intratendinous.[36] Kruas-Hansen, et al., placed circumferential sutures to compress portions of the tendon and showed that these compressive sutures limited blood supply and created lesions consistent with tendonitis and focal degeneration at the core of the tendon distal to the sutures. The authors concluded that hypoxia could be a major contributing factor to the formation of tendonitis lesions and supported the theorem that suture patterns used to repair tendon lacerations should minimally affect blood supply to the laceration site to reduce inflammation which may be detrimental to appropriate healing.[36]

Testing of Repair Methods

Tendon laceration repairs are tested in cadaver tendons prior to attempting use in clinical situations.[9-12,14-20] Ex-vivo tests are difficult to design to accurately simulate a real life situation. Tendon laceration repairs are usually tested in a single cycle to failure whereas in a living animal tendons undergo cyclic loading. Repeated (cyclic) loading of a tendon, is a process known as conditioning.[2,26] Conditioning produces a tendon that is less stiff, as the collagen fibers are repeatedly stretched beyond their limits.[26] This decreased stiffness seen with cyclic loading may decrease the strength of a tendon repair when comparing ex-vivo conditions to in-vivo conditions.

The actuator displacement for each tensile testing machine can be set and varies between 8.5 mm/sec and 25 mm/sec amongst different published reports evaluating flexor tendon laceration repairs in horses.[9-12,14,18,19] In our testing machine this reflects a strain of 0.5 % to 1 %. Strain is defined as the change in length, or stretch, of the tested tendon over the original length of the tendon. In vivo equine tendons undergo strain of 2 to 4 % at a walk.[6-8,37] Strain rates on equine tendons within casted limbs have not been evaluated. Having a higher strain rate increases the stiffness, or the ultimate tension, with which a tendon fails.[37] This could increase the strength of tested repairs in a live animal.

Load to actuator displacement curves are recorded during in vitro testing of tendon laceration repairs. The curves demonstrate the behavior of the material with an applied force. These curves model stiffness or deformation of the tested material and have different appearances depending on the material tested and testing parameters (e.g. cyclic testing often has decreased stiffness with repeated cycles; increased loading rate tends to increases stiffness due to viscoelasticity of tendon tissue).[37]

Laceration Repair

It has been shown that suturing lacerated tendons can produce a mechanically stronger and histologically superior repair tissue than un-sutured tendon lacerations.[24,25] All horses in the studies discussed hereafter were maintained in

casts post-operatively to support a sutured or un-sutured repair. Bertone, in a controlled research trial compared three repair methods used to repair superficial digital flexor tendons after a 3 cm section was removed from the middle of the tendon.[24] One group was left un-sutured, a second was repaired with a double locking loop of carbon fiber and a third with a double locking loop of nylon suture. Horses were euthanized at 6, 12 and 24 weeks after repair. Breaking load was not significantly different between any of the repairs at each time interval. However, the breaking stress (defined as the breaking load divided by the cross sectional area) of the nylon sutured tendons at 24 weeks was twice as great as any other repair. This was due to the smaller cross-sectional area of this repair, withstanding the same loads as the larger tissue scar seen with the other repairs. At 24 weeks, the carbon fiber repairs produced a marked inflammatory response and significant tissue necrosis. The nylon repairs had minimal inflammation present, and mature scar tissue was organized longitudinally. The un-sutured tendons had only moderately organized tissues and the cellularity of the tissues suggested it was less mature than the sutured repair.[24] This study confirmed that sutured repairs were superior to un-sutured repairs but underscored the importance of the type of material used in the suture. Sutured repairs healed with a more biologically normal scar tissue that was as strong as the larger callous formed in un-sutured tendons. However, horses develop significant reaction to carbon fiber implants when compared to other species.[24]

Jann compared un-sutured tendon lacerations to those repaired with a three loop

pulley technique using 1 polyglyconate at 5 and 9 weeks.[25] Jann tested common

and lateral and long digital extensor tendons and superficial and deep digital

flexor tendons. He found the load to failure was significantly greater for sutured

verses un-sutured repairs at week 5 and 9. The average maximum load at failure

of the sutured repairs at 5 and 9 weeks were 2427 N and 6363 N, respectively. In

comparison, un-sutured repairs maximum load at failure for 5 and 9 weeks were

923 N and 5364 N. Maturity scores for the histologic appearance of the scar

tissue were significantly (P <0.05) higher in sutured, than in un-sutured tendons at

both weeks 5 and 9.[25]

Characteristics of an Ideal Suture Pattern

An ideal flexor tendon repair would fulfill four major criteria: 1. allow minimal

post-tenorrhaphy gap, 2. provide minimal interference with intrinsic vasculature,

3. prevent adhesion formation outside the tendon repair and within the tendon

sheath, and 4. provide immediate weight bearing so the tendon can be used

normally. Studies in dogs have shown that a gap greater than 3 mm between

repaired tendon ends prevents normal tendon healing and leads to an increased

risk of rupture during the first 6 weeks of rehabilitation.[30] Human studies have

shown that gap formation as small as 1 mm was associated with increased

formation of adhesions, was detrimental to tendon function, and led to poor

clinical outcomes.[31-35] Seradge prospectively compared two repairs; one that formed a gap of 1.3 mm and one that formed a gap of 0.6 mm between the flexor tendon ends. In the larger gap group 18.5% of the repairs required surgical reduction of adhesions formed post-operatively, and only 6.2% in the group that had a gap of 0.6 mm required a second surgery to reduce adhesion.[33]

Crowson, et al evaluated the effect of the three loop pulley suture versus the locking loop on the intrinsic vasculature of the superficial digital flexor tendon in anesthetized horses.[13] He performed tenotomy and subsequent tenorraphy with either a three loop pulley, or locking loop pattern using the same suture material, 2 polydioxanone, in each repair. He also placed circumferential ligatures surrounding a single tendon to evaluate its effect. The horses were then administered heparin and euthanized. The flexor tendons were removed and examined histologically. This study showed both patterns had decreased vessel density when compared to a normal tendon, but that the 3LP had significantly more vessels in each cross sectional area examined than the locking loop pattern. The study found that any laceration repair technique will further reduce blood flow to the lacerated tendon ends, but this effect should be minimized by using suture patterns that do not apply circumferential pressure to the tendon.[13]

Adhesion formation is common after tendon laceration repair and has been linked to the presence of suture (foreign material), injury within the tendon sheath and

post-operative immobilization.[35] Adhesions limit a horse's ability to return to function by creating persistent lameness and altered function of the affected tendons through altered structural and mechanical properties.[38] Adhered tendons do not glide appropriately and will not transmit forces from muscle to bone appropriately. Research in human medicine has shown that the sooner a person can begin passive post-operative mobilization after repair the fewer adhesions they will form.[35] The greater the strength of a laceration repair, the smaller the gap formation post-operatively. In addition, the stronger repair will allow a more rapid return to passive motion post-operatively as the repair is able to withstand more of the load placed on the tendon.[35] For instance, the three loop pulley is only able to withstand 1/3 of the normal weight bearing load of the equine superficial digital flexor tendon when it is first placed in a tendon and needs to be supported in a cast to prevent the repair from gapping open. If a repair was created that could withstand greater than the normal weight bearing load, the horse could immediately begin walking and loading the flexor tendons after repair and not require immobilization in a cast.

Therefore, achieving a stronger repair method should help achieve two of the major goals of an ideal tendon repair (minimize adhesion and gap formation) but the method by which strength is achieved needs to be balanced with how much the repair affects the intrinsic vasculature. This has proven difficult to achieve in the horse.

As will be discussed, no suture patterns currently used in equine surgery are strong enough to support the full weight of an averaged size horse immediately after repair, at a walk, without pulling through the tendon or breaking. It is suggested that any repair be supported with some form of external coaptation (a partial limb cast or a Kimzey splint) or the support of a Robert Jones bandage, for up to 4 -6 weeks.[11] External coaptation, including casts or splints, fixes the limb in partial flexion and decreases the pull on the repair site by decreasing tension on the flexor tendons. These external coaptation devices have been shown in human studies to increase adhesion formation and produce more immature scar tissue because of the reduced motion.[31]

Traditional Suture Patterns

The two traditional suture patterns used in studies evaluating healing in sutured versus un-sutured tendon lacerations are the three loop pulley (3LP) (Figure 2), or the locking loop (LL) (Figure 8). Both of these suture patterns have been examined in controlled experimental studies for their mechanical properties in equine tendons.[9,11,12] Adair compared the 3LP to the LL pattern sutured with either #1 polypropylene or #1 polydioxanone and found the 3LP pulley withstood a greater load to failure than the LL regardless of the material used in all tendons evaluated.[12] Adair did not evaluate the load to 2 mm gap formation in any of the repairs in his study but he did note that the 3LP formed a larger gap (2.97 cm)

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prior to failing than the LL (2.13 cm). Easley compared a single, double or triple LL to the 3LP sutured with nylon. Double or triple LL were formed by placing a second or third LL pattern across the tendon laceration. The 3LP was as strong as the triple LL, and both patterns were the strongest of the repairs.[9] The triple LL and the 3LP had a mean force at failure of 304 N. The 3LP formed a gap of 18 mm at failure while the triple locking loop had formed a gap of 23 mm. Jann compared the LL to the 3LP with a single strand of 3-0 polydioxanone, a single braid of three strands of 3-0 polydioxanone, or a double braid of six strand of 3-0 polydioxanone.[11] Jann found that the 3LP provided more support, less tendon distraction, and less tendon matrix constriction and distortion than the LL pattern.

The current gold standard for repair of tendon lacerations in horses is the 3LP suture pattern using #2 polydioxanone.[38] However, this pattern falls short of an ideal repair in many ways. Jann concluded, based on previously reported in-vivo loads placed on equine flexor tendons, that none of the patterns he examined could maintain tendon apposition under normal loading conditions in a living horse at a walk.[11] The 3LP withstands only 1/3 of normal weight bearing load at a walk (equivalent to 3559 N), therefore repairs are typically supported with some form of external coaptation for 4 to 6 weeks postoperatively to allow some tendon strength to return before subjecting the repair to full loads.[9,11,12] Additional criticisms by the authors of the studies evaluating the 3LP repair include the amount of exposed suture that could presumably lead to adhesion formation or

serve as a nidus for infection.[9,11] Placement of a 3LP has also been shown to compromise blood flow and tissue healing in repaired tendons and to have deleterious effects on the intrinsic vasculature of the SDFT, similar to the locking loop, as discussed earlier.[13]

Novel Suture Patterns

In an attempt to create a better tendon repair, many in-vitro studies have been performed in horses to evaluate novel suture patterns, or tendon implants, often borrowed from human medicine. These repairs all focus on maximizing the strength of the repair, and minimizing gap formation at the detriment of the tendons blood supply or the risk of adhesion formation.[14,18,19] These methods will be discussed in the following paragraphs and include bioabsorbable tendon plates, implants and various suture patterns.

i. Tendon Plates

Jenson et al. developed a bioabsorbable tendon plate (Figure 6) and evaluated its strength in comparison to the 3LP with 2 polydioxanone in repair of equine deep digital flexor tendon (DDFT) lacerations in vitro.[14] The plates were made from poly-L-lactic acid and shaped to conform to the mid-metacarpal palmar surface of an adult DDFT. Each plate had sixteen holes in the proximal and distal third of the plate for a total of 32 holes in each plate. The holes were used to place five

simple interrupted full thickness sutures and two figure-of-8 full thickness sutures at each end of the plate using 2 polydioxanone. The peak force for failure of plated tendons was 1507.8N, which was significantly (P>0.05) higher than those repaired with the 3LP (460.9N). The plates failed by pulling out of the tendon. The authors noted that they had concerns over how the apparatus would be accepted into biological tissue. They felt that the nature by which the plate was attached to the damaged tendon with circumferential sutures could limit tendon healing by vascular compromise, harboring sepsis, inducing adhesions or reducing normal tendon motion. To date there have been no published reports of the in-vivo use of these tendon plates.

ii. Bridging Implant

Poly-L-lactic acid has been used as an implant to bridge the ends of tendon lacerations that were unable to be apposed and sutured.[39] The implant, a flexible cylinder, was sutured to each cut end of the lacerated tendon to bridge the gap and hold it in place. Four horses reported in a clinical trial reported by Eliashar experienced no complications associated with the implant which appeared to become well incorporated in the healing tendon gap scar tissue. Two of the four horses (50%) returned to work within a year, while the other two remained lame. The horses in this study were kept in external coaptation for up to 16 weeks and

no control group was used. Due to the study design, the authors were not able to determine if the implant contributed to improved tendon healing or not.[39]

iii. Savage Suture Patterns

A Savage suture pattern commonly used in human medicine has been evaluated in equine tendons in two separate studies.[18,19] The suture pattern uses a grasping technique that has been experimentally shown to be superior in both strength and resistance to gap formation in human studies. The technique places either six or ten strands of suture across the laceration site. These strands form equally spaced units around the circumference of the tendon. The epitenon, or loose connective tissue surrounding the tendon, is optionally sutured and closed over the repair in these methods using the Lin-locking epitenon suture. (Figure 9) Research in human medicine has shown that suturing the epitenon increases the strength of lacerated tendon repairs by 10 to 50% over core suture alone by increasing the amount of suture that crosses the laceration site.[40]

Smith evaluated a ten-strand version of the savage suture technique (Figure 5) with or without a Lin-locking epitenon suture in an ex vivo study using equine superficial digital flexor tendons.[19] A distraction rate of 8.5 mm/sec was used in this study. Smith carried out the repairs using either 2 polydioxanone or 2 polyglactin 910 suture and compared them to the 3LP sutured using one of the two suture materials. All Savage suture patterns failed by suture breakage at the

knot-suture interface while the 3LP patterns all failed by suture pull out from the tendon. The ten-strand Savage with or without the Lin-locking suture was significantly stronger than the 3LP regardless of suture material used. The addition of the Lin-locking suture made the ten-strand Savage significantly stronger (998 N) than without the epitenon suture (872 N). Use of 2 polyglactin 910 significantly increased the strength of any of the Savage repairs over the use of 2 polydioxanone in the same repair (978 N vs. 765 N without epitenon suture or 1105 N vs 890 N with an epitenon suture). The opposite was true for the 3LP where repairs made using 2 polydioxanone were significantly stronger than 3LP repairs performed with 2 polyglactin 910 (382 N vs 292 N). Smith did not evaluate the load required to produce a 2 mm gap in these repairs but found a gap at failure of 17.6 mm for the Savage repair without epitenon suture and 18.9 mm with the epitenon suture. The gap at failure for the 3LP was 31.7 mm which was significantly larger than the Savage repairs. Smith concluded that although the ten-strand Savage was three times as strong (978 N-1105 N) as the 3LP (292-382 N) there could be difficulties using the pattern in clinical cases. The pattern requires 360-degree access to the tendon to place it appropriately and it is technically challenging to perform. Smith also noted that the circumferential nature of the pattern and its locking attributes may theoretically affect blood flow at the repair site because of disruption of the peritendonous tissues in placement.[19]

A six-strand version of the Savage technique (Figure 4) has also been evaluated by Everett, et al.[18] in comparison to the 3LP. The study was performed on cadaveric equine superficial digital flexor tendons. This study did not use an epitenon suture and performed the repairs using 2 polydioxanone. Everett used a distraction rate of 25 mm/sec. This study found the six-strand Savage had a higher ultimate load to failure (421 N) than the 3LP (193 N). However, the two suture patterns had similar resistance to 3 mm gap formation of 102 N for the Savage pattern and 109 N for the 3LP. Similar to the previous study the authors concluded that there may be some limitations to the use of the suture pattern in in-vivo trials because the pattern may affect blood flow and that the overall strength of the pattern was not strong enough to resist gap formation in standing horses.[18]

iv. Tendon Implants

In the early 2000's human studies started to investigate tendon laceration repair methods that utilize implants placed entirely within the tendon.[15-17] Erol examined two variations of a stainless steel coil surrounding a wire placed within sheep tendons.[16] (Figure 10) Model 1 was formed of a single 5-turn spiral coil of 0.8 mm wire. The coil was formed out of one end of the wire turned back and wrapped around itself. Model 2 had two separate pieces of wire. A 7-turn spiral coil of 0.8 mm wire formed in the same fashion as Model 1 with an additional T shaped wired attached to the proximal end of the spiral. The T shaped component

was made of 1.5 mm wire. The diameter and distance between the spirals was the same for each model, but the value was not stated in the paper. This study tested the implants in lacerated cadaveric sheep Achilles tendons compared to a LL suture repair. It found that Model 2 withstood a higher tensile force to ultimate failure (28 Kilogram-Force or 274 N) than the LL technique (22 Kilogram-Force or 216 N) when distracted at a rate of 20 mm/sec.

Hipara developed and studied a barbed device made from nitinol tubing, a flexible alloy of nickel and titanium.[15] (Figure 11) The device was easily embedded within either end of the lacerated tendon ends. Hipara compared the strength of one or two of the devices in porcine profundus flexor tendons to three sutured repairs including the six-strand Savage, the Kessler suture (equivalent to the LL suture) and a four strand cruciate repair using 6/0 monofilament nylon. (Figure 12) Two of the devices proved to resist the same force to produce a 3 mm gap as the six-strand Savage technique at a distraction rate of 10 mm/min of 80 N and 82 N, respectively.

The aim of the nitinol and barbed suture devices in intra-tendinous laceration repair was to minimize required dissection of paratenon surrounding the damaged tendon for repair to maintain extrinsic repair, minimize exposed suture outside the tendon leading to possible adhesion formation and hopefully a greater strength of

repair.[15,16] Another intra-tendinous repair is the subject of this study – a stainless steel suture and anchor device.[17]

Stainless Steel Anchor Device

The stainless steel suture device (SA) (Teno-Fix Tendon Repair System, Ortheon Medical, Columbus, OH) evaluated in this study is a commercially available product used for the repair of tendon lacerations in human orthopedic surgery. It consists of two stainless steel anchors placed within the tendon on either side of the laceration and connected with a stainless steel suture. The anchors are 4.0 mm in length and have an outer diameter of 2.2 mm and contain an inner core surrounded by a coil (Figure 13). The 2-0 stainless steel suture is 0.3 mm in diameter. The suture is fed through the anchors and the tendon ends are apposed with slight bunching of the tendon ends. A steel bead is crimped onto the suture to lock it in place and the epitenon is closed over the incisions made to implant the anchors and around the laceration (Figure 7). Studies described in dogs and humans have shown the device is well tolerated, producing a healed tendon with minimal scarring when compared histologically to a commonly used sutured method.[17,20-23,41]

Su first examined the device experimentally in forelimb flexor tendon lacerations of 16 dogs to evaluate if the device interfered with primary tendon healing.[23] The dogs were maintained in external coaptation for the first four weeks after surgery.

The limbs were maintained in an elevated position to prevent weight bearing and the coapation allowed for passive flexion and extension exercises. Of the 16 dogs evaluated, 7 healed without gap formation or rupture of the apparatus. In 9 of the sixteen cases, the dogs removed the external coaptation against the investigators wishes prior to the completion of the four week period, and only three of these cases healed primarily with no gapping. Only one of the dogs evaluated developed peritendinous adhesions. Histologic examination of the tendons showed the device did not impede primary healing of the tendons or produce excess inflammatory responses in any of the examined tendons.

Su also examined the SA device for strength characteristics.[20] He compared a single device placed in cadaveric human flexor tendons to a four strand locking cruciate suture technique, commonly used in human medicine, and found no difference in strength between the two repairs (66.7 +/- 10.9 N and 70.0 +/- 11.8 N respectively).

Lewis examined the strength of three SA devices versus a Kessler suture technique (equivalent to the LL suture) in the repair of cadaveric human Achilles tendon and found the devices were superior in strength to the sutured repair.[17] The devices withstood stresses of 1.19 +/- 0.12 N/mm^2, and the Kessler withstood 1.03 +/- 0.51 N/mm^2 at a distraction rate of 0.80 in/min. These stresses are calculated by dividing the cross sectional area of the tendon by the peak force at

failure. The study does not report the average cross sectional areas of the tendons making it difficult to extrapolate the peak force at failure.

A multicenter, randomized, blinded clinical trial was performed to evaluate the device in human flexor tendon injuries.[21,22] Of eighty-five injured flexor tendons, thirty four were treated with a single SA system and fifty-one served as controls. The controls were sutured with a cruciate pattern, well established in human orthopedic surgery. All patients were prescribed the same rehabilitation program post-operatively. Nine of the sutured repairs ruptured, while none of the tendons repaired with the SA device ruptured. No differences were noted between groups in terms of range of motion, pinch or grip strength, pain, swelling or neurologic recovery. Kubat reported use of a single SA device in a patient after a previous sutured repair ruptured. The device was well tolerated and remained intact even in the previously damaged tendon.[41]

The device is favored in human orthopedic surgery because it is simple to place in comparison to other repair techniques and allows a more rapid return to mobilization and function.[17,41] Unlike previous methods, this suture uses an anchor system to lodge a linear stainless steel suture completely within either end of the severed tendon, so no portion of the suture is located outside of the tendon.[17,20-22] Investigations into the viability of this device have not been previously reported in the horse.

III. Objectives

The objective of our study was to determine if the *in vitro* strength of a novel tenorrhaphy technique for equine tendon repair using stainless steel suture and anchors (SA) was superior to the three loop pulley (3LP) sutured repair. The design of this study should prove or disprove that the SA technique is equal in strength to the current standard of equine tendon laceration. Should the device prove to be as strong as the 3LP it will justify further investigations *in vivo*, to assess the SA's effects on the dynamics of equine tendon healing.

IV. Materials and Methods

Collection of Samples

Pairs of forelimb superficial digital flexor tendons (SDFT) were collected from eight adult horses, 3 geldings and 5 females, euthanatized for reasons unrelated to this study. The horses ranged in age from 5 to 15 years (median 9 years), and breeds represented included American Quarter Horse (5), Tennessee Walking Horse (1), Thoroughbred (1) and Warmblood (1). The horses were evaluated at a walk and trot prior to euthanasia for the absence of lameness originating from the forelimb flexor tendons by one investigator (EB) using the AAEP lameness scale. The distal limb was also evaluated using ultrasound examination by two investigators to determine that the tendons were structurally normal. Cross sectional area of the flexor tendons within zone 2B[42] was recorded for all tendons and ranged in size from 122.5 mm^2 to 137.3 mm^2 with a mean of 128.2 mm^2 +/- 17. 0 mm^2.

Immediately after euthanasia, the paired SDFT were collected by transecting the tendon proximally at the level of the carpo-metacarpal joint and distally at the level of the proximal sesamoid bones. The tendons were rinsed with 0.9 % saline

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solution, wrapped in gauze soaked with saline, and sealed in plastic for freezing. The tendon specimens were preserved at -70C until testing was performed. All tendons were tested on the same day.

Experimental repairs

On the day of testing, the tendons were thawed at room temperature to 30C and each pair was transected at its midpoint. One tendon of each pair, selected at random, was repaired with a 3LP suture pattern using #2 polydioxanone, and the other was repaired with the stainless steel SA device. A metric ruler was placed adjacent to each tendon during repair as a guide for the distance of the suture bites. The 3LP repair with size #2 polydioxanone was placed as previously described, with suture bites 1&6 placed 2 cm from the site of transection, bites 3&4 placed 3 cm from the site of transection and bites 2&5 placed 4 cm from the site of transection.[9] (Figure 2) Tension was placed on the suture until the tendon ends were apposed and then the suture was tied with a surgeon's knot followed by two square knots.

The stainless steel SA system (Teno Fix Tendon Repair System, Ortheon Medical, Columbus, OH) was placed as described by Su et al in 2005.[22] The SA system consists of a 2-0 multifilament stainless steel suture and two stainless steel anchors (Figure 7). Placement was accomplished by making a small stab incision through the paratenon at a distance 2 cm proximal and distal from the severed end

of the tendon. An obturator and a delivery tube supplied with the suture were used to place an anchor within the tendon at this level (Figure 14). The anchor is placed into the tendon through the stab incision with the obturator facing towards the lacerated end of the tendon. The exposed end of the obturator is then twisted, causing the anchor to rotate into place within the tendon using a spiral motion (Figure 15). The anchors engage the tendon substance by capturing fibers between the core and corkscrew like coil.[22]

A multifilament stainless steel suture was then passed through the anchor, crossing the severed ends, and was pulled through the second anchor placed in a manner similar to the first anchor. The suture was then placed in a crimper and tightened until the cut ends of the tendon were apposed and beginning to bulge.

The stainless steel suture was cut and the paratenon closed routinely with 4-0 polydioxanone in a simple continuous pattern. A total of four stainless steel sutures were placed, evenly distributed in the superficial digital flexor tendon (Figure 7). A single surgeon (EB) performed all repairs.

Mechanical Tensile Testing

Immediately after repair the tendons were transported to the laboratory in phosphate buffered sodium chloride for testing. An electromechanical materials testing machine (Q Test 100, MTS, Eden Prairie, MN) coupled with a high speed

camera recording at 60 frames per second (Scout scA640-120gm/gc, Basler, Exton, PA) was used to perform tensile testing. Custom designed clamps were used to grip the tendons for the tests. The clamps were engineered in a fashion similar to those used by Jenson, et al.[14] Briefly, they consisted of two 2.5 X 3.0 cm plates with 5 mm spikes, placed at 3 mm intervals (Figure 16). The plates were compressed against the tendon with threaded bolts, so the spikes penetrated the full thickness of the tendon. The distance between grips was set at 150 mm and the tendon ends were trimmed, if needed. The samples were placed under a preload of 1N prior to testing and tests were carried out at a displacement rate of 8.5 mm/sec until failure, which was comparable to previously performed studies.[12,14,19] Force to 2 mm gap and force at failure were measured for both types of repair. Failure was defined as a sudden drop in the tension as recorded by the material testing machine. Method of failure was defined as suture pull-out, suture breakage, or implant failure. The method of failure was recorded and reviewed on high speed video using video software (MaxTraq, Innovision Systems Inc., Columbiaville, MI) (Figure 17). Statistical analysis was carried out using commercial statistical software (Minitab, Minitab Inc, State College, PA) and paired T-tests to compare the absolute difference in tension between the SA repair system and the 3LP repair at a 2 mm gap, and at failure.

V. Results

No grip failure or slippage of the tendons occurred during tendon testing, and all tendons completed the testing phase immediately after sutured repair.

Load at 2 mm Gap Formation (Table 1)

The mean maximum load to create a 2-mm gap in the SA repair (114.5 N +/- 21.5 N) was lower than, but not significantly different from the 3LP repair (164.9 N +/- 67.7 N, P = 0.09).

Load at Construct Failure, Failure Mode, Gap at Failure (Table 1)

The mean +/- SD ultimate failure load for the 3LP repair (363.5 N +/- 83.7 N) was significantly stronger than the SA repair (132.4 N +/- 26.8 N, P = 0.0001). The mode of failure was suture pull-out for all 3LP repairs, and anchor pull-out for all of the SA repairs. The gap at failure for the SA repair (6.8 mm +/- 1.3 mm) was significantly smaller than for the 3LP repair (19.1 mm +/- 3.2 mm, P = 0.000005). (Figure 18)

Load versus Actuator Displacement

The load versus actuator displacement was plotted for each of the tenorraphy patterns to produce a load displacement curve. (Figure 19) These curves show the SA repair is not as strong as the 3LP as displacement increases after a 2 mm gap at the tendon ends. However, it appears that the SA repair is stiffer during initial testing as evidenced by the steeper slope of the displacement curve.

VI. Discussion

In this *ex vivo* investigation, the SA repair was not significantly different in load to 2 mm gap formation than the 3LP. However, the ultimate load to failure of the SA repair was only 36% as strong as the 3LP repair. The mode of failure for both repairs was failure of the implant-tendon interface, resulting in pull through of the implanted material, versus failure of the implants themselves. The larger gap at failure seen for the 3LP versus the SA repair is likely the result of the suture used in the 3LP stretching prior to pulling out of the tendon, which is not the case for the stainless steel suture in the SA repair. This stretching was visually appreciated during the tests. The results of this study indicate that the SA repair, in the fashion it was used in this study, is not strong enough to maintain lacerated equine superficial digital flexor tendons in apposition without external coaptation.

The in-vivo load placed on a forelimb equine superficial digital flexor tendon at a walk has been reported to be 362.9 kg (3558.8 N for a 450 kg horse).[6] Both the 3LP and the SA repairs have been shown to withstand less than 10% of this load. Currently the strongest repair method that has been tested is a bioabsorbable tendon plate with an ultimate load to failure of ~1500 N, which is less than 50% of the required load at walk.[14] However, most tendon laceration repairs are supported in some form of external coaptation post-operatively, which one would

assume lessens this load.[38] Unfortunately, no data currently exists as to what the in-vivo load is on a flexor tendon while the limb is maintained in flexion with external coaptation. Without this information we are left to speculate as to the adequacy of our sutured repairs when they are protected with a cast.

When comparing these repairs, it could be argued that the tension to gap formation is as important for tendon laceration repair as the ultimate failure, because of the effect gap formation has on tendon healing.[24,30-35] Studies have shown in dogs that a gap greater than 3 mm prevents normal tendon healing and leads to an increased risk of rupture during the first 6 weeks of rehabilitation.[30] Human studies have shown that gap formation as small as 1 mm were associated with increased formation of adhesions, were detrimental to tendon function and led to poor clinical outcomes.[31-33,] In chickens, gap formation was associated with increased adhesion formation, and increased tendon callus size.[34] However, until we know the amount of load external coaptation is able to eliminate from a laceration repair we cannot determine if this gap could be maintained in-vivo. External coaptation would need to eliminate 95 to 98% of the load placed on the SDFT at a walk to support either the 3LP or the SA repair to a 2 mm gap, and this is a significant weakness of both repairs.

Despite a lower tensile strength to failure, the SA repair shows promise regarding other goals of tendon repair including minimizing adhesion formation and

preventing disruption of tendon perfusion.[2,25] The 3 LP pulley has been criticized for excessive suture exposed outside of the tendon, contributing to adhesion formation and preventing the normal gliding function of tendons. One advantage of the SA repair is that it is entirely intra-tendinous, and only the small epitendinous suture is exposed, providing minimal opportunity for adhesion formation.[22] This may provide a beneficial effect in terms of biological healing of the equine tendon laceration, and will require further investigation in vivo.

Support for the use of the SA suture in the horse includes studies in dogs which have shown minimal scarring, fibrosis or negative effects on tendon healing.[17] None of the repairs showed any evidence of adhesion formation from the epitenon. The SA device is currently used routinely in human medicine with good functional outcome.[2-22] The device is favored because it is simple to place in comparison to other repair techniques and allows a more rapid return to mobilization and function.[20-22]

One drawback of our study was the use of frozen specimens. Ideally, our repairs and testing would have been performed on fresh cadaver tendons, since freezing has been shown to alter the biomechanical properties of tendons and make them weaker.[43,44] Specifically, the tendon fibers can become disrupted during the freeze-thaw cycle which could greatly affect the sutured repair. The collagen fibrils lose their tight bonds as the water freezes between them and expands,

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pushing them apart. The intra-tendinous nature of the SA repair uses the strength of the tendon fibers to provide the strength of the repair, more so than the 3LP repair, since the anchors of this system rely on intact tendon fibers to grip for strength.[22] Unfortunately, using fresh tendons in this study was not technically feasible, due to the logistics of testing and the availability of fresh specimens. Testing of the SA system in fresh specimens may increase the load at failure for this system.

Another drawback of the study was inherent in our testing protocol. The strain for our test varied between 0.5% and 1%, at a distraction rate of 8.5 mm/sec, which is less than the strain reported in horses at a walk.[7,8] Having a higher strain or strain rate increases the stiffness, or the ultimate tension with which a tendon fails. This could increase the strength of the SA implant or the 3LP.[37,45] A study has shown that this effect is negligible.[45] We were unable to adjust this parameter in our testing unit but it was consistent between the two repairs and it is consistent with other studies. A distraction rate of 8.5 mm/sec was also used in the study examining the 10 strand Savage, by Adair using 50 cm/min (8.3 mm/sec) testing the 3LP and Jenson using 500 mm/min (8.3 mm/sec) to test tendon plates. A much faster rate of 25 mm/sec was used by Everett to test the 6 strand Savage and Easley testing both the LL and the 3LP (150 cm/min). Jann tested the 3LP and LL at rates varying between 12 to 15 mm/sec. These studies, regardless of strain rate, all found similar strengths for the 3LP (Everett;193 N, Smith;382 N, Adair; 307

N, Easley; 303 N, Jenson;460 N, Jann;131 N). These findings show that studies evaluating the 3LP at higher strain rate (Everett; 193 N) did not have a higher failure point than those at the lower strain rate (Smith; 382 N) and that other variables have a stronger effect on the final strength of the repair.

We used four stainless steel suture systems in each flexor tendon repair for a number of reasons. First, the strength of a single unit in a cadaveric human tendon was found to be 45 N to produce a 2mm gap.[20] Assuming a linear relationship, four implants would withhold 180 N, which is similar to previously reported strengths of the 3LP in horses.[9,11,14] We felt that because equine tendons fail at a higher strength than canine or human tendons repaired in the same fashion and that because the SA device relies on the strength of the tendon fibers itself to provide the strength of the repair, that each implant would provide a greater strength in equine tendons than in humans. Our repair withstood 132 N, which equated to approximately 33 N per implant. The reasons for this decreased load could be related to differences between tendon architecture between humans and horses or an uneven distribution of forces across each of the four implants. Second, the implant fills a small amount of space in the tendon end it is placed in and we found that four implants fit easily into the tendon in parallel. The device has not been evaluated if it is placed at variable angles or staggered within the tendon and it warrants investigation to see if altering the angle to place more suture systems in different patterns may produce a stronger repair.

An additional factor that cannot be ignored regarding our SA device is its cost. Each unit costs roughly 250 US dollars and comes with two anchors, multiple strands of suture and a pre-loaded crimper. Therefore, we required four of these units for each tendon repair. This is a significant increase in cost, when compared to the 3LP repair which only costs the price of the suture material, or 11 US dollars.

This study investigated the SA, a human tendon laceration repair system, for equine flexor tendon lacerations. The results of the study found the SA repair was comparable in strength to the 3LP to a 2mm gap, but the SA repair only achieved 36% of the ultimate load to failure of the 3LP. These results support further investigations into use of this implant, specifically regarding methods by which its ultimate strength can be improved. Further in-vitro studies evaluating a greater number of implants, implants used in a different configuration or developing a stronger implant itself are required before the implant can be tested in-vivo in the horse.

VII. References

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Appendix 1: Figures

Figure 1: Flexor tendon laceration

Figure 2: Three loop pulley suture pattern
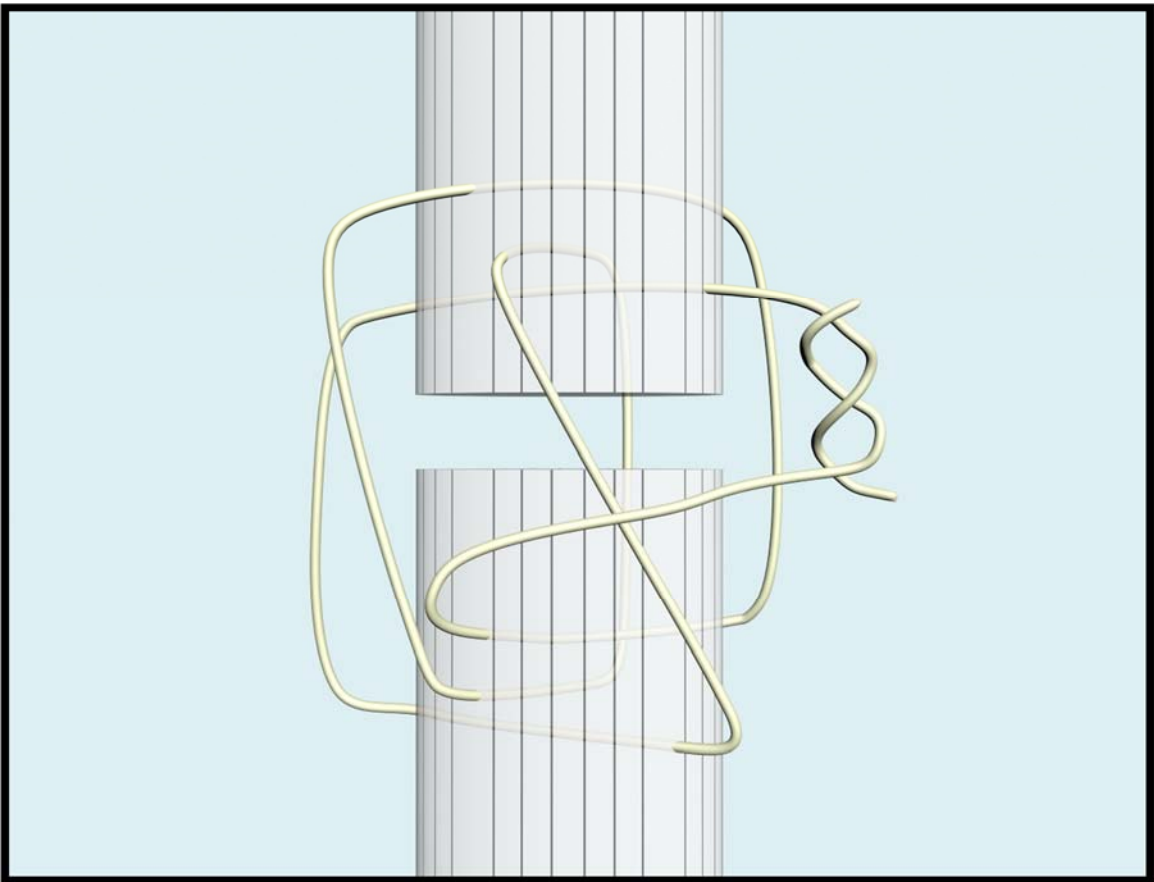
Figure 3: Tendon laceration in full limb external coaptation or cast

Figure 4: Six-strand Savage suture pattern (Everett, 2010) Used under Fair Use
guidelines
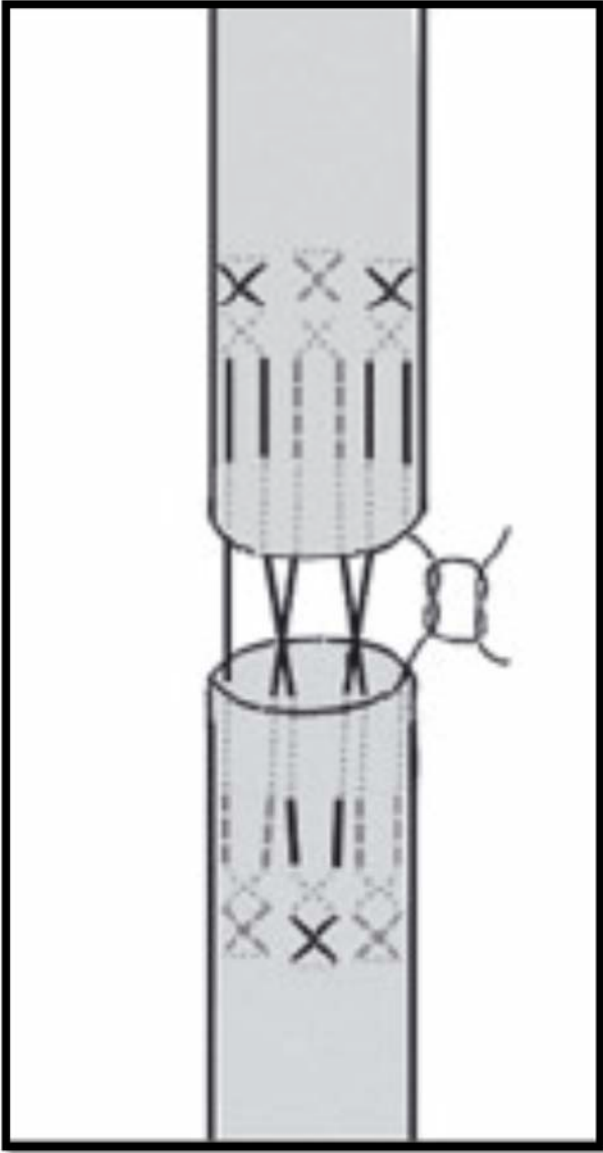
Figure 5: Partially completely ten-strand Savage (Smith, 2010) Used under Fair Use guidelines
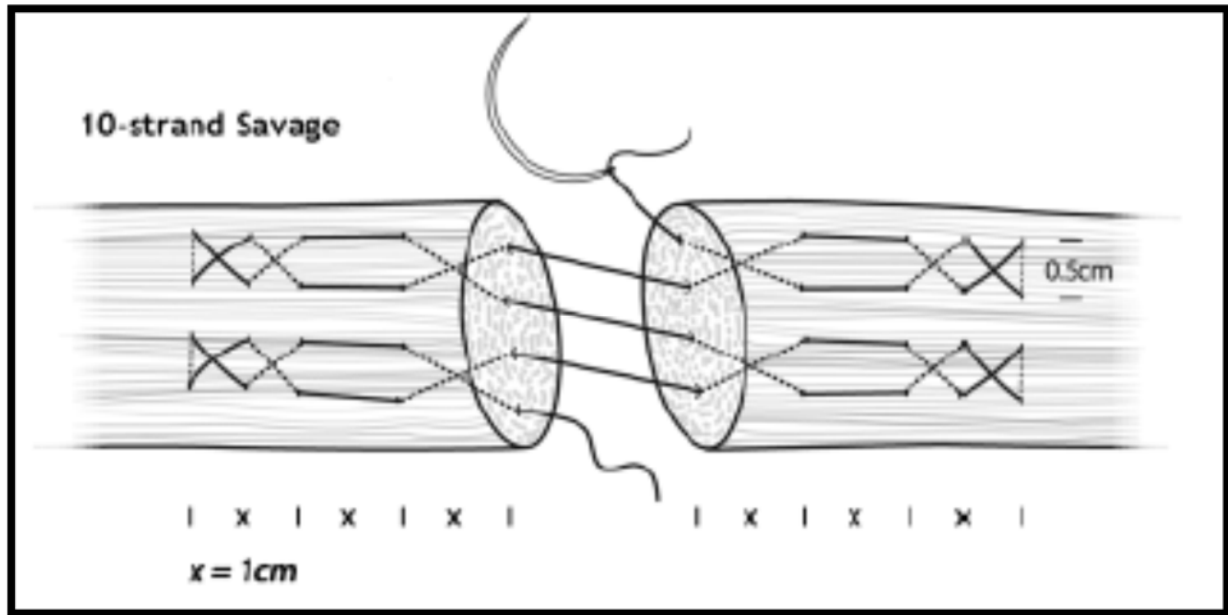
Figure 6: Bioabsorbable tendon plate placed within an equine deep digital flexor tendon
(Jenson, 2005) Used under Fair Use guidelines

Figure 7: Stainless steel suture and anchor system
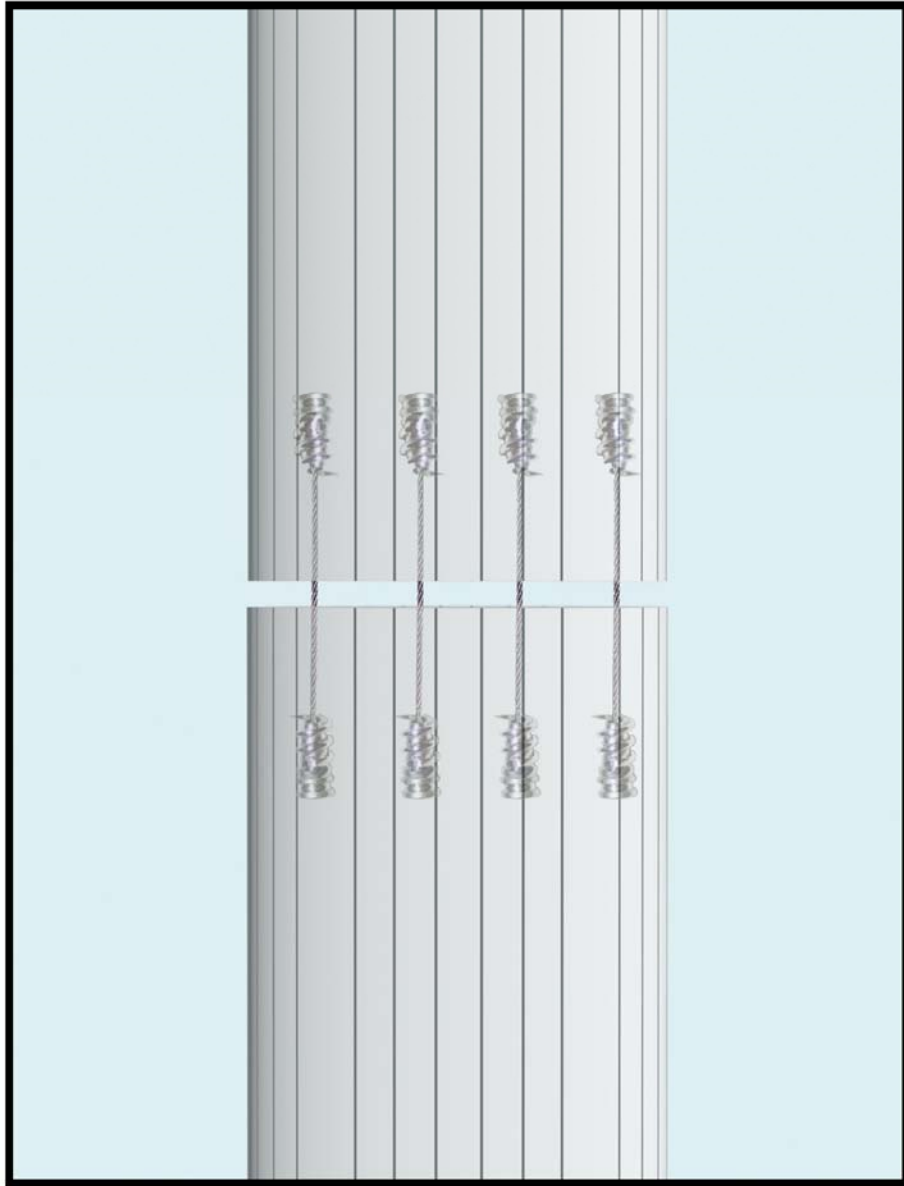
Figure 8: Locking- loop suture pattern (Adair, 1989) Used under Fair Use guidelines
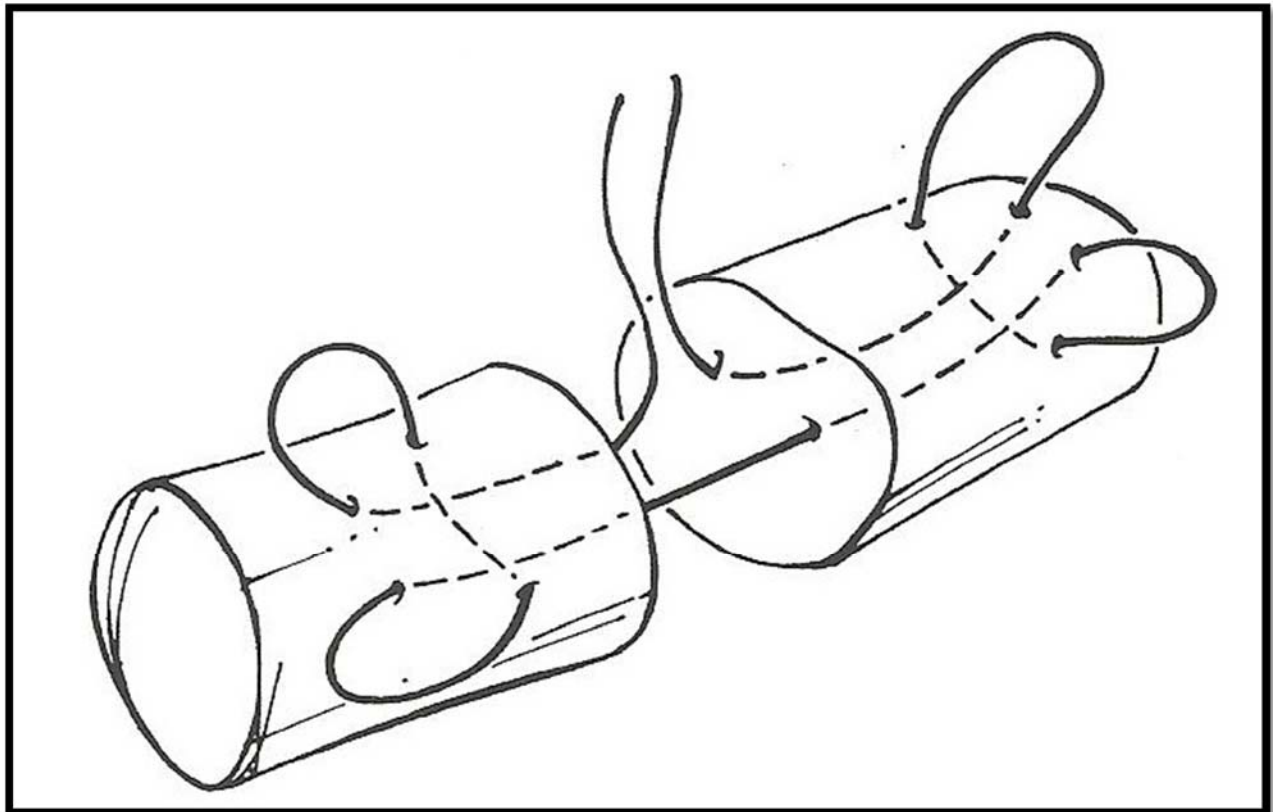
Figure 9: Lin-locking epitenon suture (Smith, 2010) Used under Fair Use guidelines
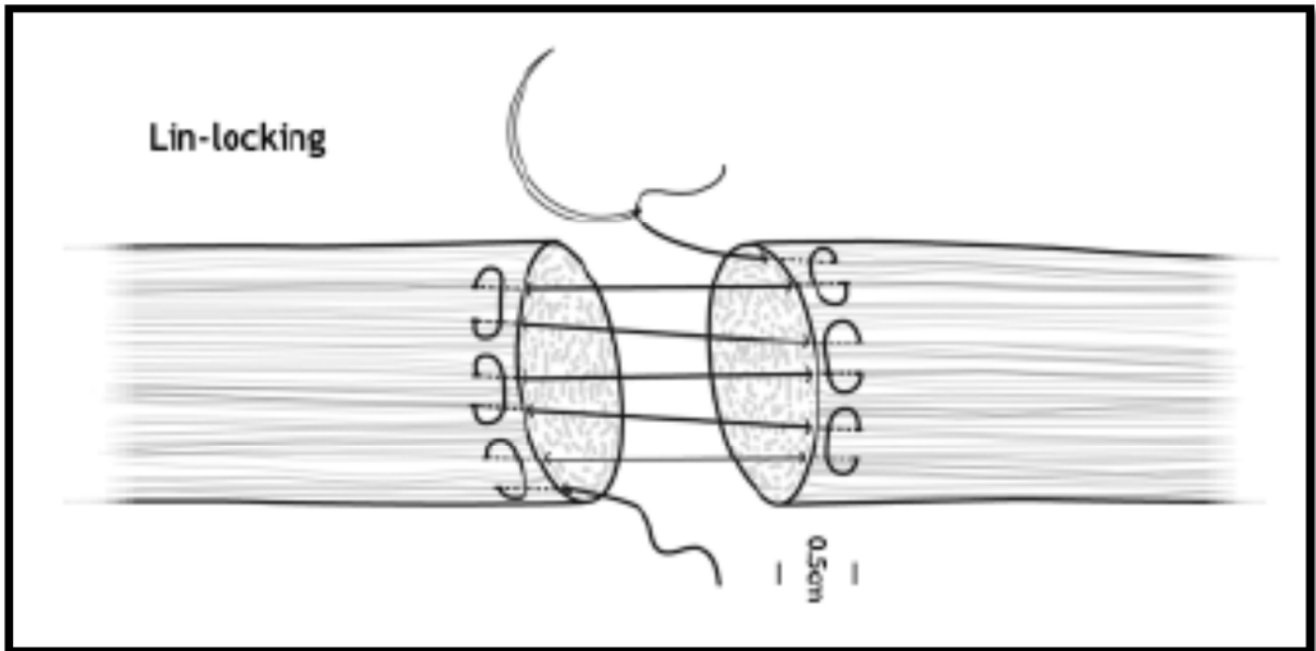
Figure 10: Intra-tendinous stainless steel implants designed by Erol, et al. (Erol, 2007)
Used under Fair Use guidelines
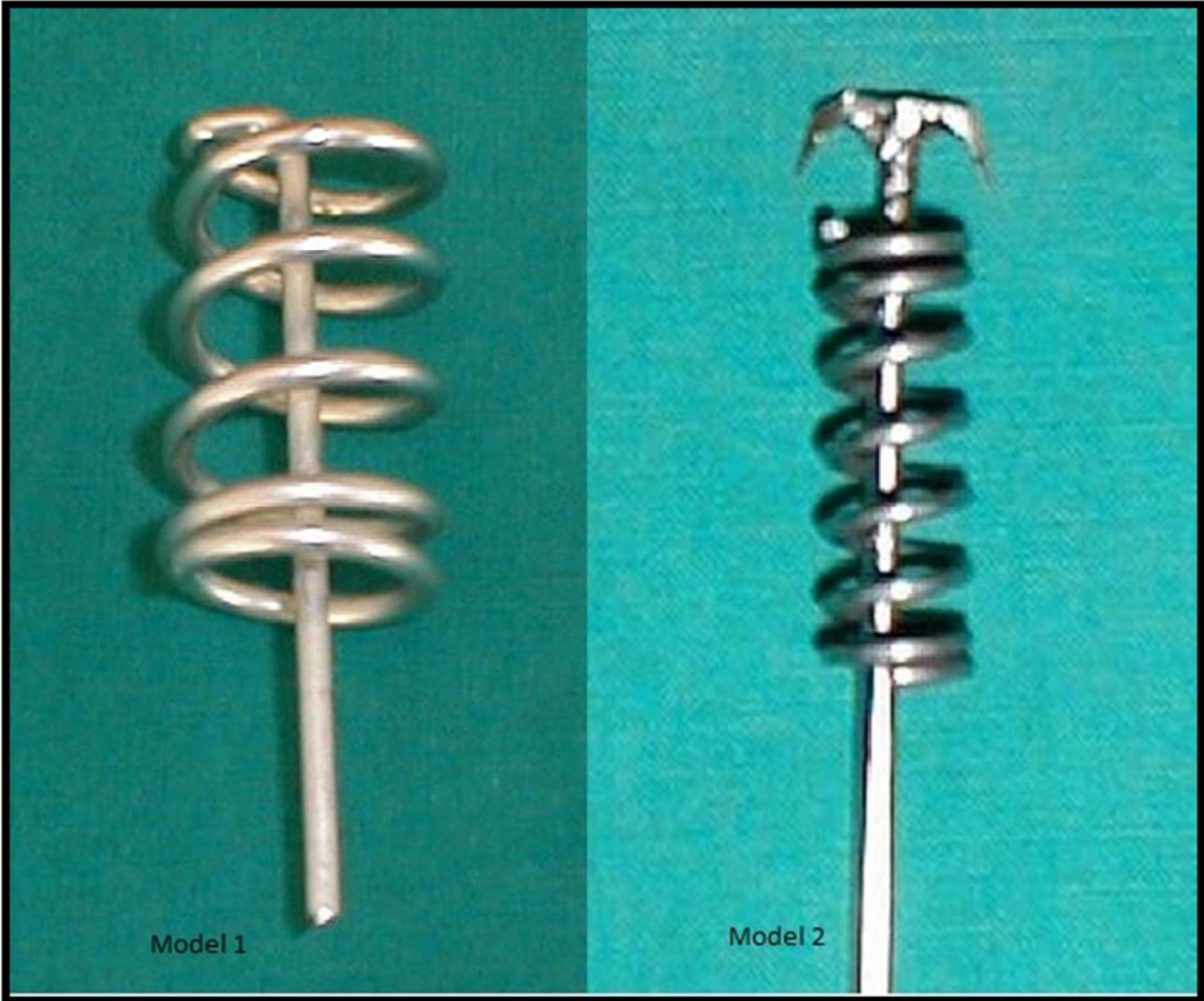
Figure 11: Intra-tendinous nitinol coil implant designed by Hirpara, et al. (Hirpara, 2010)
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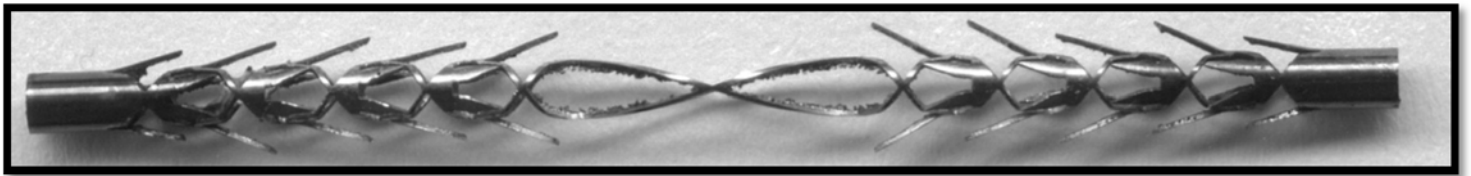
Figure 12: Four-strand cruciate suture pattern. (Hirpara, 2010) Used under Fair Use
guidelines
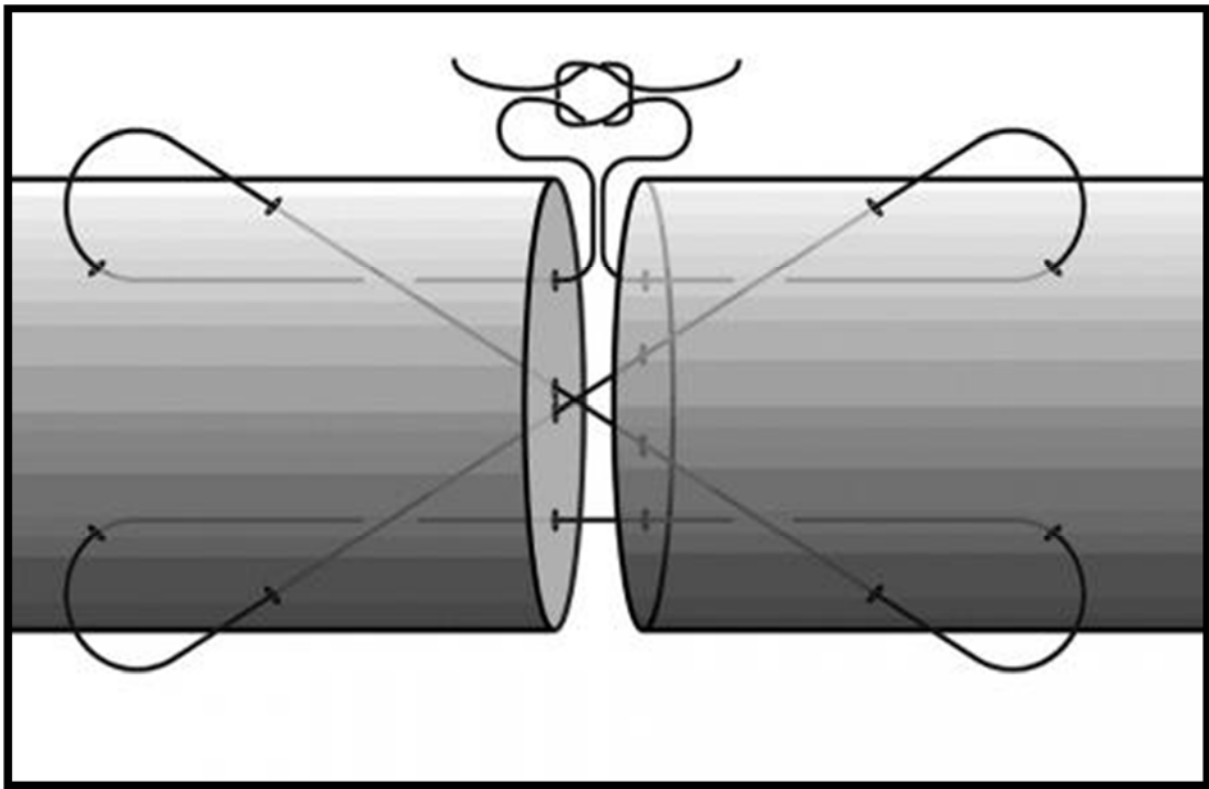
Figure 13: Stainless steel anchors and suture system
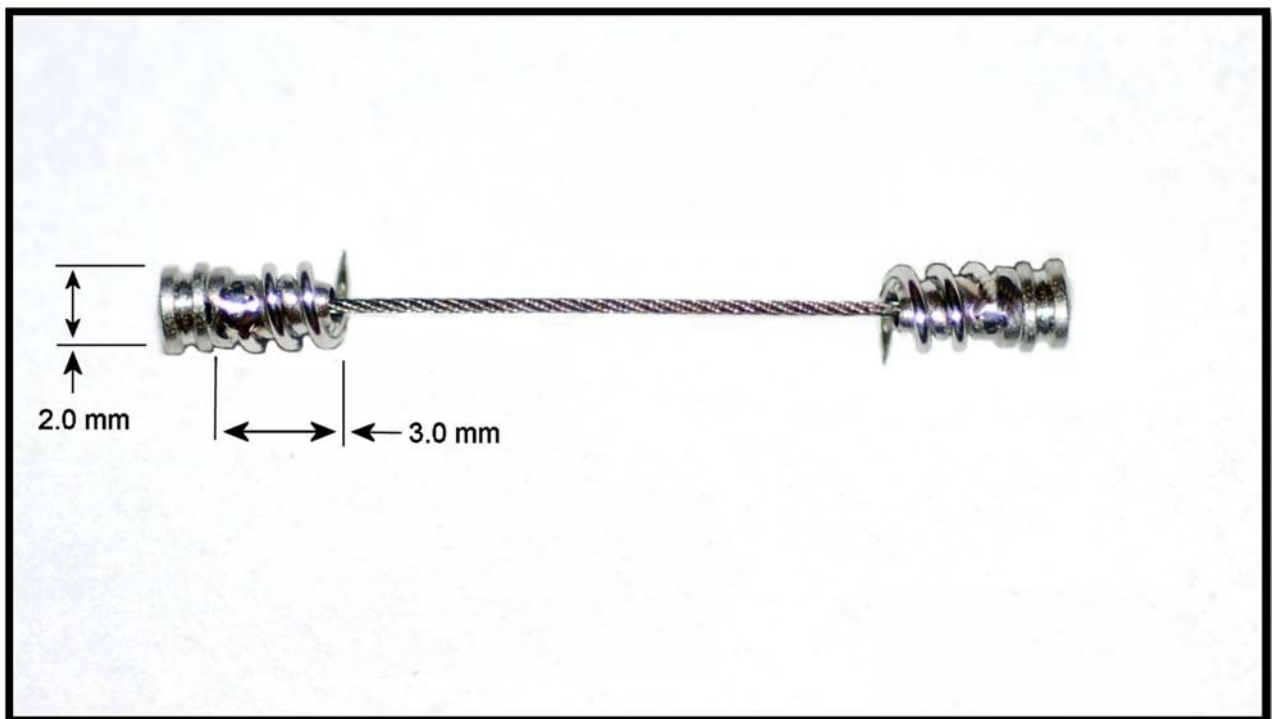
Figure 14: Obturator of stainless steel and anchor system

Figure 15: Obturator twisting the anchor into place within the tendon end
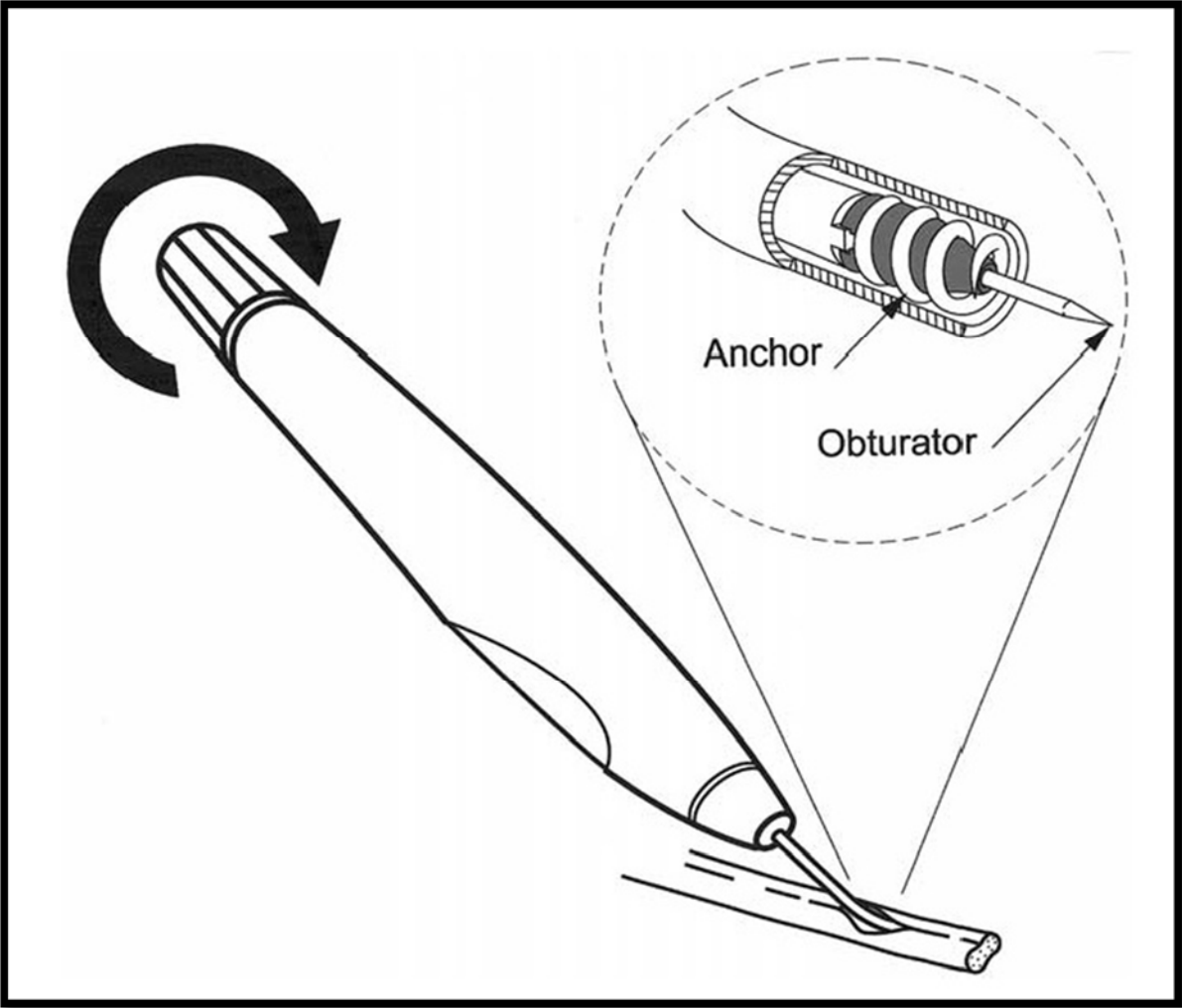
Figure 16: Clamps used to secure tendons to the tensile testing machine
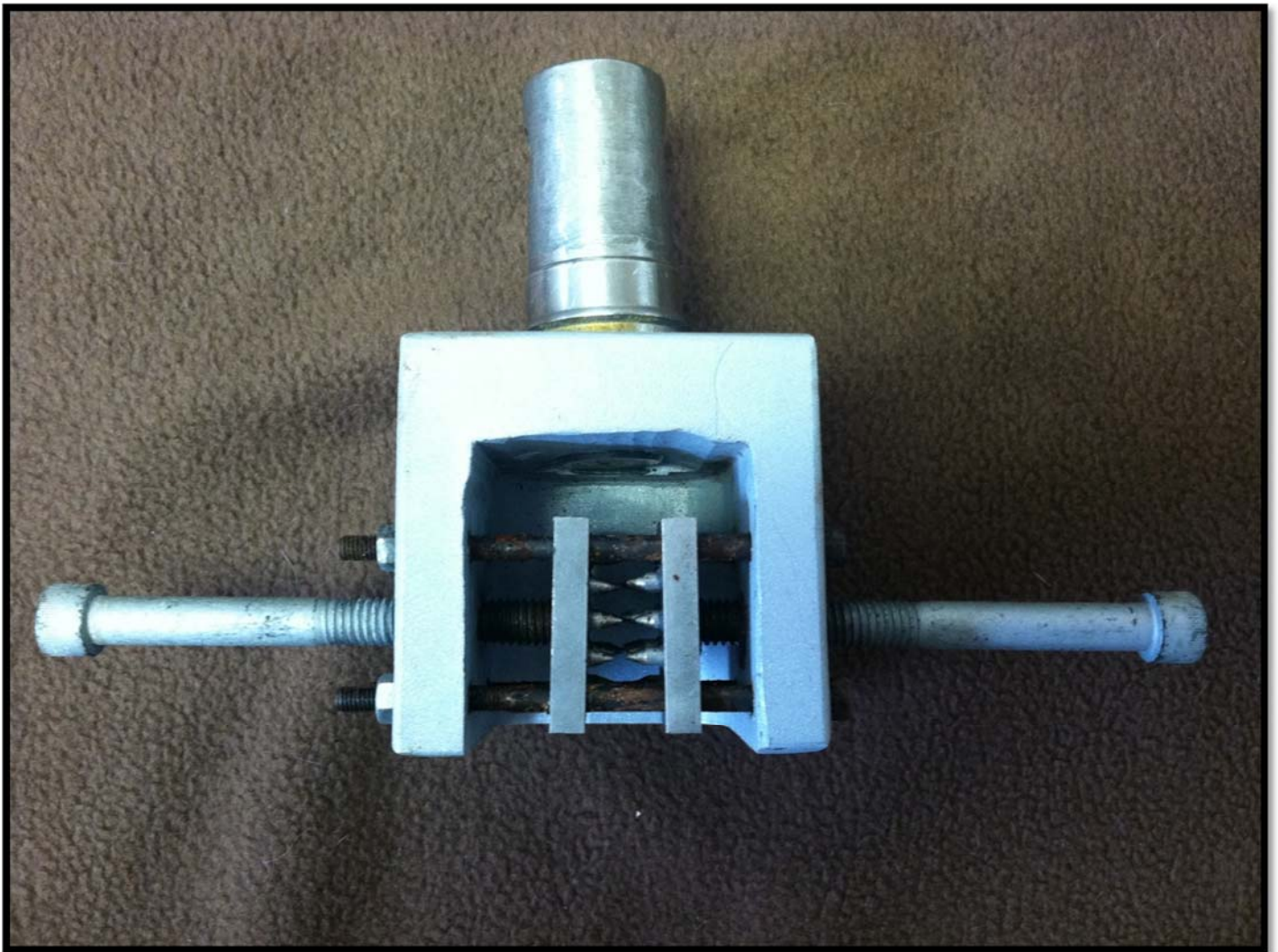
Figure 17: Testing set-up with Q-Test 100 and high speed camera in place
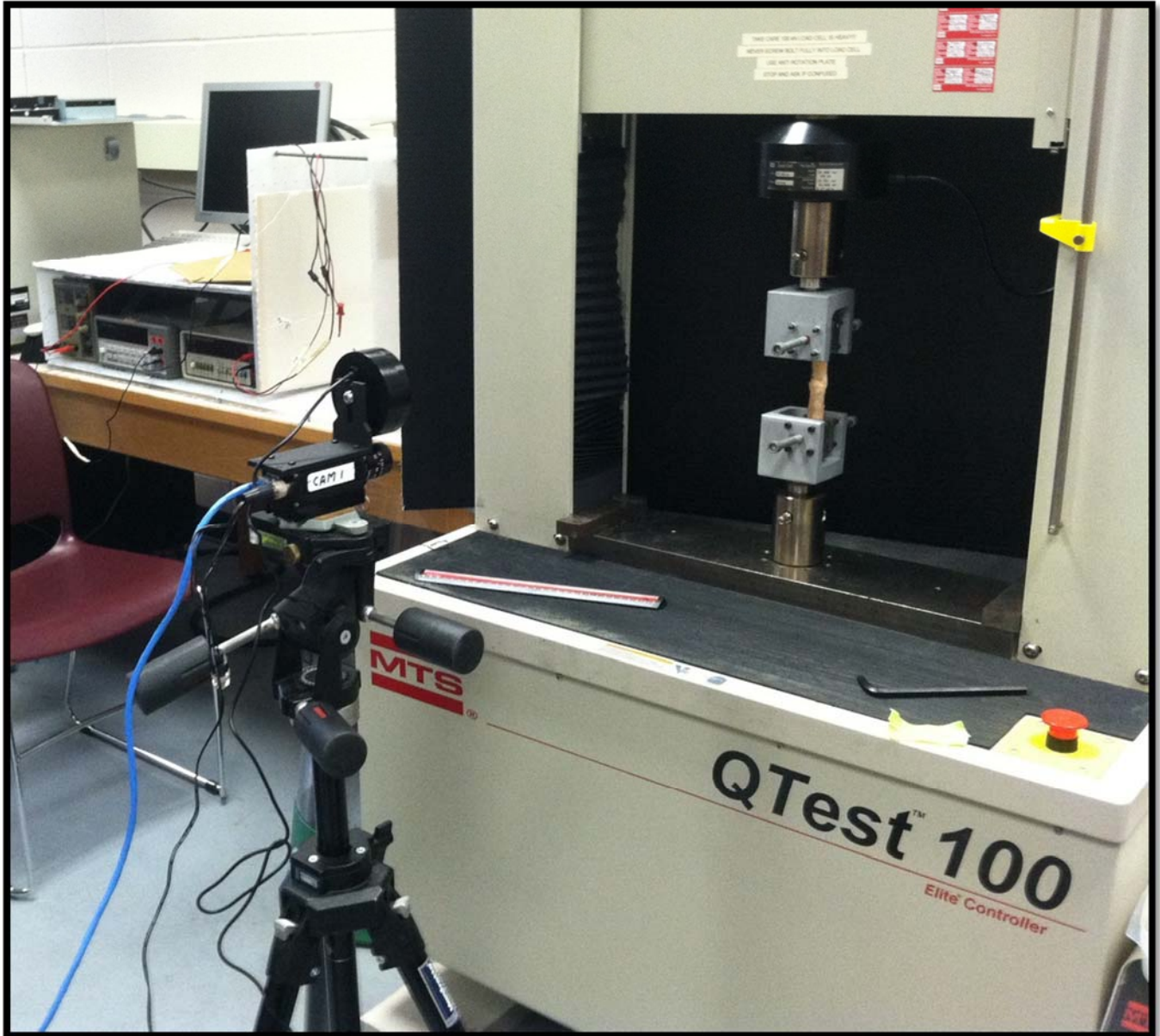
Figure 18: Gap at failure for the SA (left) and 3LP (right) repairs
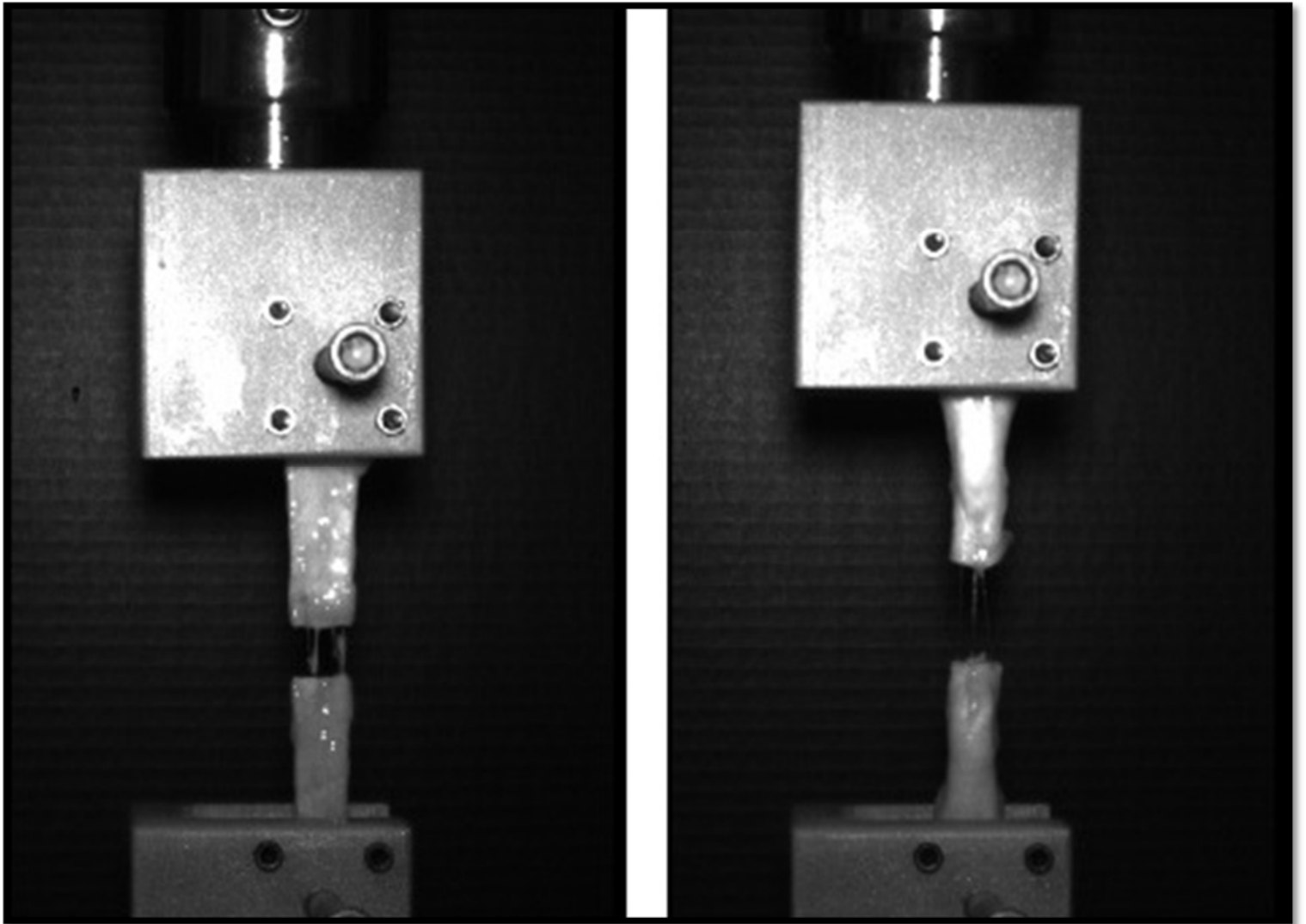
Figure 19: Example of a load versus actuator displacement for SA (blue) and 3LP (red).
Horse #6 is pictured.
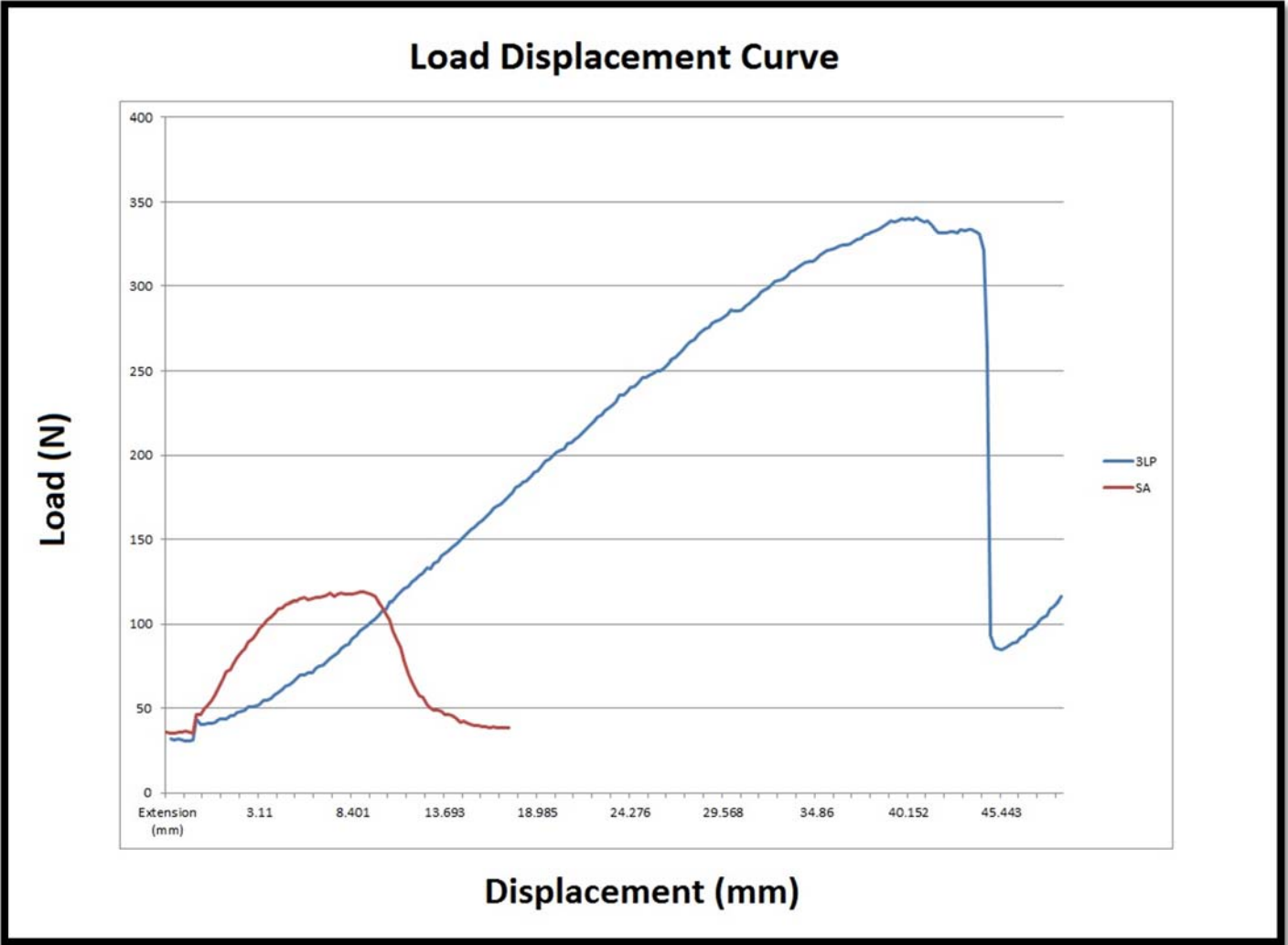
Appendix 2: Tables

Tendon Repair	Load at 2 mm Gap (N)	Load at Construct Failure (N)	Mode of Failure	Gap at Failure (mm)
3 LP				
1	41.718	344.932	Suture pull out	23.5
2	111.507	230.798	Suture pull out	16.8
3	118.063	288.036	Suture pull out	17.4
4	192.364	490.701	Suture pull out	19.6
5	157.409	340.651	Suture pull out	24.9
6	259.076	465.208	Suture pull out	18.3
7	202.289	323.307	Suture pull out	16.2
8	237.317	424.427	Suture pull out	16.1
SA				
1	118.038	118.44	Implant failure	7.9
2	110.85	111.811	Implant failure	6.5
3	140.868	155.876	Implant failure	8.5
4	113.344	165.704	Implant failure	8.3
5	102.726	136.562	Implant failure	5.1
6	67.819	78.838	Implant failure	5
7	124.01	135.054	Implant failure	6.4
8	138.557	156.618	Implant failure	6.7

Table 1: Load at 2 mm Gap, Load at Construct Failure, Gap at Failure and Mode of
Failure for each repair

Appendix 3: Load versus actuator displacement curves for each horse
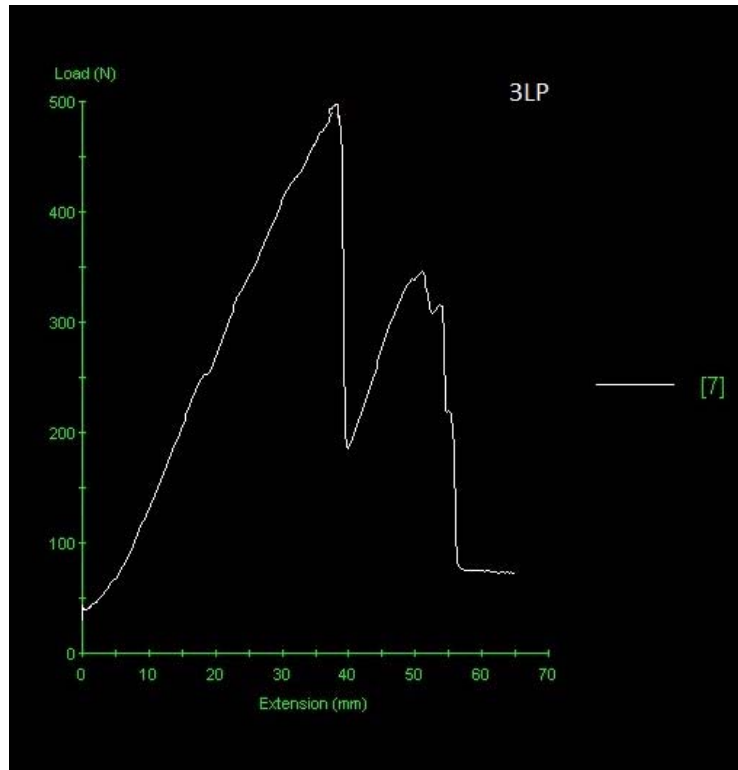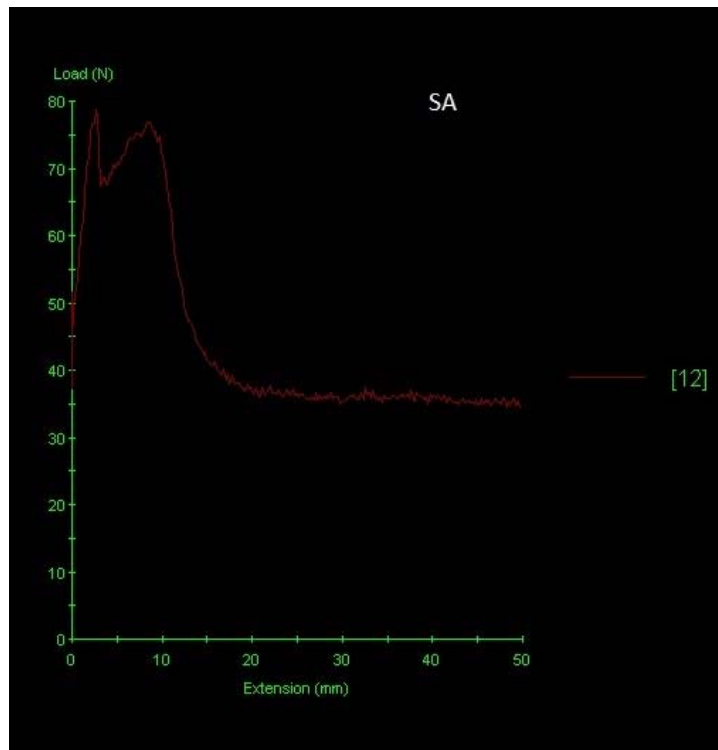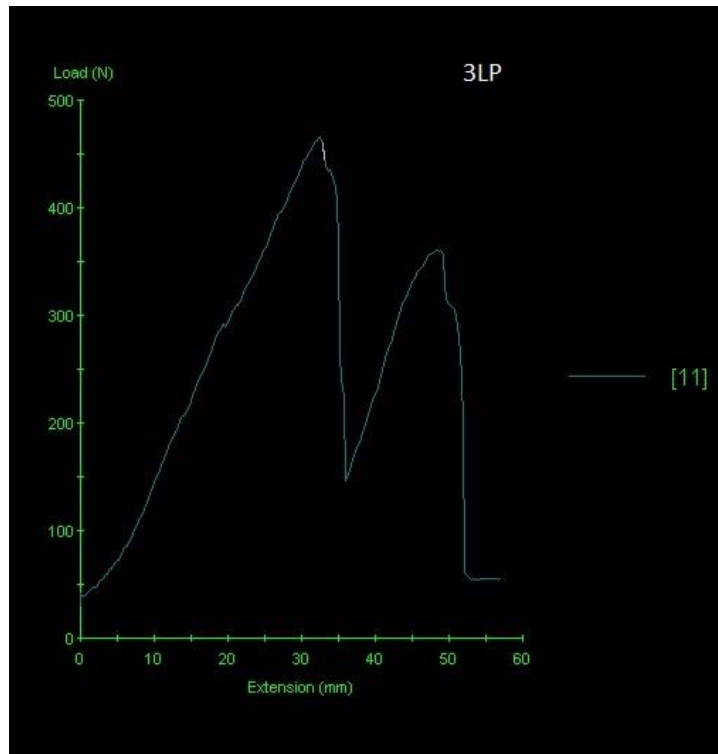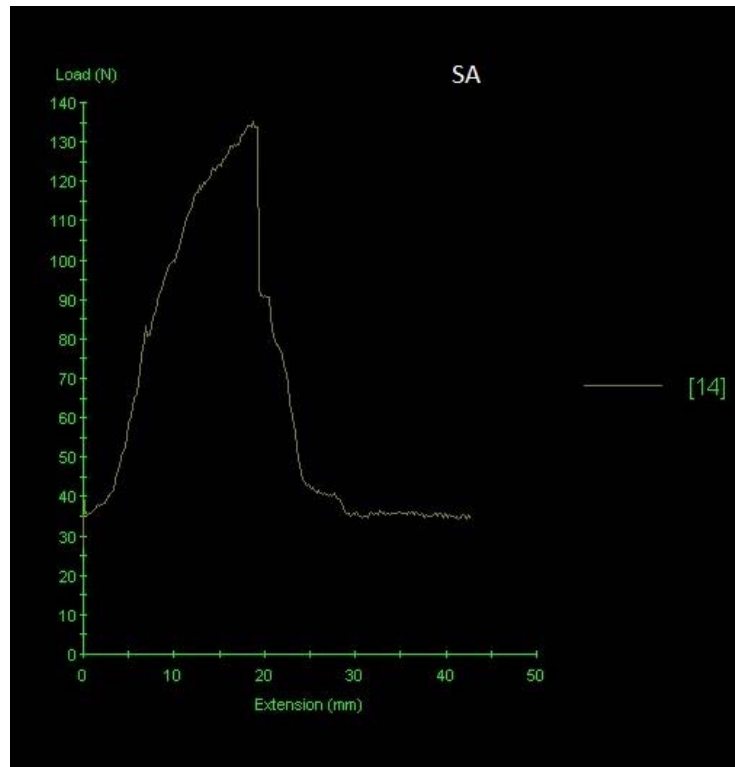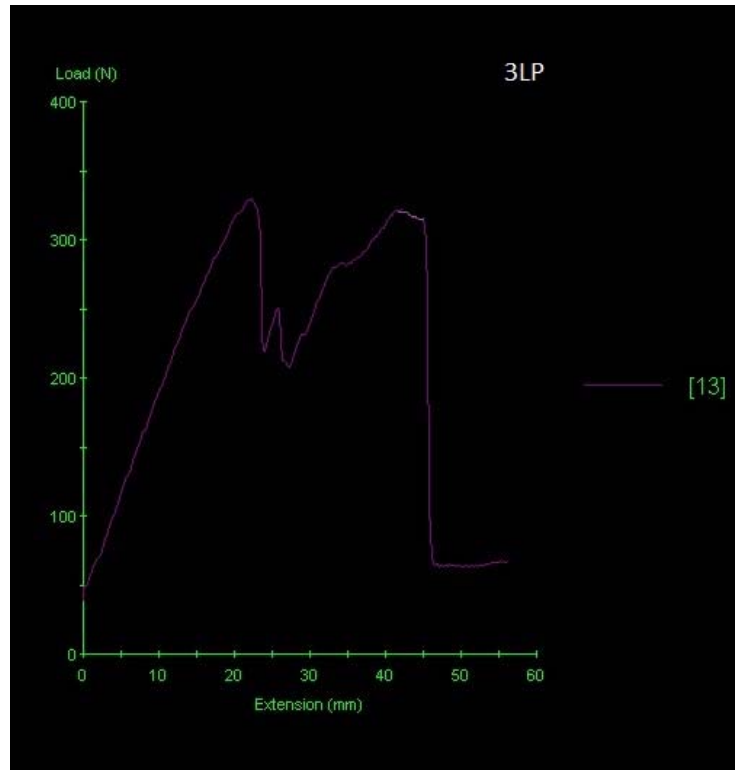
Horse 1:
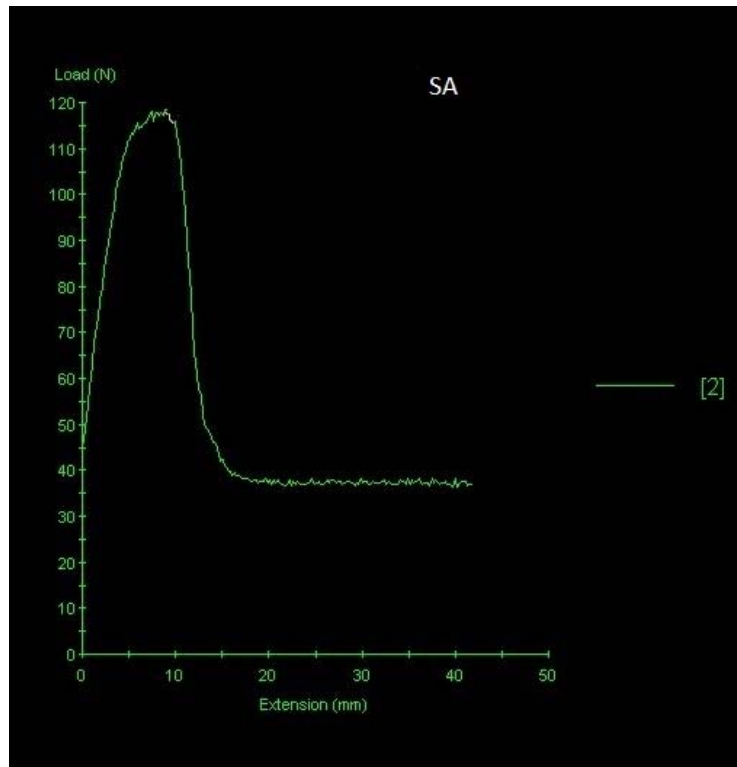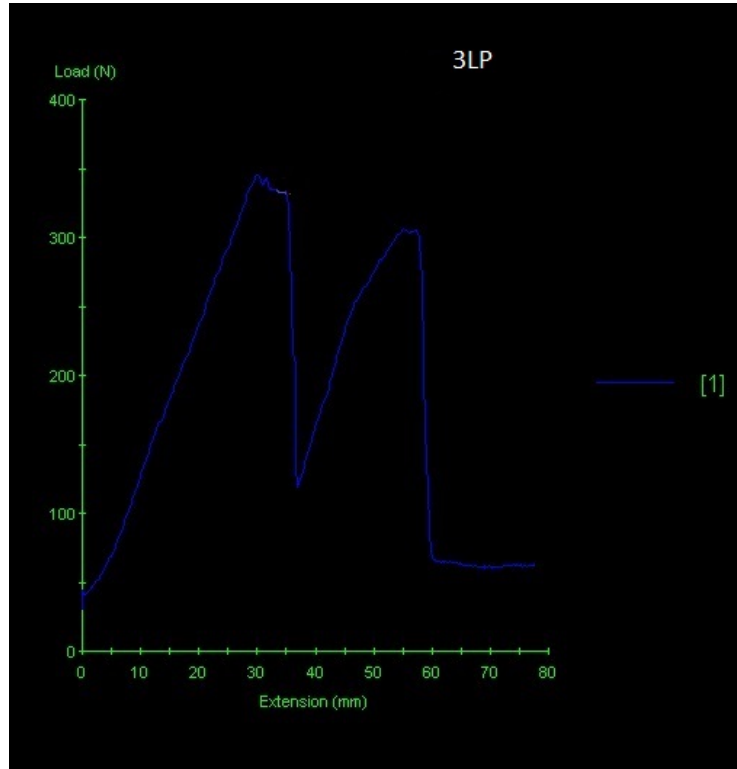
Horse 2:
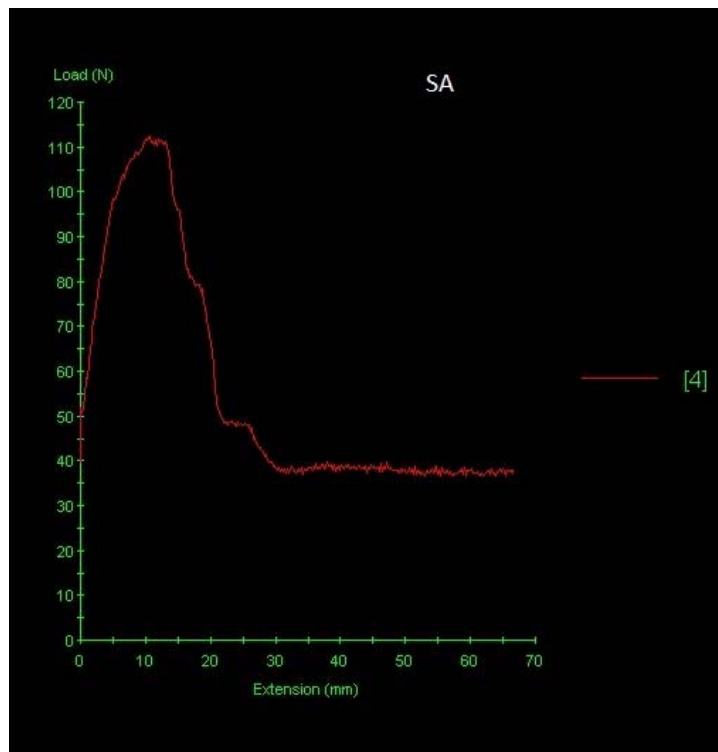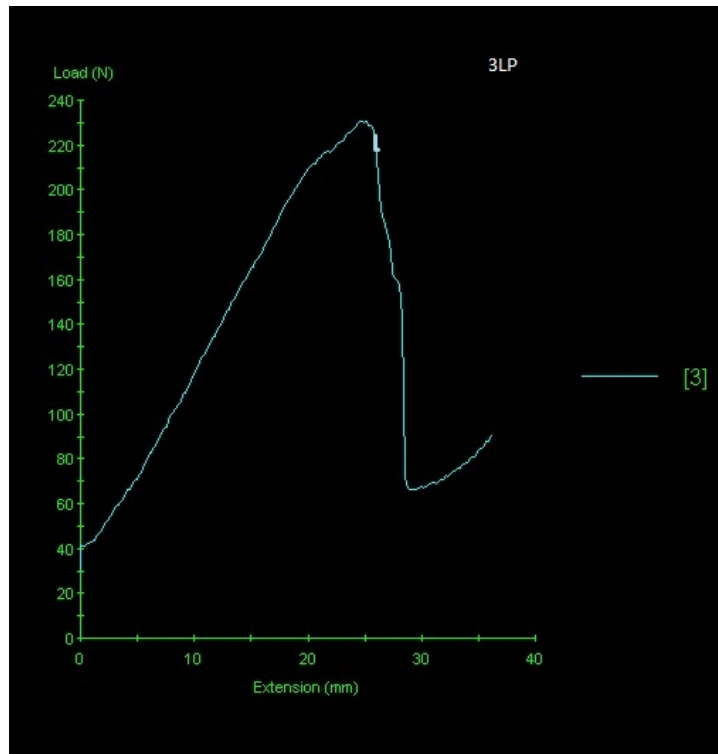
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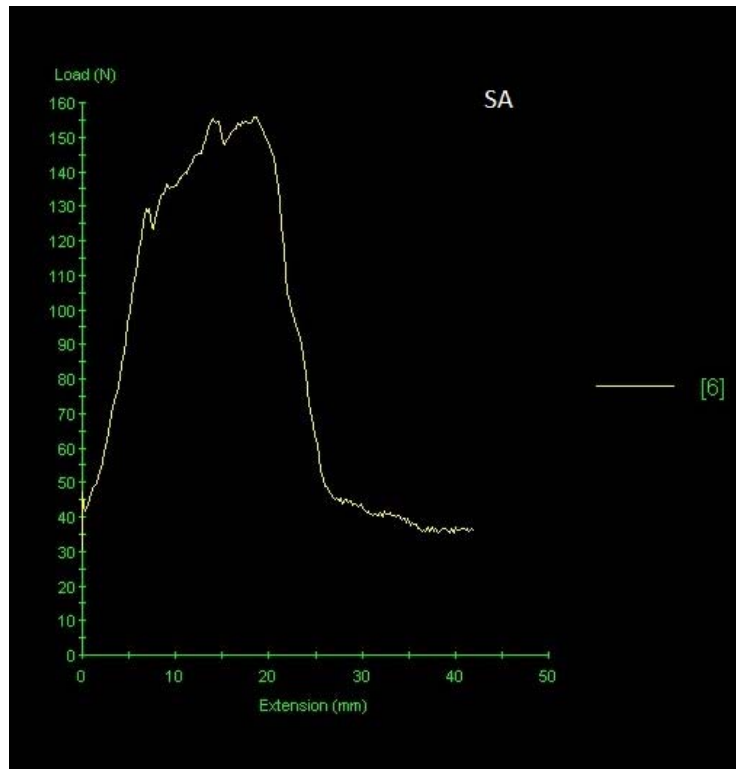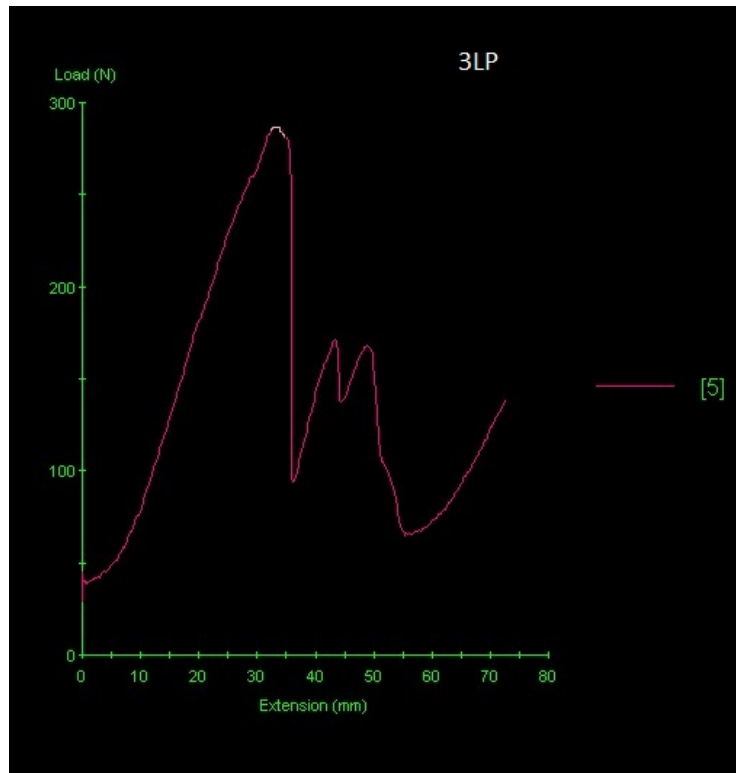
Horse 4:
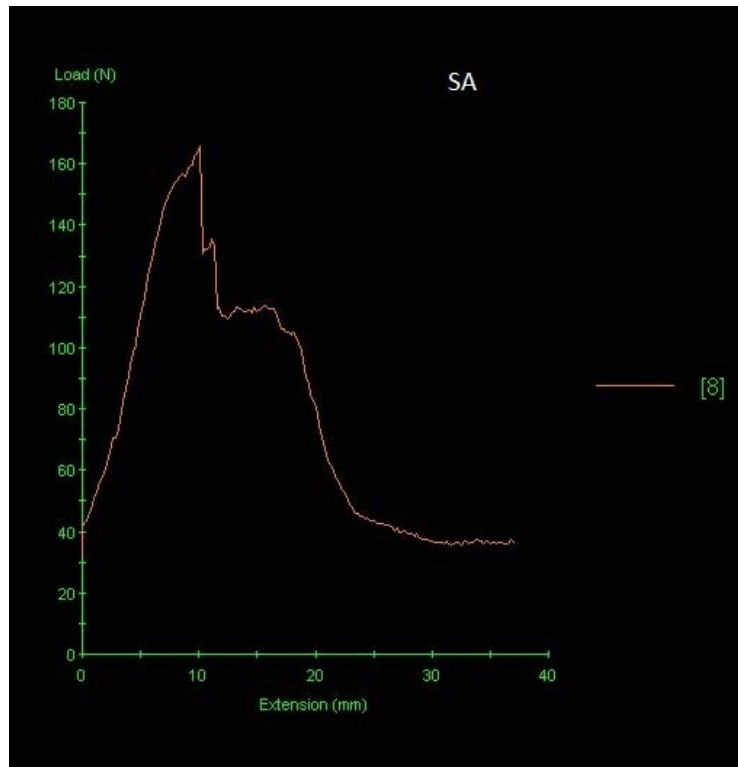
Horse 5:

Horse 6:

Horse 7:

Horse 8: