Surgical Approach Limits Skin Downgrowth Around a Percutaneous Device

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Disclosures:

Introduction:
Percutaneous, osseointegrated devices, used for attaching exoprosthetics to the residual limb of patients with limb loss, have been clinically used in Europe for the last two decades. This procedure often uses a two-stage surgical technique [1, 2] for implantation in which a device is initially placed into the medullary canal of the residual limb and allowed to heal and integrate. Months later, a second surgery is performed to install a percutaneous post followed by attachment of the exoprosthetic component. Recent translational studies in the United States have reported successful outcomes with a one-stage surgical approach in various animal models [3, 4]. Although the data indicate reduced infection rates, the distal skin edge continues to downgrow along the implant surface in an attempt to avulse the device to reestablish the homeostasis. It is not clear whether one-stage surgery exacerbates or limits this downgrowth response. Thus, the goal of this study was to histologically evaluate the differences in downgrowth between two-stage and one-stage surgical approaches. The hypothesis tested is that the one-stage surgical approach maintains the same downgrowth rate when compared to a two-stage surgical approach.

Methods: Devices consisted of two components, (1) a Ti6Al4V subdermal component porous coated with commercially pure titanium (THORTEX INC., Portland, OR USA), (diameter = 18.6 mm, shelf height = 3.3 mm, and overall height =8 mm) and (2) a Ti6Al4V percutaneous post (height = 5.15 mm, diameter = 5 mm) with a machine smooth finish with an arithmetical mean roughness (RA) of 0.64 μm. Using an institutionally approved protocol, ten, 4-week old female IAF Hairless Guinea Pigs (strain code 161; Charles River, Raleigh, NC) weighing on average 381±36 g were included in this study. Animals were assigned into two groups; the first group was designated as two-stage surgical approach (n=5), and the second was implanted in one-stage surgical approach (n=5).

Two-stage surgical approach: Under sterile conditions, each animal received a subdermal device implanted into a blunt-dissected pocket created through a midline incision, posterior to the scapulae roughly 12 mm from the midline. The incision site was sutured closed and the animal was allowed to recover for 3 weeks. The subdermal component received a percutaneous post at the second surgery. For the second surgery, a 4 mm biopsy punch was used to expose the center of the subdermal barrier, through which a percutaneous post was threaded tightly to create the fully assembled percutaneous device. Once in place, the percutaneous site was dressed with sterile gauze and covered with Tegaderm™, a breathable membrane dressing. Animals were allowed to freely ambulate for 4 weeks and euthanized at the end of this period.

One-stage surgical approach: The same surgical procedure as outlined above was used to place a subdermal device into a blunt-dissected pocket created through a midline incision, posterior to the scapulae roughly 12 mm from the midline. The subdermal component received the percutaneous post at the time of the first surgery. Once the device was in position, the incision site was sutured closed and the percutaneous site was dressed with sterile gauze and Tegaderm™. Animals were allowed to freely ambulate for 4 weeks and euthanized at the end of this period.

Histopathological Evaluation: Devices and the surrounding tissues were harvested at necropsy and fixed with modified Karnovsky’s fixative and embedded in poly(methyl) methacrylate. A precision saw (LS10 Lapidary Slap Saw, Lortone Inc., Mukilteo, WA) was then used to obtain 2 mm thick sections from each specimen. Representative sections from each of the devices were ground to 75 μm thickness, and polished to an optical finish. All slides were stained with H&E for light microscope (Nikon eclipse Ni) analysis (NIS elements 4.0 imaging software). N=5 slides were analyzed for the two-stage treatment specimens. N=4 slides were analyzed for the one-stage samples, one slide was not analyzed due to gross processing artifact; specifically tissue was sheared from the implant during processing. The percent downgrowth for each group was defined as the ratio of the length of exposed porous coating without any epithelial or dermal attachments to the total length of available porous coating. All statistical analysis was performed using SPSS 17.0.

Results: The two-stage surgical approach significantly decreased downgrowth (p=0.027) by nearly 50% when compared to a one-stage approach (Figure 1), thus disproving our hypothesis. Two-stage device interfaces showed 16±6% downgrowth of exposed porous coating of the subdermal disk four weeks after the second surgery. In contrast, the one-stage approach showed 28±7% downgrowth of porous coating of the subdermal disk at 4-weeks post implantation. The histological data, however, indicated that the interfaces were stabilized by fibrous ingrowth and interdigitation with the porous coating regardless of the surgical technique used.
Discussion: The two-stage surgical approach showed a limited downgrowth when compared to a one-stage approach, thus disproving the tested hypothesis. Based on these histological data, it can be concluded that two-stage surgical approach can help limit downgrowth and improve the longevity of the implant. These data corroborate the use of a two-stage surgical approach which is in line with the European clinical techniques. By implanting the device in two stages, healing and integration can take place prior to exposing the device to the external environment and potential pathogens. Establishment of soft tissue-device integration and fibrous capsule envelope around the implant could act as a physical and biological barrier against invading bacteria; this may limit the wound-healing responses, which seem to reduce the epithelial downgrowth rate.

Significance: This study clearly shows that although one-stage surgeries have been a successful technique for implanting percutaneous prosthetic devices, the two-stage surgical technique further inhibits downgrowth, extending the in vivo quality and function of the device.

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References: