CHOICE OF NERVE ROUTES FOR MULTICHANNEL LEG CONTROLLER IMPLANT

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ABSTRACT

Intraneural tripolar sacral nerve rout electrodes have proved to be a safe reliable method of nerve stimulation for bladder control in paraplegia. By analogy, it is suggested that a 12-channel implant using electrode mounts of a similar but expanded design giving individual control of stimulation of L2-S2 roots, right and left, may offer several significant advantages over the various existing methods of lower limb control involving stimulation of peripheral nerve trunks or motor points.

INTRODUCTION

Practical artificial control of lower limb muscles for standing and walking in paraplegia requires patterned electrical stimulation of motor axons at some site between the anterior horn cell and the motor end plate. One difficulty has been to devise an adequate, reliable, simple-to-use system which minimises excessive muscle fatigue. Various techniques have been explored in recent years, both in experimental animals and in patients. Those most used include: Transcutaneous stimulation using skin surface electrodes; Percutaneous wires placed neat to the motor points of the desired muscles; Nerve-trap or nerve cuff electrodes implanted at open surgery; Muscle surface (epimysial) electrodes placed on or attached to the muscle at open surgery; Electrodes placed surgically using cannulas or endoscope; or variants upon these themes.

MRC LOWER LIMB CONTROLLERS

In the MRC Neurological Prostheses Unit, London, England, we have used a combination of 'nerve trap' [1] and 'trocar' electrodes, connected by implanted cables to an array of implanted 'radio' receivers or to an implanted multiplexer [2]. The 'nerve trap' electrodes consist of a silastic cuff containing one or more electrodes, and are used for those situations where the nerve can be dissected without difficulty +(for example femoral or common peroneal nerves). 'Trocar' electrodes are mounted on the end of a flexible cable, and are introduced using a cannula in the from of an insulated trocar. These electrodes are used for nerves which cannot be easily dissected such as superior and inferior gluteal nerves.

In ther lower limb, both of these arrangements have proved somewhat unreliable in service, with too many displaced, broken and poorly-functioning electrodes. Other designs of electrode have seemed to be similarly liable to displacement and fracture, particularly in the lower limb [3]. Because an adequate lower limb controller has many electrodes, a mean time between failure (mtbf) of (say) 2 years for individual electrodes may mean that the system as a whole requires repair every few months, and this would clearly not be acceptable in service.

LUMBOSACRAL NERVE ROOT STIMULATION

Many years ago, G.S.Brindley [4] explored the possibility of making long-term connections to many spinal roots for the purpose of electrical stimulation for useful leg movements. He used intradural electrode arrays ('books') to trap up to 12 roots at a time. However, there seemed to be several disadvantages to the method. Whole roots gave rather complex movements, while splitting motor roots reduced their viability. At the time, it was not known whether intradural book electrodes would be harmless or durable in man [5]. The development was therefore not pursued beyond the stage of animal experiment. However, the method was subsequently developed [6] for intradural sacral anterior root stimulator implants (SARSI), now used for control of bladder, bowel and erection in paraplegia [7]. There are now over 300 patients with these implants of MRC design, and we know that the electrode mounts are safe and reliable. It therefore seems worth for leg control in paraplegia, and reviewing the expected advantages and disadvantages in peripheral nerve and nerve root electrodes.

Advantages of peripheral nerve

1. One can dissect nerve branches to single muscles, giving easily-analysed movements;
2. Peripheral nerves are relatively tough structures, compared wit roots;
3. No laminectomy required.

Disadvantages of peripheral nerve

1. Multi-channel implants using cuff electrodes require extensive surgery and hence many scars;
2. Trocar electrodes often become displaced and cease to work;
3. Percutaneous, epimysial or trocar electrodes are all effectively monopolar. This limits the control of recruitment (v inf);
4. Percutaneous and trocar electrodes are placed by trial stimulation. This procedure may leave them near a branch or twig, so that only part of the muscle is activated;
5. Electrode and cable breakages have been common, particularly in gluteal electrodes;

6. Extensive surgical incisions may be associated with an increased probability of implant infection [8];
7. Some movements (e.g. hip flexion) are difficult to obtain because the nerves are inaccessible.

Advantages of intradural nerve root stimulation using book electrodes

1. Reliability of this arrangement is now well established from SARSI;
2. All electrodes have similar impedance Z, and threshold and maximal voltage for stimulation (V_{thr} and V_{max});
3. Books may be used as tripoles, enabling anodal block (or possibly high frequency Wedensky block) if necessary;
4. Conus-level deafferentation can be done at the same time, so as to abolish spasticity or spasms is necessary [5].

Disadvantages of nerve root stimulation

1. Movements are mixed - limited degrees of freedom available;
2. Root damage will be fairly common if the roots have to split in order to increase the degrees of freedom;
3. Requires a lumbar laminectomy.

IMPLANT FAILURES

Among these theoretical advantages and disadvantages, the comparisons which we can make from our own experience are those of failure rate and implant infection. Table 1 details our experience of lower limb implant failures. For our lower-limb multichannel implants, mtbf is about 11 months. For individual (3-channel) SARSI, current mtbf is about 13 years. No SARSI failures have occurred in the electrode, but in two cases of failure (out of 300 implants) the cable failure has been so close to the electrical mount as to prevent the repair. Of 23 faults (occurring in 300 implant-years) recently analysed in a long-term SARSI follow-up series [9], six were receiver faults, twelve connector faults and five cable faults. The striking contrast is the absence of failures of intradural electrode arrays. in comparison with 37 peripheral electrode failure in 6 patients.

IMPLANT INFECTION

In a recent survey [8] we found that 3/144 SARSI patients had an implant removed on account of infection. No more implant infections have occurred to date, in 300 patients. In one of our 6 patients with a multichannel lower limb implant, infection followed each of three separate attempts at implantation, separated by intervals of years. In another patient, infection followed an attempted repair (Table 1).

Patient Number	Implant in	Implant out	Number of electrodes	Number of faults	Implant-years
1	Jun 77	/	6,7#	6	12.5
2	Jun 77	/	6	0	12
3	May 81	Sep 81	8	0*	0.4
3	Jun 84	Jul 84	8	1*	0.1
3	Jun 88	Jul 88	24	2*	0.1
4	Dec 80	Jun 82	6#	11	1.5
5	Sep 83	Apr 87	12#	12	2.6
6	Apr 85	Oct 88	14	5 +*	3.5
Totals			84	37	32.7

Table 1. Faults and infections in multichannel lower limb stimulator implants.

* = implant removed because it was infected

= several electrodes were replaced during the life time of the implant

+ = number of faults when last tested. Although found to be infected in Oct 88, the implant was not removed for another 8 months.

ROOT DAMAGES AND DEGREES OF FREEDOM

In SARSI patients, postoperative root damage is evidenced by loss of responses seen at the time of surgery. The time-course of degeneration after operative root damage means that such loss occurs 2-5 days after surgery. Recovery may occur over a few weeks or require 6 - 12 months. The latter course is the more common. Root damage is not uncommon after SARSI, and is often associated with the splitting of roots into anterior and posterior components, so that the posterior root can be cut and the anterior preserved. To minimise the likelihood of damage, roots should therefore probably be unsplit, wand this highlights a major question concerning the use of roots for lower limb FES, which is the limited degree of freedom. Are the essential degrees of freedom likely to be attainable without splitting roots? We need to review what roots will give what combinations of movements, what combinations of movements are needed for useful paraplegic standing and walking, and what combinations (if any) are forbidden.

ROOT VALUES OF MUSCLES OF THE LOWER LIMB

Table 2 (published lumbosacral root values) gives the innervations, according to three authorities [10,11,12]. There are some differences between these accounts, principally in the extent of innervation of iliopsoas. None does more than hint at the variability and degrees of pre- and post-fixation. Our own observations of S_2 and S_3 during SARSI operations add a little to this, particularly for glutei, biceps femoris gastrocnemius/soleus, and toe flexors (Table 3).

Muscle group	MRC 'Aids'[12]	Gray [10]	Brain [11]
Psoas	L1,2,(3)	L2,3(4)	L1-5
Iliacus	L1,2,(3)	L(2),3	L1-5
Quadriceps femoris	L(2),3,4	L(2),3	L2-4
Adductors	L2,3,(4)	L2,3,(4)	L2-4
Sup.glut.maximus	L4,5,(S1)	L4,5,(S1)	L4-S1
Gluteus maximus	L5,S1,(2)	L5-S2	L5-S2
Med Hamstrings	(L5),S1,(2)	L(4),5,S1	L4-S1
Biceps femoris	L(5),S1,(2)	L5-S3	L5-S2
Soleus	S1,2	L5,S1,2	L5-S2
Gastrocnemius	S1,2	S1,2	L5-S2
Tibialis posterior	L4,5	L4,(5)	L5,S1
Toe flexors	L(5),S1,(2)	L5-S2	L5-S2
Small mm foot	S1,2,(3)	L5-S2	L5-S2
Tibialis anterior	L4,(5)	L4,5	L4,5
Toe extensors	L5,S(1)	L5,S1	L4-S1
Peroneus	L5,S1	L5,S1	L5,S1

Table 2. Root innervation of leg muscles. The first column are our already published results [12], and other two from Gray [10] and Brain [11].

Muscle	S2	S3	S4
Gluteus maximus	10	0	0
Biceps femoris	9	3	0
Gastrocnemius/soleus	10	2	0
Toe flexors	8	10	0

Table 3. Lower limb muscles innervated by sacral roots S2-4 in 11 patients, from the first SARSI series of 11 patients [16]. One patient was omitted because hid roots were asymmetrical and anomalous.

GAIT MOVEMENT SYNTHESIS

We can derive from Tables 2 and 3 the likely root values of the major movements of the leg (Table 4). The next question is whether a pattern of root stimulation can be found which adequately mimics the norma l gait sequence. We now need to know the sequence of torques and angles required for the basic components of a synthetic dynamic gait. Figure 1 is derived from the results for torques and angles at hip, knee and ankle obtained by Pedotti [13]. He recorded EMG from the more accessible muscles of the lower limb (not including hip flexors), and recorded hip, knee and ankle angle and floor loading during normal gait. This allowed derivation of hip, knee and ankle torques in the sagittal plane. The angle and torque sequences of Figure 1 are

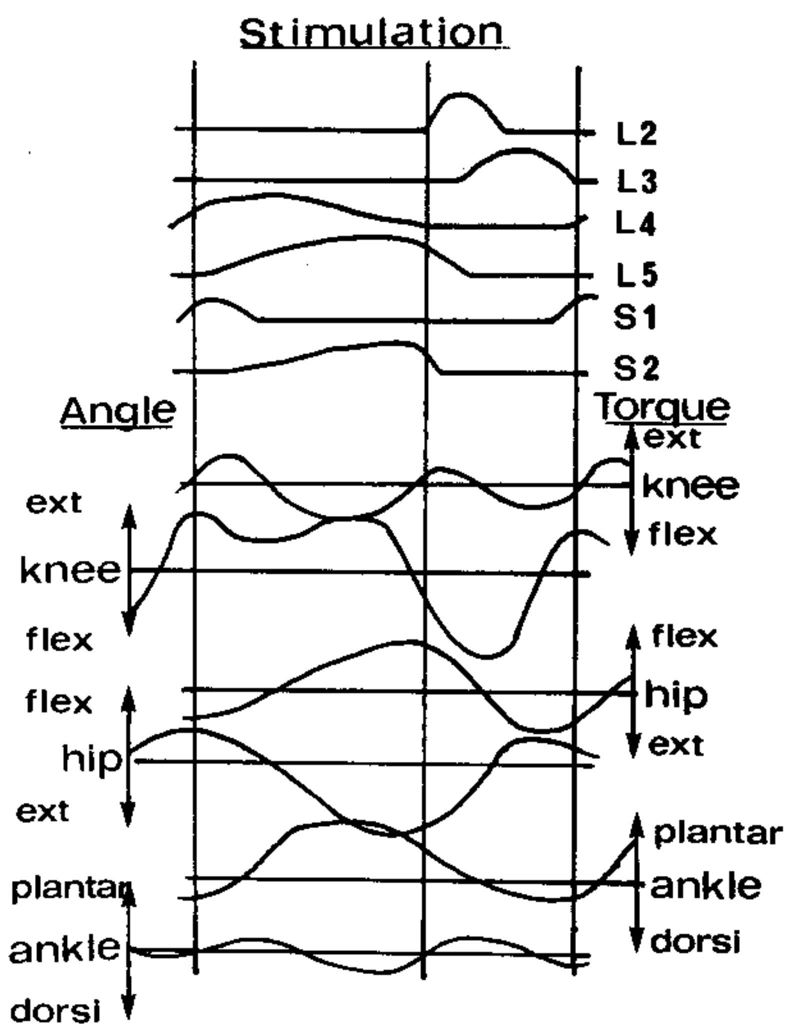

Figure 1.

obtained by averaging by eye the results for his three normal subjects. We can use these diagrams to build a sequence of torques, attempting to use single-joint and double-joint muscles appropriately, and using synergists which have the same root value as much as possible (Table 5). It appears that through the gait-cycle from toe-off to toe-off the sequence of activation of ipsilateral roots is L2-L3-L4-L5-S1-S2-L2- ..(with some overlap), as indicated in the notional pattern of stimulation sketched in the upper part of figure 1.

Movement	Root value
Hip flexion	L2,3
Hip Adduction	L2,3
Hip abduction L(4),5,S1	
Hip extension	L5,S1,(2)
Knee extension	L3,4
Knee flexion	S1
Foot dorsiflexion	L4,5
Plantar flexion	S1,2

Table 4. Likely usual major movements from motor root stimulation (derived from Tables 2 and 3)

PROBLEMS

Questions remaining to be resolved include the following:

1. One obvious exception to this general pattern is the need for weak dorsiflexion (L5) from toe-off until late swing. Just sufficient dorsiflexion to prevent foot-drop is needed during swing, while at heel strike strong dorsiflexion is required, in order to let the foot down to plantargrade in a springy way. However, L5 is otherwise inappropriate during the swing phase, because is causes hip extension and abduction. It becomes appropriate just at heel-strike, when hip abduction is called for as well as strong dorsiflexion. So it may be necessary to arrange for weak toe-raising during swing to be achieved with a spring, calliper or peroneal stimulator.
2. The lower extent of the innervation of iliopsoas. Strong hip flexion from L5 would be a sever embarrassment during the stance phase of gait, but weak hip flexion would not matter much. Only Brain [11] predicts any hip flexion from L5.
3. Will it be necessary to cut obturator nerves? Pedotti's data do not cover coronal forces, but it seems likely that strong adduction during the swing phase would be a problem, leading to scissoring. However, simple self-observation shows that adductors are activated simultaneously with hip flexion at toe-off, so some adductor action in this phase is clearly

Toe-off L2

Hip flexion
(weak dorsiflexion-see text)

To take the foot of the ground and swing the leg forward

Mid swing L3

Hip flexion, knee extension
(weak dorsiflexion-see text)

To complete the forward motion of the foot, extend the knee and use the knee torque to arrest the hip flexion

Just before heel-strike L4;5

Hip extension - to complete the halting of hip flexion, and bring heel towards ground
Knee extension - so that knee does not collapse on heel strike
Ankle dorsiflexion - strong, so as to let the foot down gently to plantargrade
Knee flexion - knee must not be locked

Just after heel-strike L4;5

Hip abduction - to enable weight-bearing
Knee extension - to ensure weight-bearing

Mid-stance L5;S1

Hip abd/ext - weight-bearing and forward motion of the trunk
Plantarflexion - to transfer weight to front of foot
This transfer makes continued knee extension unnecessary, so ramp down L4 while ramping up S1

Late stance S1;2

Ramp down glutei to transfer weight to other leg
Plantarflexion maintained or increased for push-off

Toe off L2

(Cycle is repeated)

Table 5. Sequence of root stimuli for gait simulation

appropriate, and nerve section may be unnecessary. In any case, the nerves to obturator internus and gemelli, which help to stabilise and protect the hip joint, should be left. One might use botulinum toxin instead of nerve section, in order to reduce adductor power reversibly if necessary.

4. The intradural L2 root may not always be long enough below the conus medullaris to be easily trapped. It will require a special design of trap in patients with a low conus, if it proves to be essential to trap it.
5. Avoidance of fatigue. Electrical stimulation using trains of short pulses activates large fibres preferentially; and large motor nerve fibres in general serve large-force but fatiguable motor units. This 'revers recruitment' is contrary to the physiological order of recruitment. So a smooth recruitment of force by small increments is difficult, tremor is prominent unless the stimulation frequency is high, and fatigue occurs rapidly, particularly if high frequency stimulation is used. In natural activation of muscle, small force, fatigue-resistant units with a low twitch velocity and low fusion frequency are recruited first ('orderly recruitment'). Methods which have been proposed for achieving electrically-controlled orderly recruitment include partial anodal block [14] and Wedensky inhibition [15]. Both of these methods require the use of tripolar electrodes with good control of current distribution longitudinally in the nerve, which in practice means the use of a nerve cuff or trap. This cannot be achieved using intramuscular or epimysial electrodes, but can, in principle, with peripheral cuff or trap electrodes. In patients with sacral anterior root electrodes it was easy to demonstrate [16] recruitment of small myelinated (detrusor) fibres before large myelinated (sphincter) fibres in the same root using an anodal block technique, but it Was hard to get the technique to work well enough to obtain maximal activation of detrusor with no sphincter activity at all, in day-to-day use with the simple amplitude-modulated position-sensitive sacral anterior root stimulator implant system. It is perfectly satisfactory and much simpler to void the using the burst-and-gap technique. However in limb stimulation situation is different; even imperfect orderly recruitment will be better than none.

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