Dynamic Tendon Grip (DTG™) Knot Array for Flexor Tendon Repair - Comparative Safety Study in In-vivo Turkey Model

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Hypothesis
The Dynamic Tendon Grip (DTG™) all suture stapler device is a novel concept to allow a strong and low-profile repair of the flexor tendon. The device is composed of an embracing loop that secures the margins of the tendon. The aim of this study was: 1) to evaluate whether the pressure applied by the suture embracing loop creates tendon necrosis. 2) to assess the tissue healing reaction following implantation of an DTG™ device.
Methods
Foot tendons of four male turkeys were partially lacerated and treated by the DTG*™* device on the left leg (n=4) and traditional Kessler suture (control) on the right leg (n=4). Uniform laceration (partial thickness) to a depth of 0.5-1 mm and a length of 5–6 mm, about 1 cm distal to the proximal vinculum was performed. The animals were allowed to roam free on the operated feet for 3 weeks. After sacrifice, the flexor tendons were harvested and assessed macroscopically for tendon healing and adhesion**,** followed by a histological analysis**.** All animals survived until their sacrifice and their surgical wound had healed without external signs of infection. One animal had a purulent discharge from the treated tendons on both feet and was excluded from the analysis.
Results
Macroscopically, In the modified Kessler group, 1/3 of the tendons were intact and 2/3 were ruptured or nearly ruptured. None of the tendons had signs of healing. 2/3 had no adhesions whereas 1/3 lacerated tendon adhered to the tendon bed. In the DTG group, 3/3 of the tendons were intact, 2/3 had signs of fibrosis as a marker of healing (figure 1) and 3/3 had no adhesions.
Histologically, in the control group mature, fibrosis was noted at the site of laceration and around the suture without any progressive inflammatory reaction. In the DTG group, mature fibrosis was noted at the site of laceration without any progressive inflammatory reaction. At the site of the loop implantation, mature fibrosis was noted superficially at the site of contact with the embracing device, without any progressive inflammatory reaction or necrosis. Within the tendon, linear areas of increased vascularization and congestion was noted.
Summary Points

- The DTG suture device supports a normal reparative-healing process - The safety results of the DTG were similar to these of standard sutures and demonstrated equivalent occurrence of mature fibrosis in both treatments.
- No progressive inflammatory reaction or necrosis was noted at the site of DTG implantation. This data suggests that the external pressure did not induce adverse effects on the tendon and its surrounding tissues.
- The presence of increased vascularization and congestion seen only in the DTG group, suggests good blood supply to healing region without necrosis or ischemia-related changes.

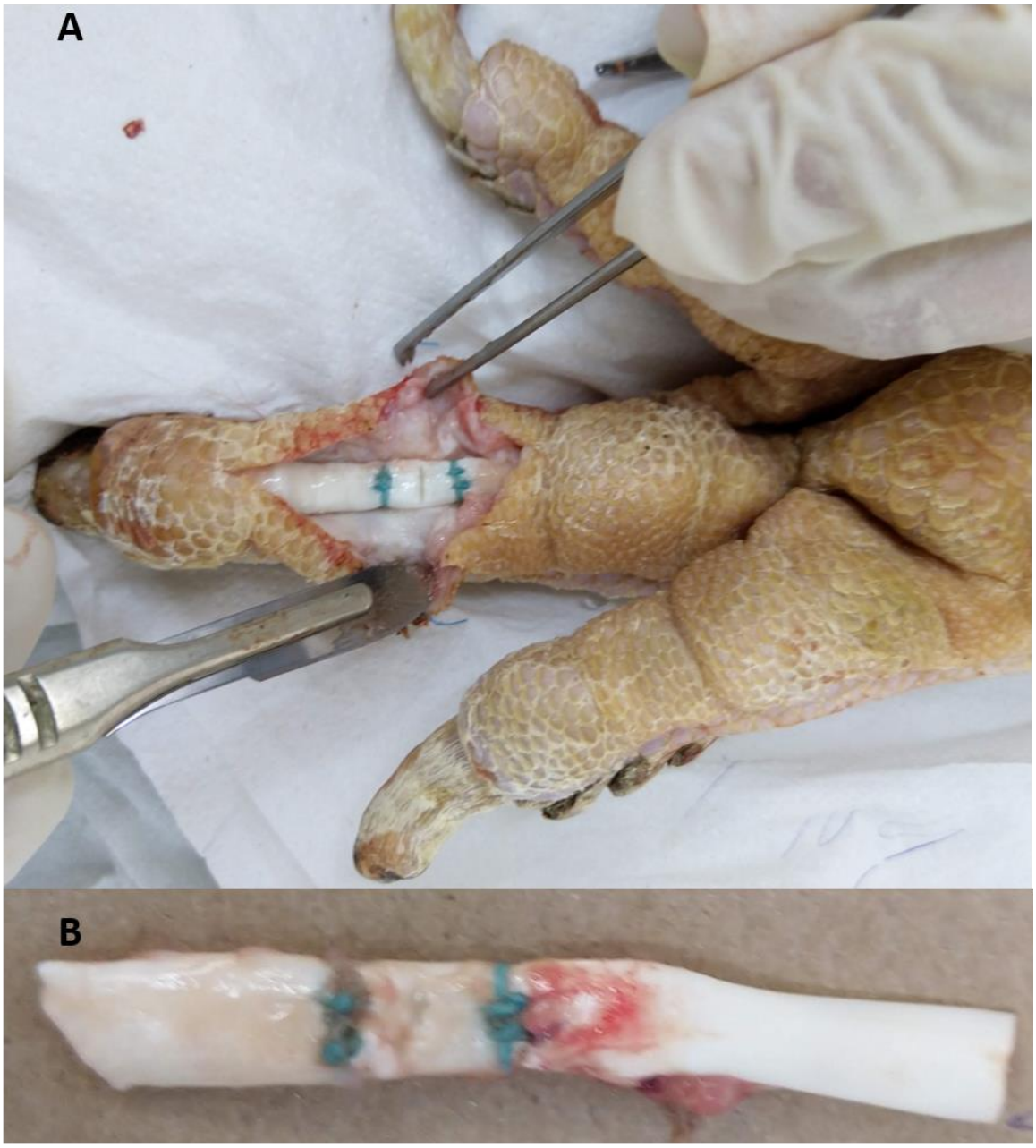

Figure 1: Uniform partial thickness laceration of a Turkey flexor tendon treated with the DTG™ implant (**A**). Macroscopic specimen of a flexor tendon 3 weeks after treatment with the DTG implant. Notice normal healing with fibrosis tissue without signs of Tendon necrosis.

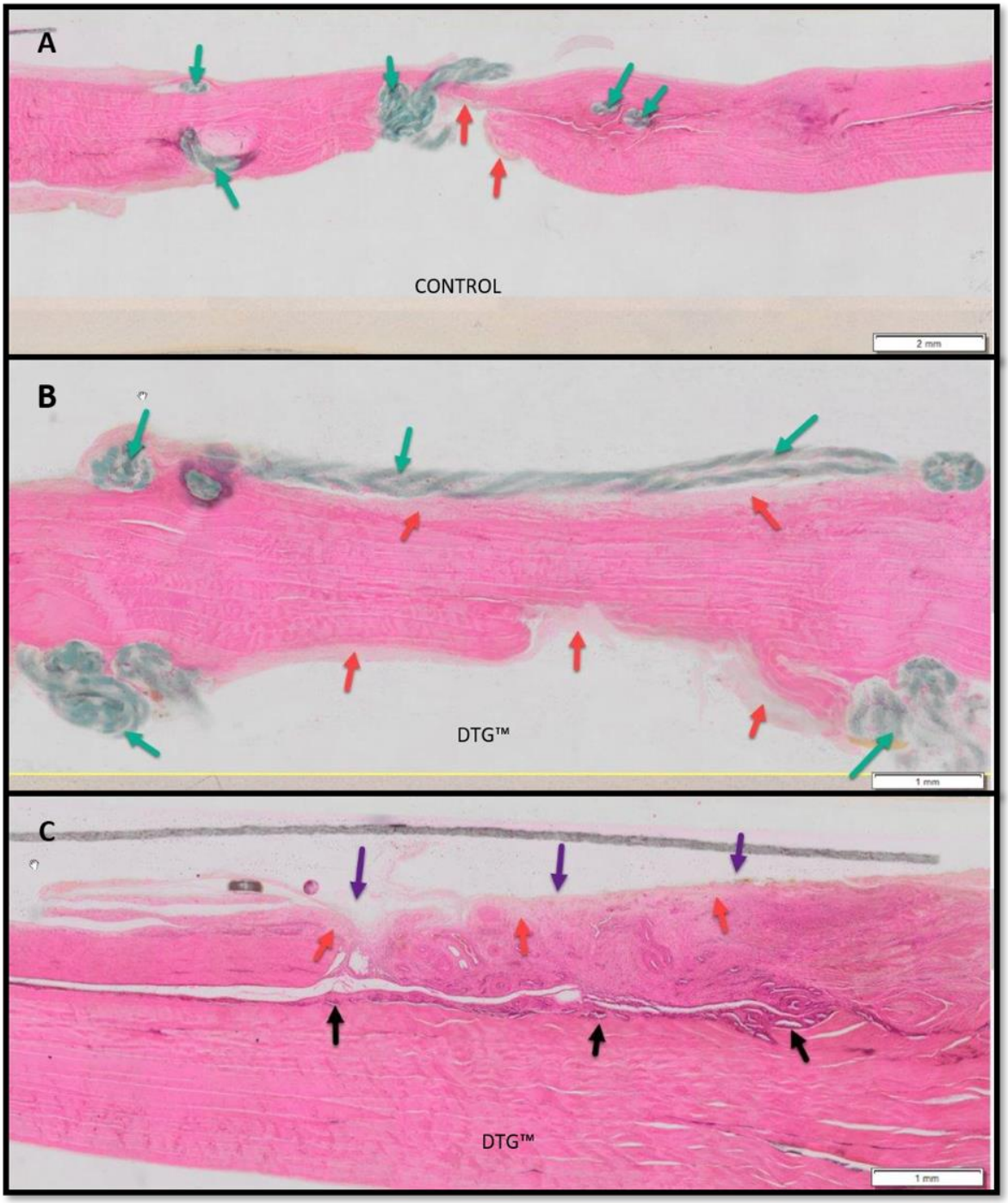

Figure 2: Site of partial thickness laceration (depth of 0.5-1 mm and a length of 5–6 mm) Treated with modified Kessler suture (A) and DTG implant (B) Red arrows indicate mature fibrosis. Green arrows indicate presence of suture cords surrounded by mature fibrotic capsule. (C) higher magnification of site of DTG embracing loop. Purple arrows indicate the location of embracing loop; Red arrows indicate mature fibrosis; and Black arrows indicate increased vascularization.