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Magnetic transcutaneous fixation: an experimental study in pigs

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ABSTRACT

Background: Magnetic subdermal implants have never been studied in the context of magnetic fixation of an external device to the body's surface. Excessive attractive force between the implant and the external device may compromise local circulation due to mechanical compression, leading to necrosis.

Objective: To evaluate the feasibility of transcutaneous magnetic fixation and assess secondary skin changes when subjected to a continuous static magnetic field.

Methods: Using the pig as an animal model, 72 implants were introduced in 12 animals. After wound healing, ultrasonography was performed to measure implant depths. Computer simulations were applied to allow magnetic attachment between implants and external devices without impairing local blood flow. External devices of different magnetic strengths were applied over the skin for 7 days. Local skin was examined and collected for analysis. A senior dermatopathologist blindly examined skin specimens and controls for abnormal findings, measuring dermal and epidermal thickness. Statistical analysis ($P < 0.05$) was performed over the data.

Results: Nineteen implants presented extrusion. The remaining 53 skin sites underwent magnetic compression, of which 43 (81%) evolved uneventfully. Implant depth varied between 4.6 mm and 8.3 mm (5.8 mm; ± 8.6 mm) with estimated pressure levels between 13.28 mmHg and 37.04 mmHg (27.6 mmHg; ±6.0 mmHg). Stronger magnets were associated with an increase in dermal thickness ($P = 0.011$) and neovascularization ($P = 0.045$).

Conclusions: Transcutaneous magnetic fixation is compatible with skin viability *in vivo*, under experimental conditions. Skin interposition between two permanent magnets resulted in a continuous static magnetic field stimulation, which showed similar effects to pulsed electromagnetic fields reported on scientific literature.

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Background

Magnetic attachment devices have been under recent experimental research for visceral[1] and vascular[2] anastomosis. They have been in the medical practice for decades, particularly in maxillofacial prosthetics. Such maxillofacial systems require osseointegrated implants that transfix the skin to allow direct contact between magnets, ensuring adequate fixation. As result, cutaneous integrity is compromised, predisposing to infection and other complications.[3-5] Although transcutaneous magnetic fixation (TMF) has been employed for hearing aid devices[6] preserving skin integrity, in such apparatus the internal implant needed to be fixed in the mastoid bone. Subdermal magnetic implants that can be introduced in a minimally invasive manner could potentially be used to fix any device to the body's surface, from external prostheses[7,8] to ostomy pouches,[9] in a number of clinical scenarios.

Subdermal magnetic implants have been studied for other purposes,[10] but to our knowledge, such implants have never been investigated in the context of magnetic fixation of an external device to the body surface. Excessive attractive force between the implant and the external device may compromise local circulation due to mechanical compression, leading to tissue necrosis. On the other hand, insufficient magnetic force may not hold the external device. Our purpose was to verify if TMF was compatible with the viability of cutaneous blood flow and living skin.

Materials and methods

To assess the feasibility of TMF and also to study skin changes when interposed between two permanent magnets, we have chosen the pig a model in our experimental research, due to the similarities between porcine and human skin.[11] Twelve male minipigs of the *Minipig br1*[12] breed weighting 21.2 kg; ± 3.0 kg were used in the experiment, with previous approval of the ethics committee for animal experimentation.

Magnetic implant and magnetic external device

The magnetic implant consisted of a silicone body, containing two synthetized N40 grade neodymium ($Nd_2Fe_{14}B$) magnets on the inside, made of medical grade silicone elastomer, designed in an ellipsoid shape (50 mm length and 22-mm width), with a flat profile (4-mm height), without sharp edges or peaks, to avoid tissue trauma. The two neodymium magnets on the inside were disc-shaped (6 mm diameter and 1.5 mm thickness) with surface field strengths of 48 mT and magnetized axially, with a nominal magnetic remanence of 1.25 T. These two magnets were identical, except for the arrangement of their polarities (north facing up and south facing down and vice versa).

The external magnetic device is a hard plastic cylinder with a flat base (30 mm diameter). This cylinder houses a pair of identical synthetized N50 grade neodymium magnets on the inside. These two magnets are arranged with alternate polarities as well. Since opposite poles attract each other and similar polarities repel, this arrangement of the four permanent magnets (two in the implant and two in the external device) ensured optimal interaction, allowing perfect magnetic attachment between the implant and the external device. To release the external device from the skin, a 180° twist of the device turned this attractive configuration to a repulsive one—Figure 1.

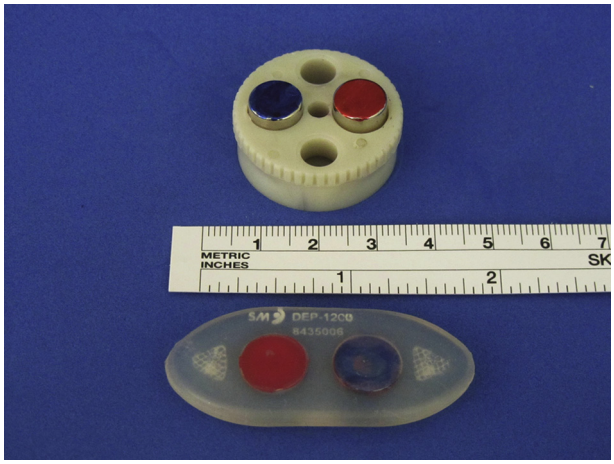

Fig. 1 – Silicone magnetic implant (below) and magnetic external device (above). Opposite magnetic poles show different colors (north-red and south-blue).

In the external device, three different pairs of 6-mm diameter magnets were employed (with surface field strengths of 0.44 T, 0.470 T, and 0.5 T) magnetized axially, with a nominal magnetic remanence of 1.4 T. Thus, for a given depth of the implant under the skin, the stronger magnets (0.5 T) in the external device raised the total magnetic momentum (increasing the attractive force exerted by the system), whereas the weaker magnets (0.44 T) had the opposite effect. All magnets used in the experiment had their magnetic field strengths measured using the LakeShore 455 DSP gaussmeter with transversal hallprobe HMNT-E04VR (LakeShore Cryotronics, Inc., Westerville, OH).

The design of the implant and external device was conceived to allow magnetic attachment without causing excessive pressure over the skin surface. Computer simulations, using the *COMSOL Multiphysics* modeling software under license n. 2072699, enabled the calculation of such pressure values—Figure 2.

Magnetic implant introduction

The animals were sedated and transported to the operating room. After venous catheterization and intubation, each pig was maintained under anesthesia throughout the procedure. Dorsal skin was trichotomized and prepared with antiseptic solution. Stab incisions were performed over dorsal skin and a straight cannula was introduced on each incision for undermining of the subdermal plane, creating a straight, narrow tunnel under the skin (Fig. 3—left). Each implant was introduced through the incision and positioned to its final place with the aid of transfixing threads (Fig. 3—right). The incisions were then sutured. At the end of the procedure, each one of