

Continuous Combination Adjustment For Rapid and Smooth Paresthesia Fitting

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Introduction

Spinal cord stimulation (SCS) has been employed for more than 30 years for the treatment of chronic pain syndromes. Technical advancements in SCS systems have improved the long-term efficacy of the therapy. These advancements include an increase in the number of stimulating contacts and more flexibility in the programmability of the devices.

With these advances, however, comes the challenge of identifying and maintaining an optimal set of stimulation parameters (contact combination, amplitude, PW, rate, etc.) for each patient. In SCS, overlap of the pain with paresthesia has been identified as the critical factor for a successful outcome [1]. Paresthesia location is determined by which spinal cord fibers are activated by the stimulation. For a first approximation, optimal paresthesia location involves identifying the stimulation contact combination that recruits the desired fibers.

SCS systems limited to discrete combinations of anodes and cathodes without independent amplitude control of each contact can cause patient discomfort when switching to a new discrete combination. The programming of such systems require the reduction of the stimulation amplitude to a subthreshold value before changing to the new discrete combination. Even motivated clinicians using well-defined optimization algorithms can find the search for the best paresthesia in discrete combination stimulators to be a numerically overwhelming task. Either an exhaustive search is undertaken which may take hours, or a limited (and possibly sub optimal) subset of discrete combinations are tried within an allotted, likely brief, period of clinical time. In contrast, a continuous combination SCS system with independent amplitude control on each contact would smoothly switch between combinations and avoid the time consuming process of reducing amplitude between each combination.

The increased spatial resolution of stimulus current fields from a continuous combination SCS system would provide an opportunity to further optimize paresthesia coverage. Electrode arrays with increased numbers of more closely spaced contacts, however, are required to fully realize the greater spatial adjustment available with the stimulation field. In typical SCS electrodes, the inter-contact spacing varies from 4-12mm [2]. If the neural target resides underneath the region between contacts on an SCS electrode array, the amplitude must be increased significantly to recruit the desired nerves. This typically results in extraneous or unwanted stimulation and, as a side effect, may limit the use and success of the therapy. SCS electrode arrays with reduced inter-contact spacing would avoid this side effect and allow a continuous combination SCS implant to fully optimize the paresthesia for a given electrode array placement.

A continuous combination SCS system with a closely spaced electrode array has been designed. The purpose of this paper is to describe the system and its application in SCS.

Method/Design

Stimulation System

A stimulation system has been designed which can adjust stimulation combinations in small discrete steps such that the process of changing spatial neural recruitment is smooth. The stimulation system assigns a single constant-current control source to each stimulating contact. The stimulation system can sink or source up to 12.7 mA from each of the 16 independent contacts.

System Programming

The novelty and efficiency of the system is in its method of programming. The system programmer employs two basic controls: a global amplitude control and a combination adjustment control. The combination adjustment control specifies the distribution of anodic and cathodic current to all contacts in the system. The global amplitude control specifies the total amount of cathodic current to be delivered to the contacts.

As an example of the programming of this system, Fig 1a shows the delivery of 2mA as a global current output to 4 contacts. The contact combination control specifies the fractional current delivered to each contact in the system; in the case of Fig 1a, a guarded cathode is implemented with the 2mA cathodic current sunk by contact 3 and 20% of the anodic current (0.4mA) sourced by contact 2 and the remaining 80% of the anodic current (1.6mA) sourced by contact 4.

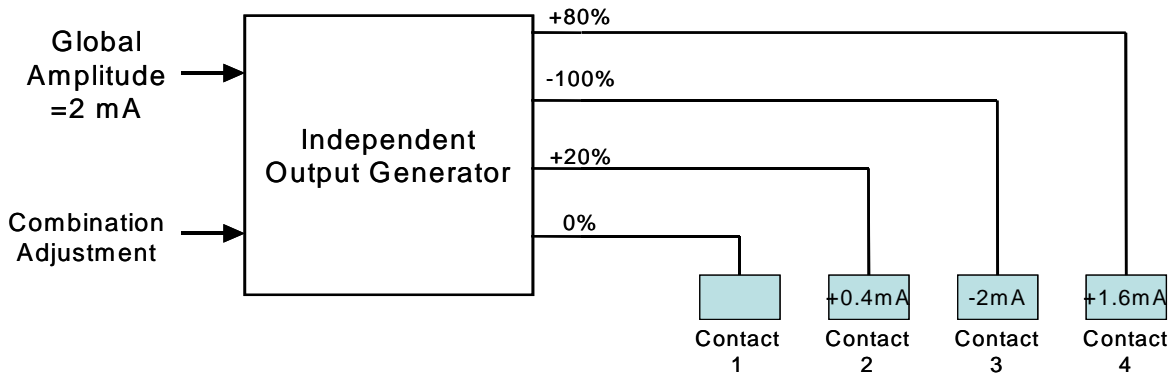


Fig 1a

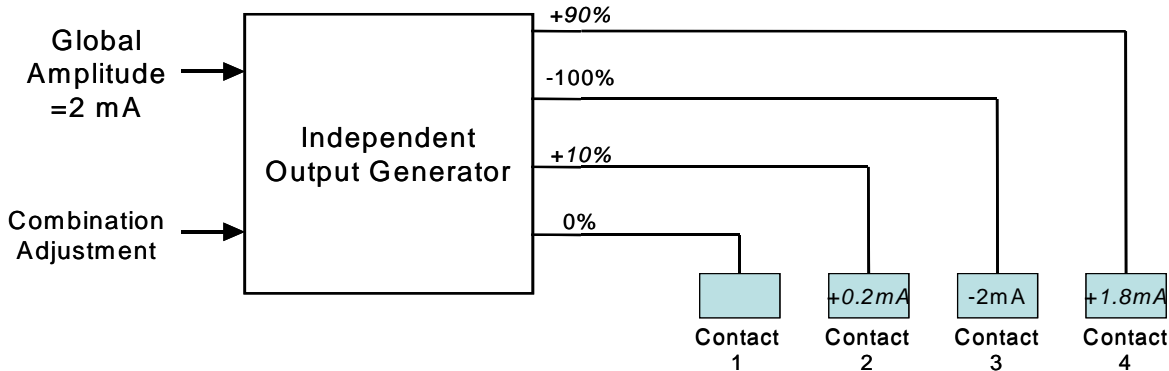


Fig 1b

Fig 1a represents a static condition of the system. If the user specifies that the tripole should shift to become more bipolar, the contact combination control is then adjusted. The next state of the system would be as shown in Fig 1b. It can be seen that the distribution of anodic current has changed to 10% (0.2mA) from contact 2 and 90% (1.8mA) from contact 4, while maintaining the constant cathodic output of 2mA from contact 3. Repeated changes of the combination adjustment control will result in a gradual shifting of the electric field along the array and the global amplitude control is used to adjust the 'intensity' of the stimulation effect. In this manner, both the position and size of the stimulation field can be modified in a continuous fashion.

Electrode Array

The ability to optimize paresthesia using the continuous configuration SCS electronics is enhanced by a closely spaced in-line electrode array. The array has eight contacts with a contact length of 3mm and an inter-contact edge-to-edge spacing of 1mm. Such inter-contact spacing allows for a smoother combination adjustment along the array, due to the likelihood that neural thresholds for closely-spaced contacts will be more similar than for contacts more widely spaced apart. Also, the greater density of contacts on the array should allow for increased likelihood of having a contact that can act as a cathode nearest to the desired neural target.

Clinical Study

This system has been employed in SCS to optimize paresthesia coverage over painful areas. In patients undergoing implantation of commercially available trial SCS electrodes, the system was tested on the closely-spaced-contact electrode array. Patients were consented prior to surgery using a consent form approved by the enrolled center's IRB of record. The patients were positioned prone on the operating table and mild sedation and local anesthesia were used to prevent surgical pain but to allow the patient to provide feedback about the paresthesia location during electrical stimulation. After a surgical incision over the spinous processes, a 14 Ga needle was inserted through the ligamentum flavum to access the epidural space, a few vertebral segments caudal to the final placement of the electrode. The closely-spaced-contact array was placed in the epidural space by the physician under fluoroscopic guidance. Once the physician was satisfied with the electrode position, the array was connected via a cable to the system outside the sterile field. An initial contact combination was programmed into the system and the global amplitude control was then increased until the patient reported feeling a comfortable paresthesia. The patient was then informed that the paresthesia would be 'moving around on their body' and was asked to report: (1) on the comfort of the intensity of the paresthesia and (2) when the paresthesia covered their painful area. The contact combination control was then continually adjusted to move the cathodic field down the array. The global amplitude control was adjusted up or down as directed by the patient's reported comfort with the paresthesia. Fig 2 shows a typical variation in the global amplitude control, as well as the current delivered from the various contacts during the adjustment of the contact combination as the electric field was moved down the array (superimposed as a cartoon on the plot).

A total of 14 patients have undergone testing with the system. All patients reported smooth shifting of the paresthesia to different dermatomes on the body as the contact combination was adjusted. Paresthesia would grow weaker or stronger depending upon the specific contact combination and the underlying neural anatomy, but patient feedback on intensity allowed for the stimulation sensation to be adjusted continuously by the operator. The intraoperative time to evaluate 71 contact combinations on a single electrode was 5.5 ± 2.6 minutes.

Results / Discussion

The system was successful in providing continuous adjustment of contact combinations while maintaining a smooth and comfortable shifting of paresthesia. The programming was efficient in terms of time: in 5 minutes, 71 contact combinations could be assessed. This compares quite favorably to recent reports of other systems which automate the SCS fitting process, in which approximately 50 contact combinations on a quadripolar array were assessed in a mean time of 67.3 ± 18.5 minutes [3]. In addition to being rapid and comfortable, a more comprehensive mapping of the 'stimulatable space' in the region of the electrode could be performed. Anecdotally, the participating physicians remarked that listening to the patient report on the location of the paresthesia assisted them in determining whether or not the electrode array position should be moved within the spinal column. The rapid adjustment of contact combinations for the entire array coupled with the patient's feedback as to the location of the paresthesia allows for multiple array locations to be attempted and mapped, thus optimizing the final location of the electrode array.

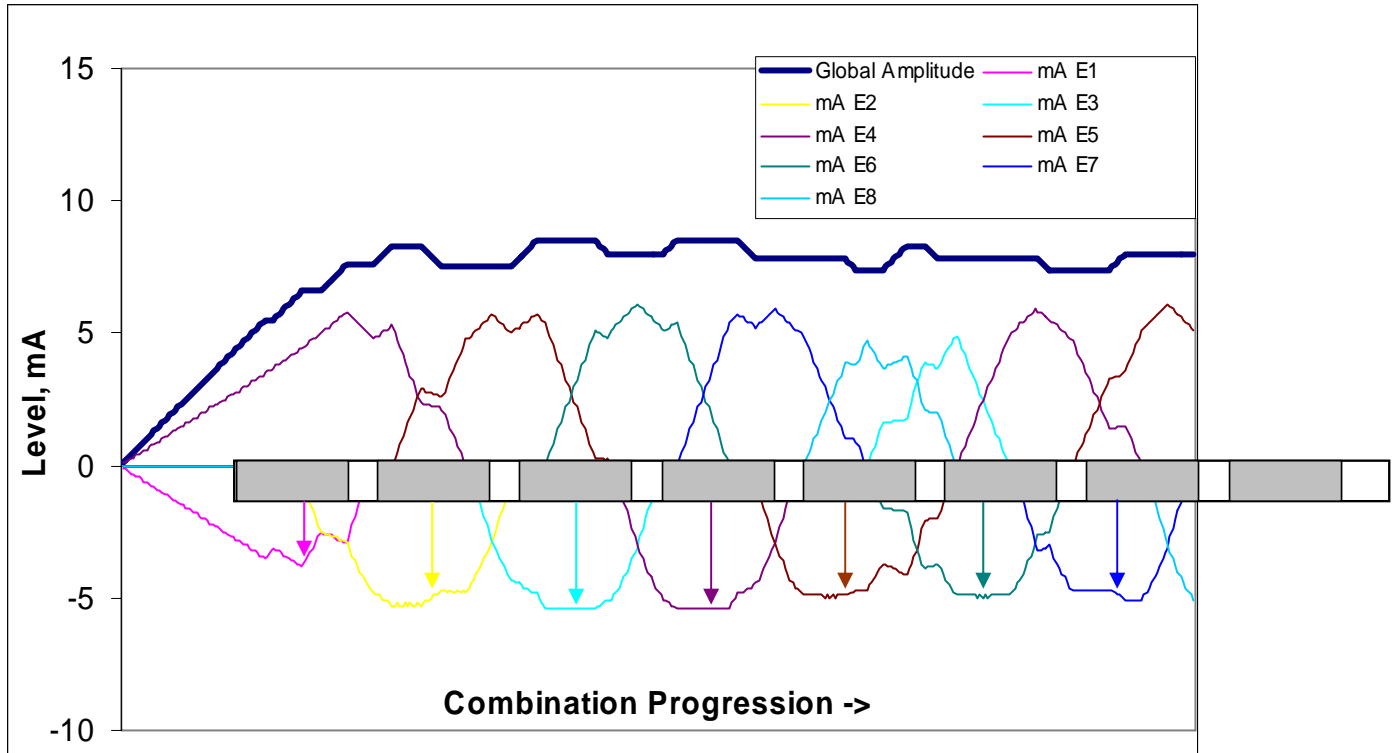


Fig 2 Variation in Global Amplitude and Individual Contact Current during Continuous Combination Adjustment in Patient 1

References

- [1] North RB et al., Spinal Cord Stimulation for Chronic, Intractable Pain: Superiority of “Multi-Channel” Devices. *Pain*, 1991. 44: p. 119-130.
- [2] Barolat G and Sharan AD, Future Trends in Spinal Cord Stimulation. *Neurological Research*, 2000. 22(3): p. 279-284.
- [3] North RB et al. Automated, Patient-Interactive, Spinal Cord Stimulator Adjustment: A Randomized Controlled Trial. *Neurosurgery*, 2003. 52(3): p. 572-580