An Electromagnetic Attachment Paradigm for Lower Extremity Prosthetic Limb Devices

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INTRODUCTION: Despite recent improvements in prosthetic limb technology, over half of patients with lower extremity amputation report dissatisfaction with their prosthesis. While most of the research community has focused on increasing device capability through powered prostheses and advanced controllers, the majority of patient-reported problems relate to shortcomings in device *attachment*. Conventional attachment methods involve a socket secured around the residual limb using suction or friction between silicone liners and skin, thus suspending the prosthesis from soft tissues. Because soft tissues deform under load, each step during gait causes these tissues to repeatedly stretch and compress about the residual bone. This motion of the prosthesis relative to the bone, known as pistoning, leads to tissue breakdown, sores, and ulceration. The problems caused by soft tissue suspension are so profound that some patients opt for percutaneous osseointegration (OI), in which the prosthesis is attached directly to bone via an implant that *protrudes through the skin*. This eliminates pistoning by not loading the soft tissues; however, OI results in a chronic wound such that patients are persistently at risk of infection The increased infection risk can also contraindicate this procedure with many amputations performed for dysvascular reasons or periprosthetic joint infection, making OI inaccessible to over 93% of patients with transfemoral amputation. Given the serious deficiencies of current attachment methods, we propose a novel attachment paradigm that transfers load directly to the residual bone (as with OI) while maintaining a closed skin envelope. The proposed system (Fig. 1A) consists of a subcutaneous osseointegrated implant, and an external electromagnet connected to the prosthetic socket. Magnetic interaction forces between the implant and the electromagnet allow for load transfer *across,* instead of through, the soft tissues. This paradigm is expected to relieve the soft tissues of suspension loads and greatly reduce pistoning. In the present work, we evaluate the feasibility of a magnetic prosthetic attachment for transfemoral amputations with regard to the system's force production capabilities, the power required during operation, and the amount of soft tissue deformation that would occur during gait.

METHODS:

To inform the implant design, multiple cadaveric dissections were conducted to evaluate the overall size, shape, and any implant features that may aid the surgical process. Using electromechanical modeling software, the external electromagnet was optimized to meet specific force, mass, and power requirements. The resulting implant and magnet designs were manufactured, and the final device was evaluated on a dynamic testbench capable of simulating the attachment loads experienced during level ground walking. To assess the performance of the system, the gap distance between the external electromagnet and the implant was measured as a correlate for soft tissue strain.

RESULTS:

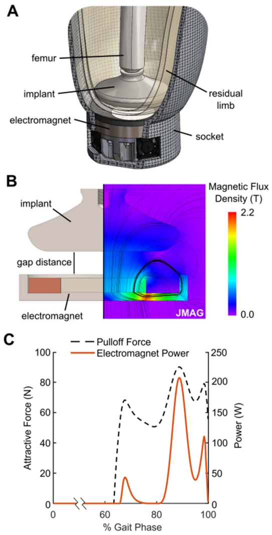
The implant design fits within the closed skin envelope of the residual limb, with an expected soft tissue coverage of 1.5 cm. The implant has a large distal end to facilitate end-bearing. Computer simulation showed that our electromagnet design can support the forces required for gait, while adding only 1.5kg to the overall mass of the prosthetic socket. Under gait-relevant loading patterns, the electromagnet produced a 90N peak force, while drawing an average power of 19W (Fig. 1B,C). Thermal simulations showed a nominal temperature increase of 3°C at the skin surface after 1000 continuous steps. The implant and electromagnet were manufactured for benchtop testing. Electromagnetic force production closely matched the simulation model (Fig. 2) at different gap distances with a root-mean-square error of 1.7 N. Dynamic testing showed minimal relative motion between the implant and the electromagnet during simulated gait.

Fig. 1: (A) Model of the proposed system. (B) Magnetic field produced by the electromagnet as simulated in JMAG. (C) Electromagnet power (right y-axis) to produce the attractive force (left y-axis) required to suspend a prosthesis during level ground walking. The electromagnet is electrically "off" during stance (0-60%) when the prosthesis is weight-bearing.

Fig. 2: (A) Testbench setup for validating prototypes. (B) Force production of the system closely matched the corresponding computer simulation model for varying gap distances and currents through the electromagnet.

DISCUSSION AND CONCLUSION:

This study demonstrates the feasibility of an electromagnetic attachment paradigm for lower extremity prosthetic limb devices. The transfer of suspension loads from the prosthesis directly to the residual bone across a closed skin envelope results in minimal soft tissue deformation without the infection risk associated with OI. This attachment method has the potential to increase the quality of life for amputation patients by improving socket fit and reducing tissue damage.


A
femur
implant
residual limb
electromagnet
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B
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gap distance
electromagnet
Magnetic Flux Density (T)
2.2
0.0
JMAG
C
Pulloff Force
Electromagnet Power
Attractive Force (N)
Power (W)
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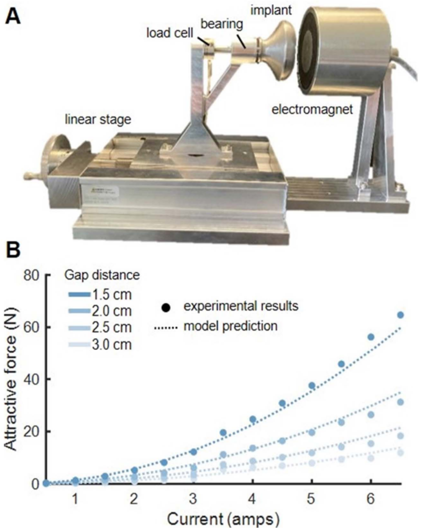
60
40
20
0
250
200
150
100
50
0
0
60
80
100
% Gait Phase


A
load cell
bearing
implant
linear stage
electromagnet
B
Gap distance
1.5 cm
2.0 cm
2.5 cm
3.0 cm
experimental results
model prediction
Attractive force (N)
80
60
40
20
0
1
2
3
4
5
6
Current (amps)