A summary on hard-wired epymisial recordings using a bone-anchored device

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Contents

1 Foreword

This paper discusses the devices outlined by Lancashire et al [1], who explore the usage of implantable electrodes that take advantage of transcutaneous prostheses. Some background is given about amputation prostheses and bone-anchored devices before delving into the paper. Furthermore, "prosthesis" refers exclusively to the bone-anchored devices, whereas mentions of "prosthetic limb" are prosthetic arms, hands, legs, etc. as appropriate.

2 Introduction

Not only does amputation result in limb loss, but also loss in the perception enabled by the limb — removing a fundamental way we gather information about the world around us. Following an amputation, stump-socket prostheses are used to restore function by attaching and securing the device onto the residual limb. This results in soft tissue being responsible for non-physiological weight bearing, causing skin abrasions [2], osteopoenia and ultimately patients opting not to use their prostheses.

Intraosseous Transcutaneous Amputation Prostheses (ITAP) [3] are an alternative attachment method which bypasses the traditional load-bearing role of the residuum. They achieve this by anchoring the device into bone and enabling stresses to be transmitted from bone through prosthesis to prosthetic limb — allowing the physiological loads necessary to maintain bone health. Furthermore, the presence of a porous flange promotes cutaneous integration akin to a deer's antlers [4].

3 Aim

The control of sophisticated prosthetic limbs generally relies on skin-surface electrodes. Lancashire et al. take advantage of the transcutaneous nature of an ITAP to implant electrodes on epymisia (the surface of muscles), and then use the prosthesis as a portal for a wired connection to the outside of the body. The position of these electrodes improve the quality of the EMG readings, reduce noise, and don't require the user to replace them periodically.

The study aims to validate this approach by extending the timescale (From 12 to 19 weeks) and number of participant animals (n = 6) from previous studies. It also explores the effects of targetted muscle reinnervation (TMR) for one animal over 12 weeks.

4 Experiment

Devices ITAP was sintered from Titanium 6–4 and press-fit into the sheep's tibia. Because it was press-fit, it included a hydroxyapatite coating to promote osseointegration. Reinforced bipolar electrode arrays with platinum-iridium electrodes were implanted aligned with the long-axis of the muscles. Gaps were filled with epoxy resin and medical grade silicone.

The experiment consisted of placing each animal on a treadmill walking at $2\,\mathrm{km\,h^{-1}}$ and having electromyographical (EMG) readings in weeks 1, 2, 3, 4, 6, 8, 14 and 19 after the implantation. On the 19th week, EMG was recorded on the skin surface for comparison.

For the animal that underwent TMR, EMG was recorded weekly for 12 weeks in the same setting. A force plate analysis was also used to assess recovery of weight bearing. That is, before and regularly after surgery the animal walked across a force plate, then weight distribution on each hind leg was measured.

The authors also analyse the change in electrode impedance before implantantion, in-vivo and after explantation.

5 Results

5.1 Morphology

Cutaneous integration was subpar for one animal for whom the ITAP was placed proximally on the tibia. Despite no signs of infection, there was necrosis of the skin after 8 weeks. The other animals with more distal prostheses displayed better outcomes. They showed good dermal integration into 90% of pores with good vascularisation of 71 blood vessels per mm^2. In places of poor integration, both downgrowth and the formation of sinuses was observed, which allowed the collection of debris.

For the sheep who underwent TMR, some muscular atrophy was noted on the muscle whose nerves were transected. While atrophy is expected in TMR, often the muscle is already imobile, but that was not the case in this study.

5.2 EMG

Epymisial EMG readings showed a reduction in noise as compared to skin readings. Typical signal-to-noise ratios (SNR) ranged from $10\,\mathrm{dB}$ to $25\,\mathrm{dB}$ week-to-week and $(19.6 \pm 7.4)\,\mathrm{dB}$ at 19 weeks. Skin surface was $(6.65 \pm 7.63)\,\mathrm{dB}$, however they were statistically different.

5.3 Others

Crosstalk is the amount of signal caused by the activation of nearby muscles which were largest when stimulating the peroneal nerve muscles and smallest when stimulating the gastrocnemius. These were between one and three orders of magnitude smaller than the targeted muscle signal.

Mean electrode impedance went from $1.3\,\mathrm{k\Omega}$ on implantantion to $2.2\,\mathrm{k\Omega}$ in-vivo, to $3.1\,\mathrm{k\Omega}$ at explantation and placement in saline.

For the animal who underwent TMR, after 6 weeks weight bearing is recovered, but it is only possible to distinguish the EMG signal from crosstalk at 10 weeks.

6 Discussion

The study used a cylindrical flange on the ITAP, which disagreed with the traditional flange shape. They speculated that the traditional dome shape would ultimately improve cutaneous integration and reduce some the observed skin damage. Furthermore, allowing the wires to flow from the flange directly into soft tissue enables a simpler surgery that doesn't require making holes on the cortex of the bone. Every path to the outside of the body requires a hermetic seal (e.g. ceramic-to-metal feedthrough), however for implantation in animal, the authors used medical grade silicone.

For the TMR case, the use of SNR as a measuring tool does not convey subtle changes, such as a reduction in EMG frequency. There is a broader desire to use TMR because of its role in restoring proprioception and some sensory feedback — this will be discussed further in the Implications section. Additionally, there was the inability to discern the effect of reinnervation and the surgery on weight bearing recovery. The authors suggest a control condition which inhibits particular reinnervation and would enable that differentiation. Further details are not discussed in this paper because we do not go into detail about the exact nerves being transected.

The use of bipolar electrode arrays limited recordings to one location. Lancashire et al. suggested the use of multielectrode arrays to gather more information about moving intention. That is, giving the ability to have considerably more information for control of the eventual prosthetic limb. Furthermore, tripolar electrodes and a reduction in interelectrode distance could be used to reduce crosstalk.

The authors final considerations are that the increase in electrode impedance in-vivo is in line with previous studies and the approach discussed is not limited to EMG and could equally be used for neural recordings.

7 Conclusions

8 Implications

Proprioception

Osseoperception

8.1 Patients

8.2 Clinical use

The most important takeaway is that this study provides further support to the use of transcutaneous bone-anchored devices as a tool to control sophisticated prosthetic limbs.

9 Problems

Stress shielding & non-physiological loads

Aseptic loosening

Bone-anchored prostheses are extremely niche

10 Is it better than any other implant that already exists?

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