Wound Healing and Gait in a Swine Model of Transcutaneous Osseointegrated Prosthetics

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Introduction: During normal human gait, the skeleton is directly loaded through a thin layer of soft tissue on the bottom of the foot. Following lower limb loss, socket prostheses are used to restore mobility. These prostheses are generally designed to fit over the residual limb and transfer load through the soft tissue covering the residual limb, soft tissue not intended to be so loaded. A number of complications may arise from the combination of the socket environment and lack of direct skeletal loading [1]. Unable to breath within the socket, the skin sweats leading to redness and irritation, swelling, rashes, sores, and blisters [2, 3]. Additionally, direct soft tissue loading may lead to pain caused by abnormal pressure concentrations as well as an increased likelihood of heterotopic ossification [4]. A bold solution to these complications has been pioneered and implemented in over 250 people with lower-limb amputations in Europe but has not been approved in the US due to a high infection rate of 8-19% in Europe and a lack of research and clinical trials in the US [1, 5]. This new technique involves a transcutaneous osseointegrated (TO) implant that allows for attachment of an external prosthesis and direct skeletal loading [1]. This preliminary study was designed to model a TO procedure for above-the-knee (AK) amputees as performed by Dr. Horst Aschoff in Lubeck, Germany [1]. The purpose of this pilot study was to look at bacterial growth and wound healing at the skin-to-implant interface, as well as the effect of TO on gait in swine. Due to the anatomical and physiological similarities between human and swine skin, Yucatan Miniature Swine were selected for this study [6].

Methods: Four intact male Yucatan Mini Pigs (9 to 10 months of age) underwent a transtibial amputation. During the surgical procedure, the tibial canal was reamed in a retrograde fashion, and the intramedullary component of the device was implanted (Figure 1). Each implant was made of Grade 5 Ti-6Al-4V. The implants consisted of a threaded intramedullary component and a smooth transcutaneous component to which a separate prosthetic could be attached. A prosthetic foot was attached during the first dressing change post-op. Dressing changes were performed at intervals ranging from 1 day to 4 days, during which both the incision and stoma were inspected for signs of infection. The wound site was cleaned at every dressing change using either a H2O2+H2O or soap+H2O solution. H2O2 solution was used on 2 pigs from day 1 until 2 weeks prior to sacrifice, at which time soap solution was used for the remainder of the study. Soap solution was used during the entire span of the study on the other two pigs. Swabs for bacterial cultures were collected pre-op, immediately post-op, and during dressing changes at the incision and stoma site using BBL CultureSwabs. A standard rating was used as a means of quantifying the amount of each bacteria or yeast found. Gait data were collected pre-op and at various intervals post-op using a forceplate (Bertec Corporation, Columbus, OH), LabVIEW (National Instruments, Austin, TX), and a video camera. The data were analyzed using MATLAB (MathWorks, Natick, MA) and a video camera-based motion capture system. MATLAB was used to calculate the peak vertical force (PVF) as a percent body weight (%BW). Dartfish Video Analysis (Dartfish, Alpharetta, GA) was used to measure the duration of the gait cycle (GC), support and swing time as a percentage of GC (%GC), and stride length for both hind limbs. The animals were sacrificed at 5, 8, 12, or 13 weeks. Histological slides were prepared and used to evaluate wound healing around the transcutaneous implant.

Results: Figure 2 shows the different stages of wound healing observed grossly. Progressive epithelialization of the granulation tissue was observed at the stoma (Figure 2F). This progression was confirmed by histology. Surgical incisions closed uneventfully except for one incidence of infection in one animal, which was treated with a single course of antibiotics. Bacterial cultures at the stoma and incision revealed the colonization of various bacteria, including mixed gram negative rods, bacillus species, enterococcus species, pseudomonas putida, staphylococcus coagulase negative, gram positive cocci, as well as consistently high levels of yeast. During the time when H2O2 solution was used to clean the wound, bacterial cultures showed no bacterial presence in pig 1, and enterococcus species at 66.6% of dressing changes as well as staphylococcus during 22.2% of dressing changes of pig 2. Cultures from pig 3 also showed 11.1% stenotrophomonas maltophilia and 11.1% gram positive cocci. Cultures from pigs 3 and 4 (soap only) showed 44.4% and 33.3% mixed gram negative rods as well as 44.4% and 66.6% pseudomonas aeruginosa, respectively. The PVF across all 4 animals averaged 6%BW difference between the intact and amputated leg pre-op, and 22% difference post-op. The duration of GC pre-op averaged .496 seconds (s) for the intact limb and .531 seconds for the amputated limb, with an average of 51.8%GC and 52.2%GC support time for intact and amputated limb respectively, and an average of 51.1%GC and 47.8%GC swing time for intact and amputated limb respectively. Duration of GC post-op averaged .634s for the intact limb and .599s for the amputated limb, with 63.2%GC and 41.9%GC support time and 36.8%GC and 58.1%GC swing...
time, respectively. Stride length averaged .70 m intact and .67 m amputated limb pre-op, and averaged .68 m and .72 m post-op for intact and amputated limb, respectively.

Discussion: During the period when H2O2 solution was used to clean the wounds, there was a very limited bacterial presence, and no clinically relevant infection was detected. With H2O2 cleaning, there was a significant amount of yeast present. Additionally, when H2O2 was used, epithelialization appeared to be somewhat inhibited. When only the soap solution was used for wound cleaning, the yeast levels were significantly lower, but bacterial presence was greater though again with no evidence of clinical infection. Soap and water cleaning, as is recommended for the cleaning of the stoma around TO in Europe, was therefore found to be sufficient and effective even for use in this much more contaminated porcine environment. The gait analysis showed a shorter GC for the amputated limb post-op, as well as a much higher swing time and much lower stance time. This may have been due to the discomfort of the animals during ambulation, leading them to avoid some weight-bearing. Furthermore, the stride length of the amputated limb was higher post-op than of the intact limb; again consistent with weight-bearing avoidance of the treatment limb. The Yucatan Mini Swine tolerated the surgery and healing process well. Observation and histology both provided good evidence that the stoma healed around the implant and began the important process of epithelialization.

Significance: This is the first TO amputation study done in a porcine model, and its preliminary data and experimental protocol will serve as a basis for future studies. Successful development of this porcine model may accelerate the introduction of TO in the US and provide an effective means of improving TO implants and techniques.

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Figure 2. Progression of healing: a) Surgical Incision (SI), b) SI healed at approximately 1 week, c) Sutures removed, d) Scab, e) Signs of yeast infection, f) Epithelialization
Figure 1. X-ray Immediately Post-Op

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