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A system and method to interface with multiple groups of axons in several fascicles of peripheral nerves

Anil K. Thota[a], Sathyakumar Kuntaegowdanahalli[a], Amy K. Starosciak[a], James J. Abbas[b], Jorge Orbay[a,c], Kenneth W. Horch[a], Ranu Jung[a,*]

[a] Department of Biomedical Engineering, Florida International University, 10555 West Flagler Street, EC 2610, Miami, FL 33174, USA
[b] Center for Adaptive Neural Systems, School for Biological and Health Systems Engineering, Arizona State University, AZ 85287, USA
[c] Miami Hand and Upper Extremity Institute, 8905 SW 87th Avenue, Miami, FL 33176, USA

HIGHLIGHTS

- Developed a distributed intrafascicular multi-electrode for neural interfacing.
- Developed multi-electrode multi-lead packaging processes.
- Developed surgical procedures to implant the distributed multi-electrode.
- Tested surgical procedures in a cadaver arm.

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ABSTRACT

Background: Several neural interface technologies that stimulate and/or record from groups of axons have been developed. The longitudinal intrafascicular electrode (LIFE) is a fine wire that can provide access to a discrete population of axons within a peripheral nerve fascicle. Some applications require, or would benefit greatly from, technology that could provide access to multiple discrete sites in several fascicles.
New method: The distributed intrafascicular multi-electrode (DIME) lead was developed to deploy multiple LIFEs to several fascicles. It consists of several (e.g. six) LIFEs that are coiled and placed in a sheath for strength and durability, with a portion left uncoiled to allow insertion at distinct sites. We have also developed a multi-lead multi-electrode (MLME) management system that includes a set of sheaths and procedures for fabrication and deployment.
Results: A prototype with 3 DIME leads was fabricated and tested in a procedure in a cadaver arm. The leads were successfully routed through skin and connective tissue and the deployment procedures were utilized to insert the LIFEs into fascicles of two nerves.
Comparison with existing method(s): Most multi-electrode systems use a single-lead, multi-electrode design. For some applications, this design may be limited by the bulk of the multi-contact array and/or by the spatial distribution of the electrodes.
Conclusion: We have designed a system that can be used to access multiple sets of discrete groups of fibers that are spatially distributed in one or more fascicles of peripheral nerves. This system may be useful for neural-enabled prostheses or other applications.

1. Introduction

The past few decades have seen significant advances in the development of neurotechnology to stimulate neural tissue to replace function lost due to neurological disability or neurotrauma. Although the most widely clinically deployed systems stimulate the cochlea (Clark, 2006; von Ilberg et al., 2011), deep brain structures (Farris and Giroux, 2011) or the spinal cord (Cruccu et al., 2007), the peripheral nervous system has also been targeted extensively. For example, systems have been developed that utilize stimulation

Abbreviations: DIME, distributed intrafascicular multielectrode; LIFE, longitudinal intrafascicular electrode; MLME, multi-lead multi-electrode; ID, inner diameter; OD, outer diameter.

* Corresponding author at: Department of Biomedical Engineering, Florida International University, 10555 West Flagler Street, EC 2602, Miami, FL 33174, USA. Tel.: +1 305 348 3722; fax: +1 305 384 6954.
E-mail addresses: rjung@fiu.edu, ranu.jung@gmail.com (R. Jung).

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of the peroneal nerve for foot drop (Kottink et al., 2004), the vagal nerve to treat epilepsy or depression (Groves and Brown, 2005), the sacral nerve to treat urinary urge (Brazzelli et al., 2006) or fecal incontinence (Jarrett et al., 2004), gastric nerves to treat gastroparesis (Zhang and Chen, 2006), and motoneurons of ventilatory and abdominal muscles to provide sufficient ventilation (Creasey et al., 1996; Walter et al., 2011).

These systems typically use an arrangement in which a single lead is used to target one or more stimulation sites. In some instances, a single lead contains multiple electrode contacts in concentric circles along its longitudinal axis to stimulate sites at pre-determined distances along the lead (Cameron, 2004; Clark, 2006; Farris and Giroux, 2011; von Ilberg et al., 2011), while other designs use multi-contact cuffs (Tyler and Durand, 2002), 2-dimensional grids of electrode shanks (Branner and Normann, 2000), or a set of contacts on a single flexible substrate (tfLIFE: (Lago et al., 2007; Micera et al., 2010), TIME: (Badia et al., 2011a,2011b)). In all of these designs, the contacts are embedded in a substrate such that the electrodes are spaced at fixed, predetermined distances from each other. This arrangement provides the opportunity for post-surgical selection of a single active channel or the selection and use of multiple channels while enabling a relatively simple implantation procedure and providing mechanical durability of the contact and its connection to the lead.

This single-lead, multi-electrode design has proven to be highly useful, but for some applications, the design may be limited by the bulk of the multi-contact array and/or by the spatial distribution of the electrodes. For example, there is great interest in interfacing with peripheral nerves of amputees in order to stimulate afferent fibers to provide sensation (Boretius et al., 2010; Dhillon et al., 2004, 2005; Micera and Navarro, 2009) and/or to record from efferent fibers to derive motor commands to control a prosthesis (Dhillon et al., 2004, 2005; Micera et al., 2010; Micera and Navarro, 2009). These systems require (or at least would benefit greatly from) interfaces at distinct sites at different locations in order to provide multiple channels of communication with a variety of fibers.

Previous work has demonstrated the feasibility of using longitudinal intrafascicular electrodes (LIFE) to provide access to small groups of axons within a peripheral nerve fascicle (Dhillon et al., 2004, 2005). LIFEs were made from Teflon-coated Pt/Ir wire (27.5 μm diameter) by de-insulating approximately 1 mm of the wire (Lefurge et al., 1991; Malagodi et al., 1989) to form one active site. In human amputees, these electrodes were used to stimulate nerve fibers to elicit discrete sensations (Dhillon et al., 2004, 2005) and to record motor activity to drive the movement of a prosthetic arm (Dhillon et al., 2004, 2005). The small size of these fine-wire electrodes and their longitudinal orientation provides a safe and stable interface to the nerve subpopulations within a nerve fascicle (Lefurge et al., 1991; Yoshida and Stein, 1999). Since this system utilizes individual wires, it is possible to place multiple LIFEs in one fascicle, in different fascicles within one nerve or in multiple nerves to provide access to multiple sites that are distributed in a region of the body. The small diameter of the fine wire that comprises the electrode/lead provides a high degree of mechanical compatibility with the nerve fibers, but also presents risks of entanglement during surgical deployment and breakage if the fine wire lead is routed in a manner that subjects it to high mechanical stress.

This manuscript reports on the development of a system that can be used to access multiple sets of discrete populations of fibers that are spatially distributed in one or more peripheral nerves. Our approach utilizes LIFE technology because it has been demonstrated to provide a stable interface to a small group of fibers. This work addresses the challenge of scaling this technology for use in distributed multi-channel systems by facilitating the surgical implantation of several LIFEs at various sites in the periphery and enhancing the strength and durability of the leads. We have developed a novel distributed intrafascicular multi-electrode (DIME) lead consisting of multiple LIFEs packaged in a single lead and an approach to deploy a plurality of these leads.

2. Materials and methods

2.1. DIME design objectives

In the peripheral nervous system, groups of nerve fibers are surrounded by perineurium to form a fascicle; groups of fascicles are surrounded by epineurium to form a nerve bundle. In humans, the diameter of the fascicles range from 0.1 to 1 mm and the diameter of peripheral nerves range from 2 to 12 mm (Gustafson et al., 2005, 2009). In the human arm the diameters of the median and ulnar nerves are approximately 3 mm (Heinemeyer and Reimers, 1999) and the number of fascicles and distribution of motor and sensory fascicles vary along the length of the nerve (Stewart, 2003; Sun et al., 2009).

The primary objective in the design of the DIME was to provide access to small groups of axons from different fascicles within a single nerve or from different nerves within a region of the body. The system should be suitable for chronic use and therefore should not induce trauma or physiological reactions that would impair nerve function or degrade health. The system should be sterilizable and implantation should utilize procedures that can be executed readily and reliably by a trained surgeon.

2.2. DIME design overview

Each LIFE consists of a highly flexible insulated wire (typically platinum–iridium approximately 25 μm in diameter) with an exposed area that forms the single electrode contact and a rigid needle that is used to insert the wire into an exposed fascicle; the needle is removed after the wire is inserted. The DIME lead (Fig. 1) consists of multiple LIFEs to enable several channels of communication with small groups of nerve fibers within neighboring fascicles. The proximal ends of the LIFEs within a DIME lead are coiled and housed in a sheath to provide robustness and ease of handling during the implantation procedure and for durability when implanted for extended periods of time. For systems that require access to nerves at different sites, multiple DIME leads can be deployed individually or clustered to form a single lead to further facilitate routing and connections.

Because the individual wires are very fine and flexible and there are rigid needles attached at the end, the DIME has been designed with a system of sheaths to protect the electrodes and prevent entanglement of the wires while handling during surgery. The multi-lead multi-electrode (MLME) management system consists of a set of sheaths for each LIFE and an outer sheath that covers the bundle of individual sheathed LIFEs. The outer sheath and then the individual sheaths are sequentially removed during the implantation procedure. Implant-grade materials are used in the construction of all components and the system is suitable for sterilization using standard ethelyne-oxide processes.

2.3. DIME fabrication process

Steps 1–3 in Fig. 1 show a schematic of the process for fabrication of a DIME with six electrodes. In step 1, the proximal portions of six insulated electrode wires (25 μm diameter Pt/Ir coated with 6 μm thick PTFE (polytetrafluoroethylene) to result in 37 μm diameter insulated wire, A-M Systems, Carlsboro, WA) are coiled to provide strain relief and flexibility. In step 2, the coiled portion of the bundle is ensheathed within an implant-grade silicone tube (MED4515, Nusil, Carpinteria, CA) of 300 μm inner diameter (ID) and 640 μm