

Polyamide 6.6 planed Polyester: A New Prosthetic Fabric for Repair of Superficial Digital Flexor Tendon Deficit in Equine

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Abstract: A new prosthetic material polyamide 6.6 planed polyester was used for repair of lacerated and cut digital flexor tendons in equine especially those accompanied by deficits and gap formation. This work was done experimentally on 17 donkeys and applied on 5 clinical cases. The prosthetic material was placed and fixed between the two cut ends to reconstruct the tendinous defect. Clinical, ultrasonographic, histopathologic and biomechanical evaluations were performed to judge the efficiency of the prosthetic implant. Satisfactory results were obtained regarding healing of the affected tendons, the return of the animals to their normal ambulation and gait. Clinical cases showed good healing in extensor tendon lacerations and superficial digital flexor cuts. Complications were encountered in a case of deep digital flexor cut with large gap. It was found that, the new Polyamide 6.6\ Polyester fabric (1:1) proved to be strong and biocompatible in addition its low cost in comparison with other prosthetic material.

[Inas N. El-Hussiney, Torad F.A., Ali K.M., Ali Marwa A. and Ibrahim.M.I. Polyamide 6.6\ Polyester: A New Prosthetic Fabric for Repair of Superficial Digital Flexor Tendon Deficit in Equine. Journal of American Science 2011; 7(8):353-361]. (ISSN: 1545-1003). <http://www.americanscience.org>.

Keywords: prosthetic material; polyamide; tendon; equine; Polyester; fabric

1. Introduction:

Tendon lacerations are very common in equine especially in the lower limbs. These injuries represent a difficult issue for equine practitioners due to the extended length of time required for healing and the high rate of recurrence (Davis and Smith; 2006 and Dyson;2004).

Repair of equine flexor tendon lacerations are usually managed primary by suturing through using large monofilament material or by second intention by immobilizing the affected limb and allowing the wound to heal.

Tendon graft included autogenous graft and synthetic graft using different synthetic fabrics (Jann *et al.*;1992 and Valdés-Vazquez *et al.*; 1996).The use of such augmentation devices help in bridging any gap that may develop after tenorrhaphy and thus serves as a scaffold and a source for fibroblasts migration and increasing the presence of dense tendon fiber bundles (El-Husseiny, 2000). Natural carbon fibers have been used by many researchers with various results (Weiss *et al.*, 1985). The formation of sinuses accompanying the use of carbon fibers limited its use especially if the risk of infection was considered (El-Husseiny, 2000).

Nylon (polyamide 6.6) is a synthetic material which proved considerable results when used for tenorrhaphy in equine limbs. It has minimal tissue reaction, low incidence of bacterial infection and can be used in contaminated wounds (Jann *et al.*;1992)

where polyamide has many characteristics as high biological properties, ability to decrease absorption of fluids, smoothness, flexibility and high resistance to rot (Tan *et al.*, 2003 and Raghavendra *et al.*, 2004). Braided polyester fibers proved to have a high breaking strength (Leknes *et al.*; 2005), resistance to crease, high tensile strength, high abrasion resistance and high capacity to resist micro-organisms, insects, body compatibility (Booth; 1975 and Gupta;1998). In addition to the woven fabric techniques produce from polyamide\ polyester is characterized by Dimensional stability, Fineness and Durability (Gupta;1998).

The aim of the present work was to evaluate the efficiency of a new synthetic mesh (Polyamide 6.6\ Polyester 1:1) for the repair of severed digital flexor tendons in equine.

2. Materials and methods

The present study was carried out on 17 donkeys (experimental animals) and 5 horses (clinical cases).

1- The experimental animals were divided into 2 groups:

- **Control group:** included 5 donkeys with apparently healthy limbs intended for biomechanical studying of the tensile strength of the normal superficial flexor tendons (SDFT).
- **Gap defect group:** included 12 apparently healthy donkeys intended for surgical interventions by implantation of synthetic Polyamide 6.6: Polyester fabric. They were

divided into four equal groups (3 donkeys for each group) according to the time of observation and follow up at 15, 30, 60 and 90 days postoperatively.

Prosthetic material:

Polyamide 6.6(polyester (50 %: 50%): a new mixture of synthetic fibers (Fig. 1) was used to insheath of experimentally transected tendons. The material was available in the form of sheet with tissue density of 1.14gm/cm³ for the polyamide and 1.38 gm/cm³ for the polyester and specifications of woven fabric polyamide/polyester in (El-Husseiny, *et al.*; 2011). This material was sterilized by autoclaving at 121°C for 30 minutes before use according to the melting point for polyester (180°C)and polyamide (263°C) (Booth;1975).

Anaesthesia and control :

All operations were performed under the effect of anaesthetic regimen composed of Acepromazine/Xylazine (o.1, 1.1mg/kg respectively) as premedication and Induction was done by Ketamine Hcl (2.2 mg / kg) while maintenance was done by intravenous injection of Thiopental sodium 5% (5mg/kg).

All animals were controlled in lateral recumbency with the operated limb uppermost.

The surgical technique:

A 5 cm skin incision was done at the mid metatarsus of the right hind limb. Following dissection of the sub cut tissues, the paratenon was incised and the SDFT was exposed, exteriorized and transected then about 2 cm of its tendinous tissue was removed. An appropriate piece of the material was wrapped in the form of a cylinder to insheath the two cut ends of the SDF tendon. The material was sutured in position with interrupted stitches using polydioxanone (PDS) suture material No. 1. Paratenon was sutured by simple continuous suture pattern using PDS suture material No. 2/0 then the skin was sutured by simple interrupted suture pattern using PDS suture material No. 1 (Fig. 2 and 3).

Postoperative care:

A series of casts with windows and therapeutic shoes were applied to gradually increase the load placed on the repaired tendon. The casts were applied on the distal part of the limb with the fetlock flexed to form a dorsal angle of approximately 190° that decreased to 170° after 15 days according to (Valdés-Vazquez;1996). Hand walking was commenced after the second cast had been removed. All operated animals received a systemic course of antibiotic (Cefotaxime

(ETHICON.PROD.CO), 25mg/kg given intramuscular.

Postoperative follow up :

Clinical, ultrasonographic, biomechanical and histopathological evaluations were performed to all operated animals.

- **The clinical evaluation** included daily observation of the seat of operation for any signs of infection or rejection, weight bearing capacity and full limb function.

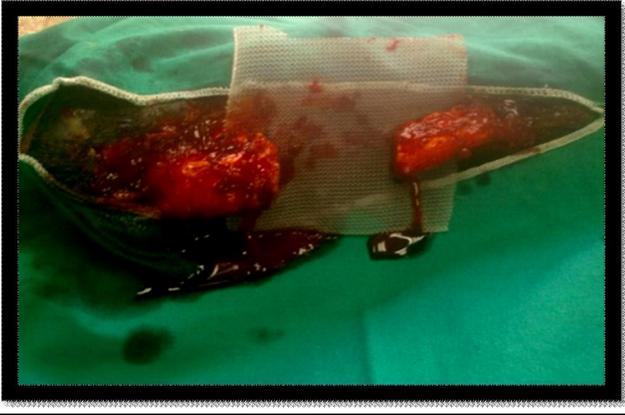
-**The ultrasonographic evaluation** included sequential ultrasonographic examination at 15,30,60 and 90 days postoperatively using a high frequency linear probe (8- 10 MHz, TOSHIBA (JUST VISION 200))

- **The biomechanical evaluation** was carried out at the Textile Division– National Research Center in Cairo; the woven sample synthesized from \polyester materials with plain 1/1 structure, using monofilament yarn, the sample was used raw without treatment.

Physical and mechanical tests before implant (El-Husseiny, *et al.*;2011) and after implant were carried out on the sample after conditioning the fabric for 24 hours under the standard atmospheric conditions (20±2°C temperature, 65 ± 2% relative humidity). using a tensile testing machine (Instron 3345®, England) accordance with (ASTM D5035). This was done after euthanasia of the control and experimental animals and collection of the tendon specimen. In the control group, A 20 cm length sample was taken from the SDF tendon at the mid metacarpal area. In the operated group, the samples included the reconstructed tissue and the host- graft interface. Samples were taken at the end of each respective observation period (15, 30, 60 and 90 days postoperatively) and tested for both the tensile strength and strain.



Fig. 1: Polyamide 6.6: polyester fabric in the form of woven fabric.



Fig, 2: An appropriate piece was wrapped around the two cut ends of the SDFT.



Fig, 3: The material was sutured in position with interrupted stitches using PDS suture material.

- **Histopathological evaluation:** Gross and histopathological examinations were performed through harvesting the implantation site to document the visibility and stability of the proximal and distal host- graft interfaces grossly. The evaluation was completed through histopathological examination according to (Bancroft *et al.*; (1996).

2- The clinical study:

The clinical study was performed by application of the new synthetic implant fabric on 5 horses admitted to the surgery clinic, faculty of veterinary medicine, Cairo University. Two cases were admitted with complete cuts in the long digital extensor tendons and 2 cases suffered from complete cuts in the SDFT. One case showed complete cut in both the SDFT and DDFT.

3. Results

The new prosthetic material (polyamide 6.6: polyester) was used successfully for repair of 12 cases of experimentally transected SDFT. The success of this material was judged according to the following evaluations:

Clinical evaluation:

- **7 days postoperatively:** an intense inflammatory reaction was observed in the form of swelling, hotness and pain on palpation.
- **15 days postoperatively:** the skin wound was completely healed with a marked swelling at the implantation site and a clear gap was detected by palpation. The fetlock angle didn't show any palmar deviation and all operated animals were able to use their operated limbs in slow movement.
- **30 days postoperatively:** the local postsurgical inflammatory reaction was subsided and the gap

between the two cut ends of the tendon was replaced by soft tissue.

- **90 days postoperatively:** the gap could not be detected and palpation of the tendon revealed homogenous, uniform structure connecting the two cut ends with difficulty in discrimination of the implant from the tendineous structure. All animals were able to use their limbs effectively in slow and fast movements.

Ultrasonographic evaluation:

-**15 days postoperatively:** the implant appeared as a thick hyperechoic band connecting the hypoechoic two cut ends of the tendon with a clear distal acoustic shadowing. Anechoic to hypoechoic areas were also noticed representing the inflammatory reaction (Fig.4).

- **30 days postoperatively:** the hyperechoic structure representing the implant was reduced while a hypoechoic structure representing the early fibrosis and granulation tissue formation was increased (Fig.5).

- **60 days post operatively:** the implant material was difficult to be distinguished with minimal distal acoustic shadowing. The area of implantation appeared homogeneously hypoechoic with detection of parallel echogenic lines representing tenofibrils that occupied about 50% of the whole thickness of the tendon (Fig, 6).

- **90 days postoperatively:** complete union between the implant and the two cut ends of the tendon .The operated SDF attained its normal ultrasonographic appearance except for the presence of distal acoustic shadowing representing the remnants of the implant (Fig. 7) .



Fig. 4: 15 post operatively, the implant appeared as hyperechoic structure connecting the two cut ends of the SDFT with clear distal acoustic shadowing (arrows).

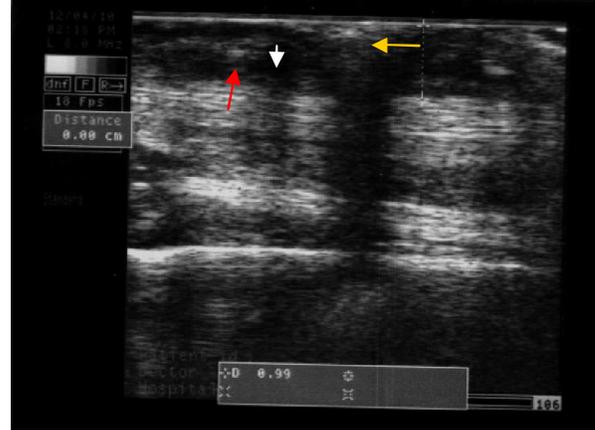


Fig. 5: 30 days post operatively, the area of implantation showed mixed echogenicity; hyper echoic areas with representing the implant material (yellow arrow), hypoechoic areas representing the early fibrosis and granulation tissue formation (red arrow) and anechoic areas reflecting the inflammatory edema (arrow head).

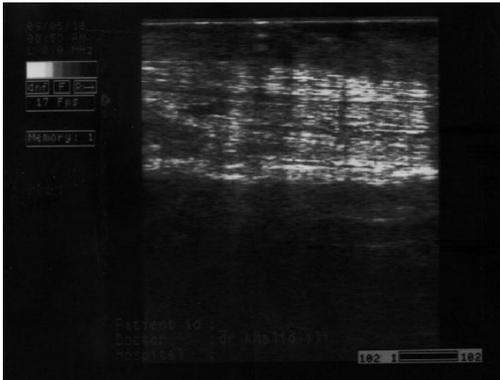


Fig. 6: 60 days post operatively, the area of implantation appeared homogeneously hypoechoic with parallel echogenic lines representing the tenofibrils occupying 50% of the whole thickness of the tendon.



Fig. 7: 90 days post operatively, showed complete union between the implant and the two cut ends of the tendon except small hyperechoic area with distal acoustic shadowing representing the remnant of the implant (arrow).

Biomechanical evaluation :

The values of the tensile strength and strain for both control and operated samples at the end of the

respective observation periods, 15, 30, 60 and 90 days postoperatively were collected in table (1):

Table(1): Biomechanical evaluation of the normal (control) and operated SDFT.

Name of sample	Time Implant	Tensile Strength (KN)	Strain (Mm)
SDFT (control)	Zero Time	1625.89 ± 20	5.529±0.7
Polyamide 6.6: Polyester implant (gap defect group)	15 days	149.033±15	1.4±0.25
	30 days	725.688±20	2.4±0.312
	60 days	980.66±15	3.2±0.245
	90 days	1504.364±30	4.4±0.521

It was observed that, 15 days postoperatively, the tensile strength was 149.033±15 KN compared with that of the normal control group

1625.89± 20 KN. This value increased in the operated group during the time of healing to reach 1504.364±30 at the end of the experiment (90 days

postoperatively) which was nearly equal the normal value of the control group. The strain of the healed tissue represented 1.4 ± 0.25 mm at the early stage, 15 days postoperatively, compared with that of the normal control (5.529 ± 0.1 mm) which increased by time to reach 4.4 ± 0.521 mm at the end of the experiment, 90 days postoperatively, which was nearly equal to the normal control value.

Gross and histopathological evaluation:

Macroscopically, 15 days postoperatively, the implant was clearly distinguished from the two cut ends of the tendon but fusion between the implant and the original tissue was good. Intense inflammatory reaction was recognized in the form of redness of the proximal and distal tissue-graft interfaces. Microscopically, granulation tissue in the form of newly formed capillaries and granulation tissue proliferation was observed associated with inflammatory cell infiltration (Fig.8 &9).

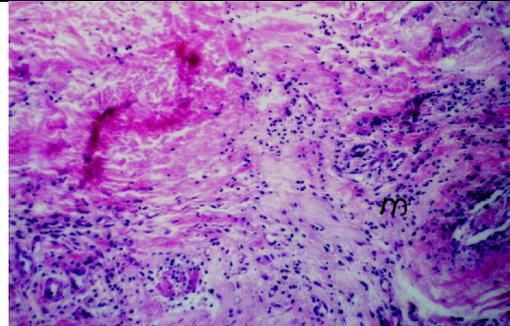
30 days postoperatively: the implant was difficult to be distinguished and the repaired tissue

became more homogenous. The inflammatory reaction was diminished as represented by mild redness all over the implantation site. Microscopically, inflammatory cell infiltration was detected associated with fibrosis and granulation tissue formation. The predominant cells were fibroblasts along with a smaller number of macrophages and mast cells indicative of active matrix synthesis of collagen and a tissue of a relatively significant strength filled the tendon defects (Fig 10 & 11).

90 days postoperatively: specimen appeared completely mature, the implant could not be distinguished as it became covered by tendineous tissue. The tendon resumed its normal gross appearance and became uniform and homogenous. Microscopically, few focal cell infiltrations were observed associated with remodeling of the tendineous fibers and realignment of the fibers into a longitudinal pattern of parallel collagen fibers. At this stage there were remnants of the implanted fabric surrounded by mature fibrous connective tissues and little macrophages (Fig.12&13).



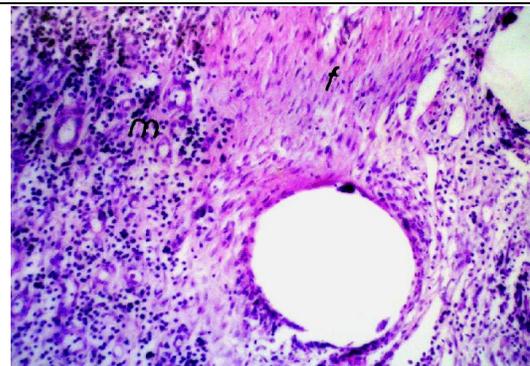
Fig, 8: Two weeks post operatively, the implanted material between the two cut ends of the tendon (red arrow) with intense inflammatory reaction in the form of redness of the tissue graft interface (yellow arrow).



Fig, 9: Two weeks post operatively, showing inflammatory cell infiltration and congested blood vessels (H and E $\times 100$)



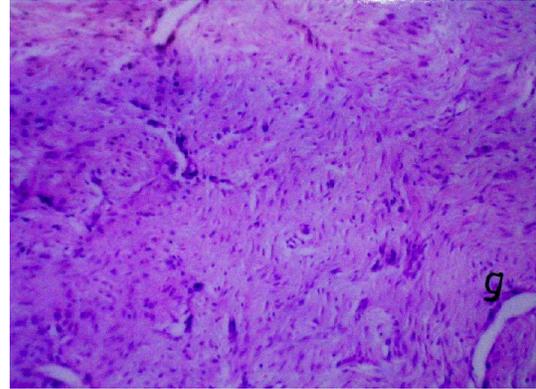
Fig, 10: 30 days post operatively, showed pink tissue (arrow) bridging the gap between the transected tendon ends. Suture material had remained interatendiniously and the prosthetic material was difficult to be distinguished.



Fig, 11: Histopathological picture one month post operatively, showing area of inflammatory cells infiltration (m) with granulation tissue formation (f) (H and E $\times 100$).



Fig 12: 90 days postoperatively, showing complete union between the graft and original tendineous.



Fig, 13: Histopathological picture three months post operatively, showing area of healing with granulation tissue (g) (H and E \times 100).

The clinical study:

The application of the new prosthesis revealed good results in the 2 cases suffered from complete long digital extensor cuts, manifested by marked improvement in the progression that occurred 15 days post implantation, (Fig. 14a, b, c & d).

Cases suffered from complete SDF cuts (2 cases) showed satisfactory results regarding the wound healing and the limb function. One month post surgery, animals used their limbs soundly in slow movements and returned to their normal progression.

One case in which there was cuts in both SDF and the deep digital flexor tendons failed and didn't show any improvement. The case was admitted with a large tendineous defect (10 cm gap) and massive skin loss. The case was considered of bad prognosis as infection and massive granulation tissue was formed and the animal could not use its limb effectively (Fig, 15).



Fig, 14a: Two year old male horse with complete laceration of the long digital extensor tendon. .Note, the presence of wound at the dorsal aspect of the metatarsus with marked flexion of the phalangeal joints due to absence of extensor tendon function.

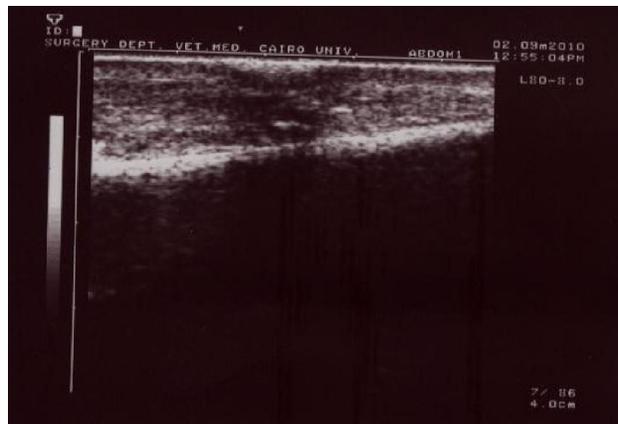


Fig. 14b: Longitudinal sonogram of the same case showed complete cut of the long digital extensor (LDE) tendon. Anechoic area (arrow) between the two cut ends representing the site of tendon cut.



Fig, 14c: One week post treatment, showing the wound healing with absence of infection

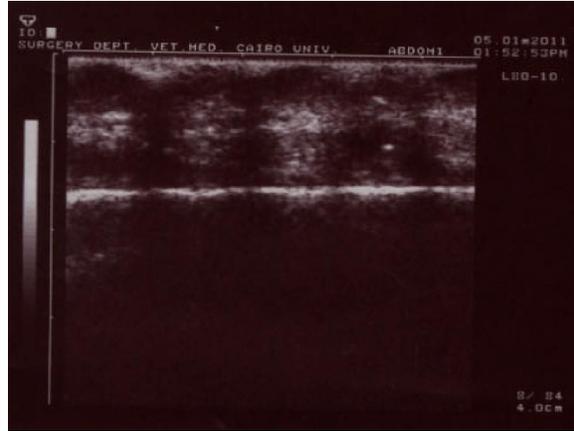


Fig14d: Ultrasonographic follow up showing the implant material as hyperechoic structure with distal acoustic shadowing between the two cut ends of the tendon (arrows).



Fig. 15: a case with complete Superficial and Deep digital flexor tendon cuts. Note large gap with massive skin loss.

4. Discussion

Severed and lacerated tendons constitute a high percentage among equine tendon injuries. The condition should be considered serious and even destructive in the field of equine surgery (El – Hussein;1996 and Stashak;2002).

The use of synthetic prosthetic material was used in different equine replacement surgeries with various results of success (Molloy *et al.*;1991).

The augmentation prosthesis used in this study (polyamide 6.6 \ polyester 1:1) was made to substitute suturing tenorrhaphy in cases of lacerated or cut tendons especially if a gap existed.

Polyamide 100% was previously used for tenorrhaphy and characterized by minimal tissue reaction with low incidence of infection if used in contaminated tissue but its low tensile strength limited its use (Lipowitz;1985). Braided polyester has a high tensile strength compared with polyglycolic

acid and polydioxanone (Leknes *et al.*;2005). The new prosthesis was composed of a combination of polyamide and polyester to obtain a biocompatible mesh with a considerable tensile strength. The material was designed in the form of a woven fabric to act as a scaffold for the deposition and orientation of the tendon fibers. It has multiple pores that facilitate the growth of capillary network and consequently oxygen delivery as the collagen synthesis is an oxygen dependent process (Jann *et al.*; 1992). The material was malleable, so it was easily handled while economically, its cost was low.

Clinically, the application of the prosthetic material (polyamide 6.6\polyester) on the experimental and clinical cases revealed no signs of rejection or infection that proved its biocompatibility due to the inert nature of the material and its resistance to bacterial contamination, similar interpretation was mentioned by (Campbell ;1992).

The progression of healing could be seen by ultrasonographic follow up which began by the resolution of the initial peritendinous inflammatory edema and ended by attaining the normal echogenic appearance (Bertone *et al.*, 1990). It was noticed that the acoustic shadow of the implant continuously decreased due to the disintegration of the implant with the appearance of the hypoechoic structures which may be attributed to the early fibrosis and granulation tissue formation.

The histopathological examination explained the ultrasonographic findings as the anechoic areas appeared at the seat of implantation were proved microscopically by the presence of newly formed blood capillaries and edema due to the early inflammation. The continuously increasing hypoechoic structures were proved microscopically by granulation tissue formation.

Complete union of the two cut ends of the tendons was clearly noticed at 90 days postoperatively with presence of very small acoustic shadow representing the remnants of the implant which appeared histologically as vacuoles surrounded by macrophage.

It had been postulated that, fragmentation of the implant caused transfer of the tensile loads and cause areas of stress that stimulate collagen synthesis thereby creating mature longitudinally oriented new tendon fibers filling the gap. The same was mentioned by (Sharma ; 2005).

The biomechanical evaluation proved the success of the polyamide implant as the tendon regained its normal features regarding ultimate tensile strength and strain. It was noticed that, the augmentation implant is reported to share stress with the graft tissue during the early collagen remodeling period as was reported by (Hope ; 2007).

Where we use the fabric in the warp direction yarn this has contributed to increase and strengthen the function of tendon, polyester for its unique properties of strength and durability (Gupta; 1998).

The clinical application of the new synthetic material favored its use in the clinical field. Out of 5 animals, 4 returned to their intended use of limb function. Two of them had the cuts in the long digital extensor tendons and revealed good healing as the cuts of the extensor tendons usually heal without complications due to the low weight supported by those tendons. Cases with SDFT cuts also showed good healing as the superficial flexor tendons usually give good prognosis as it carries less of the weight of the animal .On the other hand the case of ruptured SDFT and DDFT failed as the DDF tendon cuts always have guarded prognosis due to they carry most of the animal's weight Especially in heavy weight horses and in such cases the postoperative

support play an important role in the success of the operation .The case was more complicated by the presence of a large gap (10 cm) and a massive skin loss. In our opinion the failure had no relation to the application of the prosthetic material and we recommend further studies on a wide scale to investigate the efficiency of the polyamide - polyester use in such cases.

In conclusion, It was found that the new prosthetic material (polyamide 6.6 : polyester) appeared to be biocompatible and gave acceptable outcome when implanted for the repair of tendon deficits in equine . The evaluation of any implanted material should always be accomplished through clinical, ultrasonographic, histopathologic and biomechanical investigations in a way that each investigation explain and interpret the other investigations.

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7/19/2011