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Development of a tension-adjustable implant for anterior cruciate ligament reconstruction

Ön çapraz bağ rekonstrüksiyonu için geliştirilen gerilimi ayarlanabilir implant

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Objectives: Several surgical techniques have been developed for anterior cruciate ligament reconstruction. We developed a new implant (polyamide loop) for the tibial end fixation, called 'loop-in-loop' fixation, and tested the technique in a canine model.

Materials and methods: The implant consists of two parts: A plastic strap with a smooth inner surface and a serrated outside surface used for gradual fixation. The other part is a plastic ring with a serrated latch. The two serrated surfaces of the two parts allow only one directional movement of the plastic strap in the ring and adjustable tightening of the graft. This technique was used in the fixation of a tendon graft in a canine model consisting of 10 animals. The animals were sacrificed at three weeks (n=2), three months (n=2), and nine months (n=6) postoperatively and the grafts were examined histologically. After obtaining histological results, a prototype of the new implant was produced and used in 10 patients.

Results: Histologic examination at nine months showed minimal cell infiltration without acute inflammation, fine collagen fibers connecting the bony tunnel and the tendon, new bone formation around the tendon and the implant, and no evidence for bone absorption. Following prototype production, 10 patients were operated on using the new tension-adjustable tibial graft fixation implant. After six months of follow-up, we did not find evidence for tissue incompatibility, hypersensitivity, or widening of the femoral or tibial tunnels. The stability of the implanted joints was adequate.

Conclusion: Maximal tendon-implant fixation strength can be achieved with our 'loop-in-loop' fixation method.

Key words: Anterior cruciate ligament/surgery; biomechanics; dogs; tendons; transplantation, autologous.

Amaç: Ön çapraz bağ rekonstrüksiyonu için birçok cerrahi teknik geliştirilmiştir. Bu çalışmada tibial uç fiksasyonu için yeni bir implantın (polyamid halka) geliştirilmesi amaçlandı. "İç içe halka" tespiti adı verilen teknik hayvan deneyinde sınandı.

Hastalar ve yöntemler: İmplant iki parçadan meydana gelmektedir. Bir parçası, iç yüzeyi düz, dış yüzeyi ise, ayarlanabilir fiksasyon sağlamak üzere testere uçlu plastik bir banttan; diğer parçası ise, içinde tırtıklı bir toka olan plastik halkadan oluşmaktadır. İki parçanın tırtıklı yüzeyleri, bantın halka içinde sadece bir yöne hareket etmesine ve greft gerginliğinin istendiği şekilde ayarlanabilmesine izin vermektedir. Bu teknik, 10 köpekten oluşan deneysel bir çalışmada tendon greftin tespitinde denendi. Hayvanların yaşamı üç hafta (n=2), üç ay (n=2) ve dokuz ay (n=6) sonra sonlandırılarak greft yeri histolojik olarak incelendi. Histolojik sonuçların alınmasından sonra, implantın yeni bir prototipi geliştirilerek 10 hastada kullanıldı.

Bulgular: Dokuz ay sonraki histolojik incelemede, akut enflamasyon bulgusu olmaksızın minimal hücre infiltrasyonu, kemik tüneli ve tendonu birleştiren ince kollajen lifler, tendon ve implant çevresinde yeni kemik oluşumu görüldü; kemik absorbsiyonu yoktu. Prototip üretiminden sonra, gerilimi ayarlanabilir tibial greft fiksasyon implantı 10 hastada kullanıldı. Bu hastaların altı aylık takipleri sonunda, doku uyuşmazlığı, hipersensitivite, femoral ve tibial tünellerde genişleme görülmedi. İmplantasyon uygulanan eklemlerin stabilitesi yeterliydi.

Sonuç: Geliştirdiğimiz "iç içe halka" tespit tekniği, istenen derecede güçlü tendon-implant tespiti sağlamaktadır.

Anahtar sözcükler: Ön çapraz bağ/cerrahi; biyomekanik; köpek; tendon; transplantasyon, otolog.

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Several surgical techniques have been developed for anterior cruciate ligament (ACL) reconstruction. More and more graft fixation methods have been introduced recently. All fixation methods have at least one advantage over the others and several disadvantages. The key is to minimize the disadvantages.

Recently, semitendinosus grafting is almost exclusively used for ACL reconstruction over bone-tendon-bone grafts. Initially, metal staples were used for tibial graft fixation, which resulted in frequent graft failure due to the necrotizing effect of excessive pressure on the tendon. Later, sutures were used, with a screw or a staple to fix the graft to the tibial cortex.

Several suture types were tested to assess the lengthening of suture-graft complex under tension and no significant differences were observed. The only difference was the amount of foreign suture material inside the graft, leading to graft widening and blocking up graft surface, without significant contribution to graft fixation.

However, our testing under tension revealed that two-thirds of the lengthening occurred in the sutures placed in the free end of the graft, and one-thirds inside the graft due to its spiral fiber inner structure. These results came from our *in vitro* cadaveric and *in vivo* surgical tests using a new graft preparation device, equipped with different tendon clips, pre-tensioning setups, and applicators (Fig. 1).[1]

Our graft preparation device has a special slot for securing the other end of the graft with the EndoButton™. This small titanium plate has four holes and folded suture threads are used to fix the doubled or quadrupled end of the graft. We found that the ensuing elongation was much smaller at the looped end of the graft compared to the sutured free end.

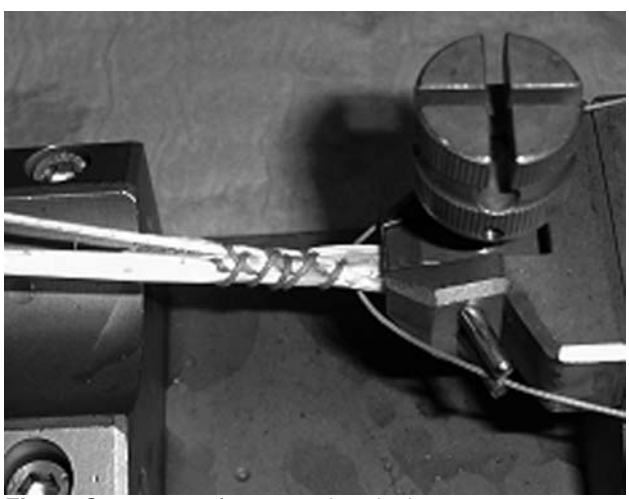

Fig. 1. Our new graft preparation device.

Based on this finding, we developed a fixation method involving a "loop-in-loop" fixation at the tibial end between the graft and the folded suture threads.

Another aspect of our development process was to find a way to securely fix the tibial end to the tibial cortex, similar to the femoral end. Further important requirement was the achievement of gradual graft tensioning to obtain optimal tightness.

MATERIALS AND METHODS

Aim of the study

To assess the effect of different suture materials on free tendon transplants in a canine model and the histologic effect of the polyamide loop of the new implant compared to other polyamide and polyester suture materials already in use.

Material selection

First, we had to find the optimal material, choosing from nonabsorbable suture materials that were already available, safe, and routinely used in clinical practice.

More than 1,200 ACL reconstructions have been performed in the past seven years in our institute using two types of plastic suture materials. The first group consists of a polyester-coated suture (EthiBond) and a noncoated suture material with the brand name Ricofil. The second group is polyamide-(nylon) coated suture material (Surgilon). Review of the postoperative follow-up of our cases did not reveal any significant difference between the two types in terms of stability. Complications included synovitis in a number of cases, limited range of motion, and septic complications.

The main aspect of material selection was its availability and tractability. Furthermore, our implant had the same fixation method with nylon (polyamide 6) cables and the Partridge cerclage system, used for femoral fractures.

Additionally, we had to assess the difference between the free and looped ends of the graft

with respect to osseo-integration inside the tunnel, remodeling, and ligamentization.

Canine model

Our experimental design was created to observe the differences between the implant materials and the effect of the plastic loop on the histologic process of graft osseo-integration and ligamentization.

With a longitudinal dissection, a 6-cm length of the Achilles tendon was removed from 10 adult, healthy Beagle dogs under intravenous anesthesia in accordance with the local regulations. One free end of the Achilles tendon graft was secured with polyester (1), and the other end with polyamide (3) suture threads. Three holes were drilled into the canine tibia at 1 cm distance. Eight-millimeter side holes were used to fix the free ends of the tendon using titanium buttons (1, 3). The middle folded part of the tendon was pulled with a loop of plastic band to the middle hole (2), and the plastic band was fixed with a titanium plate to the bony surface.

Of 10 animals, two were sacrificed at three weeks, two at three months, and the remaining six animals at nine months postoperatively. The affected part of the tibia was removed from each animal for histological studies (Fig. 2).

Graft-tibia specimens were fixed in 7% buffered formalin solution. After all specimens were decalcified in 27% EDTA solution, they were cast in paraffin blocks and dissected into 7-10 micrometer slices. To asses the presence and number of macrophages, occasionally immunohistochemical examination was performed with the monoclonal antibody Dako CD68.

Histological examination

The slices were examined under light microscope according to the following criteria:

1. The presence and extent of foreign body reaction at three weeks, three months, and nine months postoperatively. Differences between drill holes with implants (1, 2 and 3) were assessed.

2. The quality of tendon osseo-integration in the drill holes.

3. The presence and extent of tendon necrosis in different drill holes.

4. The presence of bone absorption around the implants and tendons.

RESULTS

Histological findings

1. In all the specimens from animals sacrificed at three weeks, granulation tissue and tissue debris were observed around all implants. There was no significant difference between the implants in drill holes 1, 2, and 3. At three months, the amount of

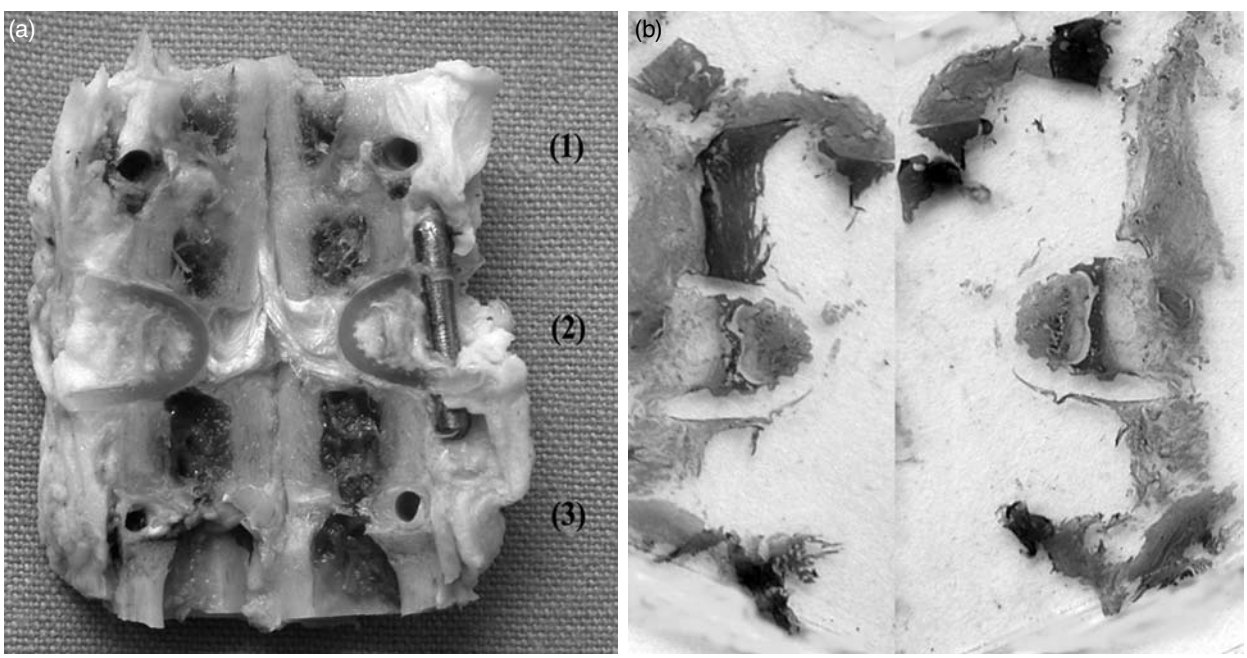

Fig. 2. (a) Macroscopic wiew of the sliced bone of the dog, and **(b)** blue ink-stained slice showing bone tunnels, tendons, and the fibers of the sutures.

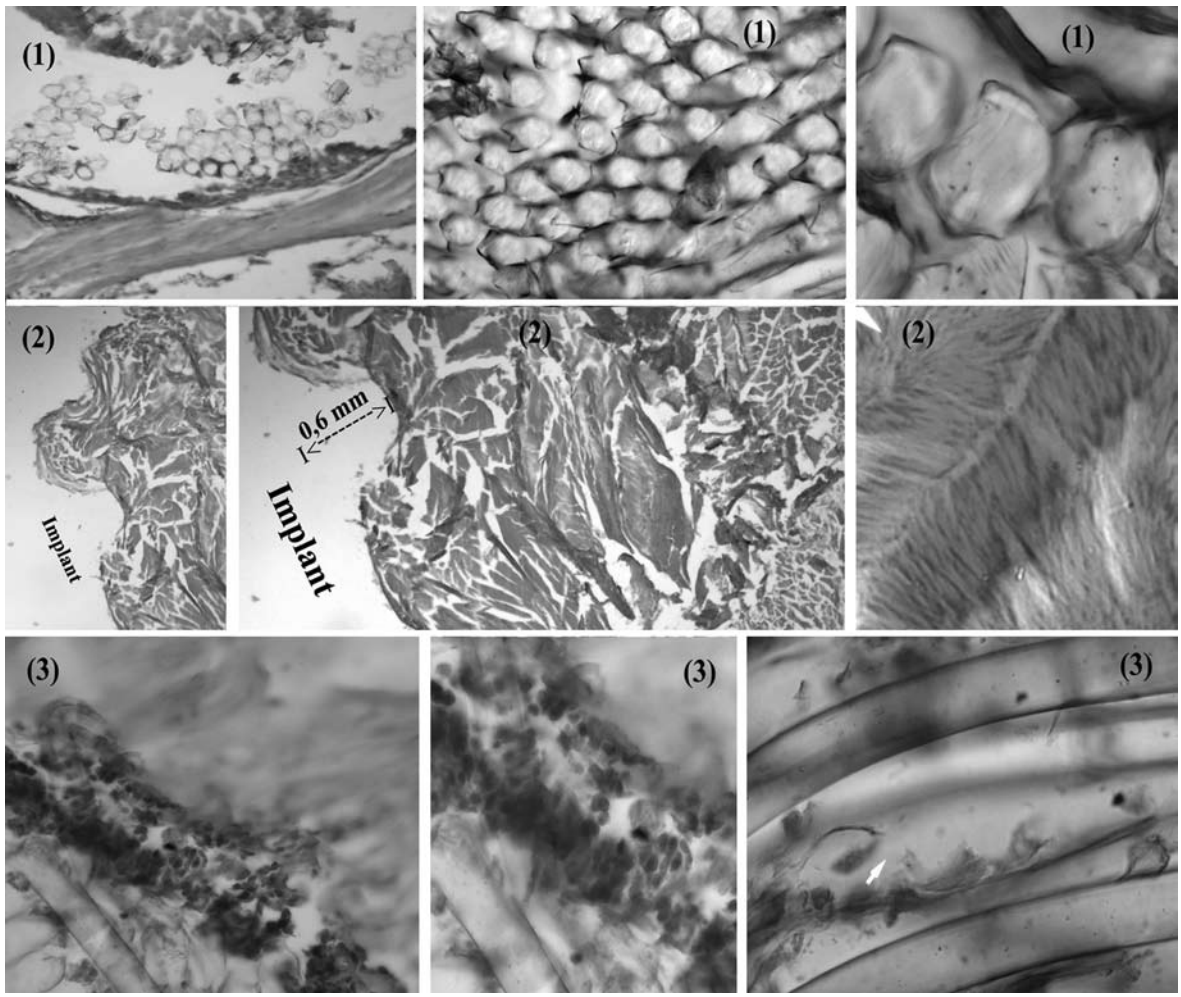

Fig. 3. Histological views are presented in three colums at magnifications of 10x, 50x, and 100x, respectively. (H-E). The space between the tendon-bone gap is filled with granulation tissue.

granulation tissue decreased, with no difference between the implants in drill holes 1, 2, and 3.

At nine months, histological findings around implants 1, 2, and 3 were as follows: The woven structure in the cross section of the suture material was clearly delineated. Among the filament threads and around the needle puncture site, there was minimal round cell infiltration, without signs of acute inflammation. Some macrophage cells, fibroblasts, and collagen fibers were observed.

Around the plastic loop (2), the amount of cell infiltration was markedly less (approximately one-

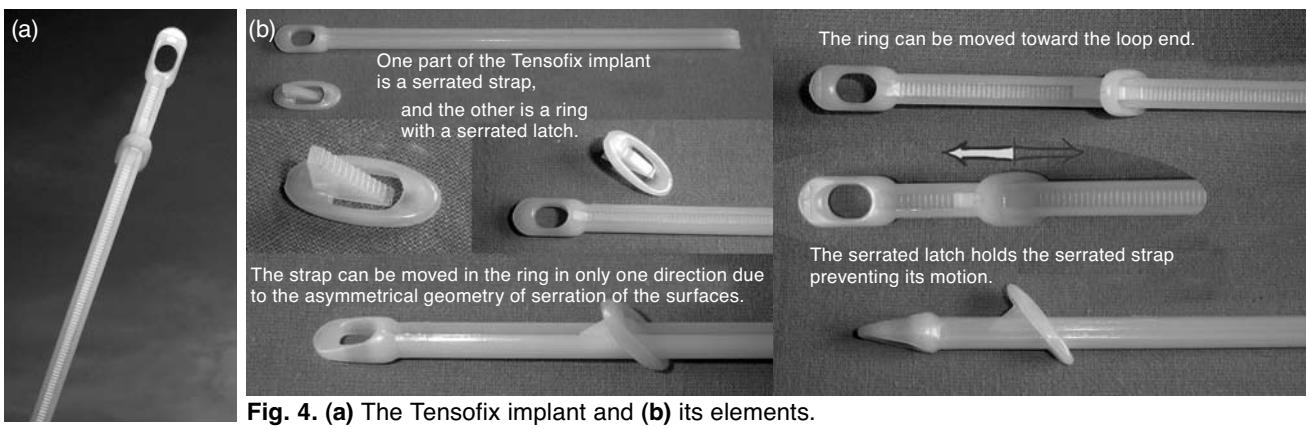

Fig. 4. (a) The Tensofix implant and **(b)** its elements.

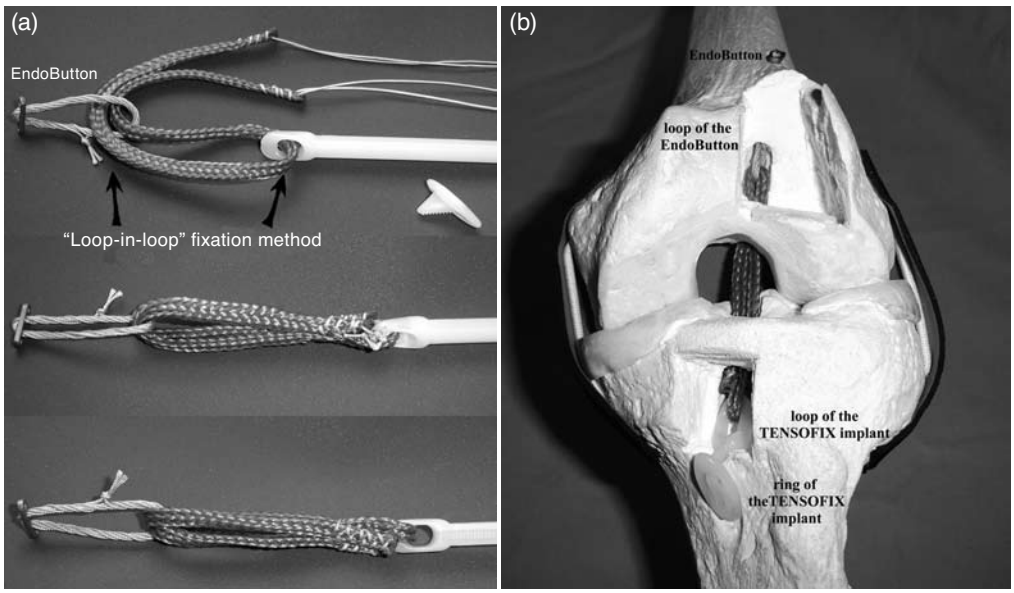

Fig. 5. (a) Plastic model of the tendon loop during graft preparation. **(b)** Plastic bone model showing the position of the implant and the graft in the knee.

sixth) than that around the implants (1) and (3). Macrophages were rarely seen (Fig. 3).

2. There was no difference in the amount of tendon osseo-integration observed in the drill holes at nine months. Fine collagen fibers (Sharpey's fibers) connected the bony tunnel and the tendon, and there was no difference between the drill holes with respect to the size of the osseo-integration zone.[2]

3. There was some evidence for necrosis at the entire length of the tendons in all the drill holes. The amount of necrosis was estimated by the number of fibrocytes (tendocytes), which showed an even

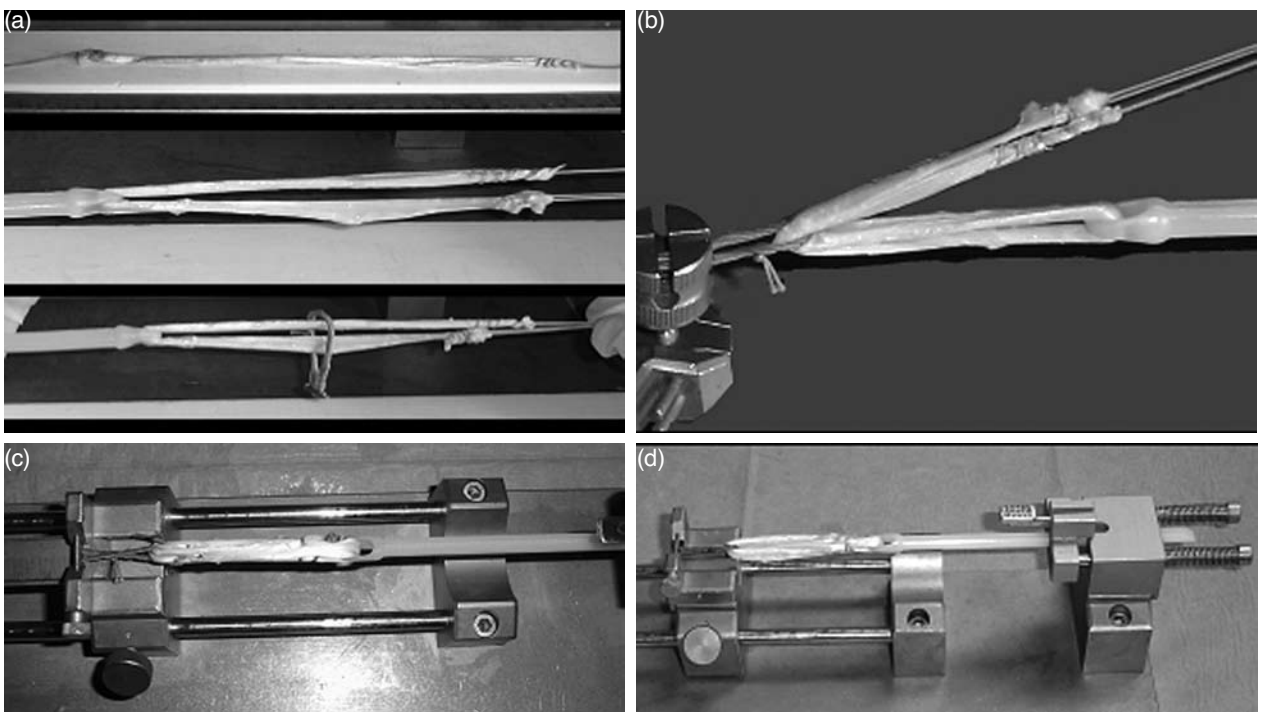

Fig. 6. (a-c) Human surgical procedures. Graft preparation with the folded tendon over the loop of the implant and the suture threads coming from the EndoButton. **(d)** Applicator designed for graft preparation and pre-tensioning of the graft with the Tensofix implant.

distribution. However, structural integrity of the collagen fibers varied, with collagen fiber fragmentation around the plastic loop (2) being only the half compared to that observed in free ends (1, 3).

4. There was no evidence for bone absorption around the entire length of the tendons and around the implants. Rather, new bone formation was seen around them.

Prototype manufacturing of the new implant

After these favorable results of animal testing we proceeded with prototype manufacturing (Fig 4, 5).[3] The same material (polyamide 6) was used, as in the tested nylon suture material and the Partridge cerclage.

Clinical application of the new implant

This new tension-adjustable tibial graft fixation implant was used in surgery of 10 patients (Fig. 6). After six months of follow-up, we did not find evidence for tissue incompatibility, hypersensitivity, or widening of the femoral or tibial tunnels. The stability of the implanted joints was adequate.

DISCUSSION

Compared to the other locations (1, 3), histologically, we did not observe increased tissue reaction, rejection, or bone or tendon necrosis around the plastic loop (2) in any of the three tendon locations at three weeks, three months, and nine months postoperatively.

Regarding structural integrity of the tendon, fragmentation of collagen fibers was lower around the plastic loop (2) compared to the free ends (1, 3).

In conclusion, the new tension-adjustable tibial graft fixation implant is a safe alternative to conventional tibial fixation methods. Yet, its use should also be justified in the long-term follow-up and by further biomechanical testing.

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