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Neurokinetics Case Study

Background	2
The Bionic Glove	2
<u>Details</u>	2
<u>Development</u>	3
<u>Commercialization</u>	3
The Issues.....	4
<u>Intellectual Property</u>	4
<u>The Market</u>	5
<u>Distribution</u>	6
<u>Clinical Trials</u>	7
<u>Product Development</u>	9
<u>Regulatory Considerations</u>	10
<u>Sales Projections</u>	11
<u>Financing</u>	12
<u>Commercial and Technical Risks</u>	13
The Researcher's Dilemma	15
Appendix A: Competition	16
<u>Markets</u>	16
<u>Glove Competitors</u>	16
<u>Indirect Competition</u>	18

This case was prepared by Beth Graham under the direction of Dr. Jim Graham, director of Venture Development at the University of Calgary, with the support of a grant from the Alberta Heritage Foundation for Medical Research to encourage discussion and learning about technology commercialization. The case is based on interviews with some but not all of the mentioned participants and while it is believed to be reasonably accurate, may not represent all the facts or views of the participants.

Background

The time is the fall of 1995. Dr. Arthur Prochazka's spin-off company, Neurokinetics Inc., was demanding much more time than he expected or wanted. He had started up the company in 1994 as a vehicle for the commercialization of his research at the University of Alberta.

Prochazka was a well-respected neuroscience professor, an expert in the development of electrical stimulation therapy for paralyzed individuals. Neurokinetics' first objective was the commercialization of the Bionic Glove, a device developed in Prochazka's lab. It allows a motion-impaired individual to grip an object.

At the same time as he was developing the Bionic Glove, Prochazka was continuing and initiating further research projects. He took a great deal of pride in the high quality of research done by his team. The business side of Neurokinetics took him away from the lab.

Prochazka found these time constraints stressful and wondered how he might find a balance between his research and the commercialization of the Bionic Glove.

The Bionic Glove

Details

The main start-up product for Neurokinetics was the **Bionic Glove**, which is based on FES (Functional Electrical Stimulation). It is an electric device that allows a motion-impaired individual to grip an object. When worn by quadriplegics who still have some movement in their wrist, the Glove senses wrist movement, and electrically stimulates different muscles in the forearm, causing the paralyzed thumb and fingers to form a pinch grip.

The Glove powers three sets of muscles:

- muscles which bring the fingers in (i.e. picking up a can of pop)
- muscles which to open the hand
- muscles which bring the thumb and the index finger together (i.e. holding a paintbrush)

The Glove is fingerless and made from a stretchy neoprene material, similar to a skin diver's wetsuit. Electrodes are attached to the Glove and positioned strategically on the individual's arm to stimulate the muscles required to perform the task. The current is monitored by a control box, which allows the grip to be adjusted.

During clinical trials, patients using the Glove were able to regain skills such as lifting heavy objects, using a hammer, opening doors with round smooth knobs, and eating finger foods. They also showed increased efficiency in performing tasks that they could already do with the aid of other devices. These tasks included writing, using cutlery, toothbrushes, keys, and drinking from a cup or glass.

Development

Development work on the Bionic Glove began in 1989. Prochazka's research team developed the product with the input of quadriplegic patients to ensure that users' needs were kept in mind right from the start. As the team worked in conjunction with patients, Prochazka recognized the Glove's "liberating" potential in helping motion-impaired individuals achieve a more independent lifestyle.

Preliminary tests performed in Edmonton involved a bench prototype comprised of a glove attached by wires to a separate control box. Users found the wires to be a nuisance. Eliminating the wires became an important goal in developing a marketable product.

Prochazka wondered whether the Glove could be commercialized in order to reach a greater number of quadriplegics. He wondered if the Glove could make a profit, and whether that profit would be enough to fund further research. Prochazka applied for and received funding from the Technology Commercialization Program of the Alberta Heritage Foundation for Medical Research (AHFMR) to explore the market potential of the Bionic Glove.

Three University of Calgary MBA students (Emily Collins, Mark Levac, and Doris Murphy) were hired to conduct a preliminary market survey. Their findings confirmed that if the Glove was marketed in both Canada and the United States, sales would indeed be great enough to support a commercial venture. As well, the supply of replacement electrodes for the product represented a business opportunity that was comparable to that of selling the Glove.

The students prepared a report of their findings, outlining the first steps to be taken in order to commercialize the Glove. They believed that the company could be launched with a minimum of corporate infrastructure -- a president, a physiotherapist, a senior administrative assistant, and a technician. Research staff would provide market and applications assistance in the very early stages of the company's development.

Commercialization

In 1994, Prochazka established Neurokinetics Inc. The objective of the new company was “to get as many motion-impaired patients as possible using the Bionic Glove in everyday life”.

Realizing that he lacked the time and expertise to commercialize the Glove, Prochazka hired a business manager to oversee the commercialization process. In 1994, with funds from AHFMR, Tricia Cisakowski was hired. She had extensive expertise in both the research and commercialization aspects of a product.

Cisakowski set up headquarters in a small room at the back of Prochazka’s lab. Her job included pursuing regulatory approval, setting up clinical trials, gaining financial backing and drawing up a business plan.

The Issues

Intellectual Property

Prior to developing the Bionic Glove, Prochazka had developed another FES (Functional Electrical Stimulation) technology -- a tremor attenuation system. Once fully developed, this system would control essential and cerebellar tremor caused by multiple sclerosis.

Prochazka published a paper in a medical research journal detailing the merits of the tremor attenuation system. Unfortunately, a patent was not obtained for the technology and Prochazka lost exclusive rights to the system. He was determined that the Bionic Glove technology would not endure the same fate.

Prochazka had assigned rights for the Glove to the University of Alberta. The University in turn licensed the Glove back to Neurokinetics. If the Bionic Glove was to be commercialized, a patent had to be obtained. A patent provides a limited exclusive right to the manufacture, sale and use of an invention in return for the disclosure of that invention in a patent specification. Patenting is a lengthy, costly and complex process.

A patent agent was consulted and a search conducted in order to assess the patentability of the Glove. Existing patents in Canada and other countries were checked to ensure that the idea was unique.

A patent specification was then filed. The specification consisted of a descriptive portion, an abstract and claims. It had to be completed within a relatively short time frame as the Canadian system operates on a first-to-file basis -- the first person who files a patent application for a particular invention is entitled to be granted a patent for that invention.

In October 1994, the Bionic Glove was protected worldwide by a PCT patent. This protection of intellectual property was critical if investors were to be encouraged to invest in Neurokinetics. Once the Glove had been patented, financial and marketing support had to be found in order to commercialize the innovation.

The Market

The preliminary market survey done by the University of Calgary MBA students described the industry, target markets, lead times, competition and regulatory restrictions.

They identified the Bionic Glove's target market as the quadriplegic segment of the medical equipment supply market. A certain amount of wrist movement was required to operate the Glove. Research indicated that the target market for Canada and the United States combined was approximately 76,850 existing patients with 2,850 new patients anticipated each year.

Allowing for disqualifying factors such as physical, psychological, and financial constraints, potential sales for the North American market totaled 4,617 existing quadriplegics and 172 anticipated new quadriplegics. This represented a total market share of approximately 6% of the total expected market for quadriplegics.

The number of annual injuries was not expected to undergo any drastic changes in the next few years indicating that the market would continue to grow at a constant rate. The study also indicated that stroke patients were another market to which the Glove may be made available. At that point, Prochazka had not conducted testing in this area, therefore it was difficult to define the stroke patient market.

The students determined that an acceptable price for the Glove was between \$1000-\$1500. The pricing of the Glove was dependent on three factors:

- Most quadriplegics relied on fixed incomes of less than \$1,000 per month.
- Medical coverage was generally only provided for essential components.
- Some patients had access to the Motor Vehicles Claims Fund, which provides vehicle accident victims with a lifetime fund of \$95,000. Patients must budget in all of their future needs (i.e. wheelchair components) out of this money.

The cost of replacing the customized electrodes in the Bionic Glove was identified as an additional source of revenue. The electrodes would retail for \$10 per package of four, including shipping and handling. The electrode replacement rate was estimated to be 8 per month (2 packages), so that electrode sales for one glove would total \$240 per year. Wear and tear meant the Glove fabric

would need to be replaced approximately once every year. The students assumed this would be done at a nominal charge, if charged at all.

Cisakowski followed up with an in-depth market study. She explored the quadriplegic and stroke markets and suggested that the Glove might also be used for brain injured patients or patients suffering from multiple sclerosis. More data was needed in both of these areas to estimate the potential market.

According to Cisakowski's research, there were about 200,000 individuals in the United States with spinal cord injury. The incidence of injury was 10,000 cases per year. In order to be able to use the Bionic Glove, people with quadriplegia had to have residual voluntary wrist extension with weak or absent thumb and finger movement. Typically, people with an injury at C6 or C7 fell into this category. When factors such as physical suitability and acceptance were taken into account, the estimate of potential users in the United States was approximately 17,000. Of the 10,000 new cases per year, there were approximately 900 potential new users.

Some of the disparity in the market estimate done by the students and the one done by Cisakowski was attributed to the growing market and the development of the Glove. Further studies were needed to take into account costs and margins, user benefits, reimbursement frameworks, user acceptance and marketing and distribution strategies.

Cisakowski also examined the stroke patient market. In the United States there are approximately 2.1 million stroke survivors, many with residual hemiplegia (paralysis of one side of the body). The motor deficits ranged from mild weakness in the affected arm to complete paralysis and spastic rigidity. To be a candidate for the Bionic Glove, stroke patients had to have good shoulder and elbow control. Clinical opinion differed on the exact percentage who could use the Glove but it was probably in the range of 5 to 10%, which conservatively translated to approximately 22,000 individuals.

Plans to implement the tremor attenuation system into the Glove's design were made in order to reach people with multiple sclerosis. However, the system was still in the initial stages of development and it was too early to be able to estimate the potential market.

Another aspect of the preliminary study that Cisakowski reconsidered was the pricing of the customized electrodes and fabric. She estimated that 100-200 customized electrodes sold at \$1.50 apiece would be purchased each year by the Bionic Glove user. Replacements for the Glove's shell/lining, available in a variety of colours, would be sold for \$200.

Distribution

Because the product was leading edge, it would be difficult to find a suitable distributor. Neurokinetics would have to approach the market directly.

Sales to spinal cord injured individuals are usually channeled through occupational therapists and physiotherapists involved in the rehabilitation process. For example, an occupational therapist might call a medical equipment sales operator and request demonstrations of equipment to best meet the needs of the patient. The sales representative would then bring a few products to the patient to try. The decision to buy would be influenced by the occupational therapist.

The Bionic Glove was already gaining exposure through clinical trials on patients in Edmonton. Neurokinetics believed it was beneficial to launch trials in other major centres. Because the trials involved the therapists as well as the patients, the Glove would penetrate the market even before it was ready for distribution. In this way, commercialization and research would occur at the same time.

Clinical Trials

Prochazka had worldwide connections to major rehabilitation centres. Neurokinetics initiated clinical trials at many of these centres to create an awareness of the Bionic Glove and establish channels of distribution. The clinical trials not only introduced Bionic Glove to the market, they also generated a list of recommendations geared towards its improvement and the reduction of overall medical costs.

The patient profile detailing the eligibility requirements for the Glove clinical trials was:

Level of injury	C5 (no wrist extension) C6 (wrist extension) C7 (wrist extension, some finger action)
Nerve damage	Minimal; healthy nerves must be intact for effective FES
Age of injury	Less than one year; more than one year: as soon after rehabilitation as possible
Age of patient	Statistics suggest most are 18-25 yrs. at time of injury, but all ages qualify
Psychological factors	Willing to accept the Glove cosmetically Accept the Glove instead of "tricks"

Over 80 control boxes were manufactured and distributed to clinics worldwide and 23 individuals with spinal cord injury were enrolled in the clinical trials (Edmonton: 5, Miami: 5, Zurich: 6, Toronto: 4, and Chicago: 3). There were plans for 20 more devices to be manufactured and supplied to proposed Australian and Vancouver sites.

To ensure that the Glove was tested properly and the best results were achieved, clinicians were trained in the fitting and operation of the Glove. The clinicians then trained the users.

Initial reactions to the Glove were very encouraging. The test patients regained the ability to perform certain tasks independently such as: lifting heavy objects, using a hammer, opening doors with round smooth knobs, and eating finger foods. Users also demonstrated an increased efficiency in performing tasks they could already do with the aid of other devices (splints or orthoses) such as writing, using cutlery, toothbrushes, keys, and drinking from a cup or glass.

After using the Glove for a period of time, the patients had a number of suggestions for its improvement.

- The lack of aesthetic appeal was an area of concern. Cosmetically, users wanted a compact device that could be concealed under a shirt sleeve. The patients were also hesitant about having electrode placement marks tattooed on their skin.
- Patients encountered another difficulty when fixing the electrodes to their skin. The electrodes were held in place by an adhesive strip much like a Band-Aid. The electrode had to be peeled off a protective covering and placed accurately on a small area marked by a tattoo -- precision that is very

difficult for most motion-impaired individuals to achieve. Most patients used their mouths to perform this task, and it was frustrating to place the sticky electrodes in this way.

- The Glove needed to be comfortable if it were to be used for daily living. The fabric had to be durable and breathable and above all the Glove had to fit properly.
- Patients found that they weren't wearing the Gloves outside because they couldn't get enough grip on their wheelchairs and they were afraid of damaging the material with rough movements.
- The trials revealed that the patients were only using the Glove for one or two purposes because it was time consuming to adjust. Re-adjustment meant a series of wrist movements and button punches until a suitable grip was found.
- The clinical trials also found that only 60% of the patients used the Bionic Glove throughout the entire test period. Many patients returned to the methods they were accustomed to rather than incorporating the Glove into daily living. Continued development of the Glove aimed to improve these results.

Product Development

Feedback from the clinical trials changed the design of the Bionic Glove. It progressed from a prototype comprised of a glove made from a tensor bandage with wires leading to a separate control box, to a sleek, neoprene glove with a simple, compact control box attached to the arm of the glove by a neoprene pocket.

To make the Glove more commercially viable, a Windows-based program was developed so that the clinician could easily set parameters for the range and intensity of the patient's movement. Once these parameters were set with the aid of a computer, the Glove functioned on its own to meet the patient's needs. A system of calibration was invented so that adjusting for a new task was done simply by pushing a button and moving the wrist to indicate in which fashion the fingers were required to move. A calibration system was also being developed to scale the range and intensity of the grip.

The cosmetic appearance of the Glove was greatly improved when the two components of the device (the glove and the control box) were joined. Using miniature electronics, the control box was reduced in size so that it could fit into a pocket attached to the arm of the Glove. Research continued on reducing the size of the control box. The device had not yet reached the stage where a shirt sleeve could be easily pulled over it.

The neoprene fabric allowed for more wear and tear, a better look, and a more comfortable fit. Neoprene is a breathable fabric that can be stretched to enable a better fit. Later versions of the Glove used a combination of mesh, leather and neoprene. The mesh prevented the Glove from being too hot and it allowed the user to see the electrode placement mark in order to adjust the electrodes without having to remove the Glove. Leather patches sewn to the neoprene in high stress areas of the hand, increased durability and allowed for a better grip so that maneuvering a wheelchair while wearing the Glove was possible.

The sixth generation Glove had a constant current output stage, which provided more consistent stimulation and reduced possible electrode discomfort. To conform to CSA standards, modifications were made to the charging connector and the circuit board was refined to improve reliability and tolerances. The circuitry that transformed stimulating pulses to high voltages was upgraded to increase energy efficiency and reduce transducer noise. A battery low light was installed. There were also plans to install a watch and a TV remote control. The researchers estimated that the Glove would be ready for market in about a year.

Regulatory Considerations

Before the Bionic Glove could be sold, it had to meet certain regulatory requirements. The initial design and prototype had to pass a rigorous approval process to be accepted and recognized in the medical field. The costs involved for receiving regulatory approval included testing, labeling, safety inspections, and filing and reporting costs needed for submission to the Medical Devices Bureau.

Tests had to indicate that the claimed benefit and performance characteristics were justified. The clinical trials would help to prove the Glove's benefits and the first steps for receiving regulatory approval were under way.

Four main regulatory requirements categories had to be addressed:

- Electrical accreditation - UL (USA), CE (Europe), and CSA (Canada)
- FDA approval
- GMP - For manufacturing (FDA monitored)
- ISO 9001 - Also for manufacturing; necessary for European sales.

Sales Projections

Sales projections were based on the following assumptions:

- The company would begin operations on July 1, 1994.
- A president, physiotherapist, technician, and senior administrative assistant would be in place at that date.
- There would already be a total of seven units at beta test sites.
- Fifty units would be manufactured to order and sold within the first year of operations.
- The Glove would be sold for an average price of \$1,200 retail (\$840 to distributors).

The projected sales of the Bionic Glove were:

	Year 1	Year 2	Year 3	Year 4	Year 5
No. of units sold to existing patients in that year	40	2,000	1,400	3,200	4,000
No. of units sold to new patients in that year	10	100	500	800	1,000
Total year sales in units	50	1,500	2,500	4,000	5,000
Cumulative unit sales	50	1,550	4,050	8,050	13,050
Total annual sales	\$42,000	\$1,260,000	\$2,100,000	\$3,360,000	\$4,200,000

The cumulative total of 13,050 Gloves sold by the end of year 5 assumed both a significant replacement cost and market penetration beyond North America.

Electrodes would be sold at the rate of eight electrodes per month per Glove at a retail price of \$10/pkg. of four electrodes, of which Neurokinetics would receive \$8/pkg. The sales forecast for electrodes was:

	Year 1	Year 2	Year 3	Year 4	Year 5
No. of Gloves in use at end of year.	50	1,500	4,050	8,050	13,050
No. of pkgs. sold during year.	492	15,374	71,560	193,200	313,200
Yearly \$ sales of electrodes.	\$3,936	\$122,992	\$572,480	\$1,545,600	\$2,505,000

Financing

A suggested seed capital investment of \$500,000 was required to launch Neurokinetics. This capital was obtained through private investment (\$300,000), the Neuroscience Network of Centres of Excellence (\$125,000), and the Alberta Heritage Foundation for Medical Research (\$75,000).

The development of innovative medical devices is a costly enterprise and required considerable financial backing. Initially, this backing was provided by the Neuroscience Network of Centres of Excellence (NNCE). The Neuroscience division at the University of Alberta was a member of NNCE.

Other assistance came from the Alberta Heritage Foundation for Medical Research. AHFMR's Technology Commercialization Program assists Alberta innovators with the transfer of new ideas and scientific findings into successful commercial health-related products and processes. Phase I funding requirements include:

- a clear, concise description of the technology, device or process
- familiarity with literature in the field, and current competitive or emerging technologies
- qualifications/training/experience of individuals associated with the project
- a convincing argument regarding potential for commercial success
- a general idea of the market size and characteristics
- potential strategy to bring the project to market
- a work plan with milestones related to the use of Phase I funds

Neurokinetics received a Phase I \$25,000 award to assess and strengthen the technical aspects of the project, verify its uniqueness and explore the potential for commercialization.

Neurokinetics then applied for a Phase II award from AHFMR. This funding is intended for continued work on prototypes, intellectual property protection, clinical trials, and development of a detailed business plan. The award for Phase II development given to Neurokinetics was \$75,000. Requirements for Phase II funding include:

- a clear, concise description of the technology, device or process
- a working prototype of the product
- the qualifications of those currently associated with the project and the technical expertise which may be needed to complete the project
- a detailed description of the technical requirements to move the project towards commercialization
- evidence of market interest and an assessment of competing technologies and companies
- assessment of potential for intellectual property protection
- the qualifications of those currently associated with the project and the business expertise which may be needed to complete the project
- an outline of a business plan, including a strategy to bring the project to market
- a work plan with milestones related to the use of Phase II funds

Prochazka also received funding from the University of Alberta and various research grants. As the project developed and crossed into the commercial market, he feared that his research might not be eligible for this funding, which remained vital to the development of the Glove.

Commercial and Technical Risks

Regulatory delay. In the medical device industry, one of the biggest barriers to product commercialization is regulatory control. Any delays in regulatory approval significantly increase the investment and time required to commercialize the product.

Reimbursement. The increasing pressure to contain healthcare costs makes the reimbursement process more difficult, especially for novel, innovative devices such as the Bionic Glove.

Pricing. Healthcare cost containment causes managed care and other private health purchasing systems to seek greater price concessions from medical device manufacturers. Products must be priced competitively but cost effectively, given other alternatives.

Financing. At the time of Neurokinetics' formation, it was becoming more difficult for start-up companies to access venture capital. Investors were concluding that the medical device industry was less financially attractive due to expanded regulatory requirements and market pressures. These pressures increased the cost of product development and commercialization, and at the same time limited return on investment.

Delays in ISO 9001/GMP implementation. In order to sell medical devices, manufacturing operations must comply with certain both quality assurance and design standards. These standards are time consuming and expensive to implement. Delays in certification resulting in delays in sales are a serious risk.

Recruitment of management. The success of a company depends upon effective and timely decisions made by its management team. For Neurokinetics, recruitment of suitable individuals was difficult because management expertise in the medical device area was scarce in Canada. As well, the lower value of the Canadian dollar was a barrier to hiring the best talent from other countries.

Research and development. Research-oriented institutions and academic medical centres are the source of most medical technology. Reduced funding of these institutions would affect Neurokinetics' ability to source new innovations and products.

The Researcher's Dilemma

Arthur Prochazka's objective in establishing Neurokinetics was to assist as many people as possible. He believed that the Bionic Glove would make everyday life easier for motion-impaired individuals. In the process of assisting a greater number of people, Prochazka hoped to generate more money to further his research. And he remained curious to find out if the Bionic Glove would make a successful commercial venture.

As a professor, Prochazka considered that his priorities were his students and his research. The demands made on his time by Neurokinetics were interfering with the time he spent with students and research projects other than the Bionic Glove. He did not wish to risk the lab's learning environment, which he had worked so hard to nurture and maintain. Prochazka even attributed the loss of one of his graduate students to the time he spent commercializing the Bionic Glove.

The way in which he was perceived by his colleagues was also important to Prochazka. It concerned him that these perceptions were changing as a result of his involvement with Neurokinetics. He had dedicated much of his life to academia and wished to continue his research for at least another 15 years.

To maintain good relations with his colleagues, Prochazka tried to keep his business dealings as open as possible. For example, he wrote letters to the department head to advise him when any company business was being conducted in the lab.

Prochazka was also concerned about how the views of his colleagues might affect his research funding, since some of his colleagues were involved in decisions on the allocation of research funding. If they thought that the Glove would make money, would they assume that he did not need funding to continue his research?

After the initial steps towards commercialization, Prochazka thought that he would have more time to dedicate to his research. Neurokinetics was intended to be secondary to his research, but this was proving not to be the case. Instead, it appeared that more and more of his time was going to be taken up by the company. Despite the time constraints placed on him by Neurokinetics, Prochazka did not wish to abandon development of the Bionic Glove. He wondered if there was some way to continue his research as well as commercialize the Glove.

Appendix A: Competition

Markets

At the time of Neurokinetics' establishment, the quadriplegic segment of the medical equipment supply market consisted of products that ranged in price from \$50 to \$30,000. The complexity of this equipment depended on the level of personalized fitting required.

There were two channels of distribution for these products: retail outlets and physician-driven sales. Financing was diverse, as funds were available through Workers' Compensation Boards, the Department of Motor Vehicles and Accident Claims Fund and other insurance bodies.

With the radical evolution of semi-conductors in general, the industry had developed and refined technology. Medical researchers from different countries were experimenting with computer-controlled devices to aid the handicapped in different areas. The use of electrical stimulation in general was gaining momentum and there were several established companies supplying medical products to the market. Aside from FES (functional electrical stimulation), companies had developed devices using Transcutaneous Electrical Nerve Stimulation (TENS), and Neuromuscular Electrical Stimulation (NES).

The risks involved in entering the FES market from scratch were high. If the FES market really heated up, new entrants could become direct competitors. However, the combined skills of the scientists and physiotherapists made Neurokinetics unique. It was estimated that these competitors would be two years behind Neurokinetics.

Glove Competitors

At the time of Neurokinetics' formation, the only closely competitive technologies came from companies such as NESS and NeuroControl. Neither of these companies were particularly strong financially and each of them had products that were more complicated and more expensive than the Bionic Glove.

The **Handmaster**, developed by NESS, was based on research conducted by Dr. Roger Nathan at Ben Gurion University in Israel. The device rigidly splinted the wrist and activated muscles according to a pre-stored pattern when a button was pushed on the control box. The control box was separate from the device. While the device was commercially available in Canada, none had been sold and in the United States as FDA approval had not been received. Some Handmasters had been sold in Europe. The cost of the entire system was \$3000 US.

The main drawbacks of the Handmaster were: the electrode placement not being customized, the separate control box and wires, and the fact that it was not suitable for patients with active wrist movement.

Prehension orthoses (wrist driven and ratchet orthosis) were devices that had successfully been used by some quadriplegic people. However, many were discarded because of problems in getting them on and off, pain caused by ill-fitting devices and poor cosmetic acceptability. It was also difficult to find an orthotist who would custom fit these devices. The cost of these orthoses was approximately \$1500 US.

The **Free Hand System** was developed by NeuroControl. It used implanted FES technology and was not yet commercially available. It was a relatively complex, invasive device requiring surgical implantation of electrodes and a stimulating unit similar to a cardiac pacemaker. Following implantation, there was a fairly extensive and complicated procedure to program an effective hand grasp. Training was required to become proficient with the system. The cost was approximately \$30,000 US.

Potential users had to wait at least two years after their injury before being considered for the implant. It was suggested that the Glove be used in the interim, while the patient awaited surgery.

Tendon transfers had been performed by orthopedic or plastic surgeons in some centres to improve upper extremity function following spinal cord injury. Potential candidates had to wait at least one year after their injury to be considered, and had to meet certain physical and psychological criteria. This approach required a significant time and financial commitment and the functional outcomes were unpredictable. As with the Free Hand system, the Glove might have a role to play in the period preceding tendon transfers.

The advantages of the Glove over the existing solutions were:

- Easy to put on and take off
- One self-contained unit, no wires or outside control boxes
- Implantation and surgery not required
- Easy to use
- Comfortable, lightweight and breathable -- made of stretchy neoprene and lycra mesh
- Cosmetically acceptable
- Reasonable cost: \$1500
- Users control the stimulation and the duration through wrist action, and are not limited to preprogrammed stimulation
- Users have the ability to perform tasks they could not otherwise perform: manipulating heavy objects, picking up objects, and using tools
- Washable

Indirect Competition

A major challenge to acceptance of the Glove was overcoming the established system that patients had developed in order to cope in everyday life. The greater the length of time since the patient's accident, the more difficult it was to introduce the Bionic Glove. Some patients did not want to spend the time and energy learning how to use this new technology. Instead they relied on:

- Other devices (splints, for example) used by rehabilitation centres to assist quadriplegic patients.
- Hand "tricks" developed by quadriplegic patients used to assist with basic hand functions.
- Personal assistants hired to help patients with daily living, and thus act as substitutes for the patient's hands and feet.

The acceptance rate for the Glove was higher with recently injured patients who had not yet developed a system. To curb indirect competition, the Glove was introduced at an early stage of rehabilitation. It was also necessary to explain exactly what the Glove was able to do so that patients' expectations did not generate false hope.