Single Entry Tunneler (SET) for Hemodialysis Graft Procedures

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This paper describes the design of the single entry tunneler (SET), devised to create a loop-shaped path in forearm subcutaneous tissue prior to placement of a vascular graft for hemodialysis access. Existing tunnelers are almost universally rigid and require high forces and multiple incisions to complete even the most simple path geometries. Furthermore, they are guided from the handle with limited tip-location feedback. This paper presents a three-stage tunneler design consisting of concentric nested tubes. The first stage is a straight stainless steel tube, the second is a smaller precurved nitinol tube, and the third is a straight inner nitinol tube. By deploying the stages in this order, SET is able to produce an approximately 180 deg looped path in tissue. A tip that is illuminated via a fiber optic cable provides visual feedback of the tip location. The SET outer diameter is limited to ensure that the precurved nitinol will not exceed its yield strain and not require an excessive force to be deployed from the straight outer stage. Therefore, a custom dilator was designed to increase the size of the tunnel to one suitable for the intended graft. A prototype of the SET tunneler and dilator system was manufactured. The device was shown to achieve the desired path in ballistics gel and was capable of at least 100 repeated-use cycles. By reducing the number of required incisions and improving ease of use during graft insertion procedures, the SET has the potential to greatly reduce the risk of infection and degree of unnecessary tissue trauma while increasing tunneling accuracy.

Design of an Osseointegrated Lower Limb Prosthetic Force Limiting Connection

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Osseointegration is the direct attachment of a prosthetic device to the bone in order to mimic the use, feel, and behavior of a missing natural limb. In a femoral osseointegrated fixture, the load is transferred directly into the bone using the same force path a natural leg would generate. This leads to better proprioception and sense of the foot contacting the ground. However, traumatic falls or impact loads present a serious concern for the amputee wearing an osseointegrated system. The conceptual device presented here offers a fully mechanical solution to these loading problems by releasing the prosthetic when placed under maximum allowable torsion loads and bending loads in the anteroposterior (AP) and mediolateral (ML) planes. The device is designed to bracket those forces with an upper limit set at 50% greater than the measured gait forces.

