A Review of Portable FES-Based Neural Orthoses for the Correction of Drop Foot

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***Abstract*—This paper reviews the technological developments in neural orthoses for the correction of upper motor neurone drop foot since 1961, when the technique was first proposed by Liberson and his co-workers. Drop foot stimulator (DFS) developments are reviewed starting with hard-wired single-channel and multichannel surface functional electrical stimulation (FES) systems, followed by implanted drop foot stimulators, and then continuing with microprocessor-based surface and implanted drop foot stimulators. The review examines the role of artificial and "natural" sensors as replacements for the foot-switch as the primary control sensor in drop foot stimulators. DFS systems incorporating real-time control of FES and completely implanted DFS systems finish the review.**

***Index Terms*—Drop foot stimulator (DFS), functional electrical stimulation (FES), gait correction, neural orthosis, peroneal stimulator.**

I. Introduction

An upper motor neurone lesion (UMNL) can result primarily from five pathologies:

- Stroke (CVA);
- Spinal cord injury (SCI);
- Multiple sclerosis (MS);
- Cerebral palsy (CP);
- Head injury.

Of these five conditions, stroke and head-injuries are by far the more prevalent problems with reported prevalence of 12 000/million for stroke and 20 000/million for head injuries as opposed to 800/million for SCI, 2000/million for MS, and 3000/million for CP [10]. The presence of an UMNL almost invariably results in a pattern of motor dysfunction and typically associated with this dysfunction is spasticity.

Subjects with an UMNL with spasticity develop seven types of functional deficit in different combinations and to varying degrees [41].

1) An overreaction to stretch or spasticity, which obstructs the yielding quality of eccentric muscle action during stance. For instance, calf muscle spasticity sometimes leads to persistent ankle plantarflexion.
2) Selective control is impaired, which prevents the subject from controlling the timing and intensity of muscle action. This deficit is displayed as weakness, however, the reflexes are intact.
3) Primitive locomotor patterns emerge due to the absence of inhibition and become alternative sources of voluntary control.
4) Muscles lose their normal patterns of modulation.
5) Proprioception may be altered.
6) Muscular control is altered by limb position and body alignment.
7) Changes occur in the mechanical properties of muscle due to loss of contractile tissue and an increase in connective tissue.

Each subject suffering from an upper motor neurone lesion-related paralysis has a unique mixture of these deficits. For instance, with stroke subjects, typically the muscles of extension of the leg, the calf and the quadriceps, are spastic and the muscles of flexion, the anterior tibials and the hamstrings are weak or inactive. An important feature of UMNLs is that electrical excitability of the associated peripheral nerves is still intact, thus facilitating the use of functional electrical stimulation (FES) to restore or enhance gait for some of these cases. For ease of use and reliability, take-home FES-based neural orthoses, typically, have one or two channels of stimulation. For UMNL-related motor dysfunction to be correctable using portable FES-based neural orthoses, suitable for take-home use, sufficient muscle function must remain to enable the subject to stand and walk, even though the walking gait is significantly disturbed. The UMNL pathology most satisfying this criterion, is stroke, however some subjects with partial-SCI, MS, or CP are also suitable.

Quite often persons who suffer a stroke recover a large amount of function by the natural neurologic recovery that occurs in the months immediately following stroke or following a period of physiotherapy, but a persistent, long-term disability in approximately 10 to 20% of stroke survivors is *Upper Motor Neurone-Drop Foot* (UMN-DF) [7], [12], [28]. UMN-DF typically involves an inability to dorsiflex the foot during the swing phase of gait (drop foot), loss of normal knee flexion, inability to "push-off," and spasticity of the calf muscle group.

In 1961, Liberson *et al.* [29] proposed application of electrical stimulation (ES) to the common peroneal nerve to correct this condition and using a foot-switch synchronized the application of ES to the swing phase of gait, using a device subsequently referred to as a peroneal stimulator (PS) or drop foot stimulator

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(DFS). This paper will present a chronological review of the literature relating to the development of DFS systems from the initial design of Liberson in 1961 to current developments. The focus of the review will be on the technical innovation present in the design of DFS systems.

The development of FES-based drop foot correction has gone through the following evolutionary stages:

- hard-wired single-channel surface DFS;
- hard-wired multichannel surface DFS;
- hard-wired single-channel implanted DFS;
- mcroprocessor-based surface and implanted DFS;
- artificial and "natural" sensors as replacement for the foot-switch;
- DFS systems incorporating real-time control of FES;
- completely implanted DFS systems.

The literature describing the development of the technology of FES-based DFS systems will be reviewed by following these evolutionary stages. During the 40-yr period covered by the review (1961–2001), some DFS systems, developed by companies, have had no reference made to their design, operation or application in the scientific, medical or engineering literature. These developments fall outside the terms of this review and will not be covered.

II. Hard-Wired Single-Channel Surface DFS

As discussed, the first reported use of electrical stimulation for hemiplegic drop foot correction was in 1961 by Liberson [29]. In this seminal paper, Liberson proposed the use electrotherapy to elicit dorsiflexion in a hemiplegic foot and synchronized the application of electrotherapy with the swing phase of gait. Prior to the Liberson paper, electrotherapy was only used "statically" for therapeutic purposes, such as muscle repair following injury. Liberson proposed the use of electrotherapy for orthotic purposes. Liberson's solution, shown in Fig. 1 was simple but elegant. A heel-switch K, when open, during swing, open-circuits the shunt resistor R, and enables the delivery of stimulus current across the stimulation electrodes, E1 and E2. The switch when closed, during stance, connects the shunt resistor across the output of the stimulator and no stimulus is delivered to the stimulation electrodes. The delivery of stimulus to the electrodes (positioned for stimulation of the common peroneal nerve) occurred when the heel-switch opens at heel-off and is terminated when the switch closes at heel-strike. The application of stimulus is thus synchronized with the swing phase of gait. This device was an example of a hard-wired stimulator, where the functionality of the stimulator is determined by the wiring of the electronic circuitry.

The system performed the essential task of eliciting dorsiflexion in the subject's hemiplegic foot at the appropriate point in the gait cycle. Clearly, however, the functionality of the system lacked sophistication and delivered stimuli in a crude fashion compared to the natural performance of the foot-lifter neuromuscular system.

Liberson referred to his use of electrotherapy as Functional Electrotherapy, as the purpose of the therapy was to replace or assist a functional movement that was lost after injury to or diseases of the central nervous system. Shortly after Liberson's

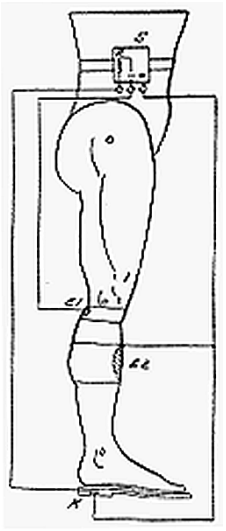


Fig. 1. Liberson's DFS arrangement. (Liberson *et al.* 1961, reproduced with permission.)

publication, Moe and Post [38] coined a new term for Functional Electrotherapy, namely FES, the term still used today to describe the technique.

Following Liberson's paper, several researchers produced similar systems. Moe and Post [38] described the use of a commercial drop foot stimulator whose housing had a curved design to facilitate its use as a belt-worn device and, as discussed, proposed the use of the term FES to describe the technique. In a very comprehensive and thought-provoking paper, Vodovnik, Dimitrijevic, Prevec, and Logar [59] from the University of Ljubljana identified as a possible problem, the production of a reflex spasm provoked by electrical stimulation or stretching of the muscles. Vodovnik described a DFS system, which purported to solve this problem by passing the stimulus activation signal through a low-pass filter to enable a slow onset and a slow break of the stimulation current. The system described by Vodovnik was referred to as the functional peroneal splint (FPS). Vodovnik also evaluated the influence of stimulation parameters on stimulation pain and after completing a series of tests, proposed a pulse duration of 300μs and a pulse frequency range of 30–60 Hz as the most comfortable range of stimulation parameters. These findings on comfort have, since been replicated by several researchers [4], [37], [15]. The FPS also incorporated the following innovative features:

- use of both manual triggering (via a hand-switch) and foot triggering using the conventional foot-switch;
- use of an EMG sensor rather than a foot-switch to trigger stimulation. They evaluated different muscles of the hand and leg as locations for the EMG sensor but encountered crosstalk problems with the EMG electrodes.

Vodovnik proposed the use of implanted stimulation electrodes to eliminate the difficulties associated with the placement of surface electrodes. This was an important suggestion by Vodovnik, as implanted stimulation is now receiving widespread attention as a possible orthotic solution for UMN-drop foot subjects who were expected to use a DFS device over a long period and for subjects where hypersensitivity to surface stimulation would prevent the use of a surface DFS system.

The work of Vodovnik and his co-workers at Ljubljana led to development of a series of commercial hard-wired single channel DFS devices at Ljubljana, namely, the PO-8 [14] and the FEPA and the MICROFES [1]. The PO-8 device was approved for use by the U.S. Board for Food and Medicines (the forerunner of today's FDA) and featured an elastic knee support with built-in electrodes. The Functional Electronic Peroneal Apparatus (FEPA)-10 featured a large intensity control knob, which could be easily manipulated by hemiparetic subjects. The MICROFES was an under-knee single-channel hard-wired stimulator developed in the late 1970s. This device used CMOS circuitry to reduce power consumption and featured a 1.5 V battery, rather than the 9 V battery in the FEPA device [1]. The device was significantly lighter than the FEPA-10 (65 g versus 190 g) [48].

In 1975, Takebe, Kukulka, Narayan, Milner, and Basmajian [54] tested a commercial drop foot stimulator manufactured by Philips. The main difference from Liberson's design was the use of an air-filled insole foot-switch. The insole was connected to the stimulator using a rubber tube, which conducted the increases in air-pressure, occurring at heel-strike, to the stimulator. Takebe *et al.* carried out a series of measurements on the subjects to assess the therapeutic benefits of FES-based UMN-DF correction, such as ankle range-of-motion, EMG activity of the Tibialis Anterior muscle and ankle torque and observed some therapeutic benefits. Takebe found that a significant number of subjects (6 out of 9) rejected the stimulator. It is worth noting that user comfort was a very important consideration affecting the acceptance or rejection of the DFS and was the reason four of the six subjects rejected the stimulator. A further subject rejected the stimulator due to the annoyance of having to correctly place stimulation electrodes each morning. The remaining subject rejected it due to problems encountered with using stairs.

Several researchers, in the following decades, suggested refinements to the basic single channel hard-wired DFS systems. Pedersen, Petersen, Hansen and Klemar, from Arhus in Denmark, [40] described the clinical evaluation of a single channel DFS (KDC 2000) device. The DFS used what was described as a heel wedge with built-in contacts to trigger application of stimulation. Pedersen *et al.* presented data on the experience of 46 patients treated with the DFS and reported that after 1 yr, the majority of patients reported that the DFS had become an integral part of their lives and that the stimulator activated dorsiflexion in all subjects and hip and knee flexion in 50% of the subjects. In 1997, Burridge, Taylor, Hagan, and Swain [7] described the use of a single-channel hard-wired stimulator, the ODFS (Odstock Drop Foot Stimulator), with several clinically useful features, notably

1) Stimulation of the hemiplegic leg could be controlled by a heel-switch worn on either the hemiplegic or nonhemiplegic side. When the switch was on the nonhemiplegic side, stimulation is initiated by heel strike and terminated by heel rise. When the switch was on the hemiplegic side, this was reversed, as previously discussed. The availability of these options is important in:
   - using the nonhemiplegic side for controlling stimulation is preferred when patients are unable to achieve a reliable heel-strike, usually because of either contracture or poor balance;
   - controlling stimulation from the hemiplegic side is preferable because it encourages the patient to weight-bear on that side during the stance phase.
2) The incorporation of miniature potentiometers to allow adjustment of both the rate at which stimulus was ramped up at toe-off and the rate at which stimulus was ramped down at heel-strike.

The adjustment of ramp-up time can be very important in subjects with calf muscle spasticity, as identified by Vodovnik [59]. The adjustment of the ramp-down time is used to avoid foot-flap or foot-slap, where termination of stimulation immediately on heel-strike causes the foot to fall rapidly. The ramp-down time maintains stimulation until the center of gravity is forward over the forefoot. Studies of normal muscle activation patterns during walking have shown that the Tibialis Anterior activation peaks between heel and toe strike [41].

In 1996, Granat, Maxwell, Ferguson, Lees, and Barbenel [16] used a single channel surface stimulator with the added feature of recording the length of time stimulation is delivered. This feature is useful in assessing the amount of use a subject makes of the stimulator outside the clinic.

III. Hard-Wired Multichannel Surface DFS

The first group to propose the use of multichannel FES was Kralj and his co-workers from the University of Ljubljana in Slovenia [27]. They described the use of three channels of stimulation in their portable stimulator, which incorporated a radio link between the heel-switch and the stimulator. The three stimulation channels enabled different muscle groups to be controlled independently, such as ankle dorsiflexors and knee flexors and extensors. A drawback of the system was that the clinician was required to make multiple adjustments to optimize the delay settings for each of the three stimulation channels following detection of the heel-off event.

Clearly, the positioning of multiple pairs of electrodes would be time-consuming and difficult and the presence of multiple leads around the legs may inhibit walking.

Kralj *et al.* were of the opinion that multichannel stimulation would not become routine until the size and weight of the portable unit (weight 1.2 kg) could be reduced by advances in integrated electronics. In order words, multichannel stimulation was not practical with the integrated circuit technology available at the time (1971). A weakness of this study is that Kralj did not report on the performance of the wireless heel-switch, which could have provided an insight into this novel feature.

A follow-up study by the Ljubljana group six years later in 1977, and published in 1979 [49], evaluated six-channel stimulation. This system was designed to evaluate, in a clinical setting, the appropriate sequence of muscle stimulation required for a particular subject's pathology and thus was not a home-use system. The system's six channels of stimulation provided flexion and extension for three joints.

An important innovation in the design of this stimulator, which could be applied in home-use DFS systems, was the use of two foot-switches and associated circuitry to prevent false triggering

of the stimulator. With Liberson's design, the occurrence of *heel-off* triggered stimulation, irrespective of the context. Thus, if a subject was standing and casually lifted their heel, stimulation would be applied—clearly not a very appropriate or satisfactory outcome. Strojnik used two foot-switches, a toe-switch and a heel-switch and monitored the sequence in which these switches were triggered. If the subject unloaded his heel in order to take a rest, the stimulus triggering pulse was disabled unless this lifting of the heel coincided with a push-off at the toe, as would occur during gait. Strojnik *et al.* also paid particular attention to providing a range of triggering options:

- free-running cycler;
- manual switch;
- heel-switch;
- heel/toe switch.

The analog six-channel stimulator system used a heel switch built into a shoe insole to control application of the six channels of stimulation. Two gait events were detected by the heel switch, heel-off, and heel-on, and these events could each be used to synchronize up to four stimulation channels. The onset of stimulation, triggered by either heel-off or heel-on, was set by one potentiometer and the duration of stimulation was set by another potentiometer (both potentiometers in the range 0.15 to 2 s). Stanic *et al.* [47] described the absence of a graphical presentation of the stimulation sequence set as a problem and referred to the difficulties associated with changing the stimulation sequence corresponding to another gait cadence (12 correlated readjustments of potentiometers were required). In the same paper, Stanic, as well as presenting on the evaluation of multichannel stimulation for gait correction, also described the use of both the original Ljubljana six-channel analog stimulator and a digital version of the six-channel stimulator. An important innovation in this new digital device, shown in Fig. 2 was that it allowed a walking rate dependent time course of stimulation sequences to be used. The previous stride times were measured and exponentially weighted to determine the required adjustment in the duration of the stimulation sequence for the next stride. Electronically, this was achieved using phase locked loop (PLL) regulation, where the inputs frequency to the PLL is the patient's cadence and the output frequency feeds the digital circuitry controlling the stimulation sequence [58].

Graphic presentation of the stimulation sequence was made possible using a bank of 16 switches. The complete gait cycle was represented by 16 discrete time intervals and in each of these intervals a stimulation sequence was released by the operation of a separate DIP switch. Stanic added to the capability for the detection of false triggering, initiated by Strojnik [49]. Using a single foot-switch at the heel (instead of two foot-switches used by Strojnik), digital circuitry was designed which distinguished between regular stimulation triggering occurring during gait and false triggering (occurring for example during shifting of the legs). Using a sequential circuit, all triggers outside the expected time interval (all heel-on triggers which occurred after the heel-off trigger, before 25% of the stride time has elapsed and after 75% of the stride time has elapsed) or not in the right sequence, were ignored. This approach to event detection was a precursor of more recent software-based finite state detection of the swing phase of hemiplegic gait [65].

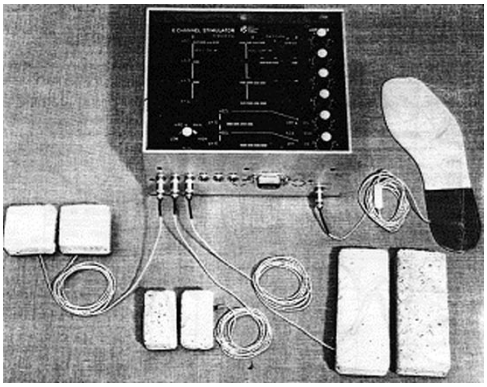


Fig. 2. The improved six-channel stimulator from the Ljubljana group. (Stanic *et al.* 1978, reproduced with permission.)

The development of this digital six-channel stimulator by the group in Ljubljana enabled multiple bursts of stimulation on a single channel to occur during a stride. This feature was considered useful in the stimulation of muscles having more than one distinct phase of activity during the gait cycle, such as the tibialis anterior, which has an activation phase at initial swing and another phase at loading response. This concept was further developed in a very comprehensive paper by Trnkoczy, Stanic, and Malezic from Ljubljana in 1978 [58]. Trnkoczy *et al.* described the development of a research multichannel stimulator composed of two units:

- a six-channel stimulator;
- a custom-designed portable digital programmer.

The programmer was composed of two parts: a keyboard unit (data entry unit), which was used to enter the desired stimulation sequences and a RAM memory unit, in which these sequences were stored. Stimulation amplitude could be set, for each channel, at eight discrete levels for each of the 16 discrete time intervals of a gait cycle. This arrangement, which was very innovative for its time, allowed for stimulation amplitude to be modulated throughout the gait cycle to match muscle activation patterns observed in healthy gait. This was referred to as "gradually modulated electrical stimulation" by Stanic, Trnkoczy, Acimovic, and Gros who evaluated this approach using the described equipment [46].

Based on Takebe's earlier finding [54], *viz.* subjects having difficulty with daily placement of electrodes, a six-channel surface stimulation system is evidently not suitable as a take-home system. It would be an impossible task for a hemiplegic subject, or their carer, to correctly place six pairs of electrodes at different muscle locations on a daily basis. A possible clinical strategy for using multichannel (>2) stimulation systems has been suggested by Malezic and co-workers [33], [34]. In a first phase of treatment, the six-channel system would be used in the clinic to enable severely disabled subjects to establish initial gait patterns and antigravity support. As the gait of these subjects improves, through treatment with the multichannel system, they might graduate to the single or dual-channel drop foot stimulators, for home use.

Another application of multichannel surface stimulation systems is to evaluate multichannel stimulation strategies prior to the use of implanted multichannel systems. However, the timing

of the stimulus patterns in these multichannel systems is problematic.

Following from the multichannel stimulation work of the Ljubljana group, Brandell [6] proposed the use of a "Universal Control Unit" to customize the triggering of six channels of stimulation from four foot-switches on each foot. Rather than using the adjustable delays incorporated into the Ljubljana systems, Brandell used a digital logic bread-boarding scheme to configure a sequence of digital logic circuitry to obtain the correct muscle activation sequence for the six muscles stimulated. The system used foot-switches at the toe, heel, and ball of the foot to trigger the digital logic. The output of the logic circuit enabled six channels of stimulation. Brandell's strategy envisaged that, having obtained a circuit configuration for a particular subject, the circuit would then be implemented, using hard-wired techniques, in a portable drop foot stimulator. A key problem with Brandell's approach to the timing of multichannel stimulation is that it would result in a fixed logic configuration, which could not adjust in real-time to changes in a subject's walking speed.

In the 1990s, a portable, compact ($25\ \text{mm} \times 68\ \text{mm} \times 150\ \text{mm}$), lightweight (200 g with battery), low-cost (<$300) two-channel drop foot stimulator was developed using hard-wired technology by the group at Salisbury District Hospital, UK [54]. The O2CHS is a very flexible 2-channel stimulator allowing a wide range of independent triggering options for the two channels of stimulation. However, setting up different stimulation options on the O2CHS is achieved using a complex combination of DIP (dual in-line package) switches and miniature potentiometer settings (10 miniature potentiometer and 10 DIP switches), that are quite cumbersome for the therapist to initially set up (Fig. 3). This system was designed as a take-home system and could be used for instance for bilateral dropped foot. The implementation of multichannel systems using hard-wired technology resulted in systems which were difficult to configure, and highlighted the need for microprocessor technology to enable a more user-friendly, programmable implementation of multichannel stimulation.

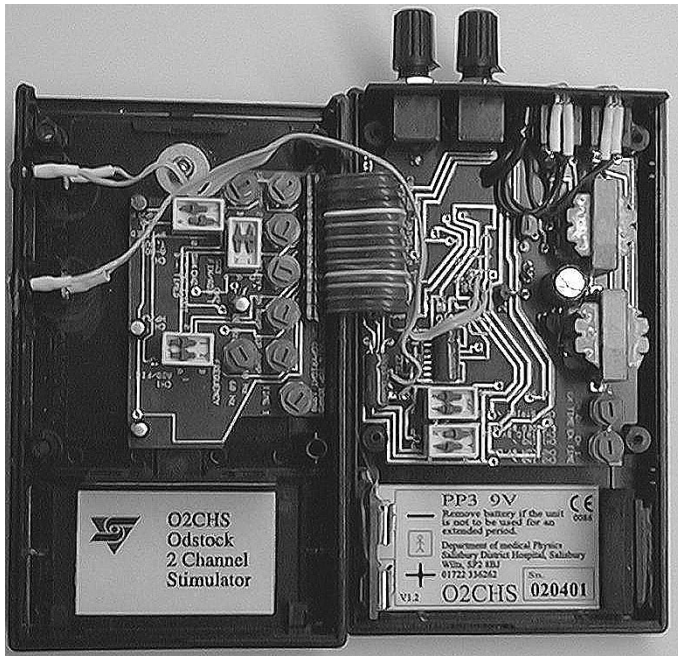


Fig. 3. Photograph of the interior of the O2CHS showing the arrangement of ten DIP switches and ten miniature potiometers used to configure the operation of the 02CHS.

IV. Hard-Wired Implanted DFS

The late 1960s saw the development of implanted electrical stimulation. In 1966 (presented in 1966, published in 1967), Jeglic, Vavken, Strnbenk, and Benedik from Ljubljana [23] described how an RF transmitter could be used to generate muscle contractions in the quadriceps muscle of a dog, using an implanted receiver and associated electrodes. A very compact receiver unit was designed and constructed (cylindrical with a length of 15 mm and a diameter of 4.4 mm). The implanted device required no batteries, electrical power was supplied to the implant by electromagnetic induction. The antenna, which transmitted an RF signal through the skin, was taped to the skin directly over the implant. Jeglic's system, while tested on animals, showed the feasibility of activating skeletal muscle using implanted stimulator technology.

In September 1969, McNeal, Wilemon, Mooney, Boggs, and Tamaki from the Ranch Los Amigos Medical Centre in Downey, CA, reported on the first application of peripheral nerve implanted electrical stimulation on motor control in stroke patients [36]. Also in September 1969, Jeglic and his co-workers [24] described the design of an implanted drop foot stimulator and the surgical procedure required for the implanted components, however no clinical data on the use of the device was presented. Jeglic, gave the rationale for using an implanted DFS (IDFS) as overcoming problems of discomfort due to stimulation pain and difficulties experienced by subjects in correctly placing the stimulation electrodes

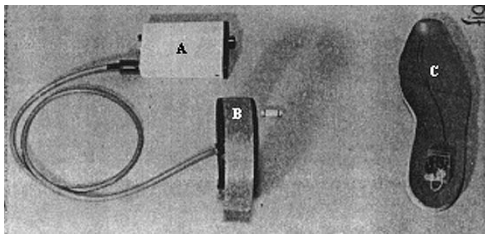
The system had three elements as shown in Fig. 4(a) and Fig. 4(b):

- control electronics incorporating an RF transmitter [Fig. 4(a):A] an inductive (transmitter) coil placed on the skin surface under the knee [Fig. 4(a):B] and a wireless foot-switch [Fig. 4(a):C];
- an implanted RF receiver unit with associated platinum bipolar electrodes [Fig. 4(b)].

In 1969, Rancho Los Amigos Medical Centre/University of Southern California collaborated with Medtronic Inc. of Minneapolis to develop a commercial implanted DFS (IDFS) [45]. The basis for this device was the same as that proposed by Jeglic [24]. *Viz*.

- Electrodes would be permanently fixed to the nerves eliminating the need for daily placement of stimulation electrodes.
- Stimulation pain would be reduced since implanted electrodes require a lower stimulation current.

A first version of the IDFS to evolve from the collaboration was ready in 1969 and was implanted in 10 subjects, the system went through two other revisions in 1970 and 1971 and subjects



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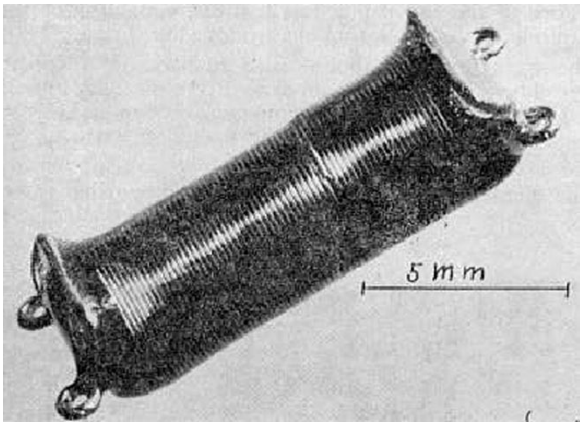


(b)

Fig. 4. (a) External elements of the implantable hemiplegic DFS. (b) Implanted element of the implantable hemiplegic DFS of Jeglic with the electrodes and receiver combined in a single unit (Jeglic *et al.* 1970).

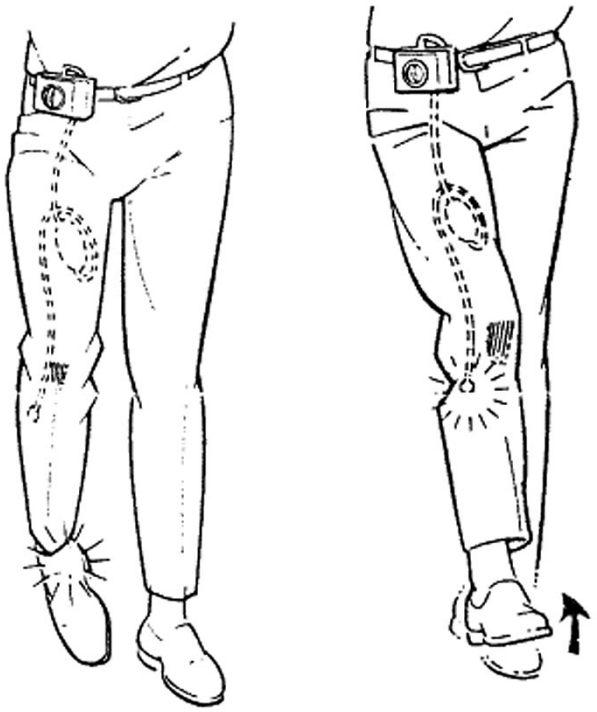
were implanted with each version of the system. During this period various modifications were made to the DFS system. The final system [61] was composed of three elements, shown in Fig. 5(a):

- an external module with a transmitting antenna and two control modules: a walking module and an exercise module;
- a wireless foot-switch transmitting to the external module;
- an implanted assembly comprising a receiver, pulse train generator, and bipolar electrode.

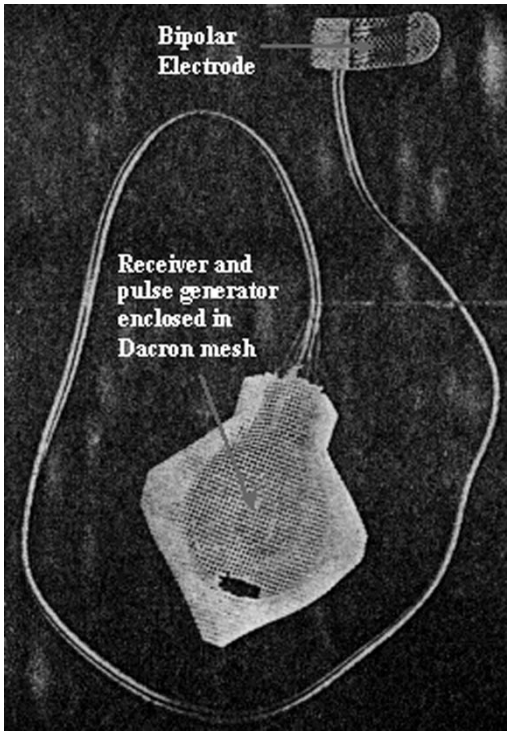
The sterilization and operating procedures required for the implant were described in detail. Two incisions were required: one on the medial aspect of the thigh to implant the receiver, another on the lateral aspect of the leg, below the knee, to expose the common peroneal nerve. A photograph of the implant assembly is shown in Fig. 5(b)

In contrast to the multichannel stimulator from Kralj [27], the external unit of this system only weighted 236 g, approximately a sixfold weight reduction compared with Kralj's stimulator.

Correct electrode placement was determined during surgery by applying stimulation. If appropriate dorsiflexion resulted, the placement was deemed correct. Otherwise adjustment was made to the placement. The system performed very well, in fifteen of the sixteen subjects who were fitted with the device, the hemiplegic foot dorsiflexed to the neutral position during swing. In 62.5% of the subjects (10 out of 16), the performance of the system was described as good. For three subjects, surgical adjustment of the positioning of the implanted electrodes was needed to correct excessive inversion or eversion. For



(a)



(b)

Fig. 5. (a) Representation of the Rancho Los Amigos implanted DFS. (b) Implanted assembly of the Rancho Los Amigos implanted peroneal stimulator (Waters *et al.* 1975, reproduced with permission).

three subjects, the system failed. One failure was the result of wound infection. Another was caused by patient rejection of the equipment, notwithstanding the fact that her gait was improved by stimulation. The third failure was due to inflammation of the nerve at the electrode site. Waters also carried out a quantitative assessment of the therapeutic and orthotic benefits of the device

by measuring: walking speed, stride length, and step frequency, before and after surgery. The therapeutic benefit, six months after surgery, was very impressive, with unassisted walking speed increasing by 29% six months after surgery. The orthotic benefit, six months after surgery, was quite good, walking speed with FES being 11% faster than walking speed without FES. This orthotic figure is very good when one considers that it is in addition to a therapeutic benefit of 29%. A follow-up study was also carried out ten years after the implant to assess the long-term performance of the implant [63]. This study found that, of the 10 subjects who had a successful clinical result following surgery:

- two subjects died within 16 months of the surgery (unrelated causes);
- one subject used the device for 36 months and then developed complete paraplegia;
- the remaining seven subjects continued to use the device successfully for an average of 11.6 yr.

The long-term success of this device was very impressive and confirmed the feasibility of using implanted systems for UMN-DF correction.

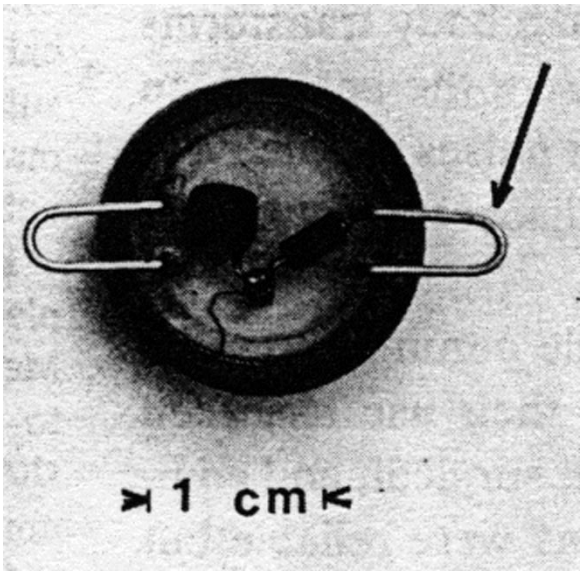
In 1987, the Ljubljana group revisited the development of a single-channel implantable drop foot stimulator [50]. Their objective was to solve what they identified as the two major problems with the existing approaches to single channel implanted drop foot stimulator design by

- developing a IDFS with improved reliability over the Jeglic implant [24];
- developing a IDFS with a simpler surgical procedure for its implantation compared to that described by Waters [61].

Strojnik [50] was of the opinion that reliability problems, and the complexity of the surgical procedures involved in fitting the implants, prevented the more widespread use of implanted DFS. The reliability of the system was improved by taking advantage of advances in biomaterial technology since the Jeglic stimulator of 1969 [24]. The simplification in the surgical procedure was obtained by significantly reducing the size and complexity of the implant [see Fig. 6(a)]. The new implant developed by Strojnik [50] was composed of a single unit, incorporating the electrodes and receiver within the same assembly.

The arrow in Fig. 6(a) shows the position of the electrodes, which could also be used as fixation loops during surgery. The compactness of the implant assembly greatly simplified the surgical procedure required to implant the device. Strojnik reported that the procedure could be completed in less than 30 min under local anesthesia. An incision was made approximately 2 cm behind the head of the fibula to expose the peroneal nerve for a length of 3 cm. One week's rest was required after the operation before stimulation was applied. This was a substantial improvement on the more complex surgical procedure required for the Waters implant [61]. The complete system is shown in Fig. 6(b), and had the commercial name IPPO.

The system was implanted in 20 subjects with very good results. Strojnik used the quality of the subject's ankle movement as a measure of the effectiveness of the system. The quality of the ankle joint movement was assessed for what was referred to as, an anomaly. This anomaly was rated on a scale of 0 to 3, with 3 corresponding to the highest level of anomaly. Strojnik found that the ankle joint anomaly changed from a severity level of 3 on all 20 subjects at presurgery to an anomaly severity level of 0 for 19 subjects and a severity level of 1 for one subject post-surgery with stimulation.



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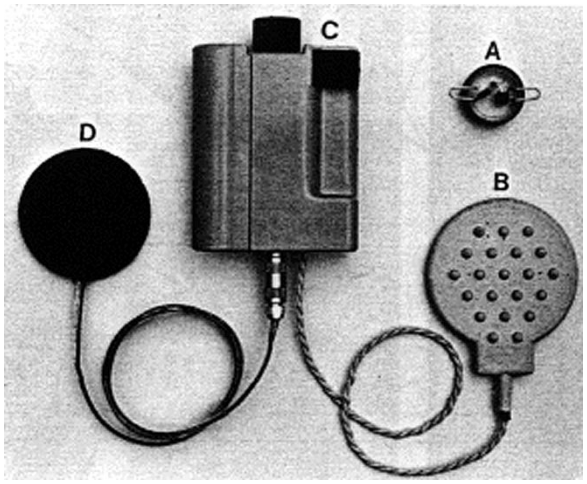


(b)

Fig. 6. (a) Closeup of implant assembly for the implantable hemiplegic drop foot stimulator of Strojnik *et al.* (b) Complete implantable hemiplegic drop foot stimulator of Strojnik *et al.* showing the implant assembly, A, the antenna, B, the external control unit, C and the foot-switch, D (Strojnik *et al.* 1987, reproduced with permission).

V. Microprocessor-Based Surfaceand Implanted DFS Systems

A. Microprocessor-Based Surface DFS Systems

The 1984 paper of Bogataj, Kljajic, Stanic, Acimovic, and Gros [2] is the first reported use of microcontroller/microprocessor technology in a DFS system. Bogataj's system was a six-channel stimulator shown in Fig. 7. Six arrays of 16 switches

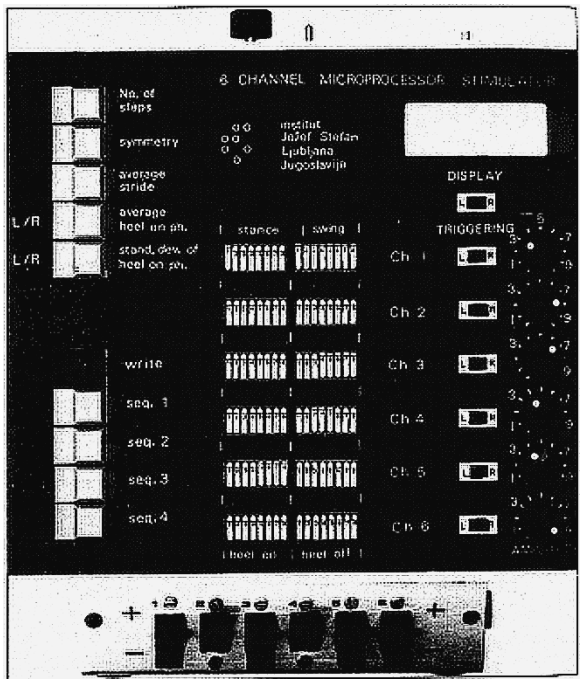


Fig. 7. Six-channel microprocessor-controlled stimulator. (Reprinted from Bogataj, Gros, Malezic, Kelih, Kljajic. Restoration of Gait During Two to Three Weeks of Therapy with Multichannel Electrical Stimulation,Physical Therapy, 1989, vol. 69, pp. 319–327, with permission of the American Physical Therapy Association.)

permit the selection of stimulation sequences for each stimulation channel, and also give a graphical indication of the selection. Switches on the right of the panel determine whether the left (L) or right (R) heel switch is used to control a particular stimulation channel.

Amplitude controls for each channel are also on the right of the panel. Measured statistical data can be displayed at the top right hand corner.

Push switches permit the storing and recall of stimulation sequences. The system included a stride analyzer, which enabled analysis of a variety of gait measurements be completed without requiring additional equipment. The parameters measured were: number of steps, mean stride time, and mean heel-on times.

This system was not suitable for take-home use, as previously discussed multichannel stimulation is only suitable for use in the clinic, thus a system like this is primarily for clinical use.

The application of microprocessor technology in surface DFS led to a very innovative DFS design by the Ljubljana group in 1992 [35]. This dual-channel device, shown in Fig. 8, had two elements:

- a programmer unit/stride analyzer;
- two-channel stimulator.

Microprocessor technology enabled the production of a device, which succeeded in combining the requirements for home use, with a stimulator meeting several of the clinician's needs regarding evaluation of the performance of the device. The system offered excellent flexibility, allowing the clinician to independently program all the stimulation parameters for each channel via the programmer unit. The only stimulus parameter adjustable by the subject was stimulus amplitude.

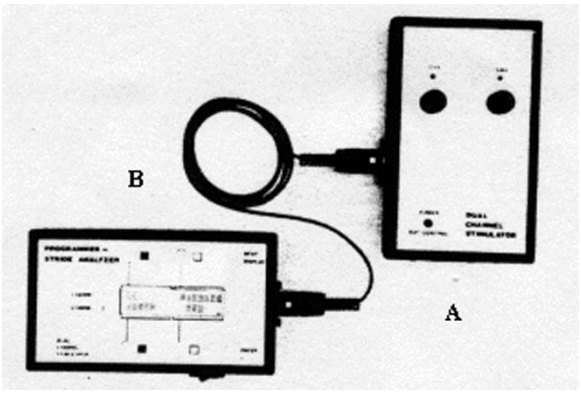


Fig. 8. Dual-channel programmable stimulator (A) with programmer/stride analyzer (B). (Malezic *et al.* 1992, reproduced with permission.)

The programmer unit also allowed the clinician to adjust the stimulation sequence settings. As with the six-channel stimulator of Strojnik [49], the duration of each stimulation sequence was adapted to the subject's cadence using a linear extrapolation of the previous four stride times, when they are equal or decreasing, and a extrapolation weighted toward the more recent ones, when the patient is slowing. Two foot-switches could be connected to the stimulator unit and if additional stimulation channels were required a cascade arrangement of the stimulators was possible.

In a feature that is particularly useful for the clinical evaluation of the stimulator, it can also gather and partly process the following parameters of gait:

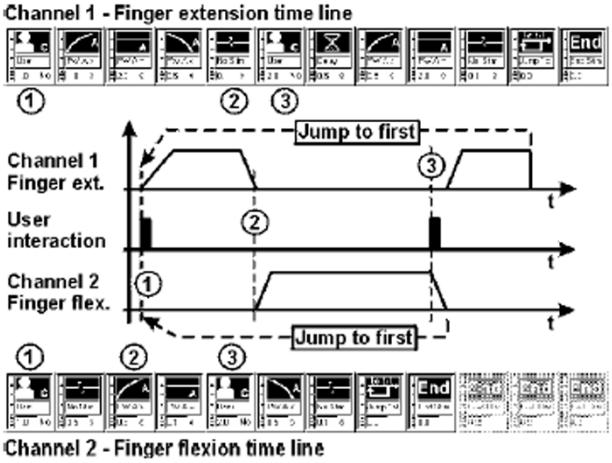
- number of strides in the recorded session;
- right and left stride duration;
- stance and swing duration.

The programmer/stride analyzer unit reads and statistically processes the data stored in the stimulator unit and displays the average value and standard deviations for the parameters recorded over 77.67 h of walking. This feature is particularly useful as it allows the clinician to assess how the DFS is performing in a home environment.

Popovic, Keller, Pappas, and Müller [42] described a very innovative programmable stimulator, which could potentially be applied in DF correction. The stimulator, shown in Fig. 9(a), is a four-channel stimulator with two sensor inputs, which could be configured as either analog or digital inputs. The unit also has a port, which can be used either to cascade additional stimulators together, to communicate serially with a PC or to trigger stimulation using a push-button. The unit is programmed using a PC-based graphical user interface (GUI). The GUI applies "drag-and-drop" technique to program the stimulation sequences, by sequentially placing icons called primitives on a time line that describes the chronology of the tasks that will be carried out by a single stimulation channel [example provided in Fig. 9(b)].

There are four such time lines and each time line defines tasks that will be executed by a corresponding stimulation channel. There are 56 primitives that describe different tasks that can be carried out by the stimulator. Stimulation programs developed with the GUI software can be stored as up-loadable files. This feature allows one to create libraries of stimulation se-

(a)



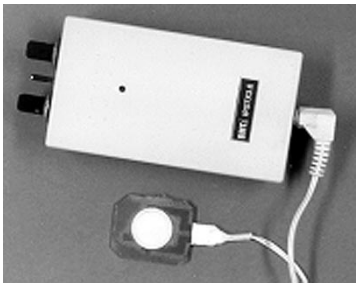
(b)

Fig. 9. (a) Complex motion programmable stimulator, showing the chip-cards used to store stimulation sequences. (b) Graphical interface used to program the complex motion stimulator, showing sequential arrangement of primitive. (Popovic *et al.* 2001, reproduced with permission.)

quences, a stimulation program developed with the GUI software, is stored on a chip-card that is plugged in the stimulator's "card read-and-write" module. The program is downloaded via the serial port. The content of the chip-card can be uploaded and displayed using the GUI software. By exchanging the chip-card (which takes 3 s) one instantly changes the function of the stimulator. This feature allows one to apply the same stimulator for various FES applications

B. Microprocessor-Based Implanted DFS Systems

Microcontroller technology was also employed in a dual-channel, implantable stimulator of Kelih, Rozman, Stanic, and Kljajic [26]. The primary motivation for the development of this dual-channel implantable stimulator was to overcome the particular problem with single-channel implanted systems reported by Waters [62]. Waters found that three of the 16 subjects implanted with the Medtronic implanted single-channel DFS system walked with excessive inversion or eversion following surgery. This problem was due to incorrect positioning of the cathode electrode relative to the branch of the common peroneal nerve. The correct placement of the electrode is difficult to determine during surgery as the subject is in the supine



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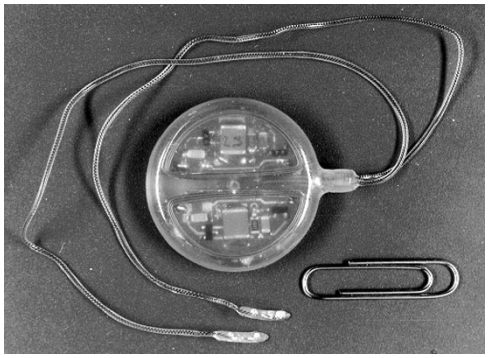


(b)

Fig. 10. (a) University of Twente implanted DFS external unit and foot-switch. (b) Implant, showing the epineural electrodes. (Holsheimer *et al.* 2000, reproduced with permission.)

position when dorsiflexion is tested. A balanced dorsiflexion response when the subject is supine does not guarantee that the same response will be obtained when the subject is upright, weight-bearing, and walking.

A solution to the problems of incorrect electrode placement during surgery, and a tendency of the electrodes to move post-surgery was proposed by Kelih, Rozman, Stanic and Kljajic [26]. They introduced a dual-channel implantable stimulator enabling control of two-degrees of freedom of foot movement, *viz.* dorsiflexion-plantarflexion and eversion-inversion. Thus, postsurgery, when the subject started to walk using the implant, the stimulus level on each channel could be adjusted to obtain balanced dorsiflexion. This system included an external programmer module to programme the stimulator parameters (amplitude and pulsewidth) and stimulation sequences, independently for each channel via a removable wire-link. The programmer module was microcontroller based and had a keyboard and alphanumeric display. The external controller was also microcontroller based using an RF output stage, with four switches for amplitude adjustment and LED bars for amplitude indication on the two stimulation channels. The receiver was implemented using hybrid technology and its two separate output stages were powered through the RF antenna.

Using the same strategy as Kelih of adjusting the level of eversion and inversion during walking using external controls, Holsheimer, Bultstra, Verloop, van der Aa, at the University of Twente, Enschede, developed a dual channel implantable stimulator, shown in Fig. 10, which used bipolar epineural electrodes and was controlled by a foot-switch [20]. Particular attention was paid to making the device small and low cost, the receiver

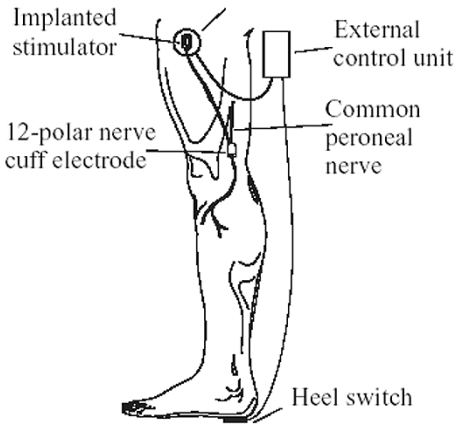


Fig. 11. Schematic of Aalborg University implanted DFS. (Haugland *et al.* 2000, reproduced with permission.)

Fig. 12. Aalborg University implanted DFS implant and external unit. (Haugland *et al.* 2000, reproduced with permission.)

unit had a diameter of 32 mm and a height of 6 mm. Holsheimer referred to the use of epineural electrodes as a means of minimizing the stimulation current required (because of the insulating properties of the epineurium) and because the location of the electrode under the epineurium would also help stabilise the electrode. At the time of writing, clinical evaluation of the system on human subjects was not published; instead some test results on animals were presented.

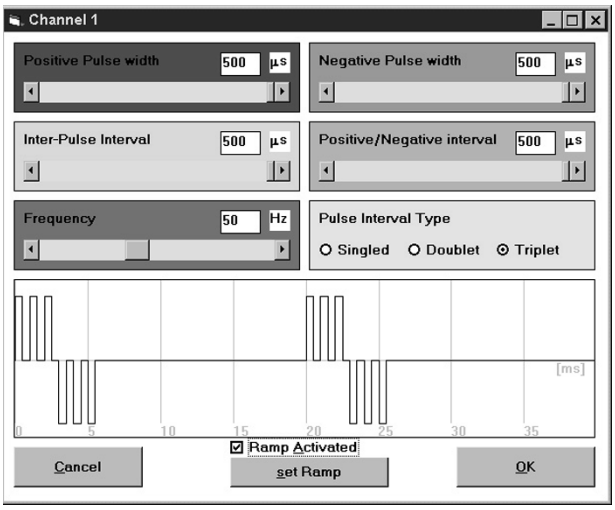
Rozman, Acimovic-Janezic, Tekavic, Kljajic, and Trlep [44] reported in more detail on the problems encountered with the Ljubljana single-channel implanted DFS system of Strojnik [50]. Rozman reported that in about 60% of patients fitted with the unit, the quality of the gait correction was not satisfactory. Rozman identified movement of the stimulating electrodes following implantation as the cause of the problem. This movement was attributed to activity in the surrounding muscles and connective tissue enfolding the whole implant. This resulted in different regions of the common peroneal nerve being stimulated. Rozman also reported that is was almost impossible before implantation to predict the selectivity of the stimulation of the common peroneal and as a result, the elicited functional movements. Rozman developed a half-cuff electrode to improve the selectivity and described preliminary results, which showed improved performance for two subjects.

Haugland, Childs, Ladouceur, Hasse, and Sinkjær [19] used microprocessor technology to develop a two-channel implantable stimulator controlled by an external foot-switch controller and featuring a 12-polar nerve cuff, Fig. 11 shows a schematic of the external and implanted elements of the system.

The cuff's 12 electrodes were configured as four tripoles placed at 0°, 90°, 180°, and 270° around the nerve, the end electrodes of each tripole being shorted within the cuff wall. Unlike other cuff electrodes for implanted DFS systems, this nerve cuff is fitted to the common peroneal nerve above the knee. The cuff arrangement is designed to ensure that at least two of the four tripoles will enable stimulation of the common peroneal nerve fascicles, which innervate both the dorsiflexors and/or everters and the dorsiflexor and inverters. A 12-polar cuff was required to provide sufficient redundancy in the number of tripolars to obtain the required selectivity. Positioning the cuff above the knee eliminates implanted wires leads crossing the knee joint (and the associated reliability problems that entails). It also eliminates surgical scars below the knee, which could be visible if the user is wearing a skirt or shorts. This cuff arrangement with built-in redundancy also eliminates the need for stimulation tests to be carried out during implantation surgery, thus reducing the required surgery time.

Haugland *et al.* reported on preliminary test results with this device on three stroke subjects. The implant, was fitted using a two-stage surgical procedure. In the first stage of the procedure, the electrode was placed on the nerve and the connector on the cable from the electrode fitted with percutaneous wires, which were connected to an external four-channel stimulator. Once the electrode had stabilized, the two channels that in combination gave the best control of the foot movement were chosen and the optimum stimulation current for the two channels was determined. In the second stage of the surgical procedure, the percutaneous wires were disconnected from the cuff electrode and an implantable stimulator with the chosen channels and currents (the stimulation current was hard-wired into the implant through component values) was fitted on the connector instead. It is proposed to change this rather tedious surgical procedure with a single procedure through hardware changes in the implant, which will allow adjustment of stimulus current through telemetry. A photograph of the implant and external unit is shown in Fig. 12.

The transmitter coils of the external unit are visible in Fig. 12 and can be seen to be relatively large (width approximately 8 cm), this size of transmitter coil was chosen to make the system robust to misplacement of the external control unit, relative to the implant, where up to a 3 cm misalignment from the implant in any direction can be tolerated. The coil is rigid and relatively large; the three subjects in this study used a pocket in bicycle shorts to house the unit, but this may not suit older subjects. Haugland *et al.* measured donning time for the system (fitting the external unit into the shorts pocket and connecting



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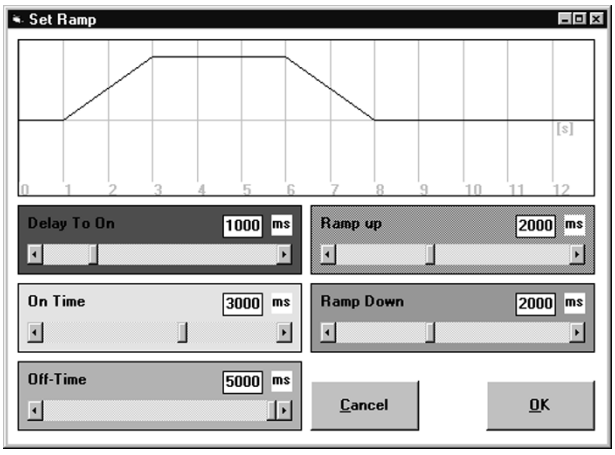

(b)

Fig. 13. GUI for University of Limerick DFS. (a) Interface for FES intensity envelope specification. (b) Interface for stimulation parameter specification. (Lyons *et al.* 1997, reproduced with permission.)

the foot-switch to the external unit) and recorded a donning time of 2–3 min.

The use of microprocessor technology in DFS systems enabled PC interfaces to be developed to program the DFS. Ewins [8], [13] reported on a dual-channel microprocessor-based DFS with the useful feature of a LabVIEW based clinicians interface. Lyons, Sweeney, Bradley, Hourigan, and O'Keeffe [31] also described the architecture of a programmable dual-channel DFS with a PC-based clinician's interface, which enabled the stimulation timing parameters for each stimulation channel and signal conditioning characteristics for each sensor channel to be programmed. The interface screen for the stimulation parameters (a) and envelope settings (b) are shown in Fig. 13. One of the benefits of using a clinician's interface is that it simplifies the required stimulator controls and thus improves the device's ergonomics, by simplifying the required stimulator hardware controls.

VI. Gait Sensors

The major problems identified with the acceptance of DFS systems by several researchers [18], [25], [27], [47], [61], [65] over the decades are; discomfort related to stimulation, the reliability and size of the foot-switch and the requirement for fitting of electrodes and the foot-switch each day.

Since Liberson's [29] development of the first drop foot stimulator to the early 1990s, the sensor used in FES-based DF correction systems had been the foot-switch. The two principle types of foot-switch have been the open-close mechanical switch and the force sensitive resistor (FSR), usually arranged as a voltage divider switch.

Early systems used the open-close mechanical type foot-switch [27], [29], [33], [34], [47], [50]. The problems encountered with this type of switch are deformation of the contacts with use leading to failure, breakage of the solder joints and sticking of the contacts. More recent DFS systems use the FSR based foot switch [7] and the problems associated with this type of foot-switch are degradation of the resistor material properties with use and solder joint breakage. Both of these problems can be minimized, circuit design changes to the stimulator circuitry can track resistance changes in the resistor over a limited range and careful packaging of the foot-switch can significantly reduce the incidence of solder-joint breakage [53].

However, it has been proposed by several researchers [9], [18], [24], [59], [61], [65], that it is desirable to use some other type of gait sensor in DFS systems for the following reasons:

1) Fundamentally the foot-switch is a contact sensor, requiring repetitive contact/noncontact of the wearer's foot with the foot-switch. Thus the forces, that the sensor is subjected to, are substantial, with forces of up to 2.2 kN expected [9]. This has major implications for the reliability of the sensor. With a DFS system, the application of the system requires that the subject brings the system home and wears it each day. For the wearer to accept this device and to overcome gadget intolerance the reliability of the system must be high and failure of any component of the system over a short period, including the sensor, is unacceptable.

2) The use of implanted DFS systems is recommended in cases where either/or:

- a subject is expected to be using a DFS over a long period;
- a subject has hypersensitivity to surface stimulation;

and where the required surgery is not a problem [24], [59], [61]. For a completely implanted system, the ability to implant the gait sensor is desirable and the foot-switch is clearly unsuitable for implantation [18], [65]. Thus, the use of a foot-switch is an impediment to the implementation of completely implanted systems.

3) Finally the information provided to the DFS system by a foot-switch is very limited, namely, presence or absence of contact by a part of the foot with the ground. This type of signal is quite adequate for the hard-wired DFS systems described, but as the sophistication of DFS systems is increased through the use of more complex control algorithms, the limitation of the foot-switch as a gait sensor should become apparent. For instance, the foot-switch provides no

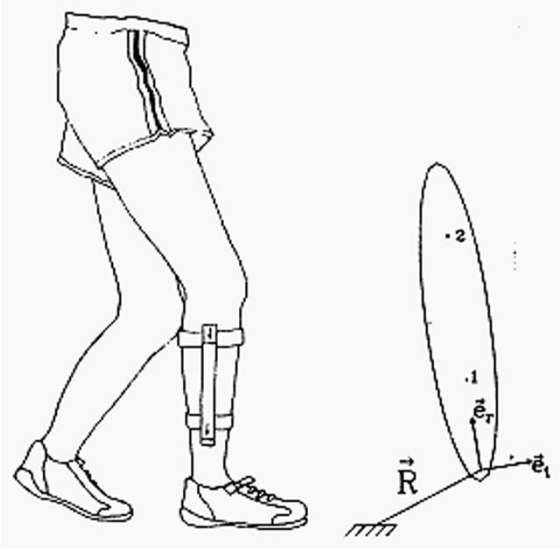

Fig. 14. Positioning of accelerometers on the subject. Four accelerometers represented by arrows are attached to a bracket at positions 1 and 2. There are two accelerometers at each location, one oriented tangentially to the bracket and the other oriented radial to the bracket. (Willemsen *et al.*, 1990, reproduced with permission, IEEE.)

information on the level of fatigue of the subject's leg musculature or on the extent of dorsiflexion produced during gait.

For these reasons, several researchers have evaluated alternative gait sensors using either another type of gait sensor, which would be suitable for implantation, or using the body's "natural" sensors.

Developments in these two research areas will now be discussed.

A. Artificial Sensors

One of the first groups to propose alternatives to the foot-switch as a gait sensor in DFS systems was Symons, McNeal, Waters, and Perry [52] at the Rancho Los Amigos Medical Centre/USC. Symons carried out preliminary evaluation of an in-house accelerometer fitted to the greater trochanter of the femur in a vertical orientation to detect heel strike. The accelerometer was tested on a 31-yr-old subject with a partial spinal cord injury walking with forearm crutches and an ankle foot orthosis and the device successfully detected heel contact. One of the advantages of accelerometers is that they are miniaturised integrated electronic components and as such are highly reliable and therefore very suitable for implantation, which was the rationale for this evaluation. The evaluation carried out by Symons was not very extensive and the device was only tested on a partial SCI subject who, due to the use of crutches, would have walked with a gait very dissimilar to that encountered in an UMN-DF subject.

Willemsen, Bloemhof and Boom [65], from the University of Twente in the Netherlands, proposed the use of an integrated accelerometer as a replacement for the foot-switch in an UMN-DF correction system. In their paper, an arrangement of four commercial single-axis accelerometers was placed on the shank, as shown in Fig. 14.

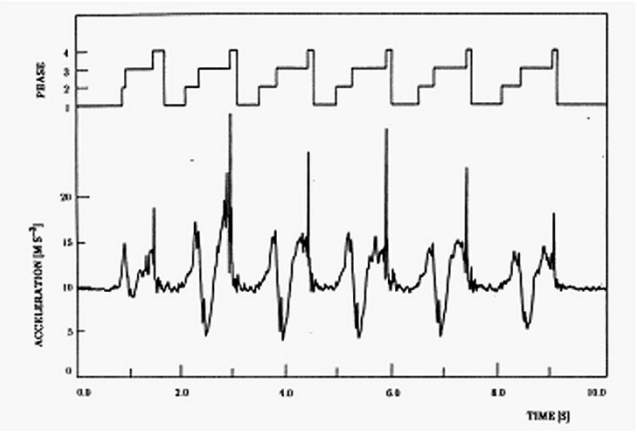

Fig. 15. Equivalent acceleration at the ankle joint with a trace showing the four walking phases obtained with foot-switches at the heel and first metatarsal head; Willemsen referred to 1 as stance, 2 as push-off, 3 as swing, and 4 as foot-down. (Willemsen, Bloemhof, and Boom, 1990, reproduced with permission IEEE.)

Willemsen [65] was able to distinguish between different phases of the gait cycle using the equivalent acceleration at the ankle joint as calculated from four accelerometers and was thus able to detect the onset of swing (push-off) and the termination of swing (heel-strike) as shown in Fig. 15. Careful attention was paid to the failure rate of detection of push-off and heel-strike. Out of a total of 106 steps, using three hemiplegic subjects, there were errors in only three steps, which is a very good performance.

Willemsen also looked at the result of using a single accelerometer closely below the knee and found similar detection accuracy. Using this result, Willemsen suggested that the successful use of a single accelerometer at this location posed the possibility of incorporation of the sensor into the simulator unit, with a resultant elimination of the sensor lead.

A follow-up paper by the University of Twente group [66] proposed a theoretical framework for the measurement of joint angles using accelerometers if the joint in question is modeled as a simple hinge joint. Willemsen, van Alste, and Boom [66] proposed fitting four single-axis accelerometers on each of the two limb segments, across which the joint angle was to be measured. A radial and tangentially oriented accelerometer was fitted at both ends of each limb segment. This, theoretical model, was experimentally evaluated by Willemsen, Frigo, and Boom in a follow-up paper in 1991 [67]. In this paper, Willemsen [67] carried out a comparison of the knee and hip joint angle measurement using the accelerometer method of Willemsen, van Alste, and Boom [66], with the accelerometers (Kyowa AS-5G) fitted to a PVC bracket on each limb segment, and using an ELITE 3D motion analysis system. The waveforms obtained using both systems are similar in shape, with the different phases of joint angular displacement detected by the accelerometer-based system. Willemsen [67], as part of their analysis of the system, carried out a comprehensive error and sensitivity analysis of the measurement setup and found a mean error of 0.1 rads (5.73 degrees) for the knee joint and 0.08 rads (4.58 degrees) for the hip joint. These errors are significantly larger than the error reported for potentiometer-based goniometric recording in the saggital plane (mean value of 2.2 degrees [22]). Willemsen [67]

identified as the major source of the error the assumption applied in the model that the knee be a simple hinge joint. The requirement for eight accelerometers to measure joint angle is quite demanding and results in a very cumbersome sensor arrangement. The real potential is for implantation, where the wiring associated with the sensors is internal and the movement of the accelerometers during walking would be eliminated by fixation of the devices to the subject's bones. The ability to measure joint angles (with a known error) using a potentially implantable configuration considerably broadens the scope of the control strategies that can be employed in an UMN-DF correction system. The use of accelerometers also has the advantage that not only is joint angle measured, but the limb segment acceleration and the gait cycle artefacts identified by Willemsen [65] are too.

Luinge, Veltink, and Baten [30] investigated the estimation of joint segment orientation, using a combination of solid-state gyroscopes and integrated accelerometers. However the system was considered suitable only for applications where the subject is almost stationary, which could be suitable for paraplegic subjects walking on crutches, but not for UMN-DF subjects.

Dai, Stein, Andrews, James, and Wieler [11] carried out a comprehensive evaluation of tilt sensors to control application of stimulus in a DFS. The tilt sensor utilized was a magnetoresistive type, the UA-1 from Midori American Corporation. The resistance of a magnetoresistive sensor changes with applied magnetic field strength. In the UA-1 device, magnets are attached to a mass of 3 g, which is suspended by double springs. The tilt of the sensor body is, therefore, converted to a linear displacement of the magnets over the surface of the MR element (InSb) by gravity and inertial forces. Under static conditions, the resistance change is proportional to the tilt angle of the sensor body over a certain angular range. Dai selected this device after a range of tilt sensors of different types, namely, magnetoresistive, electrolytic and mercury had been evaluated. The sensors were evaluated using the following characteristics:

- mechanical reliability;
- signal stability of the sensor in daily living;
- simplicity of sensor signal conditioning;
- cost.

Dai identified how a tilt sensor on the thigh or shank, which measures the inclination of that limb segment with respect to a fixed reference, could be used to identify the toe-off/heel-off and heel-strike events. Dai identified that the shank tilt signal has a slow rising phase, corresponding to the forward leaning of the upper part of the shank segment that starts just before heel contact, and a faster falling phase, corresponding to backward leaning that starts after the toe comes off the ground. The subject's heel comes off the ground during gait when the shank is in the middle of its forward-leaning phase.

Dai *et al.* use this information to synchronize application of FES to the swing phase of gait. This approach was tested on a UMN-DF sufferer who was two years post-stroke. The system incorporated a Finite State Controller, where the stimulus was turned on when the tilt signal rose above an ON threshold, which corresponded to a pre-defined forward leg position and the stimulus was turned off, if the tilt signal fell below an OFF threshold position or a pre-set maximum period of stimulation was exceeded. Using the Finite State Controller a lock-out state was entered following stimulus to prevent the stimulation being turned on by secondary signal peaks that occurs in some subjects. A second stimulus could only be turned on after the leg had fallen below the second level so that a repetitive stimulation will not occur if the leg rests in a forward position. The system performed well: the subject walking as fast as she could with an AFO, but without the restriction or bulkiness of an AFO. Dai *et al.* also designed an elegant prototype DFS with the tilt sensor incorporated into the DFS unit, eliminating the need for a wire to the sensor and its associated reliability and cosmetic problems. Another advantage of the tilt sensor approach with respect to the foot-switch is that the tilt sensor approach allows the subject to walk bare-foot around the home or to change footwear without the need to change the placement of the sensor.

Another approach to finding an alternative to the heel switch is to train an alternative sensor to identify the events traditionally detected by foot-switches. Sweeney and Lyons [51] described the use of Fuzzy Logic techniques to detect toe-off and heel-strike using a knee goniometer.

B. Natural Sensors

A very elegant solution to the problems of gait sensors in FES-based UMN-DF correction systems is to use the body's own sensing mechanism. Haugland and Sinkjær [18] described the use of recordings from a cuff electrode, on the sural nerve, to control the application of stimulus to the common peroneal nerve of a hemiplegic subject. The sural nerve is purely sensory, whose inputs are touch sensors on the lateral part of the foot (the shaded area of Fig. 14). Haugland and Sinkjær proposed that, the conventional heel switch in a DFS system be replaced by a single sural nerve cuff, which monitored whether or not the affected foot was supporting weight, and used this information to control the application of stimulus in the DFS. Recording nerve signals is referred to as Electroneurography and the corresponding signal is called an Electroneurogram or ENG.

A representation of Haugland and Sinkjær's system is shown in Fig. 16. As can be seen from the figure, a tripolar whole nerve cuff electrode is fitted on the sural nerve of the subject, at a location approximately 7 cm proximal and 3 cm posterior of the lateral malleolus of the subject's ankle. The three output wires of the electrode are passed sub-cutaneously up along the lateral part of the lower leg and exit through the skin approximately 25 cm above the lateral malleolus.

These three wires and a wire from a ground electrode fitted externally around the ankle joint are input to a neural amplifier located in the portable amplifier-controller-stimulator unit. Leads from surface stimulation electrodes positioned for stimulation of the common peroneal nerve are also connected to the stimulator inputs of the portable unit. This unit also houses a series of filtering and artefact suppression stages used to process the ENG signal. Finally heel-strike detector circuitry, uses the processed ENG signal to control the activation of the peroneal stimulator, also located in the portable unit.

Artefact suppression is required as the cuff electrode picks up EMG activity from the activation of muscles of the lower leg and stimulus artefact from the stimulator. Haugland and Sinkjær found that these two forms of artefact must both be suppressed

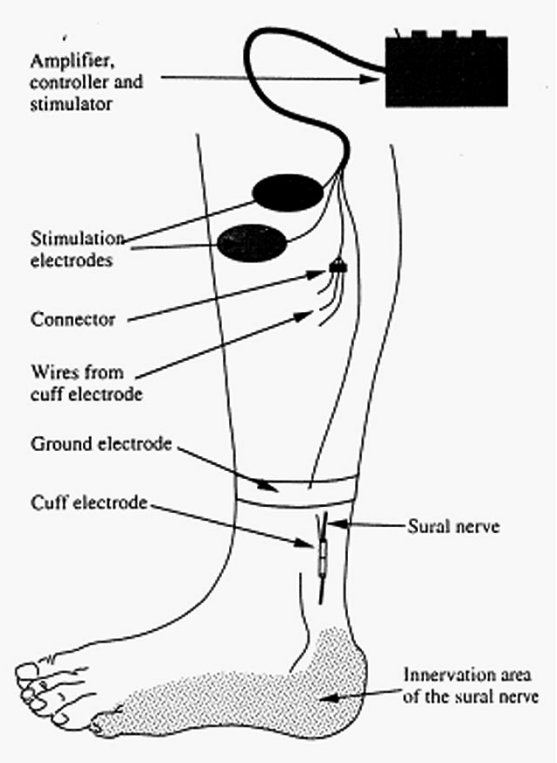

Fig. 16. Representation of the DFS controlled by the recorded signal from a cuff electrode on the sural nerve, with the innervation area of the sural nerve shaded. (Haugland and Sinkjær, 1995, reproduced with permission IEEE.)

in order to use the recorded signal to accurately detect the heel-strike event.

The system was tested on a 35-yr-old subject with hemiplegic drop foot, who during local anaesthesia, was implanted with the cuff electrode on the sural nerve in a neurosurgical procedure described by the authors as simple and reliable. This work on UMN-DF correction also represented the first human study demonstrating a functional use of cutaneous mechano-receptors recorded by an implantable whole nerve recording. A few problems were identified with the system:

- the need to eliminate the wires going through the skin—the development of an implantable neural amplifier was proposed as a better alternative;
- some false detection of the heel-strike occurred, though the extent of this problem was not reported. The false detections were attributed to the high sensitivity of the nerve signal to small, fast inputs to the skin, i.e., if the foot slid lightly across the floor during swing.

VII. Control Systems

One aspect of DFS systems that has received little attention is closed-loop control of stimulation intensity. In all of the systems described to date, FES intensity is only modulated at ramp-up and ramp-down, no consideration is made of muscle fatigue and its possible influence on dorsiflexion.

Stanic, Trnkoczy, Acimovic, and Gros [46] described the use of gradually modulated electrical stimulation, where stimulus intensity (to 8 above threshold levels over 16 intervals during the gait cycle) is adjusted during swing to reproduce the ankle moments observed in healthy gait. Stanic *et al.* used a RAM-controlled stimulator, where the RAM stored the required stimulation sequence. Stanic reported that improved gait correction was achieved with the gradually modulated electrical stimulation than with constant amplitude stimulation.

Prochazka and Wiles [43] evaluated closed loop control of dorsiflexion angle using a length sensor attached across the ankle joint. Prochazka and Wiles found a reference input to the controller of 90°, which was provided by a length sensor on the subject's wrist, was optimal for gait.

Mourselas and Granat [39] described a prototype DFS, which applied closed loop control of dorsiflexion angle using fuzzy techniques. The fuzzy controller was implemented on a PICmicro (Microchip Technology, Inc.) microcontroller and ankle flexion was monitored using a flexible resistive goniometer. Heel contact was also monitored using a FSR foot switch. The closed-loop system consistently performed better than the open-loop system by providing improved dorsiflexion.

Lyons, Wilcox, Lyons, and Hilton [32] used closed loop control techniques to modulate DFS FES intensity, during the swing phase of gait, to match the tibialis anterior muscle activation patterns observed in healthy gait, to the FES intensity envelope, replacing the conventional trapezoidal-shaped FES intensity envelope.

In the future, it is expected that, as sensor issues are resolved through implantation or the use of "natural" sensors, more attention will be paid to the incorporation of novel control techniques in DFS systems for the modulation of FES intensity to provide more optimized delivery of stimulation and also to regulate dorsiflexion in the presence of disturbances, such as fatigue and spasticity.

VIII. Implanted Sensing and Stimulation

In 2000, Hansen, Haugland, Kostov, and Sinkjær [17] described a system to test the use of an adaptive logic network (ALN), which was trained to detect the heel strike and heel-off events from an ENG signal, recorded from the sural nerve, thus *cloning* the function of a heel switch. The implanted system used in this study is the first step in the path to implanted sensing and stimulation, where the stimulator and the sensor controlling activation of the stimulator are both implanted. The subject, a 32-yr-old female, was instrumented with:

- A tripolar cuff electrode, 2.8 mm in diameter, inserted on the sural nerve, to record cutaneous activity from the lateral side of the foot sole. The sural nerve cuff was fitted through an incision, just anterior to the lateral malleolus. Lead wires were lead subcutaneously across the knee to an implanted neural amplifier, located on the lateral side of the upper leg. The implanted amplifier was externally powered through an electromagnetic coupling, and transmitted the recorded ENG outside the body using frequency modulation.
- A four-channel 12 polar stimulation cuff electrode, 5.8 mm diameter, inserted on the common peroneal nerve through an incision behind the knee. Lead wires were lead, subcutaneously, to an implanted two-channel stimulator connected to two selected

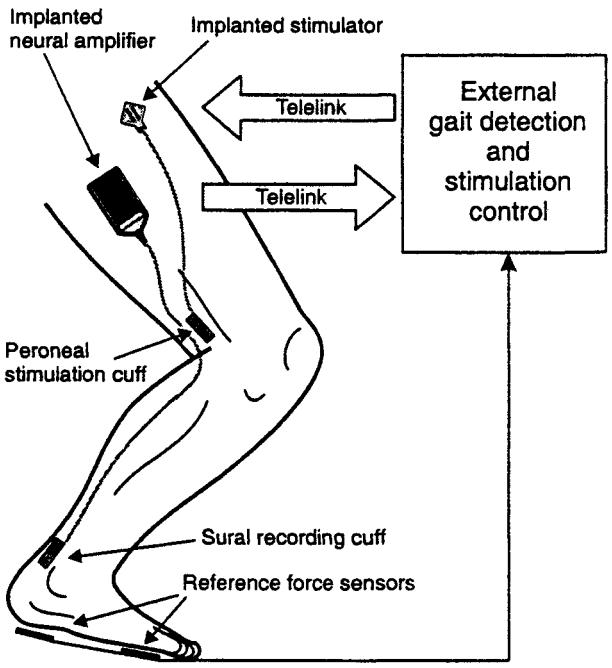

Fig. 17. Schematic of the Aalborg University implanted stimulator and sensing arrangement. (Hansen *et al.* 2000, reproduced with permission.)

channels in the cuff electrode. An external stimulator controller transmitted pulsewidth modulated energy bursts to the implanted stimulator selectively for the two channels. The stimulator controller was operated using a digital signal emulating a heel switch.

A schematic of the experimental setup is shown in Fig. 17.

An external unit interfaced to a PC was required to control the stimulator, to power the implanted ENG amplifier and to house the ENG signal processing electronics. However, this paper demonstrated that the elements for implanted sensing and stimulation are developed, with the next challenge being the miniaturization of the external unit.

IX. Discussion and Conclusion

Following Liberson's first demonstration of the use of FES for the correction of drop foot in 1961 [29], there were extensive developments in DFS systems in the following four decades.

The 1960s and 1970s saw the development of other hardwired single channel DFS systems from groups at the Josef Stefan Institute / University Rehabilitation Institute / University of Ljubljana, Ljubljana, Slovenia and elsewhere [12], [38], [54], [59], [60] with varying results.

Some of the problems identified with these systems (the difficulty in correctly placing stimulation electrodes and the sensation of pain experienced by some subjects) led, in the late 1960s and early 1970s, to the investigation of the feasibility of DF correction through implanted means [23], [24], [36], [45], [61]. Rancho Los Amigos Medical Centre (RLAMC)/University of Southern California and the University of Ljubljana, Slovenia, were the pioneering centers for implanted single channel systems, with RLAMC being the first center to present data on the functional use of an implanted DFS on stroke patients [36].

The 1970s and 1980s saw the investigation of multichannel stimulation by Ljubljana [27], [49], [58], while most of this work (4 and 6-channel FES) was not directly applicable to take-home DFS systems, several techniques, which were ultimately applied to DFS systems, were developed, namely:

- the use of sequential circuit techniques to prevent false triggering of stimulus;
- a gait analysis tool, referred to as the stride analyzer, was developed and later incorporated into a programmable two-channel surface DFS.

In 1988, the Ljubljana center reported on the use of dual-channel implanted stimulation for drop foot correction, to overcome the problem of incorrect positioning of the cathode electrode relative to the branch of the common peroneal nerve, as experiences by several researchers with single channel IDFS systems [26]. The dual-channel, implantable, stimulator enabled control of two-degrees of freedom of foot movement, dorsiflexion-plantarflexion and eversion-inversion. When the subject started to walk using the implant, the stimulus level on each channel could be adjusted to obtain balanced dorsiflexion. This was an important innovation and this approach is currently used by more recent IDFS devices developed at the University of Twente, the Netherlands [20] and at Aalborg University, Denmark [19].

The 1990s saw new centers investigating single channel surface DFS [7], [16], [56], [64], these centers brought new perspectives to the application of these systems. Salisbury District Hospital, U.K. developed a very successful clinical DFS programme, with more than 1500 systems supplied for use in the user's own home.

This period also saw several centers investigating replacements for the foot-switch, notably the tilt sensor, accelerometers and gyroscopes [11], [30], [51], [64]–[66]. The University of Edmonton, Canada, evaluated the use of tilt sensors as the sensing mechanism for a DFS, and ultimately incorporated this sensor into a DFS product called WalkAide [64]. A novel feature of this DFS was that, a person could use the equipment, while walking barefoot around their home, due to elimination of the foot-switch. The University of Twente, the Netherlands, carried out an evaluation of accelerometers as gait sensors and were able to detect gait events using these devices, however joint angle measurement required a cumbersome arrangement of accelerometers and required that the subject be walking very slowly for accurate results. This work, did however, point to the potential of a new family of implantable, artificial sensors, developed for other applications, but suitable for DFS use [65]–[67].

The late 1990s saw the application by Aalborg University, Denmark of "natural" sensors as a sensing mechanism to trigger application of FES in drop foot correction, where the detection of ENG signals from a cuff electrodes on the sural nerve provided foot-contact information sufficient to trigger application of FES for DF correction [18]. This novel development made possible, DFS systems which had implanted stimulation and sensing, which was demonstrated by the Aalborg center in 2001 [17].

One area of DFS systems research that has received little attention over the period under review, is real-time control of stimulation intensity. Some initial work was carried out in Ljubljana in the late 1970s on modulating FES intensity during the gait

TABLE I
SUMMARY OF THE DFS STUDIES REVIEWED WITH THE NUMBER OF DROP FOOT SUBJECTS TESTED AND THE COMMERCIAL NAME OF THE DFS IF APPLICABLE

Reference	Commercial name of System	Type of system	# patients in study
Bogataj et al, 1989	N/A	6-channel microprocessor controlled surface DFS	20
Brandell, 1982	N/A	Hard-wired universal logic controlled 6-channel surface DFS	1
Burridge et al, 1997	ODFS	Single-channel hard-wired surface DFS	56
Dai et al, 1996	N/A	Tilt sensor	1
Granat et al, 1996		Single channel hard-wired surface DFS	17
Hansen et al, 2000	N/A	Machine learning in a DFS with natural sensor interface	1
Haugland et al, 1995	N/A	Surface DFS control with "natural" sensors	1
Haugland et al, 2000	N/A	Implanted stimulation and sensing DFS	3
Liberson et al, 1961	N/A	Single channel hard-wired surface DFS	7
Lyons et al, 2000	N/A	Real-time modulation of FES intensity	1
Malezic et al, 1984	N/A	6-channel digital surface stimulator	11
Malezic et al, 1987	N/A	6-channel digital surface stimulator	10
Malezic et al, 1992	Dual Channel Stimulator	2-channel programmable surface DFS	21
Moe and Post, 1962	N/A	Single-channel hard-wired surface DFS	3
Mourselas & Granat, 2000	N/A	Closed loop control of dorsiflexion in a DFS	2
Pedersen et al	KDC 2000A	Single-channel hard-wired surface DFS	46
Prochazka & Wiles, 1983	N/A	Closed loop control of dorsiflexion in a DFS	5
Rozman et al, 1994	IPO	Single-channel hard-wired implanted DFS	2
Stanic et al, 1978	N/A	6-channel analog DFS (11 patients) 6-channel digital DFS (4 patients)	11
Stanic et al, 1977	N/A	Real-time modulation of FES intensity	2
Strojnik et al, 1979	N/A	6-channel programmable stimulator	20
Strojnik et al, 1987	IPPO	Single-channel hard-wired implanted DFS	20
Sweeney & Lyons, 1999	N/A	Fuzzy detection of gait events	1
Symons et al, 1986	N/A	Trigger switches for implanted DFS	7
Takebe et al, 1975		Hard-wired single channel surface DFS	9
Vodovnik et al., 1965	FEPA-10	Single-channel hard-wired surface DFS	5
Acimovic et al, 1987	FEPA-10 MICROFES IPPO	Single-channel hard-wired surface DFS Single-channel hard-wired surface DFS Single-channel hard-wired implanted DFS	670 120 35
Waters et al, 1975	Neuro-muscular Assist	Medtronic Inc., USA	16
Willemsen et al, 1990	N/A	Accelerometer detection of swing in DFS corrected gait	4
Wieler et al,	WalkAide	Surface DFS incorporating a tilt sensor	9

cycle to match ankle moments in healthy gait [46]. Prochazka and Wiles tested closed loop control of dorsiflexion angle using a length sensor across the ankle joint [43]. At Strathclyde fuzzy closed loop control of dorsiflexion was evaluated using a flexible resistive goniometer [39]. The University of Limerick investigated matching the FES intensity envelope to the Tibilalis Anterior activity pattern recorded in healthy gait [32].

In the future, it is expected that, as sensor issues are resolved through implantation or the use of "natural" sensors, more attention will be paid to the incorporation of novel control techniques in DFS systems for the modulation of FES intensity to provide more optimized delivery of stimulation and also to regulate dorsiflexion in the presence of disturbances, such as fatigue and spasticity.

Table I summarizes the DFS studies reviewed for this paper, with the number of DF subjects tested and the commercial name of the DFS used, if applicable. It is clear from Table I that very few of the studies reviewed have evolved into commercial devices.

Table II identifies the commercial devices associated with these studies and the number of units manufactured during the review period (1961–2001).

Considering the incidence of stroke alone, the number of DFS units manufactured over a period of 40 yr by these companies, is very low ($<14\,000$). This low volume of sales of DFS units is of concern and must reflect a fundamental problem either with the technology or with the perception of the technology. It is the authors' opinion, that this poor volume of DFS sales can be attributed to the fact that the commercial DFS devices available are primarily single channel hard-wired surface devices.

As discussed in this review, surface DFS systems have several problems, which can limit their scope:

- limited number of subjects are suitable for surface DFS;
- limited number of subjects will continue to use the DFS in the long-term.

Subjects selected to use surface DFS devices must:

- tolerate the sensation of stimulation;

TABLE II
COMMERCIAL DFS DEVICES REVIEWED WITH ESTIMATES OF THE NUMBER OF UNITS MANUFACTURED DURING THE PERIOD 1961–2001

Commercial Name of DFS	Reference	Manufacturer of System	Approx. # units produced (to 2001)
PO-8 / FEPA-10	Vodovnik et al., 1965	Soca & AMF, Slovenia	5,500
MICROFES	Acimovic et al, 1987	Gorenje, Slovenia	500
IPPO	Dimitrijevic et al	Gorenje, Slovenia	100
Neuro-muscular Assist	Water et al, 1975	Medtronic Inc., USA	~20
ODFS	Burridge et al, 1997	Salisbury District Hospital, UK	1,500
KDC-2000A	Pedersen et al, 1986	Elmetec A/S, Denmark	6,000

- achieve FES-elicited dorsiflexion with a stimulus intensity within the subject's tolerance.

We estimate, based on clinical experience, that only approximately 50–70% of the UMN-DF sufferers, referred for surface DFS assessment, adopt surface DFS for correction of their disability. This subset of UMN-related drop foot sufferers, experience another series of problems when using the device over an extended period [56], [57]:

- difficulty placing the electrode at the correct location on a daily basis;
- difficulty operating the equipment on a daily basis, including setting up the foot-switch;
- difficulty tolerating the sensation of stimulation;
- skin allergy problems with electrodes.

The extent to which, these types of problems are experienced by current users of surface DFS systems, was identified by the group at Salisbury District Hospital, using the IMPULSE questionnaire [57]. This questionnaire surveyed long-term users of the ODFS single channel hard-wired DFS device, of the 140 users surveyed, 70% (98) replied. Only 13% report that they had experienced no problems with the equipment. The most commonly experienced problem was with finding the correct electrode positions (72%), with 17% of respondents reporting this to be severe problem and 37% a moderate problem. The second most commonly reported problem for respondents was difficulty with wearing wires and foot-switches (58%). The next most reported problem was that of donning and doffing the equipment (47%), 15% thought this problem severe and 20% felt it to be a moderate problem. Finally, 36% reported the sensation from electrical stimulation to be a problem. Again, we estimate, based on clinical experience, that approximately 25–30% of DFS users ultimately reject the device.

This poor level of adoption, adherence, and satisfaction with using surface DFS must be considered in the context that the Salisbury group provide very good support to the client base of ODFS users with comprehensive follow-up sessions with patients and training for therapists and patients on the use of the equipment [53].

A previous survey by the same group [56] found that 40% of stroke users of the ODFS required assistance in donning and doffing the equipment.

A. Recommendations for Future DFS Systems

We would suggest that 2-channel implanted systems would solve many of the problems identified by these surveys, by eliminating the need to position electrodes on a daily basis, eliminate the problems of skin allergy associated with electrodes, eliminate the stimulation sensation experienced in surface FES, and ideally eliminate the need to fit a foot-switch daily. This type of DFS should also increase the number of UMN-DF subjects who could achieve FES-elicited dorsiflexion. Two-channel implanted DFS is proposed as 2-channel of stimulation are required to obtain balanced dorsiflexion following surgery.

Implanted DFS would thus be the primary long-term DFS vehicle proposed. The priority groups to be targeted for implanted systems should be:

- subjects who cannot benefit from surface DFS, due to stimulation sensation problems; and
- subjects who are successfully using a surface DFS, but are expected to be long-term users of such a system.

Short-term users of DFS could still use surface DFS devices, if they can tolerate the sensation of surface stimulation.

B. Equipment Recommendations

While a large proportion of current DFS users are in the 50–60 age group, a significant proportion of potential DFS users will be 60 and older. It is thus important that, the required surgery to implant these systems be as minimally invasive as possible, to limit the resultant trauma. This needs to be an important design objective for Implanted DFS (IDFS) systems.

The IDFS needs to be microprocessor controlled so that a variety of control algorithms can be implemented to customise the function of the device to the specific requirements of the subject and the systems should have a PC-interface so that therapists can program the device using a GUI.

There should be upward compatibility between surface and implanted versions of the stimulators. Features available on the surface systems must also be available on the implanted systems, so that subjects using a surface DFS and converting to an IDFS will not lose any functional performance. It is expected that IDFS systems will have more complex control strategies than surface DFS, as implanted/"natural" sensors provide a greater variety of sensor options.

Finally, as a longer-term goal, these systems should have the capability of maintaining closed-loop control of dorsiflexion to adjust for disturbances, such as fatigue and spasticity.

C. Training and Support Recommendations

Proper training of therapists, on the adjustment of the IDFS controller after surgery, in conjunction with proper training of the users and their carers, on the use of the IDFS, is very important to ensure that the full capabilities of the system are being

exploited and that the subject is obtaining maximum possible benefit from the equipment.

Extensive and regular follow-up service to patients, after initial fitting of the IDFS, needs to be provided to ensure that the user or their carer is using the equipment properly, to determine if any adjustment to the operating parameters is required and to identify any possible problems with the equipment.

D. Healthcare Provider Recommendations

Health care providers need to be made aware of the benefits of IDFS devices for drop foot correction, as the cost of DFS systems must be covered by health providers if proper exploitation of this technology is to be achieved.

This has implications for the clinical evaluation of IDFS systems, as health authorities will not financially support these systems, unless there is a clear health/social gain to be derived from using them, over the existing treatment. A comprehensive, multicenterd trial on the evaluation of an IDFS, meeting the suggested equipment recommendations, needs to be carried out to provide evidence to health care providers that IDFS is the correct approach for the long-term treatment of UMN-DF.

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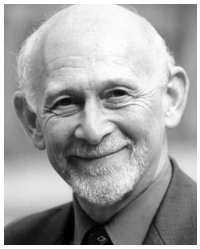

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