The Design Process Applied to the Development of Orthopedic Transcutaneous Electrical Nerve Stimulation (TENS) Devices for the Treatment of Acute Pain

by

Kenneth Jerome Francis Michlitsch

S.B., Mechanical Engineering
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ABSTRACT
The principal objective of this study was to apply a structured design process to the development of novel orthopedic devices that incorporate transcutaneous electrical nerve stimulation (TENS) for the treatment of acute pain. A modular design was adopted which allows a standardized controls and battery package to be used in a variety of splints, braces, and immobilizers. Prototype knee and wrist splints were created as platforms to test modularity and to serve as proofs of concept. This paper serves as a case study in the application of a structured design process.

Thesis Supervisor: Ernesto E. Blanco
Title: Professor of Mechanical Engineering

Muchas Gracias

With any large accomplishment in life, credit will go to a few or even a single person, but very little can be accomplished without the support of a great many people so that one person can shine. If I can take a little liberty and create a Dickensianly long sentence, I'd like to thank Dr. Bill Colston of the Medical Technologies Program (MTP) at Lawrence Livermore National Laboratory (LLNL) for his total commitment to seeing that I had both a gratifying master's project and the resources to accomplish that project (I enjoyed bankrupting you, Bill); thanks are also due to Dr. Luiz DaSilva of MTP for taking a chance on an engineer in a group of physicists; to Bob Langland of LLNL, for putting up with Kirk and I over the last three years, for many free dinners, for working to finagle finances, for giving me the freedom to identify projects I found intellectually stimulating, and for other things too numerous to mention here: thank you; to Steve Michelson, CEO of Cyclotec Medical Industries, for allowing a student you knew very little about to come in and have significant influence over the direction of your company - I learned a great deal in large part due to the autonomy I was given to develop my own ideas and follow pathways whose commercial viability wasn't always clear; to Ernesto E. Blanco, Professor of Mechanical Engineering at MIT, for agreeing to supervise a thesis project from 3000 miles away - his support and direction provided the guidance I needed to complete a large project in a very limited amount of time; to Dr. Sergey Pevney, Director of Biofil Ltd. in Russia, for wonderful background information and for rapid fabrication of TENS control device parts vital to the success of the project; to Dan Schumann and Kelye Allen of the LLNL plastic shop for their use of innovative techniques in the prototype production of my knee brace that allowed me to produce production-quality parts at reasonable costs; to Woodie Manchester for flex circuitry; to Ginny Morgan of Ginny Inc. for keeping me on track about what was really possible and for amazingly fast turnaround in the development of the first wrist splints; to my coworkers at LLNL for always keeping life lighthearted; and, finally, to my family and friends whose love and support are as deep and endless as the sea and the stars in the sky: there is absolutely no way I'd be at this point without them.

In the course of my studies, several people very dear to me have passed away.
I dedicate this paper to their memories. I am a better person because they were.

Grandma Jane Fortino
Grandpa Math Michlitsch
Uncle Nino Pontarelli

And so tonight, I, along with one of my great heroes, can take pride in the words of that black spiritual, "Free at last. Free at last. Thank God, Almighty, I am free at last!!"

TABLE OF CONTENTS

1.0 INTRODUCTION

A structured design process was applied to the development of novel orthopedic devices that incorporate transcutaneous electrical nerve stimulation (TENS) for the treatment of acute pain. A modular design was adopted that allows a standardized controls and battery package to be used in a variety of splints, braces, and immobilizers. Electrode arrays were developed for many different areas where TENS therapy has been shown effective including the neck, cervical spine, wrist, shoulder, elbow, hand, thumb, scapula, abdomen, knee, hip, and ankle. A prototype knee immobilizer and a wrist splint with integrated TENS technology were created as platforms to test modularity and to serve as proofs of concept.

Therapeutic TENS devices developed as a new modality for the treatment of pain in the late 1960s due in large part to a greater understanding of the nervous system and the ways in which pain signals are transmitted and muted. Gate control theory, the seminal work on pain developed by psychologist Ronald Melzack and physiologist Patrick D. Wall whom met while faculty at MIT [1], most directly led to TENS. It holds that the painful stimulation applied at afferent nerve endings is not the same as the painful stimulation transmitted to the brain. Instead, stimulation is pooled at the dorsal horn of the spinal cord. There, the substantia gelatinosa modulates the signal actually passed to consciousness based on input from both nerve endings modulating pain and those modulating touch. Melzack and Wall theorized that an increase in the stimulation of nerve endings modulating touch would decrease the sensation of pain due to 'gating' at the dorsal horn. TENS seeks to stimulate touch nerve fibers at a pain site with low current electrical waveforms below the threshold of nerve endings modulating pain.

TENS is an attractive alternative to conventional methods of relief for the symptomatic aspects of pain. Drug therapy can be highly addictive with severe side effects. Surgical procedures are even more drastic than medication, can lead to debilitation, and are often ineffective. TENS has been proven safe with very minimal side effects. Its contraindications are few and clinical trials have shown that it can help a significant percentage of people that needlessly suffer from pain.

Pain is often classified into two categories, acute and chronic, based on its duration. Acute pain is short lived with an identifiable cause and purpose. Chronic is much longer lasting, and its cause and purpose is not always clear. TENS has traditionally been used as a pain modulation technique in the treatment of chronic pain. However, research suggests that TENS is most effective in early treatments and when applied close to the onset of pain. It is therefore perhaps better suited to the modulation of acute pain. Acute pain sufferers represent a much larger patient population than chronic sufferers. This study sought to seamlessly integrate TENS into products aimed at the acute pain market.

Acute pain sufferers have different needs than those with chronic pain. They generally live more active lifestyles and require therapies sympathetic to their needs. Currently available TENS devices consist of a TENS stimulator connected by long, entangling wires to TENS electrodes placed at the site of pain. The user alters stimulation parameters to find optimum settings. The devices are often unwieldy and their use is not

always intuitive. Advances in battery technology and microprocessing capability have made it possible to create more intuitive, essentially wireless TENS devices that limit impact and interference with the lifestyle of the patient.

This papers presents an engineering study aimed at applying a structured design process to the development of orthopedic TENS devices for the treatment of acute pain. The major steps in a generic design process are concept development, system-level design, detail design, testing and refinement, and production ramp-up. Concept development can be further delineated into identification of customer needs, establishment of target specifications, analysis of competitive products, concept generation, concept selection, refinement of specifications, economic analysis, and project planning.

A new and innovative modular TENS control device was adopted as the platform from which an entire product line is being developed. The product line focuses on three areas of concurrent development: 'Band-Aid™' TENS devices; remotely operated TENS devices; and orthopedic braces, splints, and immobilizers with integrated TENS technology. This study focused on the final area. Specifically, α prototype knee immobilizers and wrist splints were developed. The devices are presented herein from problem statement through prototype in relation to the structured design process. Methodologies for each of the constitutive steps in the process are provided in the context of application to these orthopedic TENS devices.

The goals of this paper are twofold:

1. To provide the practitioner of product development with a case study for examination and discussion of the major steps of development, design methodologies, pitfalls, and lessons learned
2. To facilitate and expand the use of TENS for the treatment of acute pain by creating devices focused on the needs of the designated patient population

Within these two goals, it is my hope that both product developers and members of the medical community can learn about the issues of importance to one another so that communication between our disciplines can proceed in a slightly more informed manner, thereby facilitating advances of importance to us all.

Before the TENS knee immobilizer and wrist splint are presented, a background chapter develops an understanding of the problem. As this paper is at least in part written for the practicing engineer, it expects very little prior knowledge about the structure or function of the human nervous system. The salient features at the cellular, organ, and patient scales are discussed. Types of pain, pain transmission and modulation theory, and methods of treating its symptomatic aspects are then presented. The background section concludes with a discussion of TENS. In turn, it addresses historical development, possible mechanisms of action, and clinical efficacy.

Once the reader has attained a solid understanding of the background and impetus for the study, a chapter on the design procedure presents a structured design process. Next, prototype discussion gets to the heart of the study and systematically examines the

application of the design process to a real-world problem: namely, the development of prototype TENS knee immobilizes and wrist splints for the treatment of acute pain. Finally, conclusions sum up the work and discuss the role of a structured methodology in successful development efforts. By remaining focused on the needs of the patient population, better products that are more relevant to the patients' needs can be developed.

2.0 BACKGROUND

Before application of the structured design process continues, an understanding of the nervous system, pain theory, and TENS is necessary. Section 2.1 lays out a simplified model of the nervous system at each of three scales relevant to any medical device: the cellular (10 μm), organ (1 cm) and patient scales (1 m). Section 2.2 then establishes a solid foundation for a discussion of pain and its treatment by addressing its physical, physiological, and psychological aspects. Pain transmission and modulation theory is developed in its historical context from Specificity and Pattern through Gate Control and opiate receptors. Gate Control theory, first proposed in 1965, provided scientific justification for the use of electrical stimulation as a method of pain modulation. The discovery of spinal opiate and nonopiate receptors shortly thereafter provided further evidence that noxious stimuli could, in fact, be modulated by selective stimulation of afferent nerve fibers.

Section 2.3 begins with a brief history of electrotherapy. It then discusses TENS, its possible mechanisms of action, its clinical efficacy, and its use as part of comprehensive therapy aimed at breaking the Pain Cycle. As a modality, TENS has been shown safe and effective in relieving the symptomatic aspects of pain.

2.1 The Nervous System

The human nervous system allows us to interact with our environment in ways that are both elegant in their simplicity and fantastically incomprehensible in their subtlety. It is responsible for the rapid transfer of information in the form of electrical signals. Section 2.1 develops an understanding of its function from the microscopic to the macroscopic level.

2.1.1 The Cellular Scale

The nervous system at this fundamental scale is relatively well characterized in the literature. Basic information on its structure and function is available from a variety of sources. The discussion here is principally developed from Review of Medical Physiology by William F. Ganong [2] and Electrical Nerve Stimulation: Theory, Experiments, and Applications by Frank Rattay [3].

The cells of the nervous system are called *neurons*. The human nervous system contains about 1 trillion neurons, which exhibit significant differentiation appropriate to their specialized functions. The great majority of these cells are concentrated in the central nervous system (CNS). The remainder comprise the peripheral nerve system, which is made up of *sensory*, or afferent, neurons that send information from the body to the CNS and *motor*, or efferent, neurons (also known as motoneurons) that send information from the CNS to the body.

Despite their specialization, most neurons are comprised of the same basic parts. The spinal motor neuron of Figure 1 illustrates the salient features.

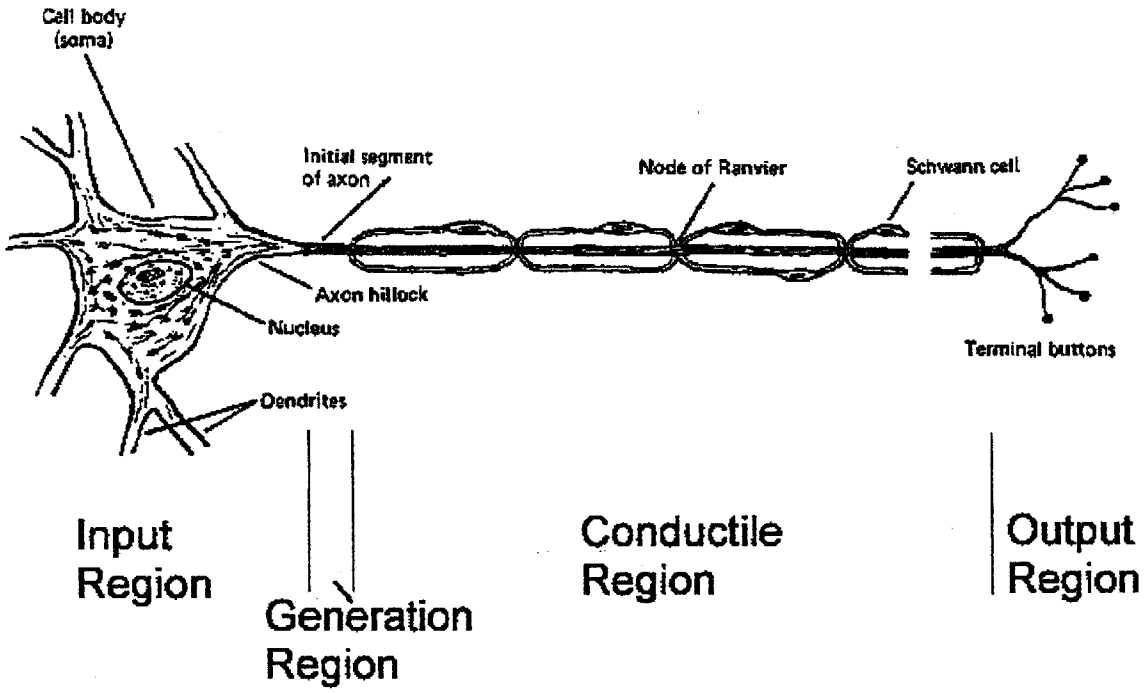


Figure 1

Spinal motor neuron with myelinated axon.
(Adapted from Ganong, William F. Review of Medical Physiology, 18th ed.
Copyright 1997 by Appleton & Lange; Stamford, Connecticut [2; p. 48].)

The *soma* is the cell body of the neuron, which encloses the nucleus. One or more processes extend out from this body. A unipolar neuron has only one process, a bipolar has two, and a multipolar neuron has three or more processes. The spinal motor neuron has 5-7. One process is usually much longer that the others and is known as the nerve fiber, or *axon*. The shorter processes are called *dendrites*. The axon carries outgoing information to areas up to a meter away from the cell body. The first section of the axon is called the *initial segment*. The initial segment generates propagated electrical impulses. At the end region, the axon divides into several branches, which conclude at *terminal buttons*. At this widening, known as the *synapse*, the neuron is in close contact with other nerve cells. The terminal buttons store synaptic transmitters that the neuron secretes to communicate with other cells. Up to 200,000 synapses, which bring in information from other nerve cells, cover the dendrites and cell body. Some promote, while others inhibit, excitation. Heat, electricity, chemicals, pressure, or other stimuli at the Input Region excite sensory neurons. These inputs sum together and propagate into the axon. If they are small, no information will be transmitted by the neuron. However, excitation above a certain *threshold* generates an *action potential*, or electrical impulse. This is commonly known as the *all-or-nothing principle*.

To summarize, four key regions make up the neuron. The Input Region, comprised of the dendrites and soma, integrates local potential changes from multiple synaptic connections. Next, a Generation Region (the initial segment or the initial node of

Ranvier) actually creates propagated action potentials when local potential changes exceed the threshold value. Then, a Conductile Region (the axon) transmits the propagated impulses to the nerve endings. Finally, an Output Region releases synaptic transmitters, and the information is conveyed to other neurons.

A long cylinder of material known as axoplasm, surrounded by an electrically excitable membrane, makes up the axon. Axon diameter and insulation by *myelin*, a protein-lipid complex composed of the cell membrane of Schwann cells wrapped around the axon, determines conduction velocity. Neurons surrounded by this complex are deemed myelinated. The myelin sheath covers the axon except at its ending and at the *nodes of Ranvier*. Nodes of Ranvier are about 1 μm in size and about 1mm apart. Myelin significantly increases a neuron's electrical insulation and, in turn, its conduction velocity.

Some nerve cells are merely surrounded by Schwann cells without the myelin wrapping; these are termed unmyelinated. Conduction velocity in unmyelinated neurons is much slower than in myelinated and is proportional to the square root of fiber diameter.

2.1.2 The Organ Scale

The sensory neurons of the peripheral nervous system embedded in the dermis of the skin are of pertinent interest to TENS (and gate theory). Peripheral neurons specialize to convey different types of information and are generally classified by either letter or number according to their specialization. Table 1 classifies the neurons by letter and lists their function, axonal diameter, and electrical characteristics. Table 2 then lists their less common numerical classification.

Table 1
Nerve fiber types in mammalian nerve.*
(From Ganong, William F. Review of Medical Physiology, 18th ed.
Copyright 1997 by Appleton & Lange; Stamford, Connecticut [2; p. 57].)

Fiber Type	Function	Fiber Diameter (μm)	Conduction Velocity (m/s)	Spike Duration (ms)	Absolute Refractory Period (ms)
A					
α	Proprioception; Somatic motor	12-20	70-120		
β	Touch, pressure	5-12	30-70		
γ	Motor to Muscle spindles	3-6	15-30	0.4-0.5	0.4-1
δ	Pain, cold, touch	2-5	12-30		
B	Preganglionic autonomic	<3	3-15	1.2	1.2
C					
Dorsal Root	Pain, temperature, some mechanoreception, reflex responses	0.4-1.2	0.5-2	2	2
Sympathetic	Postganglionic sympathetics	0.3-1.3	0.7-2.3	2	2

*A and B fibers are myelinated; C fibers are unmyelinated.

Table 2
Numerical classification of sensory neurons.
(From Ganong, William F. Review of Medical Physiology, 18th ed.
Copyright 1997 by Appleton & Lange; Stamford, Connecticut [2; p. 57].)

Number	Origin	Fiber Type
Ia	Muscle spindle, annulo-spinal ending.	A-α
Ib	Golgi tendon organ.	A-α
II	Muscle spindle, flower-spray ending; touch, pressure.	A-β
III	Pain and cold receptors; some touch receptors.	A-δ
IV	Pain, temperature, and other receptors.	Dorsal root C

Note that small diameter A-δ and dorsal root C fibers are the *nociceptors* – nerves that convey painful excitation. The A-δ fibers are myelinated and conduct information much more rapidly than the C fibers. Pain provoked by A-δ fibers is usually of short duration but is sharp, distinct, and well localized. Pain carried by C fibers is more of the dull, aching variety that is diffuse and long lasting [4; pp. 2-3]. Also notice that the much

larger diameter and faster conducting A-β fibers transmit touch and pressure stimuli. This will be of particular interest when discussing Gate Control theory in Section 2.2.

2.1.3 The Patient Scale

The patient scale encompasses the whole of the human nervous system, which influences reflexes, hearing, vision, smell, taste, posture, autonomic actions, emotions, memory, behavior, temperature, touch, pain, and a host of other life-sustaining activities. The nervous system is far too broad a topic to discuss here in any detail, but of pertinent interest to TENS are the transmission pathways governing touch and pain. How does stimulation of sensory neurons at a location significantly remote from the brain enter consciousness; affect emotion, memory, conditioning, etc.; and provoke a coordinated response from the body? Is it possible to modulate the information passed to the brain and thereby diminish or relieve the symptomatic aspects of pain? This section attempts to explain the sensory pathways in somewhat general terms. Although some details are still unclear, especially in the cognitive functions of the brain, the pathways are well characterized in the literature, and have been for some time. The discussion here is primarily based on Essentials of Neurology by Lord Walton [5] and An Evaluation of Transcutaneous Electrical Nerve Stimulation for the Treatment of Pain Related to Spinal Cord Injury by Jason N. Doctor [6]. Secondary information is also derived from Relief of Pain by TENS by Bengt Sjoelund and Margareta Eriksson [7], and Pain Mechanisms: A New Theory by Ronald Melzack and Patrick Wall [1].

The sensory pathways are seen in Figure 2.

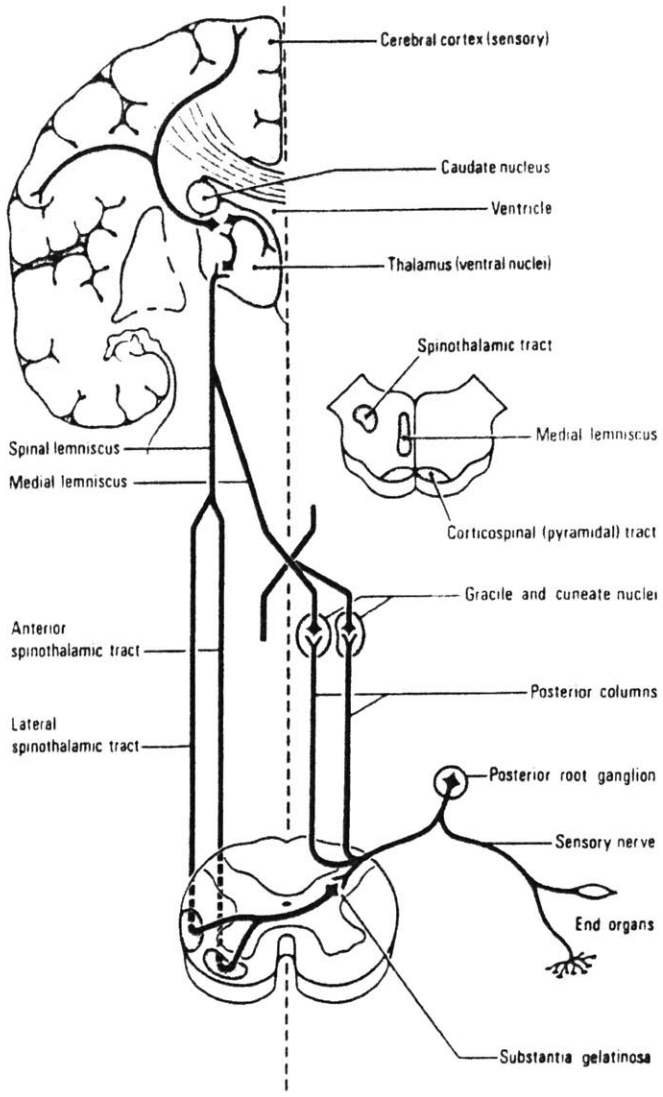


Figure 2

The sensory pathways. The central fibers of the sensory nerves enter the cord through the posterior roots. The ascending branches of those mediating fine touch, vibration and kinaesthetic sensation run in the posterior white columns to the gracile and cuneate nuclei. Here they relay and cross to form the medial lemniscus, which traverses the medulla and pons and midbrain. The fibers mediating pain and temperature and gross touch enter the dorsal grey column and relay in the substantia gelatinosa. The second order neurons cross the cord and form two tracts, the anterior and lateral spinothalamic tracts. These come together in the medulla and then join the medial lemniscus. This large sensory bundle of fibers (the lemniscus) which carries all forms of sensation from the opposite side of the body terminates in the ventral nuclei of the thalamus. From the thalamus, tertiary neurons pass to the sensory cortex. (The small drawing to the right shows the positions of the medial lemniscus and the spinothalamic tract in the medulla.)

(Conybeare's Textbook of Medicine, 16th ed. W.N. Mann, Editor.
Copyright 1975 by Churchill Livingstone; Edinburgh, UK [8].)

Action potentials regulating touch, pain, temperature, etc. are synaptically transmitted to the cells of the first sensory neuron in the posterior root ganglia. These neurons are bipolar, having peripheral dendrites that convey afferent impulses from the sensory receptors, and central axons that enter the spinal cord in the posterior nerve roots or dorsal horn [5; p. 164]. Here, all impulses are pooled and the analgesic effects of TENS are thought to take place. Neurons arising from the substantia gelatinosa modify or 'gate' the sensory stimuli (especially pain) sent on to transmission cells (T cells) based on the pool of incoming impulses. T cells then convey the information on to higher levels. Section 2.2 discusses gating in more detail.

After gating in the posterior horn, pain and temperature impulses cross the spinal cord and travel up the lateral portion of the spinothalamic tract on secondary neurons. Most touch stimuli travel up the posterior column for a short distance, then cross over the midline and join the anterior portion of the spinothalamic tract. Meanwhile, other impulses travel up the posterior columns. The sensory fibers of the spinothalamic tracts enter the brain at the medulla oblongata. Figure 3 presents the major structures of the brain.

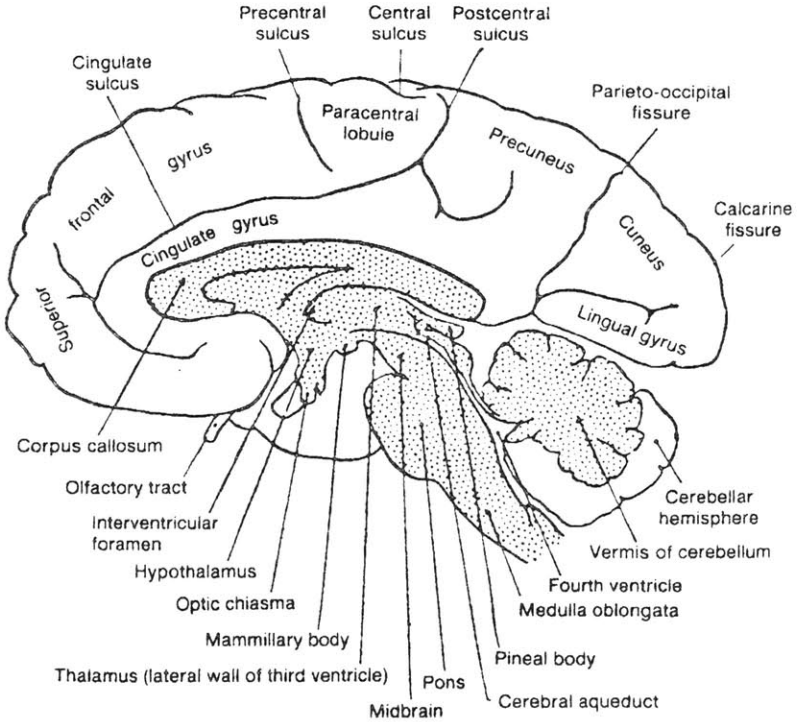


Figure 3

A diagram of the medial aspect of the right cerebral hemisphere.
(From Gardner, E. Fundamentals of Neurology, 4th ed.
Copyright 1963 by Saunders; Philadelphia and London [9; p. 128].)

Upon reaching the medulla oblongata, the fibers travel upwards through the pons and midbrain and terminate in the thalamus. This represents the end of the sensory portion of the nervous system. Tertiary fibers communicate with the sensory cortex and coordinate a response.

The thalamus regulates emotion while the cerebral cortex deals with higher order functions such as memory and learning. Although great progress has been made in determining *where* different forms of information are processed or stored in the brain, *how* such information is stored and processed into a response is still unclear. For TENS, perception is of much greater importance than response. Although studies have shown that pain can be modulated directly in the brain [6], TENS acts at lower levels in the spinal cord. For our purposes, it is therefore unnecessary to discuss processes of the brain in more detail at this time.

This section gave a brief description of the nervous system at the cellular, organ, and patient scales. It provided the necessary background for an informed discussion on pain: what it is, how it's caused, and methods of controlling it. These, and other issues, are developed in Section 2.2.

2.2 Pain

Yes – Pain! Only you cause humans to become really human.
-Alphonse de Lamartine: Harmonies

Pain. The word conjures complex and highly personal images of hardship. However, pain can act as a diagnostic aid and lead to a comprehensive treatment program aimed at correcting pathology, controlling symptomatic manifestation, and preventing recurrence. Its symptomatic aspects can broadly be grouped into three categories: physical (trauma, heat, cold), physiological (spasm, inflammation, sensory deprivation, ANS dysfunction), and psychological (emotional). Alleviation of its symptomatic aspects must occur in conjunction with an attempt to rehabilitate the structure that has given rise to the symptoms [10; p. 7]. This section begins with a description of acute and chronic pain and discusses the pain cycle. It then continues Section 2.1's analysis of the pain transmission pathways by developing our understanding in a historical context and specifically focusing on the mechanisms of pain transmission and inhibition. Finally, it lists current techniques available for the relief of pain.

2.2.1 Acute vs. Chronic Pain & the Pain Cycle

Pain has an element of blank;
It cannot recollect
When it began or if there were
A time when it was not.
-Emily Dickinson

Pain is often classified into two types, acute and chronic, in accordance with its duration. Acute pain is short lived, normally lasting no more than a few weeks. It usually leaves

no permanent psychological distress, and its cause and purpose are readily identifiable. By effectively treating the cause while modulating the pain (with heat, massage, medication, TENS, etc.), relief and rehabilitation can rapidly be obtained [11].

Chronic pain is a different and much more complex animal. Pain that has lasted longer than 6 months is generally termed chronic. Chronic pain is both a physical and psychological problem. Its cause is often unclear, its biological purpose is suspect, and it can persist indefinitely. Chronic pain patients frequently abuse medications, undergo surgical procedures without benefit, and become depressed, hypochondriacal, and hysterical [10]. By some estimates, chronic pain is the most costly health problem in the United States. When direct medical expenses, lost income, lost productivity, compensation payments, and legal fees are all added together, the annual bill approaches $50 billion [11].

In their book Clinical Transcutaneous Electrical Nerve Stimulation, Mannheimer and Lampe describe the pain cycle [10; pp. 7-9]. When trauma occurs, the corresponding pain causes the body to protect itself by guarding. Guarding produces muscle tension, which reduces the blood supply and increases metabolites in the affected area. Prolonged guarding leads to fatigue of the nerve fibers and more pain. This, in turn, leads to more guarding, more psychological stress; and the pain is progressively amplified. Clearly, it is important to manage the pain response in order to prevent the pain cycle in those with acute pain, and to break the cycle in those with chronic pain.

If acute pain persists without improvement for more than a few weeks, it may very well become a chronic disorder. Therefore, it is imperative that the cause of such pain be treated quickly and aggressively in conjunction with a pain modulating technique such as TENS to relieve the symptomatic aspects. It must be noted that strictly treating the symptomatic aspects without addressing the cause can precipitate false expectations of healing and lead to chronic behavior. Although most clinicians agree that TENS could be very useful in the treatment of acute pain, research has surprisingly focused on its application to chronic pain. The reasons are many and are described in more detail in Section 2.3. This study sought to integrate TENS into user-friendly, over-the-counter orthopedic devices for the symptomatic treatment of acute pain. Chapter 4 details these efforts.

2.2.2 Historical Development of Pain Theory & Descending Pain Inhibition Pathways

Until the publication of Melzack and Wall's seminal work on pain transmission in 1965, thoughts on pain were nearly equally divided into two opposing schools of thought - and had been since before the turn of the century. In 1894, M. von Frey and A. Goldscheider independently proposed pain transmission theories: specificity and pattern, respectively. Specificity held that "pain is a specific modality like vision and hearing, with its own central and peripheral apparatus," while pattern theory held that pain is produced by "intense stimulation of nonspecific receptors."[1] In pattern theory, there was no such thing as specific fibers or specific endings.

In light of Section 2.1, it is clear that neither theory is strictly correct. Pattern theory recognized the significance of both stimulation intensity and summation in the central nervous system, but it did not, and could not, account for the physiological fact of neuronal specialization. Specificity theory accounted for specialization, but it also assumed a direct link between the point of stimulation and the brain and did not account for central summation.

Melzack and Wall recognized of the shortcomings of both theories and focused on the role of the substantia gelatinosa in pain transmission and modulation. Their work is generally referred to as the Gate Control Theory of Pain. They conceived pain transmission as the control loop seen in Figure 4.

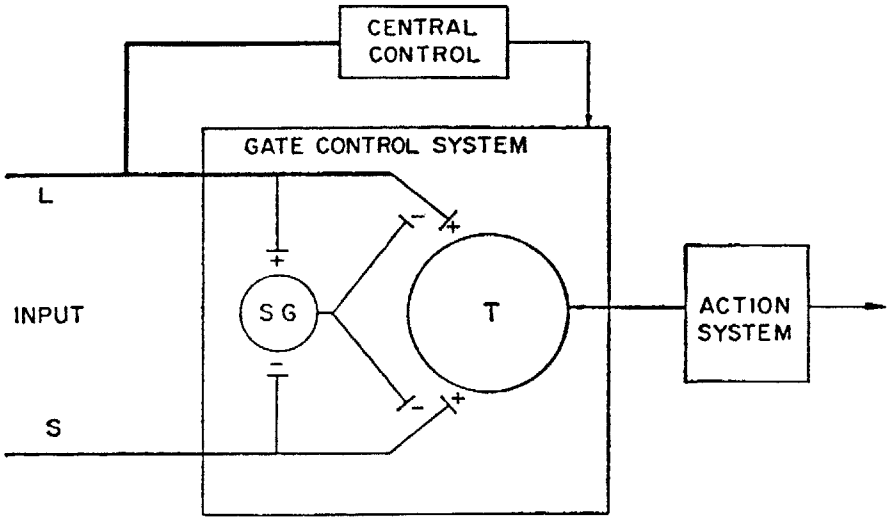


Figure 4

Schematic diagram of the gate control theory of pain mechanisms: L, the large-diameter fibers; S, the small-diameter fibers. The fibers project to the substantia gelatinosa (SG) and first transmission (T) cells. The inhibitory effect exerted by the SG on the afferent fiber terminals is increased by activity in L fibers and decreased by activity in S fibers. The central control trigger is represented by a line running from the large-fiber system to the central control mechanisms; these mechanisms, in turn, project back to the gate control system. The T cells project to the entry cells of the action system. +, Excitation; –, inhibition.

(From Melzack, R. & Wall, P. D. *Pain Mechanisms: A New Theory.* Science, Vol. 150, Number 3699. 11/19/65 [1].)

The theory holds that the painful stimulation actually transmitted to the brain (and other higher levels) is not the same as the painful stimulation applied at afferent nerve endings. Instead, the substantia gelatinosa modulates the signal based on incoming input from small and large diameter nerve fibers. Signals from small diameter axons (including the

A-δ and dorsal root C fibers that transmit pain) act to increase the intensity of pain sent to higher levels while signals from large diameter fibers (including A-β fibers that transmit touch) act to decrease the intensity of pain. Thus, the substantia gelatinosa acts as a 'gate' to regulate pain.

Meanwhile, the central trigger accounts for the ability of attention, emotion, and memory to influence afferent conduction. Efferent fibers from the brain can act by descending inhibitory pathways and activate the control cells in the dorsal horns. Thereby, the brain can directly close the gate [4; p. 13]. Examples include war victims and athletes who often do not experience pain until after the battle or athletic contest is complete.

Although the new theory was not perfect in explaining the highly complex mechanisms of pain, it focused further research on the mechanisms of both transmission and the descending inhibitory pathways. This research directly led to several 'new' treatment modalities for control of the symptomatic aspects of pain. TENS is one such modality. TENS seeks to stimulate large diameter A-β fibers in the painful area with non-painful, low current electrical waveforms - thereby closing the gate. Wall and Sweet [12] conducted the first clinical trials with electrical stimulation based on gate control in 1967. Section 2.3 discusses TENS in much greater detail.

A great deal of work has been done since 1965 in an attempt to prove or disprove the gate control theory. The research has led to a much fuller understanding of the physiological mechanisms and descending inhibitory pathways of pain. Significantly, the method in which the body regulates, modulates, and transmits information between neurons is much clearer at the chemical level. In 1973, Terenius discovered that endogenous opiates and opiate-like drugs bind to specific receptors in the brain to produce their pain relieving effect [4; p. 14]. Serotonin was the first inhibitory neurotransmitter identified. The discovery of opiate peptides, which inhibit pain transmission in the dorsal horn of the spinal cord and in the brain, soon followed. The first peptide was termed enkephalin, and the others are known as endorphins [11].

The descending pathways of pain inhibition have also been characterized much more fully. They are mentioned here briefly. Pain can be inhibited at several different physiological levels. The integrated activity of neurons at these levels is collectively known as the descending pain system. Inhibition appears to occur in the CNS at four levels. The first three levels are in the brain: first, within the cortex and diencephalon, then in the periaqueductal gray (PAG) of the midbrain, and finally in the rostroventral medulla, which includes the nucleus raphe magnus (NRM). The fourth level is the aforementioned dorsal horn of the spinal cord. Opiate and nonopiate neurotransmitters act at these levels to inhibit pain [6; pp. 9-10].

A new generation of drugs developed after the gate theory is also expected to gain FDA approval in the very near future. These analgesics attack specific pain mechanisms and promise to be more effective with fewer side effects.

2.2.3 Methods of Treating the Symptomatic Aspects of Pain

Now that we know what pain is, how it's transmitted, and how it's modulated, the focus must shift to its treatment. Many treatment modalities exist, but the gold standard by which all other treatments are assessed is analgesic medications. Drug therapy acts at all four levels of the descending pain system, as well as peripherally by relieving hyperalgesia (increased sensitivity to noxious stimuli) which occurs at the site of injury [2].

Available drugs are broadly grouped into narcotics and non-narcotics. The best and most widely used non-narcotic drug is aspirin. Aspirin reduces inflammation and desensitizes nociceptors. However, the threat of serious side effects in children requires that care be taken in its administration. Of the narcotics, morphine is the standard. 20-25 other narcotic drugs are also in use; these are either wholly synthetic or semi-synthetic opiate derivatives and include heroin, codeine, Darvon, and Demerol. Narcotic side effects include sedation, confusion, nausea, constipation, and depressed respiration. Unfortunately, all of the more powerful analgesics are highly addictive. There is no efficacy ceiling, so the dosage can always be increased as a tolerance is developed. However, increasing the dosage increases the incident of side effects and physical addiction. Other available drug therapies include the antidepressants, tranquilizers, antihistamines, anticonvulsants, and corticosteroids [5, 11].

Long-term, intractable chronic pain, at times leads to more drastic surgical methods of pain relief. Figure 5 illustrates several of these procedures.

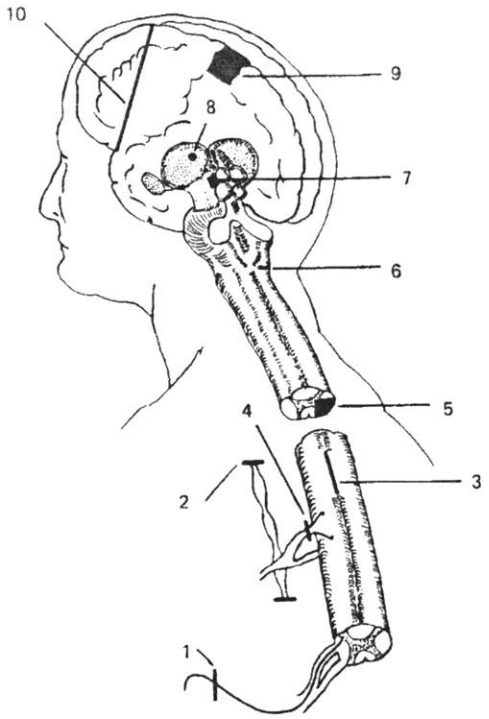


Figure 5

Diagram of various surgical procedures designed to alleviate pain: 1, nerve section; 2, sympathectomy (for visceral pain); 3, myelotomy to section spinothalamic fibers in anterior white commissure; 4, posterior rhizotomy; 5, anterolateral cordotomy; 6, medullary tractotomy; 7, mesencephalic tractotomy; 8, thalamotomy; 9, cingulate gyrectomy; 10, prefrontal lobotomy.

(From Ganong, William F. Review of Medical Physiology, 18th ed.
Copyright 1997 by Appleton & Lange; Stamford, Connecticut [2; p. 138].)

Other, more traditional methods of pain relief should be attempted before drug therapy and surgery. These include rest, temporary immobilization, stretching, application of heat and cold, exercise, and massage. Psychological treatment may also be appropriate when the cause of pain cannot be identified or when lifestyle adjustments are necessary to deal with the pain. Some people find relief in alternative therapies, such as acupuncture and chiropractic. The placebo effect should also be attempted: a consistent 1/3 of patients responds to placebos for pain relief.

Finally, there is electrotherapy; this includes direct stimulation of the brain and spinal cord via surgically implanted electrodes at the four levels of the descending pathways and stimulation of afferent neurons via electrodes placed on the skin surface in an attempt to close the gate in the dorsal horn (TENS).

This section has developed an understanding of acute and chronic pain, as well as the pain cycle. It's also explained the pain transmission pathways in a historical context while focusing on the mechanisms of inhibition. Finally, current techniques available for the relief of pain were discussed. Section 2.3 concludes the background chapter by focusing more closely on TENS: its history, an explanation of the technology, its mechanisms of action, and its clinical efficacy.

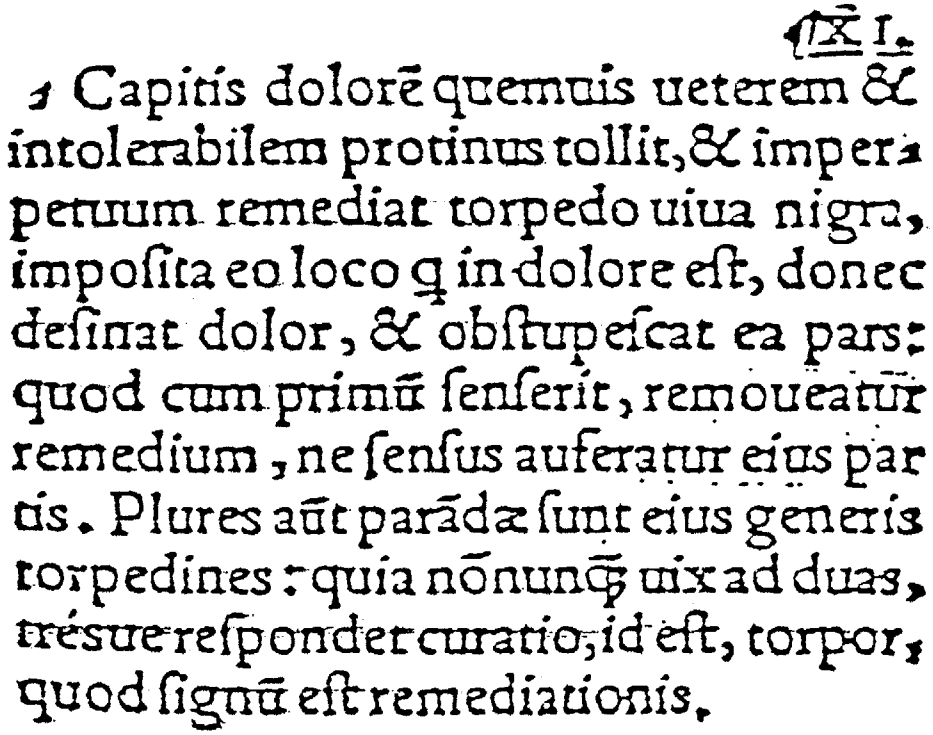
2.3 TENS, a 'New' Modality for Pain Modulation

This section begins with a history of electrotherapy. It then discusses TENS and its possible mechanisms of action. Finally, clinical efficacy is addressed.

2.3.1 A Brief History of Medical Electricity

Is there a thing of which it is said,
"See, this is new"?
It has already been,
in the ages before us.
The people of long ago are not remembered,
nor will there be any remembrance
of people yet to come by those who come after them.
-Ecclesiastes 1:10-11

Although the modern use of electricity for pain modulation only dates to the mid-1960s, its origins can be traced at least to ancient Rome, and probably to Egypt circa 2500 BC. Stone carvings in tombs of that era indicate that an electric fish native to the Nile was used to treat pain [7; p. 3]. The book Compositiones Medicae by the Roman physician Scribonius Largus contains the first written record of such treatments. Written in the year 46 AD, the text recommends use of a torpedo fish for the treatment of headache and gout [3; p. 3]. Figure 6, excerpted from an 18th century text, reproduces a section of Largus's work.



CXI.

Capitis dolorē quemuis ueterem & intolerabilem protinus tollit, & imperatorium remediat torpedo uiua nigra, impoſita eo loco q̄ in dolore eſt, donec deſinat dolor, & obſtupeſcat ea pars: quod cum primū ſenſerit, remoueatur remedium, ne ſenſus auferatur eius partis. Plures aūt parādæ ſunt eius generis torpedines: quia nō nunq̄ uix ad duas, trēsue reſpondet curatio, id eſt, torpor, quod ſignū eſt remediationis.

SCRIBONIUS LARGUS DESIGNATUS
"Scripta mea Latina medicalis, codex instar"
editio prima, cap. XI. De compositione medicamentum liber.
Ed. J.M.Berthold, Argentor, 1786.

Figure 6

An excerpt from the first written account of the use of electrical stimulation for the treatment of pain, written in 46 AD by the Roman physician Scribonius Largus.
(From Jenker, F. L. Electric Pain Control. Copyright 1995
by Springer-Verlag; New York [2; frontispiece].)

The translation of Figure 6 reads:

> Chapter XI: Unbearable headaches, as enduring as they may be, are relieved immediately and cured forever by the living black electric ray if it is held in contact with the aching area until pain disappears and this part is numbed; as soon as this is felt, the remedy should be removed such as not to interfere with sensation. There are several species of these fishes; since the effect does not occur at once, but after 2 or 3 applications, healing, that is numbness which is the sign of healing...

The text goes on to say:

> Chapter XIII: For every type of podagra place an electric ray under the feet, just when the pain comes on. But do not stand on a dry part of the beach, but where the sea is wetting it. Keep the contact to the ray long enough to make foot and skin areas numb up to the knee. The pain will disappear immediately and will hold cured for the future. In this fashion Antheros, a public employee, who had been liberated by Tiberius, was cured [13; p. 5].

Of course, electrical eels aren't really suited to clinical use. With an increased understanding of electricity came devices that allowed for its generation and storage.

Richard Lovett published the first book written in English on medical electricity in 1756 under the title Subtil Medium Proved. John Wesley, founder of the Methodist Church, was an early proponent of electrotherapy and published his own text on the subject in 1759. Wesley saw electricity as the soul of the universe [10; p. 1]. W. J. Oliver, an American Physician working in the mid-19th century, reported that he could effectively modulate pain during surgery by applying well-moistened dressings attached to copper wires above and below the area of surgery. Although this and other early work was promising, anesthetics were introduced a few decades later, and the scientific community quickly abandoned electrical stimulation as a method of pain modulation. Interest wasn't rekindled until research in the 1950s and '60s led to the gate theory [7; pp. 6-7].

The underpinnings for modern scientific thought about the efficacy of electrical stimulation can be traced to Melzack and Wall's now famous gate control theory, first published in 1965. It gave credibility and directly led to the development of TENS. Shortly after the gate theory was published, researchers attempted to modulate pain by direct electrical stimulation of the dorsal column of the spinal cord. In 1967 Wall and Sweet conducted the first trials on the clinical use of TENS for the treatment of pain [12]. TENS seeks to stimulate afferent A-β fibers with low current electrical stimulation applied at a pain site via conducting electrodes. The gate theory predicts that this non-painful stimulation can diminish or block the painful stimulation transmitted to higher centers. TENS was originally used to evaluate which patients would respond favorably to direct stimulation of the dorsal column. It quickly became apparent that afferent stimulation was nearly as effective as direct stimulation in relieving pain for many patients [10; p. 3]. Thus, TENS was born as a new and freestanding modality for the treatment of pain. It has since evolved into an industry valued in excess of $200 million annually.

2.3.2 What is TENS?

The gate control theory of pain suggested that nociceptively evoked activity in ascending pathways could be modulated by mechanoreceptive (touch) stimuli. It followed that if an extra supply of mechanoreceptive stimuli could be generated at a pain site, the intensity and duration of the pain should be reduced or eliminated. Large, mechanoreceptive (A-β) nerve fibers can be selectively activated with electrical current due to their low inner longitudinal resistance [7; p. 21]. Low resistance allows stimulation at intensities below threshold for other nerve endings. The easiest way to selectively activate these fibers is by attaching electrodes to the skin at the site of pain. A non-painful, alternating current electrical waveform is then applied to the electrodes. This technique is known as Transcutaneous Electrical Nerve Stimulation, or TENS. Most TENS devices produce asymmetric biphasic waveforms with a narrow pulse followed by a negative spike with exponential delay. This produces a zero net DC current. A few devices produce a monopolar spike [14; p. 2]. Figure 7 shows a few common waveforms.

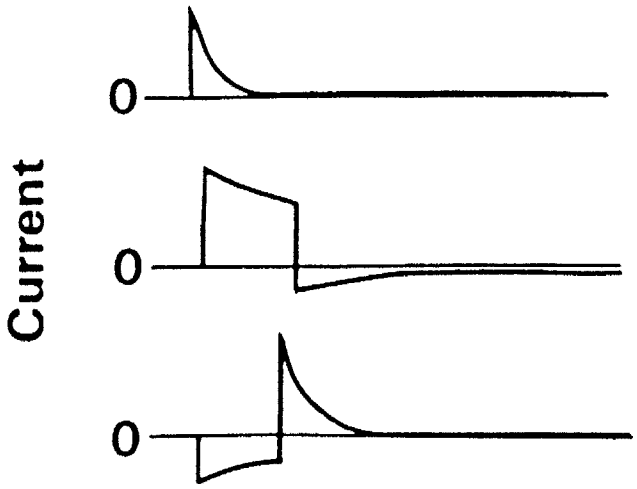


Figure 7

Commonly used TENS waveforms.
(From Mykleburst, Joel B. Neural Stimulation, Vol. I.
Copyright 1985 by CRC Press; Boca Raton, FL [14; p. 3].)

The stimulation parameters - frequency, pulse width, and amplitude - can be altered to activate different pain modulation mechanisms. Frequency refers to the number of electrical waveforms delivered per second, pulse width is the duration of each waveform, and amplitude refers to the height of each pulse above baseline. Skin resistance, body weight, and inter-electrode distance all influence amplitude. Thus, amplitude is often adjusted on a patient-to-patient basis in the milliampere range in order to find an optimum setting [6; p. 29]. Frequencies used range from 1-200Hz, while pulse widths vary between 0 and about 500μs. Much progress has been made in the clinical use of TENS since its inception. Patients who do not respond or are uncomfortable with one set of parameters, or mode, are often more receptive to a different mode. A discussion of the basic modes currently in clinical use follows.

Conventional (high frequency/low intensity) TENS
Conventional TENS is based directly on the gate theory and was the mode used by Wall and Sweet in the very first TENS study [12]. Conventional TENS consists of high frequency (50-100Hz), small pulse width (40-100μs) and moderate intensity waveforms.

Several researchers report that this is the most clinically successful mode [15, 16]. It produces a tingling sensation and immediately increases the pain threshold. The onset of relief is very rapid, but the after-effect is limited, usually lasting no longer than the period of stimulation [17].

Acupuncture-like (low frequency/high intensity) TENS
Acupuncture-like TENS employs low frequencies (1-4Hz), large pulse widths (150-250us), and high intensities near the pain threshold. Motor nerve fibers must be activated, and visual muscle twitching should be produced.

In contrast to conventional TENS, this mode produces a gradual increase in the pain threshold. After-effect is longer as the threshold gradually decreases back to baseline [17].

Burst Stimulation
TENS efficacy has a tendency to temporarily decrease over the period of one therapy session. The body seems to adjust to the stimulation parameters and decrease their effectiveness in a process called accommodation. Burst TENS modulates the frequency by sending waveforms in packets, or bursts, thereby not allowing the body to adjust. Waveforms are delivered for a period of time, stopped, then restarted. The bursts are conducted at frequencies ranging from 0.25-2Hz. The burst mode can be conducted with either conventional or acupuncture-like TENS parameters [17].

Modulation TENS
Much like the burst mode, modulation TENS seeks to limit the body's accommodation, or ability to adjust to one set of parameters. Beginning with either conventional or acupuncture-like settings, frequency, pulse width, and amplitude are dynamically altered during stimulation in a range of up to 50% around the baseline.

TENS has been used successfully for relief of the symptomatic aspects of many different types of acute and chronic pain including dental procedures, labor and delivery, musculoskeletal problems, traumatic and post-surgical orthopedic conditions, postoperative recovery, spinal trauma, chronic back pain, and a host of other conditions where avoidance of narcotic analgesics is desirable [18]. TENS has no major side effects or drawbacks. It is safe and is effective in a statistically significant portion of the patient population as discussed in Section 2.3.4.

Although no deaths or serious injuries have been reported, TENS is contraindicated during pregnancy, for patients with pacemakers, and for use across mucous membranes. It is also to be avoided in patients with dementia or psychological disease. The most commonly reported problems are skin allergies or irritation due to energy absorption from the TENS device to the skin [17]. Skin problems can usually be avoided by the use of non-irritating electrogels and by correct placement of TENS electrodes on the surface.

TENS does not treat the cause of nociception, but merely attacks its symptomatic aspects. It must therefore be stressed that TENS should be used as part of comprehensive therapy aimed at breaking the pain cycle. If used properly TENS has the ability to help a great number of people that needlessly suffer from pain.

2.3.3 TENS: Possible Mechanisms of Action

Although TENS was originally justified on the basis of the gate theory, newer research has led to a fuller understanding of the mechanisms activated by TENS stimulation. It now appears that conventional and acupuncture-like modes activate different mechanisms in the descending pain pathways. Several of the prevailing theories are touched upon here.

Gate Control

Gate control has already been discussed extensively, and is only touched upon here. Stimulation of large diameter afferent fibers inhibits input from small diameter fibers, thereby blocking the pain signal. Gating is thought to take place in the dorsal horn of the spinal cord. The theory predicts analgesia at frequencies between about 75 and 150Hz, but suggests that relief should stop immediately after stimulation is removed. Conventional TENS can be justified on the basis of this theory.

Endogenous Opioid Pathways

Acupuncture-like TENS is thought to act by the release of endogenous opiates [19, 20]. To test this theory, researchers used the opiate antagonist naloxone to determine whether the analgesic effects of TENS could be reversed upon its administration. The effects of acupuncture-like TENS were reversed while conventional TENS analgesia was unaffected, suggesting that the acupuncture-like mode acts by the release of endogenous opiates while the conventional mode acts by other mechanisms [21]. There is also speculation that TENS analgesia is modulated by non-opiate substances, such as GABA, adenosine, or glycine, but little research has been conducted to substantiate these claims [15].

Peripheral Nerve Block

This theory suggests that TENS acts in a manner consistent with local anesthetics that block nerve conduction [13; p. 32]. Impairment of both painful and non-painful sensation during and after TENS has been clinically observed. It appears that C-fibers may be more susceptible to inhibition that myelinated fibers. Thus, conventional TENS may inhibit small afferent input while stimulating large afferent fibers. According to the gate theory, both actions should reduce pain [15].

Others suggest that analgesia occurs as a consequence of sensory distraction with a continuous peripheral stimulus, and not by central neuronal modulation [22]. Some even feel that at least certain TENS modes do nothing more than provide a placebo effect that allows patients to heal themselves [23]. Alternatively, one study concludes that the effects of long-term TENS usage cumulate over time, thus producing plastic changes in the neural pathway [24]. Still others suggest that nerve fatigue leads to a decrease in sensation. From a clinical standpoint, perhaps the mechanisms of action are unimportant: TENS has and will continue to bring relief to many patients that have not been able or do not wish (due to side effects) to seek relief by conventional means. Section 2.3.4 focuses on clinical efficacy.

2.3.4 Clinical Efficacy

Double-blind clinical trials to determine what percentage of patients truly benefit from TENS have been very difficult because a placebo cannot be found that is both believable to the patient and doesn't provide some physiological effect [15]. Also, stimulation parameters, pain syndromes, social and psychological considerations, duration of therapy sessions, length of observation, other concurrent pain modalities in use (drugs, massage, exercise, heat, cold, etc.), and a host of other factors have varied from study to study. With that said, Doctor compiled a review of the most reliable studies conducted on TENS efficacy [6]. Table 3 reproduces the review.

Table 3
Notable controlled TENS trials.
(From Doctor, Jason N. An Evaluation of Transcutaneous Electrical Nerve Stimulation (TENS) for the Treatment of Pain Related to a Spinal Cord Injury, Appendices 1-2. Doctoral Thesis: Univ. of CA, San Diego & San Diego State Univ., 1996 [6].)

Study	Subjects	Treatment [Design Features*]	Results
Melzack (1975)	N = 53 Chronic Pain	Negative Response Sight Control (n = 15); no output (n = 7). Crossover. [e]	Active TENS sig. decreased pain relative to control.
Cooperman et al. (1975)	N = 50 Post Surgery	Active TENS (n = 26) and Sham (n = 24). [b]	Active TENS sig. less med. usage. No sig. difference in duration of ICU stay.
Thorsteinsson et al. (1978)	N = 93 Chronic Pain	Active TENS and Placebo TENS (no current). Crossover. [a]	Active TENS sig. less pain than control.
Long et al. (1979)	N = 150 Chronic Pain	Supra-threshold TENS, subliminal TENS, no battery TENS. Crossover.	Supra-threshold TENS sig. less pain than control.
Ali et al. (1981)	N = 40 Elective Cholecystectomy	Active TENS (n = 15), no stimulation TENS (n = 10), no TENS (n = 15). [b]	Active TENS sig. less medicine usage, sig. higher pO_2.
Hansson & Ekbolm (1983)	N = 62 Acute Orofacial Pain	High Freq. TENS (n = 22), Low Freq. TENS (n = 20), Placebo TENS (n = 20). [b]	No sig. difference between high and low freq. TENS. Active TENS sig. less pain than placebo.
Abelson et al. (1983)	N = 32 Rheum. Arthritis with Wrist Involvement	Active TENS vs. Placebo (no stimulation). Crossover. [a, c]	Active TENS sig. less pain and greater grip strength than control.
Lewis et al. (1984)	N = 28 Osteoarthritis with Knee Pain	Active TENS vs. Placebo (no stimulation). Crossover. [a, c]	Sig. improvement in pain index & decreased med. usage in both groups. No sig. difference between groups. 46% response rate active vs. 43% response rate placebo.

Langley et al. (1984)	N = 33 Rheum. Arthritis and Chronic Hand Involvement	High Freq. TENS, Low Freq. TENS, Placebo TENS. [a, b, c, d, e]	All groups showed sig. decreases in resting & grip pain. No sig. diff. btwn groups on power or work scores, overall pain, joint tenderness, grip or resting pain.
Lehman et al. (1986)	N = 53 Chronic Low Back Pain	Acupuncture TENS (n = 17) Active TENS Low Freq. (n = 18), Placebo TENS (n = 18). [a, b, c]	No sig. diff. btwn groups on physician ratings of pain, self-rated pain, trunk strength, back flex/ext, med use, return to work, post-tx or f/u. All groups showed sig. improv. over time.
Smith et al. (1986)	N = 18 Caesarian Section Surgery	Active TENS (n = 9), Placebo TENS (n = 9). [b, c]	No sig. diff. btwn groups post treatment on pain or med. usage.
Ordog (1987)	N = 100 Acute Trauma Outpatients (Sprains, Lacerations, Fractures, etc...)	Active TENS, Placebo TENS, Active TENS + 3 Tylenol, Placebo TENS + 3 Tylenol. [a, b, c]	Active TENS sig. diff. than placebo at day 2 but not at day 30. No sig. diff. in med. usage for active or placebo.
Finsen (1987)	N = 51 Lower Leg Amputations	Active TENS (n = 17), Sham TENS (n = 19), Sham TENS + Chlorpromazine. [b, c]	No sig. diff. btwn groups on level of pain or med. intake at 4 weeks or 1 year follow-up.
Deyo et al (1990)	N = 145 Chronic Low Back Pain	Active TENS (n = 36), Sham TENS (n = 36), Active TENS + Exercise (n = 37), Sham TENS + Exercise (n = 36). [a, b, c, d, e]	No sig. diff. in any outcome for subjects receiving active or sham TENS. Sig. improvement was obs. in every group pre to post, but rtn to baseline at 3 months.
Marchand et al. (1993)	N = 42 Chronic Low Back Pain Patients	Active TENS (n = 14), Placebo TENS (n = 12), control (n = 16). [b, c]	Active TENS group showed sig. greater reductions in pain intensity post tx than other two groups. But, no diff. between active TENS and placebo on unpleasantness ratings. Both showed sig. diff. in comparison to control.

*[a] = double-blind trial.
[b] = noncrossover randomized design.
[c] = credible placebo with functional "on" light and/or hum. Or all units encased to preserve blind.
[d] = attention focus control across conditions.
[e] = verbal suggestion to placebo group that active treatment may or may not produce a sensation.

Doctor feels that studies made after 1984 are somewhat more reliable as they used better experimental design and more plausible control conditions. Taken collectively, the results on efficacy are somewhat inconclusive. However, even if TENS can produce little more lasting analgesia than placebos, this still represents a very significant portion of the patient population (30-50%) and justifies its use as a method of pain intervention.

Also note that studies dealing with acute pain generally give favorable results. If the effects of TENS do, in fact, cumulate, this is not surprising. For the purposes of this study, the focus is on acute pain of short duration. As can be seen from Table 3, most work has focused on chronic pain, but the evidence available suggests that TENS is most effective during the first therapy sessions. If this is true, it may be much better suited to acute pain relief.

Section 2.1 developed a broad-based understanding of the human nervous system. It examined the system's function from the micro- to macroscopic levels. Section 2.2 then discussed acute and chronic pain, the pain cycle, the transmission pathways, mechanisms of modulation, and available treatment options. Finally, this section gave a history of electrotherapy, explained TENS, discussed its possible mechanisms of action, and reported on its efficacy. We can now proceed to the design process and its application to the development of stand-alone orthopedic TENS devices for the treatment of acute pain.

3.0 DESIGN PROCEDURE

A structured design process was used in the development of orthopedic TENS devices. The major steps of a generic design process are concept development, system-level design, detail design, testing and refinement, and production ramp-up. Concept development can be further delineated into identification of customer needs, establishment of target specifications, analysis of competitive products, concept generation, concept selection, refinement of specifications, economic analysis, and project planning.

This study diverges somewhat from the generic process in that a platform technology (TENS) and market opportunity (acute pain relief) had already been chosen before its inception. Thus, a modified technology-push, platform process was employed as will be discussed in more detail. Also, this study sought to create prototypes as opposed to mass production devices. Although design for manufacturing was continually examined throughout the process to ensure that prototypes could be mass-produced at acceptable costs, the prototypes have not yet been transferred to mass production. Testing and refinement are currently underway, and production ramp-up has not yet begun.

Chapter 3 provides a broad understanding of the product development process as laid out by Ulrich and Eppinger in their book, Product Design and Development [25]. Section 3.1 describes a generic, market pull process. Section 3.2 then focuses on variants of the generic process - specifically on a mixed technology-push, platform product process applicable to the current study. Once the process is understood, its application to the development of modular, orthopedic TENS devices is developed in Chapter 4.

3.1 A Generic Product Development Process

This section seeks to develop a methodology for attacking product development. As anyone that has ever participated in a development effort can attest, product development is not simply an algorithm, which can be followed and expected to produce quality goods. However, a structured methodology provides a framework in which creativity can flourish in a manner similar to Shakespeare finding freedom within the constraints of a sonnet. The structure focuses and clarifies thought while establishing a clear path through a problem with distinct goals and expectations. Modifications to the basic approach can, and should, be made to increase its relevance to a particular design challenge. Sections 3.1.1-3.1.5 each define a phase in the generic development process.

3.1.1 Concept Development

Concept development covers the front-end process of product development. The major objectives of this phase are to identify the needs of the target market, generate and evaluate alternative product concepts, and select a single concept for further development. A concept defines the form, function, and features of a product [25; p. 16].

Concept development can be further broken down into its constitutive parts. These include identification of customer needs, establishment of target specifications, analysis of competitive products, concept generation, concept selection, refinement of

specifications, economic analysis, and project planning. Figure 8 presents these constitutive parts are their relationships to one another.

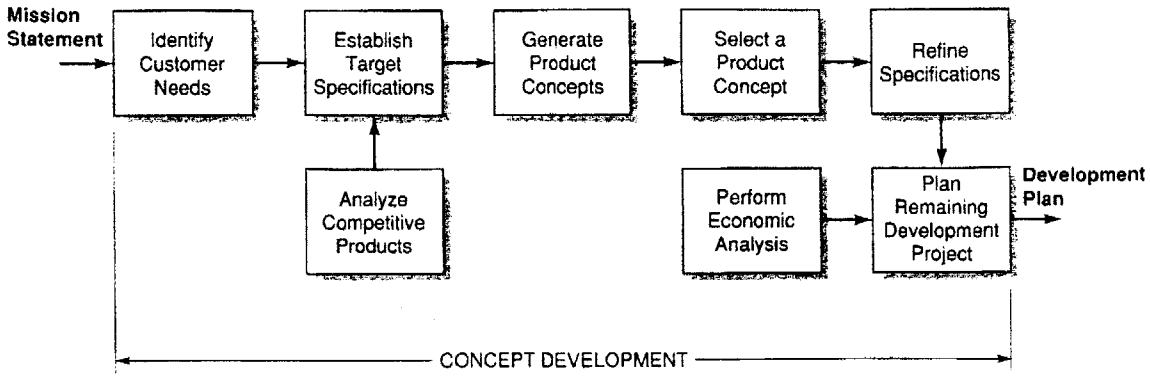


Figure 8

The constitutive steps of concept development.
(From Ulrich, Karl T.; Eppinger, Steven D. Product Design and Development. Copyright 1995 by McGraw-Hill, Inc.; New York [25; p. 18].)

Ulrich and Eppinger define these steps in more detail as follows [25; pp. 18-19]:

Identify Customer Needs
This step seeks to gain an understanding of what is truly important to the customer. Its output should be a list of customer needs weighted according to importance.

Establish Target Specifications
Target specifications translate customer needs into technical descriptions of a product's expected performance. Specifications consist of a metric and a target metric value.

Analyze Competitive Products
Benchmarking products can provide a wealth of ideas for new products while fostering an invaluable understanding of the competitive landscape. It also yields a baseline when setting specifications, generating and selecting concepts, and performing an economic analysis.

Generate Concepts
Concept generation is an intensely creative process that draws from many unique and seemingly unrelated sources and skill sets. The goal of this step is to create a group of product concepts. At this early stage, the concepts usually consist of little more than a drawing and a brief written description.

Select a Concept
Once a group of concepts has been developed, each must be systematically analyzed and eliminated until a preferred concept is chosen for further development. This is often an iterative step and may lead to further concept generation and refinement.

Refine Specifications
Once a concept has been selected, the target specifications must be refined in light of the constraints inherent in the chosen design, cost vs. performance trade-offs, and limitations identified through modeling efforts. The development team commits to specific values for the metrics.

Perform Economic Analysis
An economic model of the product is built to justify further development. It also examines trade-offs among development costs, manufacturing costs, etc.

Plan Remaining Development Project
The goal of this step is to create a detailed development schedule that minimizes development time and identifies the necessary resources required to complete the project.

Concept development sets the stage for future product success or failure. Thorough, innovative, and comprehensive work in this early stage is critical to achieving long-term goals. Once a concept has been selected and the go ahead has been received for further development, the process moves into system-level design, as discussed in Section 3.1.2.

3.1.2 System-level Design
This phase seeks to define product architecture and divide the product into subsystems and components. A final assembly scheme is also detailed. System-level design leads to a geometric layout of the product, functional specifications for the subsystems, and a preliminary process flow diagram for final assembly [25; p. 17].

3.1.3 Detail Design
Detail design continues the work started in system-level design. The geometry, materials, and tolerances of all unique parts are specified and all outsourced parts are identified. Control documentation is developed that includes drawings or computer files defining all parts and their associated production tooling, specifications for purchased parts, and process plans for fabrication and assembly [25; p. 17].

3.1.4 Testing & Refinement
In this phase, several pre-production versions of the product are fabricated for evaluation purposes. First, α prototypes are constructed with parts of the same geometry and material properties as those intended for the actual product. However, the parts are often fabricated by methods that differ from those actually seen in mass production. These early prototypes are tested to determine whether they meet the specifications set earlier in the process and to evaluate how successful the development effort has been in meeting the documented customer needs.

Once α prototypes that adequately achieve development goals have been created, β prototypes are often fabricated from parts produced by the same processes as those expected in the production model. Final assembly may still occur in a different manner. Lead customers thoroughly test these prototypes in their own environment. Performance and reliability issues are addressed and necessary changes are incorporated into the final product [25; p. 17].

3.1.5 Production Ramp-up

The goal of production ramp-up is to train the work force and resolve any remaining production problems. In this phase, the product is fabricated by the intended production system. The transition from ramp-up to ongoing production is gradual. At some point, the product is launched and made available to the consumer [25; pp. 17-18].

Sections 3.1.1-3.1.5 have provided an overview of the major steps in a generic product development process. Within each of the steps, the work of many different disciplines must be integrated to ensure a quality product. Table 4 provides a look at some of the issues addressed by various key disciplines at different steps in the process.

Table 4

Responsibilities of key disciplines during each phase of product development. (From Ulrich, Karl T.; Eppinger, Steven D. Product Design and Development. Copyright 1995 by McGraw-Hill, Inc.; New York [25; p. 15].)

Concept Development	System-level Design	Detail Design	Testing and Refinement	Production Ramp-up
Marketing				
• Define market segments. • Identify lead users. • Identify competitive products.	• Develop plan for product options and extended product family.	• Develop marketing plan.	• Develop promotion and launch materials. • Facilitate field testing.	• Place early production with key customers.
Design				
• Investigate feasibility of product concepts. • Develop industrial design concepts. • Build and test prototypes.	• Generate alternative product architectures. • Define major subsystems and interfaces. • Refine industrial design.	• Define part geometry. • Choose materials. • Assign tolerances. • Complete industrial design control documentation.	• Do reliability testing, life testing, and performance testing. • Obtain regulatory approvals. • Implement design changes.	• Evaluate early production output.
Manufacturing				
• Estimate mfg. cost. • Assess production feasibility.	• Identify suppliers for key components. • Perform make-buy analysis. • Define final assembly scheme.	• Define piece-part production processes. • Design tooling. • Define quality assurance processes. • Begin procurement of long-lead tooling.	• Facilitate supplier ramp-up. • Refine fabrication and assembly processes. • Train work force. • Refine quality assurance processes.	• Begin operation of entire production system.
Other Functions				
• Finance: Facilitate economic analysis • Legal: Investigate patent issues	• Finance: Facilitate make-buy analysis • Service: Identify service issues.		• Sales: Develop sales plan.	

As discussed previously, this generic process is not entirely appropriate for all development efforts. Significantly, it requires modification before application to this study. Section 3.2 describes situations in which divergence from the generic process is justified, and details alterations that must be made to the basic methodology in each case. It then examines the altered process used in the development of orthopedic TENS devices for the treatment of acute pain.

3.2 Technology-push, Platform Product Process

Different types of products require different development processes. The generic process applies to the most common situation in which a market opportunity has been identified and the process seeks to satisfy that need. Variations on this basic model exist. Table 5 summarizes several variants.

Table 5

Variants of the generic development process.
(From Ulrich, Karl T.; Eppinger, Steven D. Product Design and Development. Copyright 1995 by McGraw-Hill, Inc.; New York [25; p. 20].)

	Generic (Market Pull)	Technology-Push	Platform Products	Process Intensive	Customized
Description	The firm begins with a market opportunity, then finds an appropriate technology to meet customer needs.	The firm begins with a new technology, then finds an appropriate market.	The firm assumes that the new product will be built around the same technological subsystem as an existing product.	Characteristics of the product are highly constrained by the production process.	New products are slight variations of existing configurations.
Distinctions with respect to generic process		Additional initial activity of matching technology and market.	Concept development assumes a technology platform.	Both process and product must be developed together from the very beginning, or an existing production process must be specified from the beginning.	Similarity of projects allows for a highly structured development process. Development process is almost like a production process.
Examples	Sporting goods, furniture, tools.	Gore-Tex rainwear, Tyvex envelopes.	Consumer electronics, computers, printers.	Snack foods, cereal, chemicals, semiconductors.	Switches, motors, batteries, containers.

The design process used in this study was actually a combination of the technology-push and platform product processes. We began with a relatively new technology, (TENS)

and found a largely untapped market (acute pain relief) in which to apply the technology. Furthermore, it was assumed that the orthopedic devices would be built around a modular technological subsystem being developed concurrently. This subsystem is described in Section 4.1.

Chapter 3 has outlined a generic methodology for product development as presented by Ulrich and Eppinger [25]. It has also discussed variants of this methodology and described the process used in the development of orthopedic TENS devices for the treatment of acute pain. Chapter 4 now details the application of this process.

4.0 PROTOTYPE DISCUSSION

TENS devices have traditionally focused on relief of the symptomatic aspects of chronic pain. The devices generally consist of a TENS stimulator connected via long, entangling wires to batteries and to electrodes placed at a pain site. This study sought to apply the same technology to the treatment of acute pain. Acute pain patients often have a different set of functional requirements for a pain modulation modality than those who suffer from chronic pain. Namely, therapies must minimize interference with active lifestyles.

Advances in batteries and microprocessor technology have made it possible to create devices that substantially mitigate the wire problems associated with traditional TENS units; these new devices can essentially be considered wireless. This is significant because even those who suffer from chronic pain have expressed an interest in simplification of the TENS units: one study found that 90% of patients preferred a device without entangling wires. The wires were found to reduce reliability, increase the waste of electric power, and interfere with the activities of daily living [26].

This study outlines the development of orthopedic, wireless TENS devices that incorporate electrode switching. Electrode switching adds another dimension of randomness, which inhibits the body's ability to adapt to stimulation parameters (see Section 4.1). Our devices simplify the user interface and reduce the need for physical therapists to ensure proper use. FDA approval is being sought for home use. These improvements collectively allow application to acute pain, which is an untapped and much larger market than chronic pain. TENS appears to have greater value when its use is initiated in the acute, sub-acute, or immediate post-operative phase as part of a comprehensive therapeutic and restorative program. TENS promotes rapid recovery while decreasing the cost of medical intervention and/or post-operative hospitalization. It may also decrease the incidence of chronicity, as well as dependence on pain medications with their associated side effects. A modular control device was adopted as the platform from which an entire product line is being developed. This product line specifically focuses on application to:

- Acute soft tissue (musculoskeletal) injuries
- Emergency room application
- Dysmenorrhea
- Immediate post-operative application in hospitals, out-patient clinics, and clinical practices such as podiatric and dental
- Adjunctive use during or after specific therapeutic procedures such as debridement, suture, and IV removal, as well as various physical therapy techniques
- Sports medicine: with or without splints and braces
- 24-48 hour continuous application in micro-current mode

Using the structured design process discussed in Chapter 3, prototype TENS knee immobilizers and wrist splints were created around the platform control device. Chapter 4 discusses each prototype in light of the previous chapter: Section 4.1 develops the technology-push, platform strategy in place prior to this study; Section 4.2 then details the development of the TENS knee immobilizer while Section 4.3 details the wrist splint.

4.1 Technology-push, Platform Strategy

Prototype TENS knee immobilizers and wrist splints were developed for the relief of acute pain around a modular control device. The TENS control unit served as a technology-push, platform product around which further development revolved. Development of an entire product line occurred (and is still underway) concurrent with the development of the modular platform. This section begins with a technical description of the control device. It then provides a conceptual overview of the three areas of concurrent development: 'Band-Aid™' TENS devices; remotely operated TENS devices; and orthopedic braces, splints, and immobilizers with integrated TENS technology. This study focused on the third area of concurrent development while providing feedback on optimal functional parameters for the modular control device.

4.1.1 Modular TENS Control Device

A modular TENS control device served as the platform from which an entire product line for the relief of acute pain is being developed. Key issues addressed in its development included benchmarking, stimulation modes, electrode switching, battery life, size & weight, manufacturing costs, styling, and ability to meet the functional requirements of future products. Each will be addressed in turn.

Benchmarking

In order to establish a baseline for development of the modular TENS device, extensive benchmarking of competitive products was performed. Figure 9 shows the stimulation parameters used in these devices.

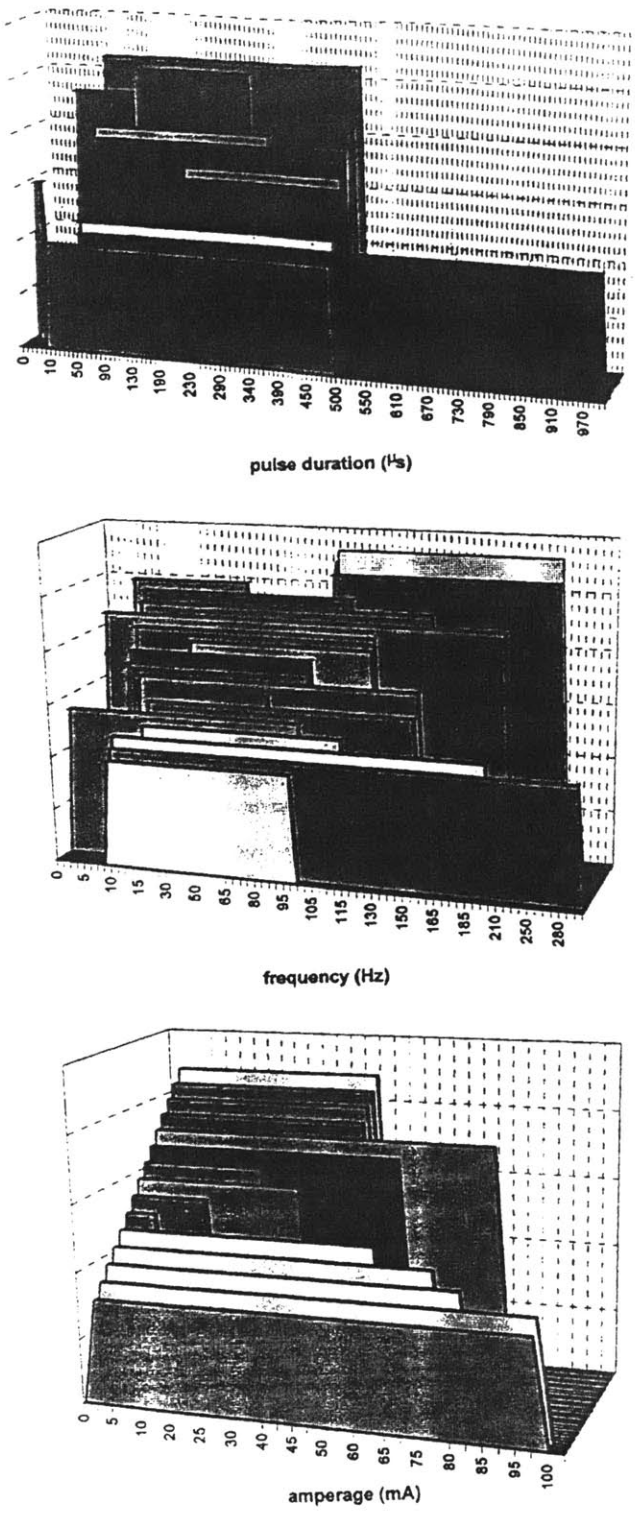


Figure 9

Stimulation parameters of benchmarked TENS devices [27].

TENS devices currently on the market collectively offer all the stimulation modes discussed in Section 2.3.2. Benchmarking showed that a typical device is:

- Dual channel, usually with independent amplitude controls but common frequency and pulse duration controls
- Powered by 9-volt alkaline or Ni-Cad rechargeable batteries
- Rarely available with complete dual channel separation and adjustability of all 3 parameters
- Controlled by buttons, switches, dials with preprinted display of settings, or LCD's
- Equipped with an LED to signal on/off and low battery
- Offered with a variety of stimulation modes including conventional, acupuncture-like, and modulation
- Not integrated well with regard to electrodes and batteries (long, entangling wires)
- Bulky and unattractive

Benchmarking provided a wealth of invaluable information about the marketplace that we seek to innovate.

Stimulation Modes

Extensive benchmarking, as well as discussions with patients and health care practitioners, led to the development of 8 stimulation modes that will offer the full range of physiological effects and address a very broad patient population suffering from pain. The modular control device will offer all 8 modes, as well as a mode that cycles through all 8. If the intensity of any mode is set to zero, that mode is skipped during the cycling sequence, thus allowing for individualized cycling paradigms. The stimulation time per mode while cycling is 7.5 minutes. Thus, cycling through all 8 modes will be complete in 1 hour. The eight stimulation modes are:

Low Intensity Settings

- CON1 (Conventional low: 100Hz, 75μs, 0-60mA)
- MOD1 (Modulation low: 50-100Hz, 75-100μs, 0-60mA)
- ACU1 (Acupuncture-like low: 1Hz, 75μs, 0-60mA)
- MICR (Micro-current low: 40Hz, 0-100μA)

High Intensity Settings

- CON2 (Conventional high: 125Hz, 125μs, 0-100mA)
- MOD2 (Modulation high: 75-125Hz, 100-125μs, 0-100mA)
- ACU2 (Acupuncture-like high: 2Hz, 125μs, 0-100mA)
- BRST (Burst high: 100Hz, 75μs with 3 seconds on/off, 0-100mA)

Electrode Switching

A very new area of TENS research focuses on electrode switching to create a spatially time-varying pattern in addition to the electrically time-varying pattern seen in modulation and cycling stimulation modes. D. W. Repperger, et al. [26, 28], have provided a very lucid account of the advantages of electrode switching, as well as preliminary clinical evidence to support its use. Figure 10(b) illustrates electrode switching for a 4-electrode system. As in Figure 10(a), electric fields can transverse

electrodes 1 to 3, but can also transverse electrodes 1 to 4. The direction of the electric fields can also be reversed in time and space, which adds another dimension of randomness and fights the brain's ability to accommodate to the stimulation parameters.

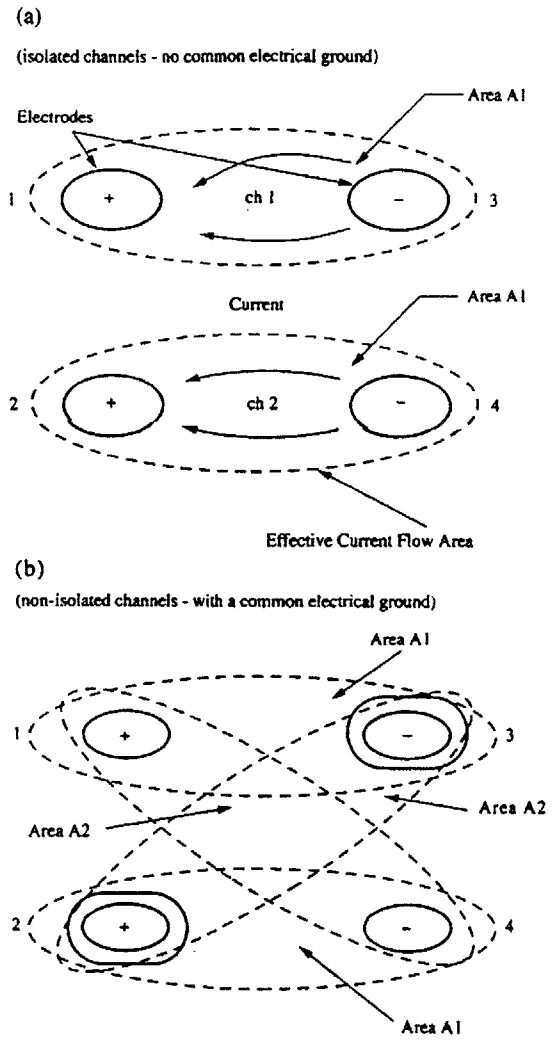


Figure 10

An illustration of electrode switching. 10(a) shows a traditional TENS device while 10(b) shows a device with a spatially varying stimulation pattern.
(From D.W. Repperger, et al. *Microprocessor Based Spatial TENS Designed with Waveform Optimality for Clinical Evaluation in a Pain Study.* Comput. Biol. Med., Vol. 27, Number 6, pp. 493-505, 1997 [26].)

Traditional TENS units have what Repperger terms the "isolation property": the path of the electric fields between the electrodes follows two isolated channels. Separate electric

grounds for each channel cause isolation. However, if a ground is common between all four electrodes, the paths of the electric fields can be controlled by a microprocessor. This is dubbed "non-isolation". It greatly increases the affected area, as well as the randomness of the stimulus. This makes the device more efficient per unit area, and reduces accommodation and extinction effects [26].

To determine the effectiveness of non-isolation, a preliminary clinical study was undertaken. Three major questions of interest were addressed: is crossover (electrode switching) preferred on or off, is modulation preferred on or off, and is pulse width preferred long or short. Four separate pain etiologies were studied: back pain due to accidents, pain due to surgery, arthritic pain, and pain due to post-polio syndrome. The results are summarized in Table 6. Overall, 81% of all patients tested preferred crossover, 56% preferred modulation, and 68% preferred a small pulse width [28].

Table 6

Percentages of responses characterized by etiology.
(From Repperger, D.W.; Ho, C.C.; & Philips, C.A. *Clinical Short Wire TENS Study for Mitigation of Pain in the Dayton VA Medical Center*. Journal of Clinical Engineering, Vol. 22, Number 5, pp. 290-297, 9-10/97 [28].)

	Back	**Surgery**	**Arthritis**	**Polio**
Crossover On-Off	On – 88%	On – 67%	On – 75%	On – 100%
Modulation On-Off	On – 55%	On – 67%	On – 50%	On – 100%
Pulse Width On-Off	Small – 67%	Small – 67%	Small – 75%	Small – 100%

This work is encouraging and suggests that crossover increases efficacy due to the larger surface area covered and due to a decrease in accommodation. The platform technology developed for this study takes Repperger's work one step farther by assigning each of the four electrodes an individual channel in addition to creating a common ground. This allows the polarity of each electrode to be individually switched and makes any electrode firing pattern possible. Only two electrodes are active at any given time while the other two are placed in an open circuit. Figure 11 illustrates the new functionality gained.

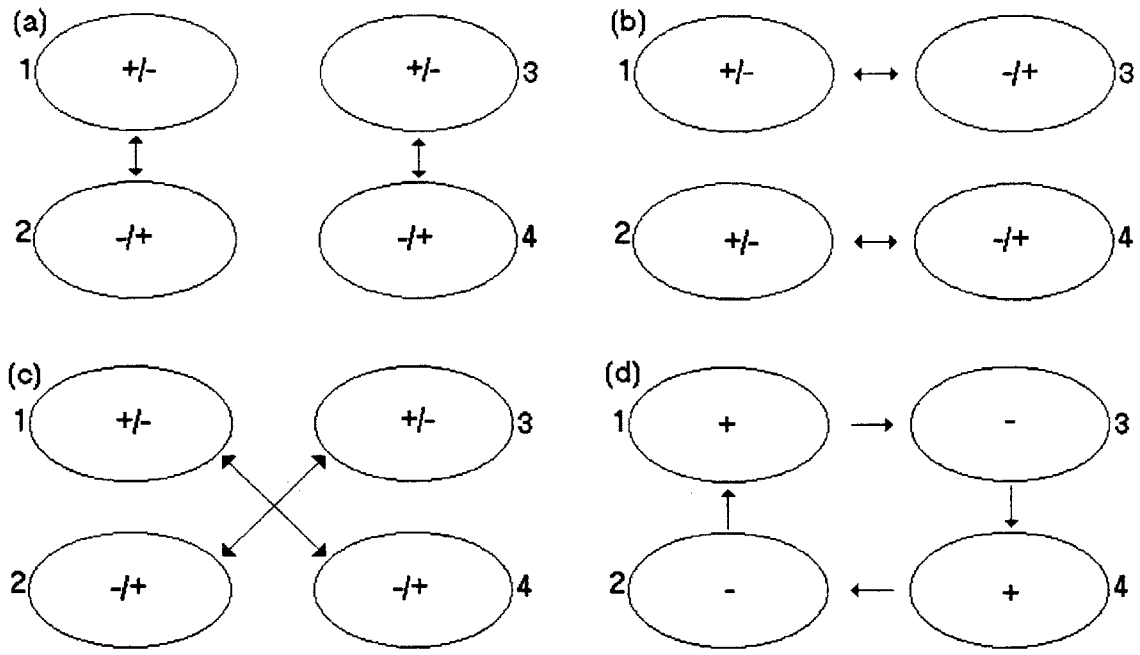


Figure 11

Possible firing patterns using the modular control device. Arrows represent current flow between electrodes. The electrodes all operate on a common ground. However, only two electrodes are active at any given time; the other two are placed in an open circuit.

Figure 11 yields a circuit diagram of the form seen in Figure 12.

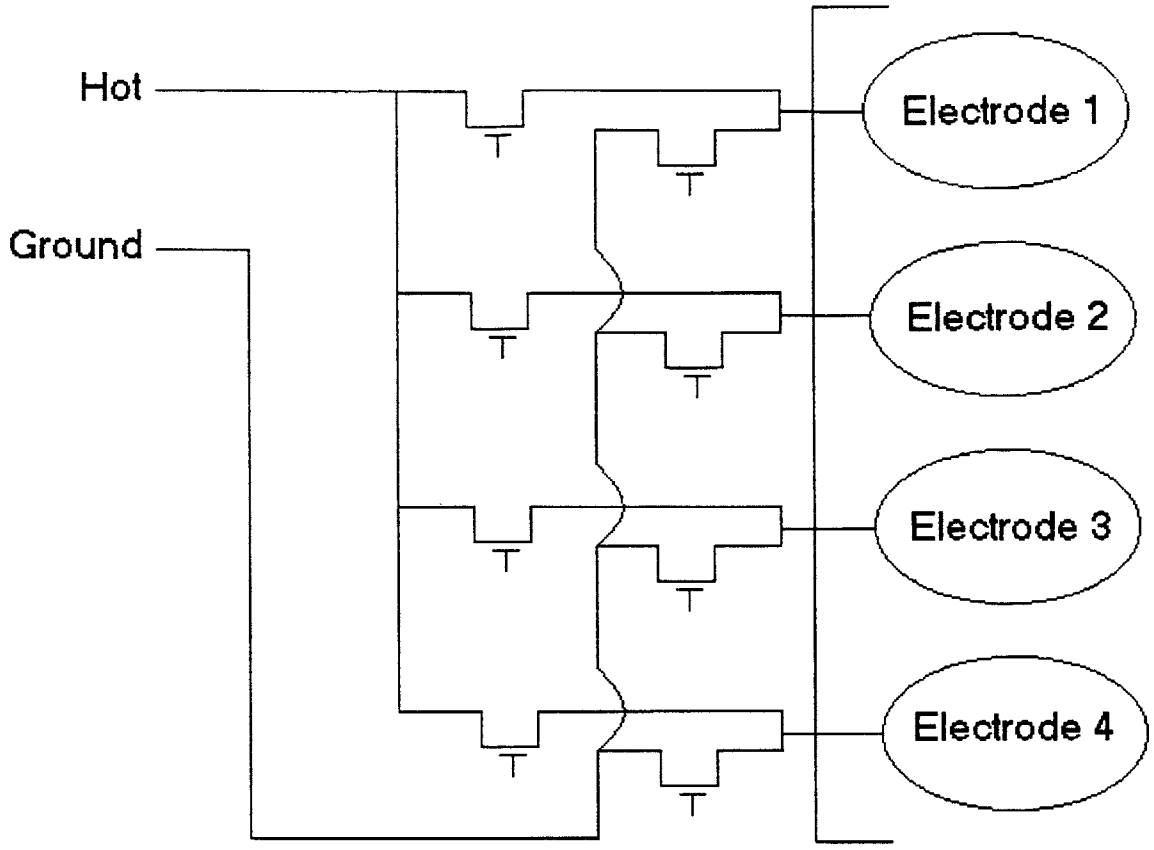


Figure 12

Circuit diagram for 4 electrodes with individual channels and a common ground. At any given time, one electrode is connected to "Hot", one is connected to "Ground", and the other two are open.

Table 6 suggests that the modular control device's increased ability to alter the spatial pattern will increase efficacy. The new functionality also provides a great deal of freedom to the patient in optimizing stimulation parameters to his specific needs.

Battery Selection

Spreadsheet analytical models were generated to determine expected battery life in a variety of operating conditions. The battery life goal at maximum intensity in the worst case mode is 24 hours. The batteries examined include lithium and alkaline for disposable applications, and NiCd and NiMH cells for rechargeable applications.

In disposable applications, lithium batteries were the obvious choice for integration into the control device due to their small size, energy density, and small voltage drop across the life of the battery. A fully charged lithium cell carries a charge of approximately 3.3 volts and dips as low as 2.7 volts before disposal. The control device can operate in this voltage range. 2 or 3 alkaline batteries would be required to ensure that the proper

voltage level is kept. The voltage range over the lifetime of a "AA" alkaline battery is 1.6-0.9 volts. Thus, 3 batteries yield a range of 4.8-2.7 volts. This is satisfactory.

In order to make the control device as flexible as possible, alternate battery power can be connected to the TENS unit. In this manner, any future product with large energy needs can have its own batteries in addition to those supplied by the modular controls package. This yields a design with an eight pin interconnect between the control device and the product line (electrodes, splints, braces, etc.), as seen in Figure 13.

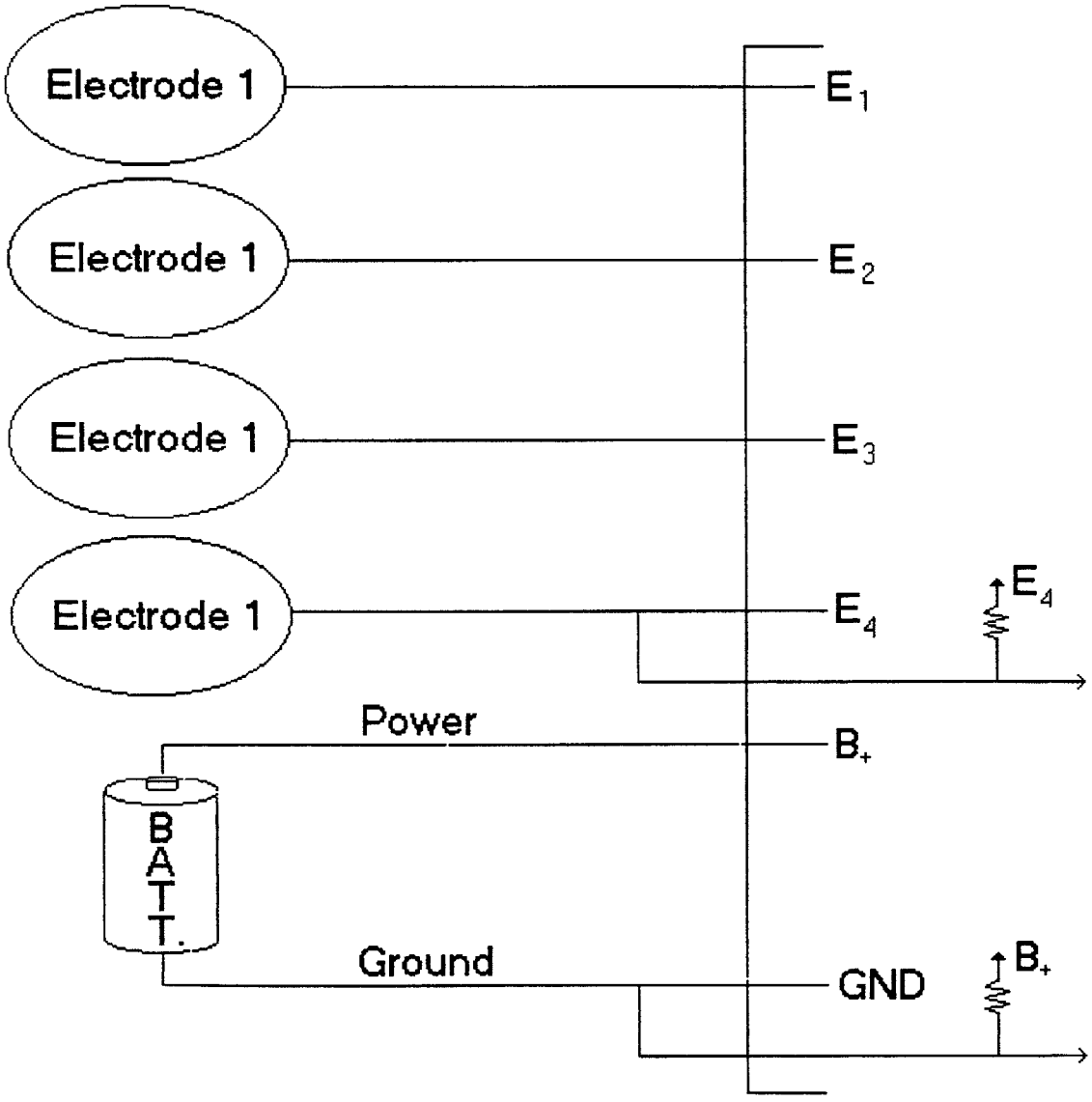


Figure 13

An eight pin interconnect attaches the control device to the product line.

Five interconnects refer to the four electrodes, while the other three are concerned with the battery. Four of the five electrode interconnects directly attach the electrodes to the control device; the fifth acts as a Boolean sensor to tell the control device whether two or four electrodes are attached. Two of the three battery interconnects attach power and ground while the third acts as a Boolean sensor to indicate whether or not alternate battery power has been connected.

Control Device Size & Weight

The modular control device must be wearable in a variety of locations. This greatly restrains the size and weight of the device. It must be miniaturized as much as possible and be extremely light to make it comfortable and unobtrusive to the patient. Preliminary size goals set the maximum dimensions at approximately 2.5"x2.5"x1". The weight must be less than 6 oz.

Manufacturing Cost

In order to remain competitive with other TENS products currently available, the manufacturing cost goal was set at $22. Table 7 relates manufacturing costs to margins and market price.

Table 7
Control device costs breakdown.

Item	Cost Goal
Direct Material	$10
Warranty/Returns	$2
Distribution Cost	$3
Conversion Cost*	$7
MFG Cost Goal	**$22**
Gross Cost Goal	**$33 (Gross Margin = 60%)**
Wholesale Price Goal	**$55**

*All costs associated with developing & mfg. The product (i.e. engineering, office supplies, production personnel, real estate).

Styling

Since this product will compete in the much more consumer-oriented market of acute pain, styling and modern industrial design are of critical importance to create excitement and product differentiation, which will in turn create sales. Industrial design refers to aspects of a product that relate to the user. These include its aesthetic appeal (how it looks, sounds, feels, smells) and its functional interfaces (how it's used) [25; p. 153]. Within the restraints imposed by cost goals, size and weight goals, battery selection, the interconnect, and a host of other issues, there remained a great deal of flexibility in designing the product. Concept generation led to a 3-button device with an LCD display. The LCD is capable of projecting icons to show current intensity & cycling on/off, alphanumeric characters to display the mode in use (as listed previously), and numeric characters to display elapsed time. The 3 buttons include an up and down to control

intensity, stimulation time, etc.; and a 3rd button to turn the unit on and off, as well as to select the mode. The first conceptual control device looked like that seen in Figure 14.

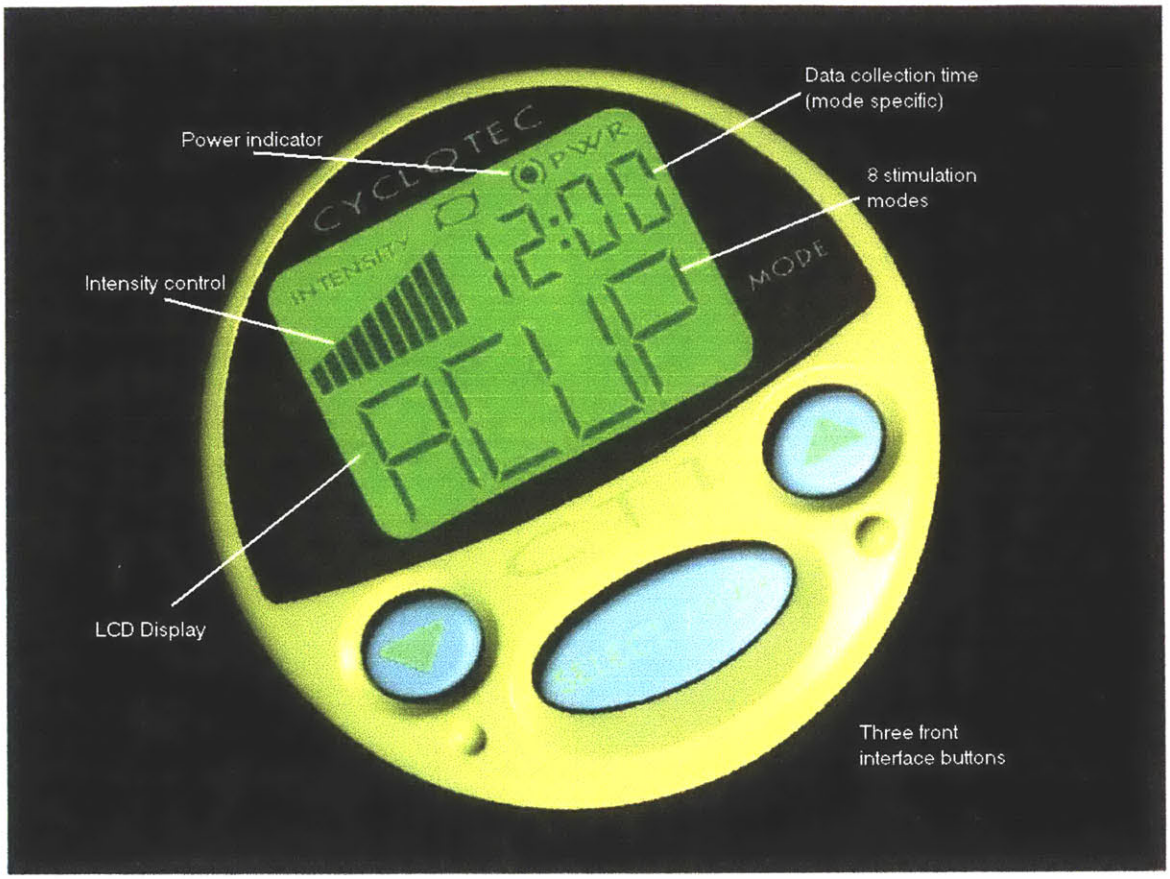


Figure 14

Early control device concept.
(Conceptual rendering by Frank Tyneski, Industrial Designer.)

Consumer feedback led in an iterative fashion to the improved final concept seen in Figure 15.

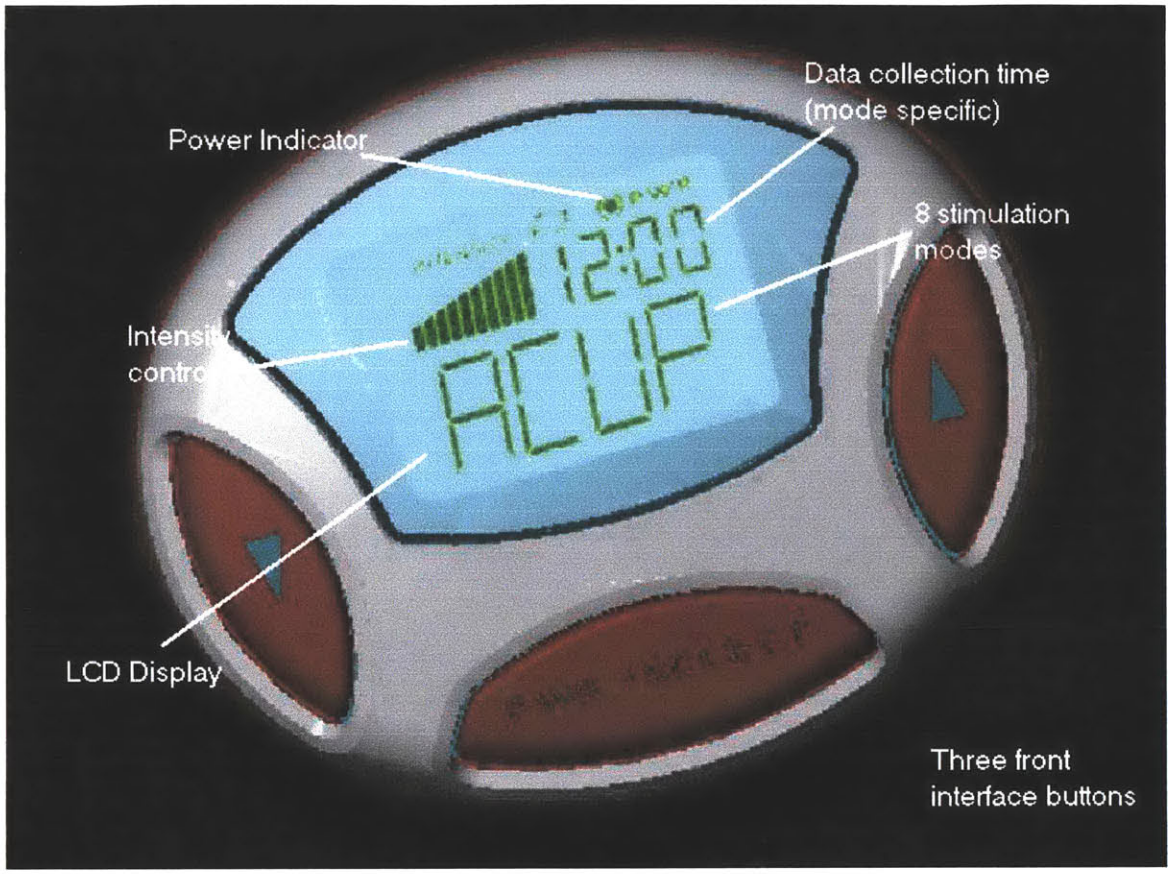


Figure 15

Chosen control device concept.
(Concept by Frank Tyneski, Industrial Designer.)

This improved concept meets cost, weight, size, and power consumption goals, has a simple eight pin interconnect, encases the battery within the device, and has attractive styling with an intuitive user interface. In cross section, a simplified schematic of the interior is seen in Figure 16.

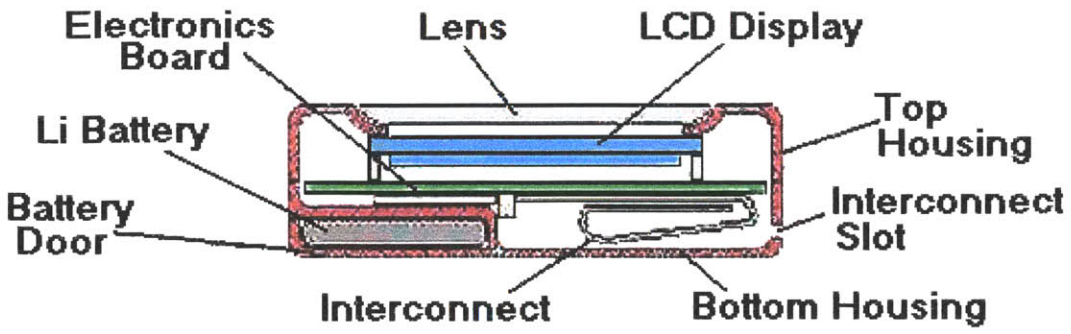


Figure 16

Simplified schematic cross section of the interior of the control device.

This design has been prototyped and is currently undergoing testing and refinement in preparation for production ramp-up.

Platform for Future Products
The modular control device has the ability to meet the functional requirements of a wide range of future products. Its small size and weight means it can be attached at almost any location on the body. Attaching additional batteries distal from the device makes applications with larger energy demands possible. The ability to operate with either 2 or 4 electrodes allows most all pain syndromes to be treated. Electrode switching and 8 separate modes enables customization to particular etiologies and patients. Low cost makes it competitive in the marketplace.

Section 4.1.1 described the platform technology from which a TENS product family has and is being concurrently developed. Sections 4.1.2-4.1.4 each describe a category of further development based on the control device platform.

4.1.2 'Band-Aid™' TENS Devices & Electrodes Designed for Specific Etiologies
Electrodes are currently available in a wide range of shapes, sizes, and disposability (from one to many uses). The techniques for their manufacture are well characterized. To create brand identity, remain essentially wireless, and incorporate the proper interconnect, electrodes will be custom made for use with the modular control device.

The first product to be marketed in conjunction with the control module will simply consist of two electrodes that can be placed anywhere pain occurs in a manner similar to a Band-Aid™. A conceptual rendering of such a device is seen in Figure 17.

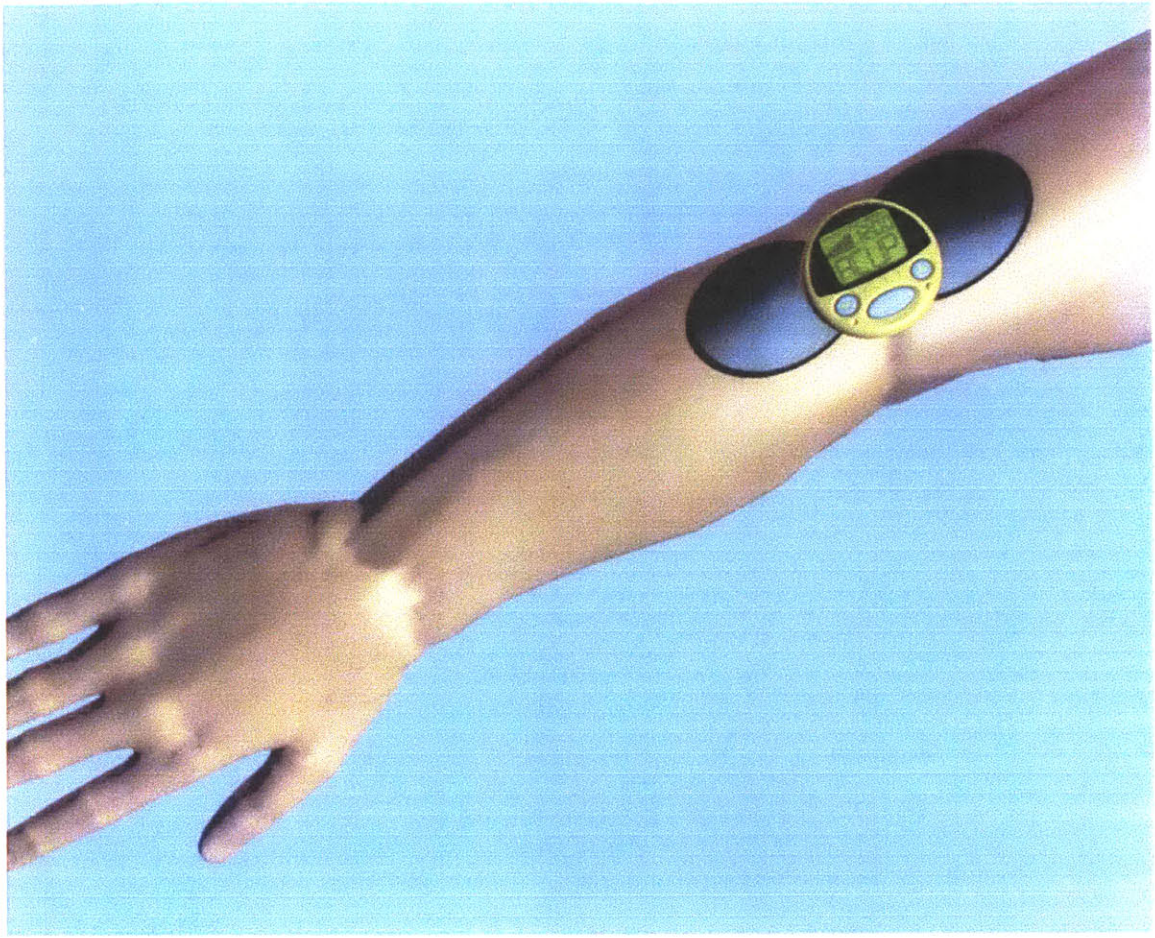


Figure 17

'Band-Aid™' TENS device concept.
(Conceptual rendering by Frank Tyneski, Industrial Designer.)

The next products will consist of electrode arrays designed for specific body regions where TENS therapy has been shown effective in alleviating pain. These include the neck, cervical spine, wrist, shoulder, elbow, hand, thumb, scapula, abdomen, knee, hip, and ankle. A conceptual rendering of an electrode array for the small of the back is seen in Figure 18.

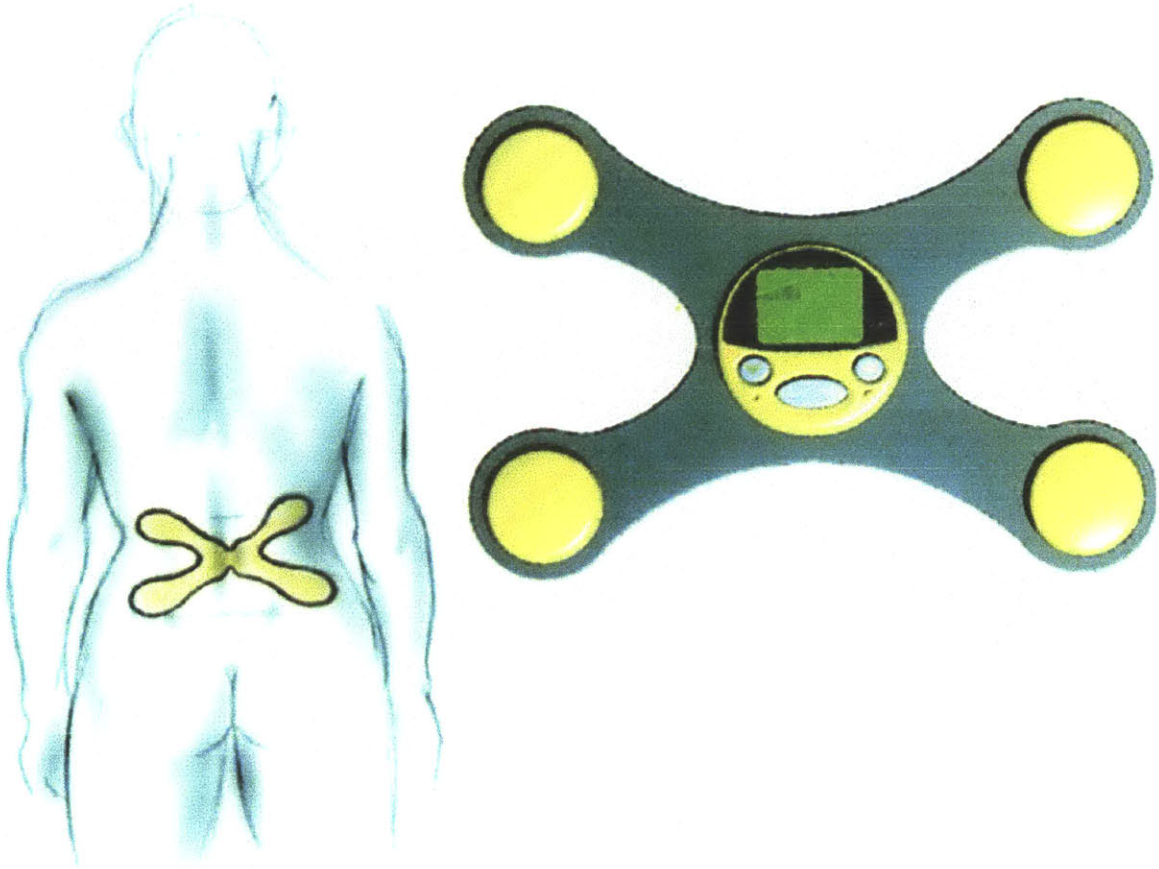


Figure 18

Back electrode array concept.
(Conceptual rendering by Frank Tyneski, Industrial Designer.)

4.1.3 Remotely Operated TENS Devices

As can be seen from Figure 18, TENS application in certain areas is difficult for a patient to perform alone. Another person might be needed to set stimulation parameters and operate the control module. Second generation products will therefore consist of remotely controlled TENS devices. The modular control platform will be slightly modified to include a receiver, and a wrist watch transmitter device will be developed. Figure 19 shows a conceptual rendering of this TENS unit, again for the small of the back.

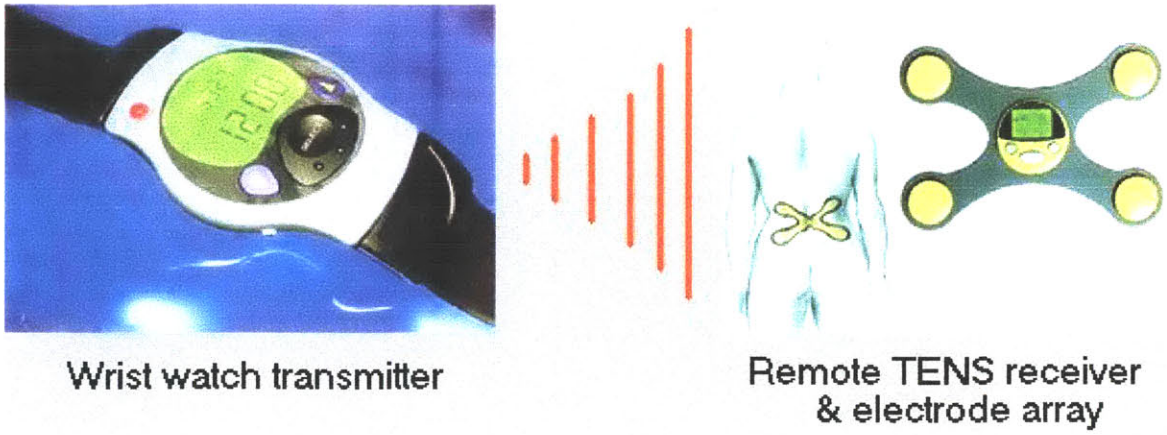


Figure 19

Remotely operated TENS device concept.
(Conceptual rendering by Frank Tyneski, Industrial Designer.)

4.1.4 Orthopedic TENS Devices

The final area of development is full integration of the platform TENS technology into splints, braces, immobilizers, and other orthopedic devices. This study details the application of a structured design process to the first products in this area, as described in Sections 4.2 and 4.3. Orthopedic TENS devices must be intuitive, robust, inexpensive, and safe, and must provide accurate positioning of TENS electrodes without the help of a health professional, all in attractive consumer products. They must also have the functionality of standard orthopedic devices that do not incorporate TENS technology. Preliminary (prior to this study) conceptual renderings of a knee immobilizer and a wrist splint are seen in Figure 20.

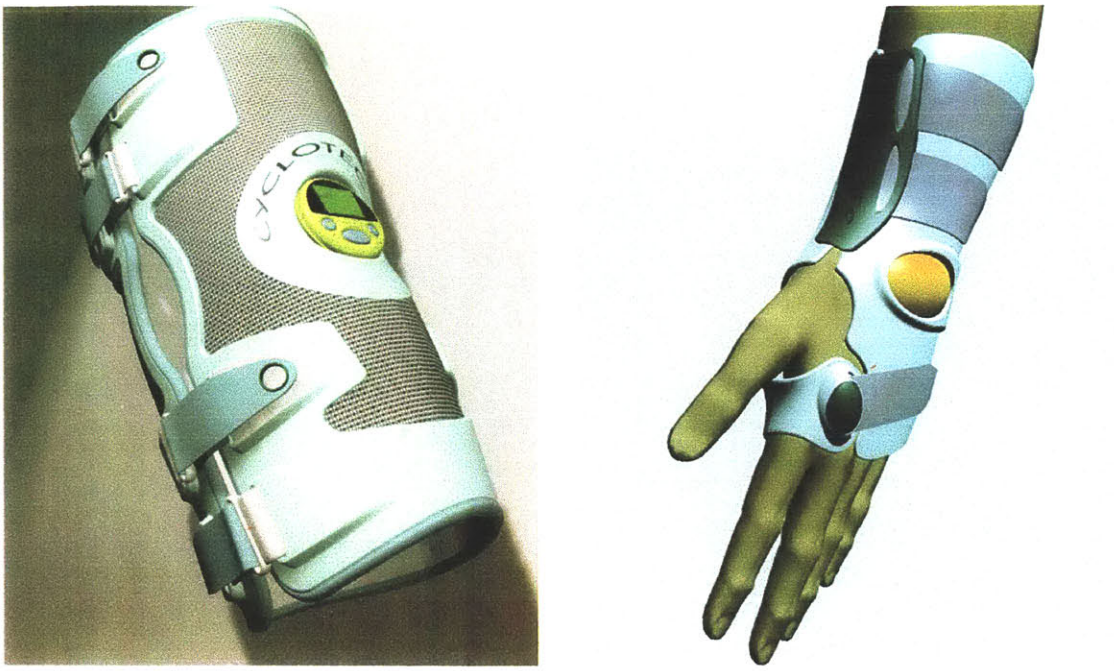


Figure 20

Preliminary renderings of a TENS knee immobilizer and wrist splint.
(Conceptual renderings by Frank Tyneski, Industrial Designer.)

Section 4.1 broadly defined the platform TENS control device and the product family based on that platform. Sections 4.2 and 4.3 now get to the heart of this study: namely, the application of a structured design process to the development of orthopedic TENS devices for the treatment of acute pain. Section 4.2 describes the creation of a TENS knee immobilizer while Section 4.3 focuses on a TENS wrist splint.

4.2 TENS Knee Immobilizer

A TENS knee immobilizer was developed for the treatment of acute knee pain. This section describes the process used in the creation of α prototypes. It also lays out the immobilizer's functionality and features in significant detail.

4.2.1 Concept Development

Section 3.1.1 outlined the constitutive parts of concept development. These parts were summarized in Figure 8. For convenience, Figure 8 is reprinted here as Figure 21.

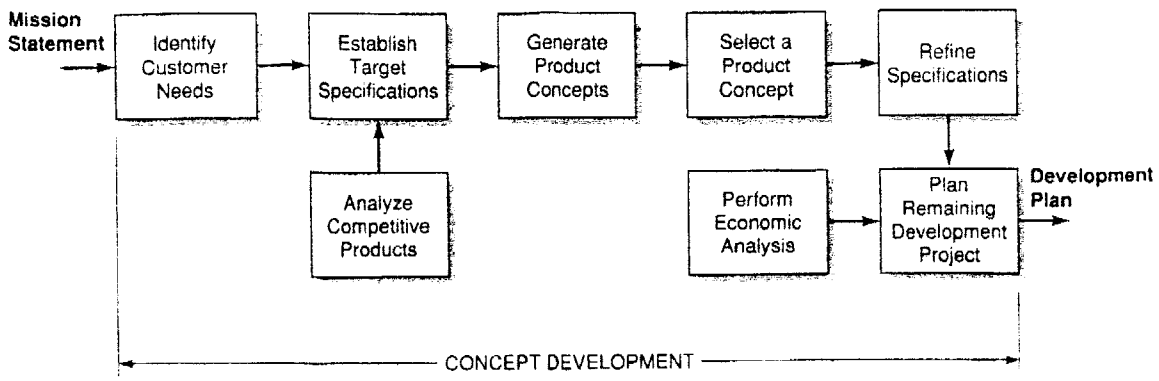


Figure 21

The constitutive steps of concept development.
(From Ulrich, Karl T.; Eppinger, Steven D. Product Design and Development. Copyright 1995 by McGraw-Hill, Inc.; New York [25; p. 18].)

Mission Statement

Development begins with a clear definition of the problem. As applicable, the definition should include a product description in very general terms, the primary and secondary markets in which the product will compete, any assumptions that are in place prior to development, and stakeholders in the development effort. Key business goals may also be enunciated at this time. Table 8 defines a mission statement for the TENS knee immobilizer.

Table 8
Mission statement for a TENS knee immobilizer.

Product Description	An orthopedic knee immobilizer with embedded TENS technology for relief of the symptomatic aspects of pain.
Primary Market	• Acute knee pain sufferers (post op., soft tissue damage, etc.)
Secondary Market	• Chronic knee pain sufferers
Assumptions	• Incorporates platform control device • Embedded TENS technology • Immobilizes knee joint
Stakeholders	• Patient • Medical suppliers (retailers) • Healthcare professionals (doctors, physical therapists, etc.) • Sales • Service • Production • Legal (patents, etc.)

Identify Customer Needs

Once the goals of development are clearly understood, an explicit statement of customer needs keeps the project vigilantly focused on the customer. To determine these needs, information is gathered from a variety of sources including personal interviews, focus groups, surveys, direct observation, benchmarking, etc. TENS products are somewhat unique in that the end patient is not necessarily the most aware of what is right and wrong with current products and techniques. Skilled clinicians with experience in applying the technology to others are perhaps as valuable a source of information. Information was therefore gathered jointly from discussions with knee pain sufferers and from clinicians. A weighted list of customer needs consolidated this information. Relative importance of an attribute was scaled from 1-5. Table 9 defines the rankings.

Table 9
Definition of rankings.
(Adapted from Ulrich, K. T.; Eppinger, S. D. Product Design and Development. Copyright 1995 by McGraw-Hill, Inc.; New York [25; p. 49].)

1 - Feature is undesirable. I would not consider a product with this feature.
2 - Feature is not important, but I would not mind having it.
3 - Feature would be nice to have, but is not necessary.
4 - Feature is highly desirable, but I would consider a product without it.
5 - Feature is critical. I would not consider a product without this feature.

Table 10 lists the customer needs and associated weightings. As much as possible, the needs are those that focus on aspects of the knee immobilizer as opposed to the modular control device, but some overlap was inevitable.

Table 10
Weighted customer needs for a TENS knee immobilizer.

Number		Need	Rank
1	The device	immobilizes the knee joint.	5
2	The device	alleviates pain.	5
3	The device	is safe with few side effects.	5
4	The device	aligns electrodes precisely & accurately.	4
5	The device	keeps electrodes in close contact with the skin.	4
6	The device	fits snugly and comfortably.	4
7	The device	is water resistant.	3
8	The device	can be easily cleaned.	3
9	Electrodes	can be easily replaced.	4
10	The device	is lightweight.	4
11	The device	is inexpensive.	4
12	The device	exhibits modern industrial design.	3
13	The device	minimizes entangling wires.	4
14	The device	actively counters accommodation.	3
15	The user	can alter stimulation parameters.	4
16	The device	maintains power for several hours of use.	4
17	The device	is easy to put on and take off.	3
18	The device	provides multiple stimulation modes.	4
19	Control device	is easily accessible.	3
20	The device	batteries can be easily changed.	3
21	The device	is robust.	4
22	The device	is non-irritating.	3
23	The device	remains at a comfortable temp. after prolonged use.	2
24	The device	can be configured with more than 2 electrodes.	3
25	The device	requires limited doctor visits.	4

Establish Target Specifications, Analyze Competitive Products

The next step, as seen in Figure 21, maps the customer needs into target specifications. Specifications consist of a metric, and a target value. Specifications are an attempt to convert the subjective customer needs into engineering terms. Target values set quantitative development goals. Customer needs yield the metrics. Table 11 presents the knee immobilizer metrics.

Table 11
TENS knee immobilizer metrics.

Metric #	Need #s	Metric	Rank	Units
1	1, 21	Downward deflection of end w.r.t. midpoint	5	ang. deg.
2	2	Change in pain pre- to post-treatment	5	% (subj.)
3	3, 22	Patients exhibiting skin burns or irritation	5	%
4	4	Avg. distance from target nerve	4	Cm
5	5,6	Avg. amt. of electrode in contact with skin	4	%
6	6	Device is comfortable	4	subj.
7	7	Time submerged before loss of function	3	S
8	8	Time to clean	3	S
9	9, 24	Time to replace electrodes	4	S
10	10	Total mass	3	Kg
11	11	Unit Manufacturing Cost	4	US$
12	12	Exhibits modern design	3	subj.
13	13	Max. length of any exposed wire	4	Cm
14	14	Intensity increase during modulation treatment	3	MA
15	15, 18	Intensity range	4	MA
16	15, 18	Frequency range	4	Hz
17	15, 18	Pulse width range	4	μs
18	16	Time to battery failure in worst case mode	4	hrs.
19	17	Time to put on or remove device	3	S
20	19	Time to activate control device & begin use	3	S
21	20	Time to change batteries.	3	S
22	23	Mean temperature of device after 1 hour of use	2	°C
23	25	Avg. # of doctor visits to gain proficiency	4	Numeric

Note that it isn't always possible to map customer needs into engineering terms. In these cases, we are left with subjective metrics that can only be judged by customer ratings of the product. Also note that some metrics correspond to more than one customer need, and some customer needs generate multiple metrics. As this study assumed the use of a modular platform technology, some of the metrics apply strictly to the control device and not the knee immobilizer. These metrics, 15-17, were not assigned target values as development of the knee immobilizer had little input into their final values. Other metrics were codependent on both the immobilizer and the control device. These; 7, 14, 18, 20, 21, 23; were assigned target values.

Once a reasonable set of metrics against which to base development had been established, target values are assigned to each metric. In order to do this in a relatively systematic way, it is important to benchmark competitive products and determine both what is realistically achievable and what minimum values must be met to be competitive. Orthopedic knee immobilizers with embedded TENS technology are not currently available in the market place. However, benchmarking still provided a wealth of

information. Various methods of pain relief were examined to determine the advantages TENS offers. This benchmarking data was given in Section 2.2.3. Next, a variety of TENS stimulators were examined to determine their strengths, weaknesses, operating parameters, etc. Much of this information was reviewed in Section 4.1.1. Finally, knee splints, braces, and immobilizers were studied to learn more about methods of immobilization, and to provide feasible values for several of the metrics in Table 11.

Knee immobilizers are available in three basic categories. The first immobilizes the knee from underneath. Steel rods are bent to conform to the backside of the leg. The rods are encased in a cloth material, which wraps around the leg and Velcroes or ties shut in the front. The second and third categories are actually comprised of rigid frame knee braces that can be locked into position. A knee brace is differentiated from a knee immobilizer by a joint at the knee. Knee immobilizers are rigid while braces allow the knee to bend. However, the knee joint in rigid frame braces can often be locked into a full-extension position, thereby acting as a knee immobilizer. Knee braces are placed over the topside of the leg and tightened down with straps that circle around the backside. The two categories of immobilizing braces are plastic or foam frames with metal side struts and composite frames. Composite frames are generally lighter and more attractive, but the plastic/foam and metal frames are much less expensive. Figure 22 shows an example from each of the three categories of immobilizers.

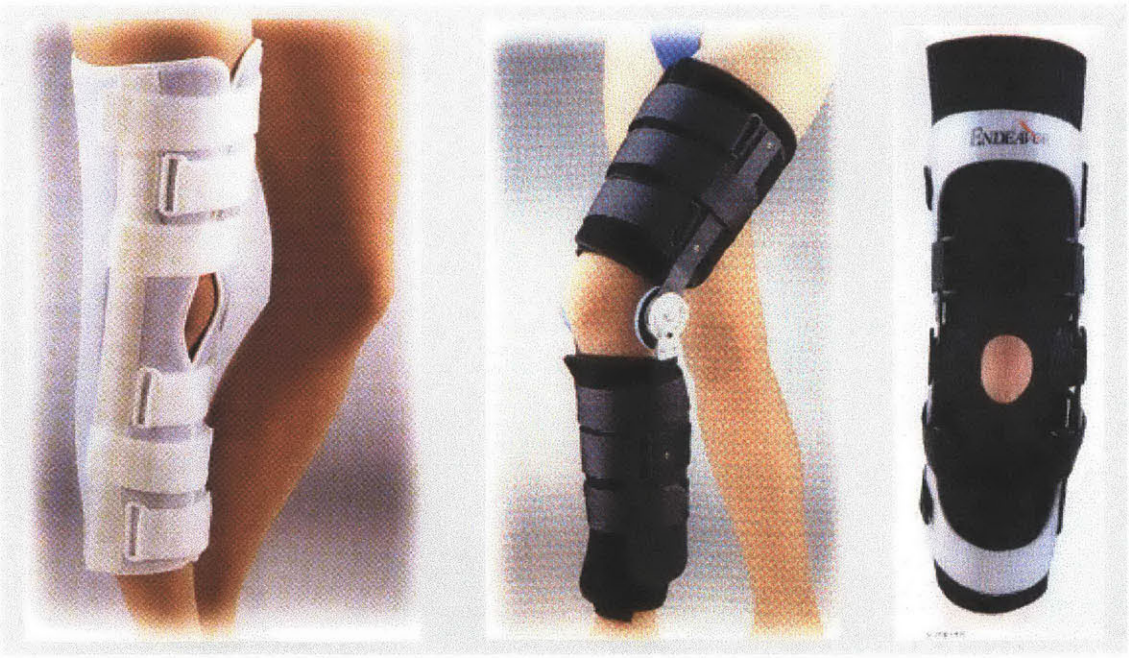


Figure 22

Different types of knee immobilizers/braces. The first picture is of a standard knee immobilizer, the second shows a cloth knee brace with metal side struts, and the third is a composite knee brace.

(From F*L*A Orthopedics' "Orthopedic and Bracing Product Guide")

Benchmarking allowed target specifications to be set in a more informed manner. Table 12 lists the target specifications.

Table 12
TENS knee immobilizer target specifications.

Metric #	Need #s	Metric	Rank	Units	Marginal Value	Ideal Value
1	1, 12	Downward deflection of end w.r.t. midpoint.	5	ang. Deg.	<10°	<5°
2	2	Change in pain pre- to post-treatment	5	% (subj.)	>30	>70
3	3, 22	Patients exhibiting skin burns or irritation	5	%	<5	<2
4	4	Avg. distance from target nerve	4	Cm	<2	0
5	5,6	Avg. amt. of electrode in contact with skin	4	%	>80	>90
6	6	Device is comfortable	4	subj.	>7/10	>9/10
7	7	Time submerged before loss of function	3	S	>15	>60
8	8	Time to clean	3	S	<180	<60
9	9, 24	Time to replace electrodes	4	S	<180	<60
10	10	Total mass	3	Kg	<2	<1
11	11	Unit Manufacturing Cost	4	US$	<50	<20
12	12	Exhibits modern design	3	subj.	>7/10	>9/10
13	13	Max. length of any exposed wire	4	Cm	<15	<10
14	14	Avg. intensity increase during modulation treatment	3	MA	<30	0
15	15, 18	Intensity range	4	MA	NA*	NA
16	15, 18	Frequency range	4	Hz	NA	NA
17	15, 18	Pulse width range	4	μs	NA	NA
18	16	Time to battery failure in worst case mode	4	hrs.	>12	>24
19	17	Time to put on or remove device	3	S	<120	<60
20	19	Time to activate control device & begin use	3	S	<180	<60
21	20	Time to change batteries.	3	S	<60	<30
22	23	Mean temperature of device after 1 hour of use	2	°C	<80	<70
23	25	Avg. # of doctor visits to gain proficiency.	4	Numeric	<3	0

*NA = Not Applicable

Generate Product Concepts

Product concept generation proceeds after the establishment of target specifications. A solid concept describes a product that will meet the ideal values of as many of the target specifications as possible. A slightly clearer problem definition is required before any solutions can be proposed. The goal is to create a knee immobilizer with embedded TENS technology for the treatment of acute pain. Chapter 2 explained how TENS stimulates afferent nerve endings to modulate pain. To apply the technology to knee pain, it is critical to know which nerve endings we are attempting to stimulate. Figure 23

shows the major nerve endings and optimal TENS stimulation sites for the lower extremity.

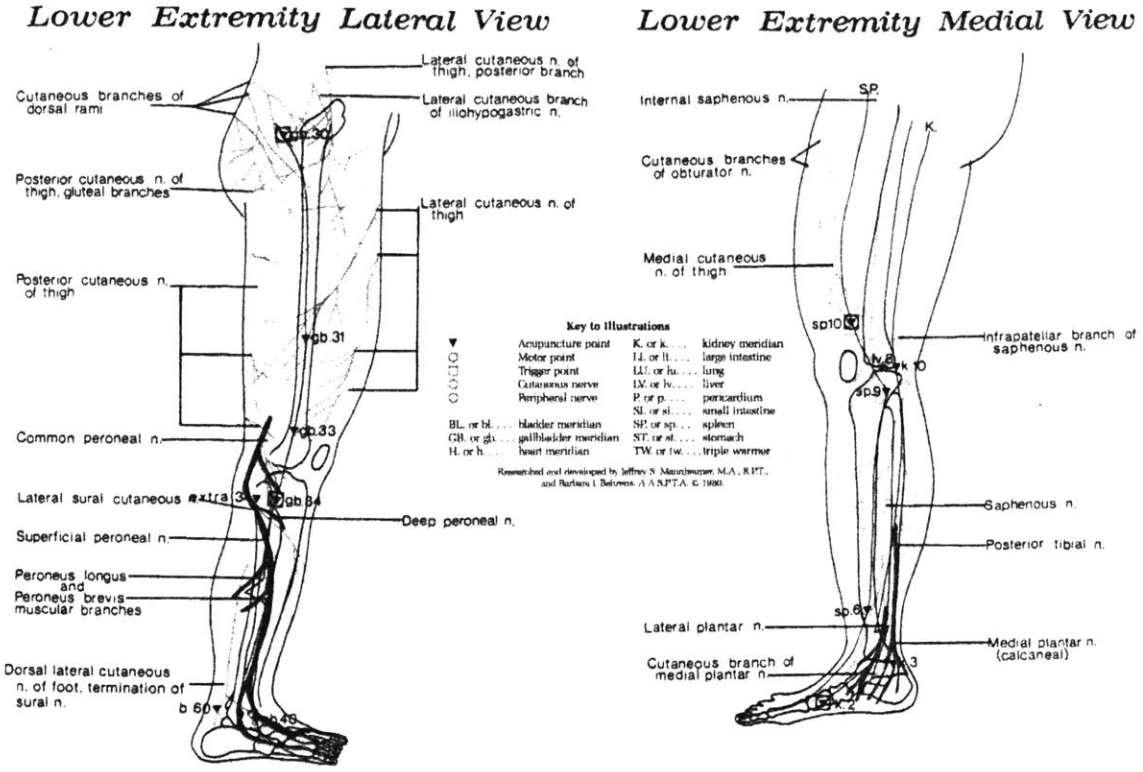


Figure 23

Optimal TENS stimulation sites and major nerves of the lower extremity.
(Adapted from Mannheimer, J. S. & Lampe, G. N.
Clinical transcutaneous electrical nerve stimulation. 8th ed.
Copyright 1988 by FA Davis Co.; Philadelphia, PA [10; pp. 301, 320, 322].)

For the relief of knee pain, TENS seeks to stimulate the points marked gb33 and gb34 on the lateral aspect and the points marked sp9 and sp10 on the medial aspect. Table 13 gives more information about the optimal stimulation sites.

Table 13
Optimal stimulation sites for TENS electrodes.
(Adapted from Mannheimer, J. S. & Lampe, G. N.
Clinical transcutaneous electrical nerve stimulation, 8th ed.
Copyright 1988 by FA Davis Co.; Philadelphia, PA [10; pp. 320, 323].)

Location	Superficial Nerve Branch	Acupuncture Point	Motor Point	Trigger Point	Segmental Level
In depression just above lateral epicondyle of femur	Lateral cutaneous nerve of thigh (anterior branch) which communicates with femoral nerve (cutaneous branches of anterior division) and infrapatellar branch of saphenous forming the patellar plexus	GB 33			L2-3 L3-4
Anterior and inferior of fibular head	Sural communicating branch of common peroneal nerve	GB 34			L2-3 L4-S2
2" above medial aspect of patellar base	Medial cutaneous nerve of thigh (posterior branch) and infrapatellar branch of saphenous (subsartorial plexus)	SP 10	Vastus medialis (femoral) (L2-4)	Vastus medialis	L2-4 L2-3
Just below medial condyle of tibia level with tibial tuberosity between sartorius and gracilis	Saphenous nerve (infrapatellar branch)	SP 9			L3-4

The key benefits of a TENS knee immobilizer over a standard immobilizer used in conjunction with a standard TENS stimulator lie in the minimization of entangling wires and in the precise and accurate positioning of TENS electrodes without the help of a skilled clinician. Concept generation therefore focused on how to seamlessly integrate TENS technology into a device similar to existing immobilizers and braces. Specifically, it focused on how to align the electrodes without a physical therapist.

Concept generation produced several ideas. The most promising revolved around elastic materials to which electrodes could be attached at specified points corresponding to those seen in Figure 23. When the immobilizer is put on, the elastic material conforms to the shape of the knee. The electrodes are always in the same place and in good contact with the leg. Circuitry can embedded inside the elastic material and routed to the control device attachment point. An early drawing outlining this concept is seen in Figure 24.

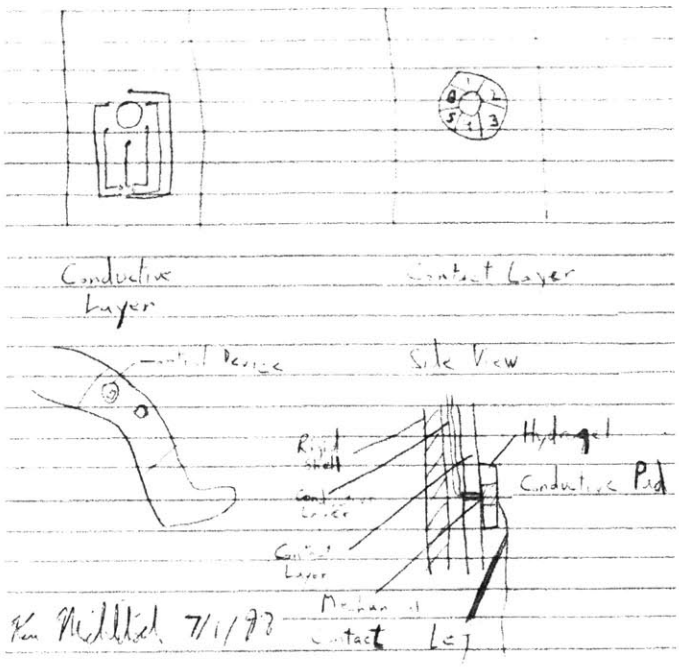


Figure 24

Preliminary electrode alignment scheme.

After evaluation against alternative methods, this was conceptually chosen as the method of electrode placement. Next, concepts were generated that integrated the electrode placement technique with the platform controls module into a device similar to existing immobilizers or braces. The main question was whether to integrate into a cloth immobilizer with metal rods or into a rigid knee brace frame made from composites, plastics, or metal. Concepts were generated for both alternatives.

The core benefit of integration into a standard cloth immobilizer is cost. These devices require very little tooling and machining and are usually hand stitched. The drawbacks include visual appeal and structural rigidity. Immobilizers do not allow for the styling seen in designer knee braces. More importantly, they are primarily fabricated from a cloth material. Besides the point at which the metal rods are inserted, they exhibit very little structural rigidity. Hence, it is difficult to find a proper attachment point for the modular control device, and is difficult to conceal wires. Also, the chosen electrode placement technique requires an elastic material to be in front of the knee when the immobilizer is put on. This is difficult to accomplish with a standard immobilizer because it fastens shut on the topside, or anterior, of the leg. However, cost issues made it worth analyzing. Concept notes written at that time read:

1. Create the basic immobilizer form with soft-splinting materials (cloth, foam, etc.) and steel rods or stays along the back for structural support.

2. Instead of having the immobilizer circle all the way around and fasten in the front, leave about a six inch gap at the front of the leg. There will be a second, plastic panel to cover this area. The cloth piece will attach via straps or Velcro to the sides of this front panel. The straps will also be used for tightening. The front panel will contain all circuitry/electrodes and the control device. The knee section will be cut out and will contain Lycra Spandex that will conform to the shape of the knee. Since this front panel doesn't need to provide structural support (rigidity is provided by steel stays), it can be made out of nearly any plastic. It also isn't too important that the plastic panel conform exactly to the front side of the leg since all it's really doing is running circuitry, providing shape, and centering the Spandex over the knee (it doesn't need to do much in the area of immobilization). It could even be a half panel that covers just the knee and the leg upper. Maybe we could get away without making a molding and still have an attractive and functional plastic front to the brace. The panel could just be a stock plastic sheet stamped to the proper shape, heated, and rolled into the appropriate arc.

Integration into a knee brace solves many of the problems seen in the knee immobilizer. Knee braces have a rigid frame along which wires can easily and discretely be routed. The frame also provides a natural attachment point for the TENS control device. The front of the knee is exposed, which means the elastic piece with attached electrodes can be stretched over this section. For immobilization purposes, the joint at the knee is unnecessary and can be removed. Knee braces also provide significant leeway in aesthetic styling. Taken collectively, TENS integration into a brace seems like the obvious choice. Unfortunately, knee braces are much more expensive than immobilizers. Fabrication from composites makes cost prohibitive. To meet cost goals, the frame can only be fabricated from plastics, cloth, and/or metal. Removal of the knee joint means the brace must be able to withstand a significant bending load. The most attractive frame would be fabricated solely from plastics, but the strength characteristics of plastics are much lower than those of composites and metals. A hybrid metal/plastic frame could clearly withstand the bending load, but metals are heavy, and hybrid braces are generally much less attractive than composite braces (see Figure 22). Figure 25 shows a preliminary drawing of the knee brace concept.

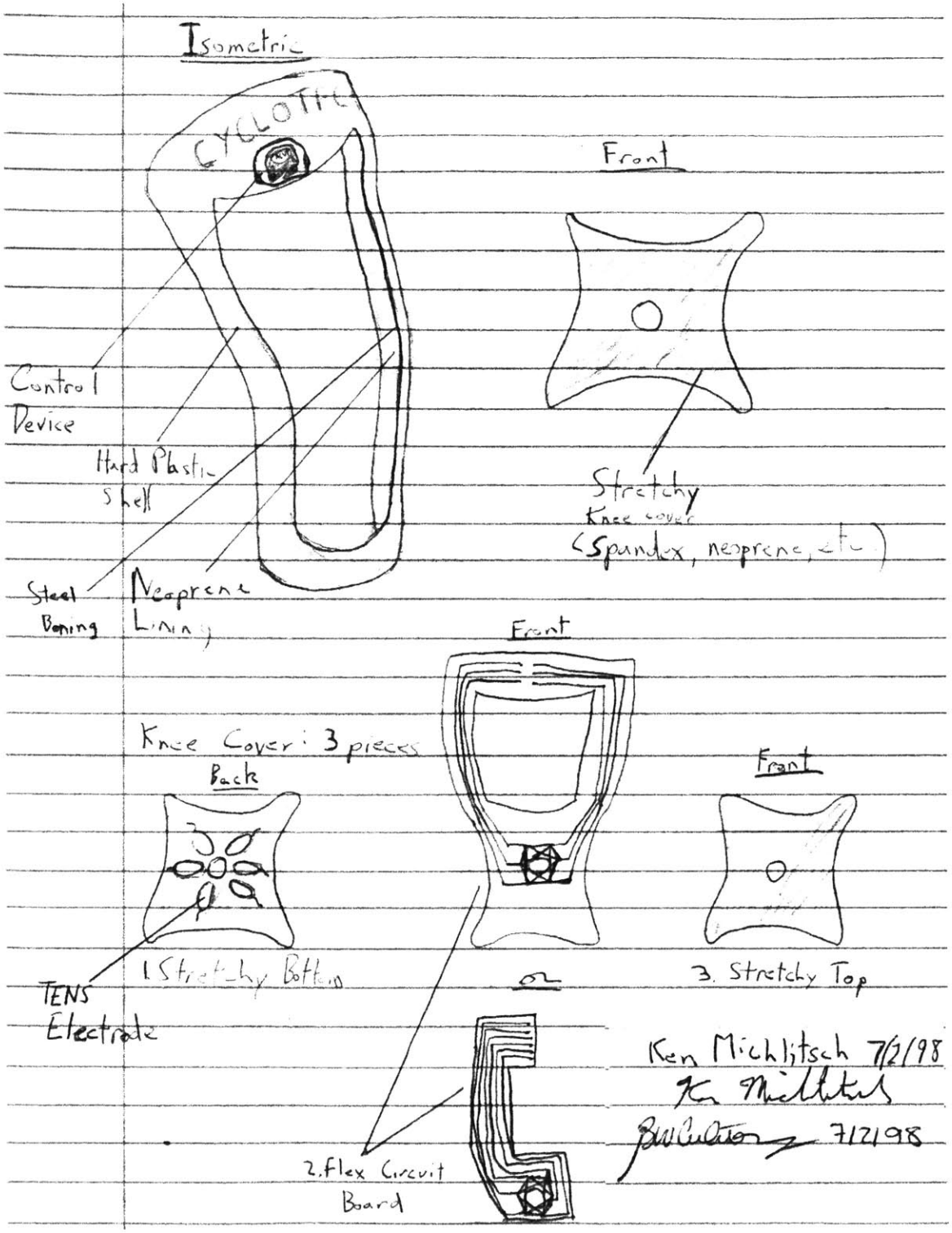


Figure 25

Preliminary TENS knee immobilizer concept.

A elastic material is draped over the knee and attached to the rigid frame. TENS electrodes are connected to the elastic material at the proper locations for knee stimulation. They attach to a flex circuitry board embedded between two pieces of the elastic material. The flex circuitry then runs along the rigid frame until it connects with the modular control device located at the top of the frame on the upper thigh. Note that the control device originally allowed for up to six electrodes. This was later reduced to four. Figure 26 shows an illustration of the fully assembled device.

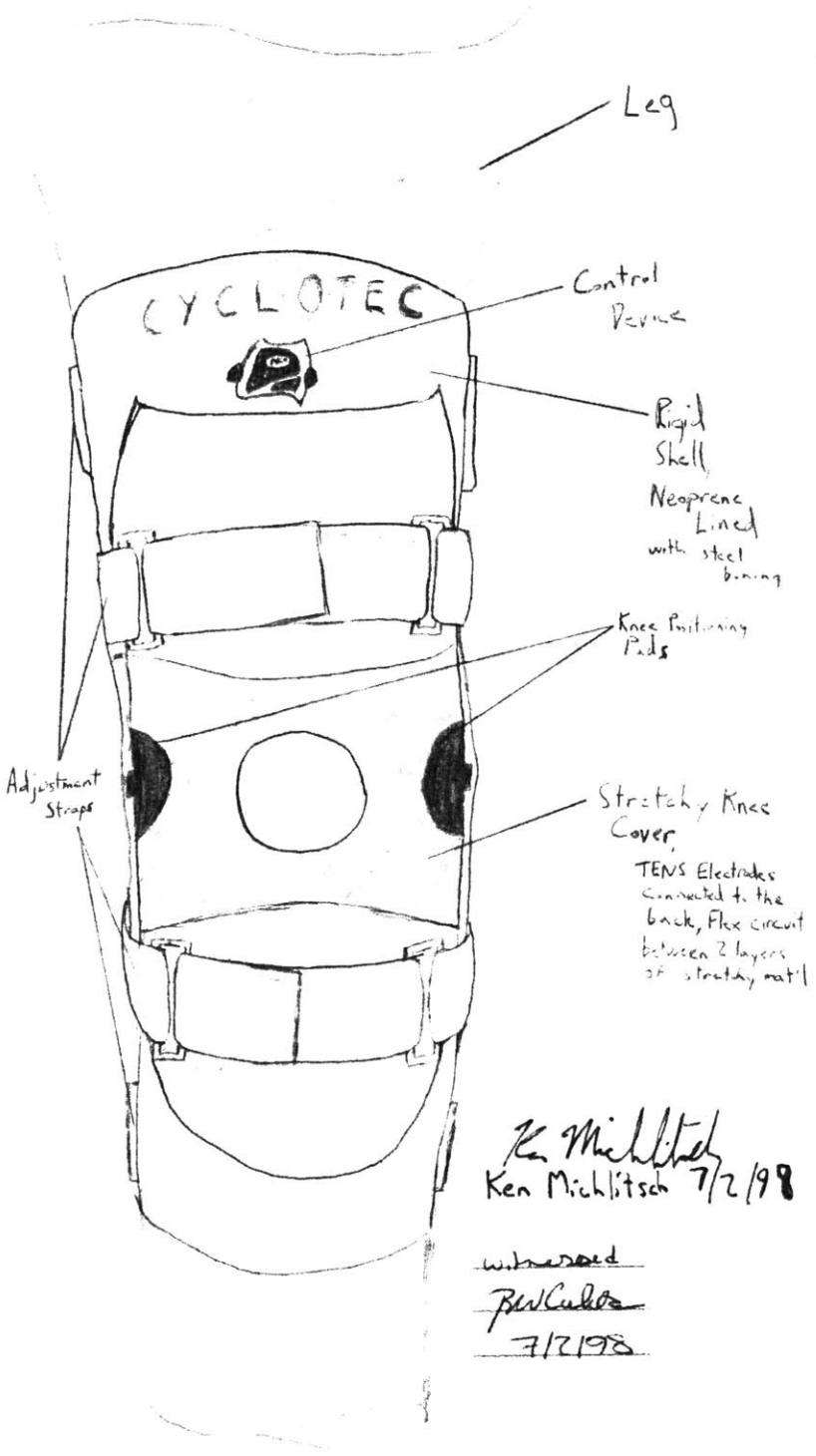


Figure 26

TENS knee immobilizer concept assembly drawing.

Concept Selection

The concepts mentioned above and several others were systematically evaluated to determine which was most feasible and which could attain ideal rankings on the most important target specifications. The key criteria used in evaluation were:

1. Ease of manufacture
2. Precision and accuracy of electrode placement
3. Minimization of exposed wires
4. Ease of handling and use
5. Knee immobilization
6. Weight
7. Cost

For some criteria, it was not immediately clear how well each concept scored. Many trade-offs that would ultimately affect performance were inherent in our assumptions of what would and would not work. To better evaluate these trade-offs, several preliminary prototypes were made as proofs of concept. Preliminary prototyping is a relatively inexpensive method of verifying or disproving assumptions. It is much easier to modify or change focus at this stage in the process than later in the process. Prototypes come in many forms as seen in Figure 27.

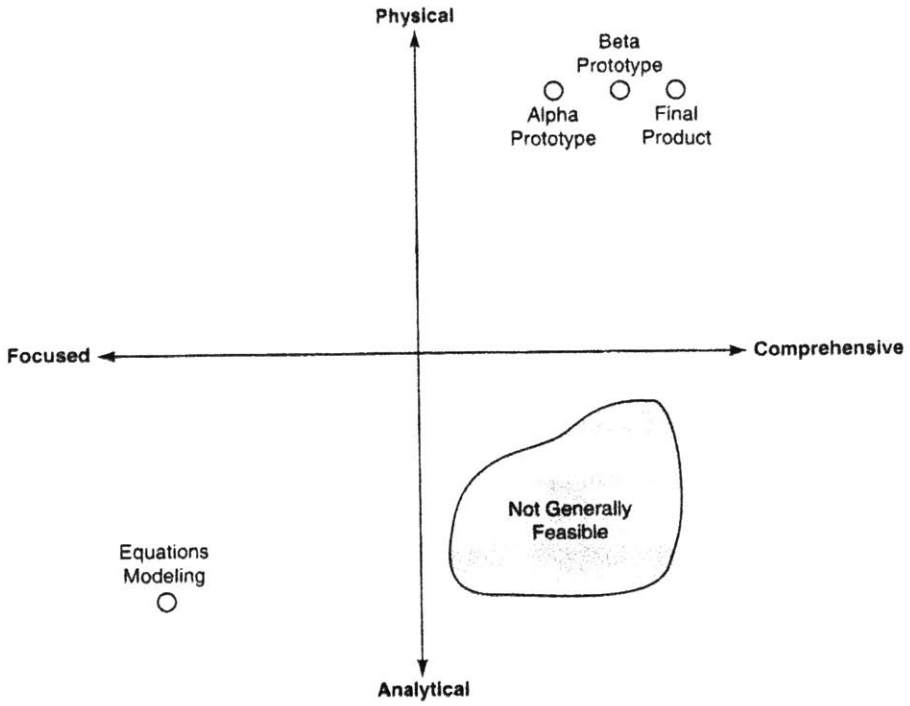


Figure 27

Types of prototypes. Prototypes can be classified by the degree to which they are physical and the degree to which they implement all of the attributes of the product. (Adapted from Ulrich, Karl T.; Eppinger, Steven D. Product Design and Development. Copyright 1995 by McGraw-Hill, Inc.; New York [25; p. 220].)

The end goal was production of an α prototype TENS knee immobilizer. Note that α prototypes are fully physical and incorporate nearly all the attributes of the final product. During the concept selection phase, prototypes focus on only one or a few key aspects of the final product. The prototypes may be purely analytical or they may attempt to approximate some physical component.

For the sake of brevity and clarity, only the preliminary prototypes created in support of the concept eventually chosen will be discussed. Prototyping led to selection of a modified version of the knee brace concept seen in Figures 25 and 26. Although the concept had clear advantages over competing concepts, two questions needed to be answered:

1. Can a rigid frame be fabricated solely from inexpensive stock plastics that will be able to withstand the applied loads expected in service?
2. Can the flex circuitry embedded in the elastic knee cover comfortably conform to the shape of the knee?

If the answer to the first question were no, the frame would have to either be fabricated from economically unfeasible composites or reinforced with heavy and unattractive metal supports. Neither alternative is particularly attractive, and a negative answer might lead to selection of an alternative concept.

If the answer to the second question were no, short exposed wires would be necessary to attach the electrodes to the flex circuitry at the midpoint of the rigid frame. This too might make an alternative concept more attractive.

To answer the first question; focused, analytical prototypes were developed. Each examined a potential failure mode. The key failure modes addressed were yielding, fracture, torsion, and buckling. Fatigue was also studied. Figure 28 presents these failure modes.

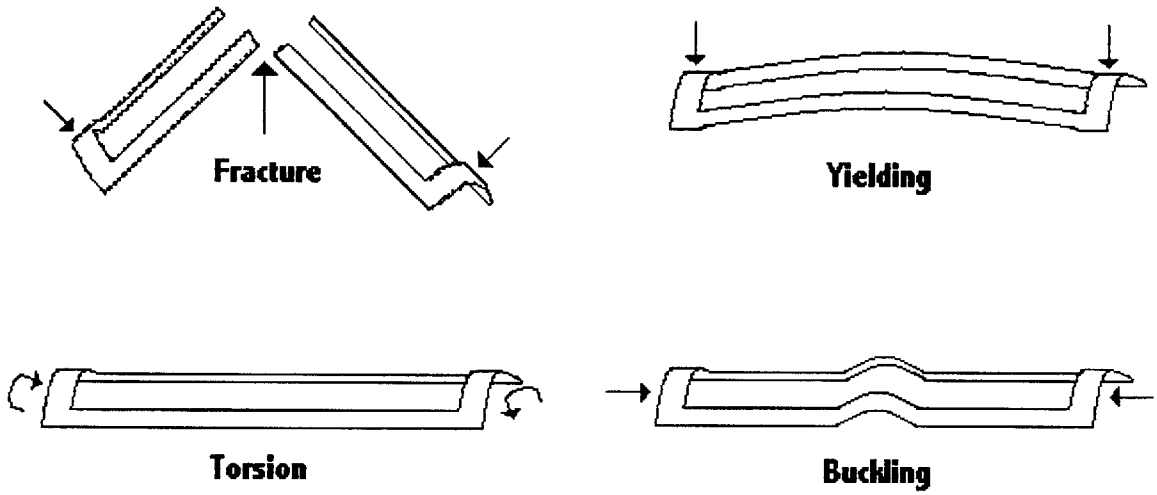


Figure 28

Failure modes evaluated with analytical prototypes.

Modeling the forces expected in service quickly eliminated buckling as a serious problem and established torsion as second-order concern. The most dangerous and probable failure mode was either yielding or fracture, depending on the stiffness of the material of fabrication. If the brace is considered perfectly attached to the leg by four straps, the it can be modeled as a cantilevered beam. The leg above the knee joint acts as a wall. Below the knee, a distributed leg weight force acts along the length of the frame. This force is negligible in relation to the bending force applied at the location of the two lower straps. The forces at the two straps are assumed equal. Figure 29 illustrates this analytical model.

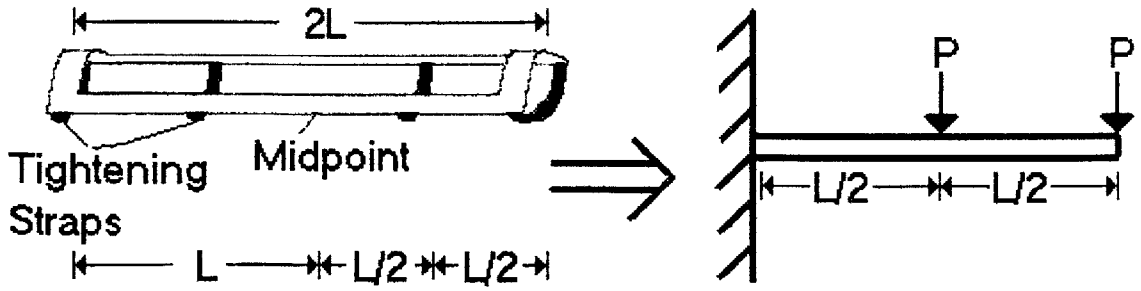


Figure 29

The frame can be modeled as a cantilevered beam.

The average person can apply under 100 lb. in bending (think of a person doing leg curls at a gym). To provide a significant safety factor, the device was designed to sustain a maximum bending load of at least 500lb. The model seen in 29 showed that the most probable point of failure was the midpoint, and failure was critically related to the moment of inertia at that point. Furthermore, a slight increase in the height provides a cubic increase in the moment of inertia. A spreadsheet model of many different plastics with different material properties was evaluated against Figure 29. By slightly increasing height in the vicinity of the midpoint, the model showed that it would be possible to fabricate from stock plastics.

To answer the second question about flex circuitry compliance, a physical prototype was created. Flex circuitry consists of a thin plastic sheet with copper traces laid down upon it. For expediency, the plastic sheet was approximated by an overhead transparency cut to the proposed shape of the circuitry. The transparency was attached to a piece of Spandex pulled taut over the knee. It did not conform as well as anticipated. Thus, a modified concept in which the electrodes have short wires that attach to the flex circuitry at the midpoint of the rigid frame was adopted. Although this means wires of minimal length will be exposed, the wires can be routed such that they will not be an inconvenience. After systematic comparison with all the other concepts, the rigid frame knee brace concept with modified flex circuitry was selected.

Refinement of Specifications

Once a concept is selected, the target specifications must be reevaluated in light of the chosen concept. Are the target specs still plausible? Are they still relevant? A reexamination of Table 12 showed that Metric #21, time to change batteries, was no longer applicable since the chosen concept did not take advantage of the control device's ability to use auxiliary power. Thus, the metric was really only relevant to the modular control device and not to the knee immobilizer. The other metrics remained relevant and attainable in the chosen concept.

Economic Analysis

A simple economic analysis helps to identify trade-offs made during development. It also gives justification for moving forward with development. Although this study was primarily concerned with the scientific and engineering aspects of product development, economic considerations must always be taken into account if a product expects to succeed. A materials list was therefore developed early in the process, and regularly refined as design changes were made. Table 14 is the final parts list for the TENS knee immobilizer. The details of how many of these materials were chosen and their function in the final design will be developed in Sections 4.2.2-4.2.5. It is of interest to note that the majority of the materials did not change from the concept selection phase through the α prototype phase. Thus, a reasonable cost estimate can be made very early in the process.

Table 14
TENS knee immobilizer final parts list.

Item	Quantity	Approx. Retail Cost	
1/4"*12"*18" Polypropylene Sheet, Medical	1	$20.00	
10"*8" Heavyweight Stretch Lycra	1	$1.00	
Coat Hooks and Eyes	4	$1.10	
2" Adhesive-Backed Velcro Hook, Medical	16"	$1.80	
2" Adhesive-Backed Velcro Loop, Medical	4"	$0.45	
Tightening Straps (2" Beta Pile II Loop)	5'	$3.15	
1.5"*4" Strap Pads	2	$2.20	
2" D-Rings with Chafes	8	$1.60	
1/8"*12"*18" Adhesive Padding	1	$4.25	
Thread	5'	$0.10	
Rivets	16	$1.00	
Wire	1'	$0.10	
Stiffener with Flex Circuitry	1	$0.25	<==Rough Estimate
Flex circuit	1	$0.25	<==Rough Estimate
2-pin Molex Connectors	2	$0.25	<==Rough Estimate
Approx. Retail Material Cost =		*$37.50*	*(Doesn't include electrodes)*

Using as a baseline a 3x markup for retail, materials should cost in the ballpark of $12.50 when the project moves to mass production. In order to achieve the ideal value of $20 for unit manufacturing costs; conversion costs, distribution, warranties, etc., cannot exceed approximately $7.50 per unit. The primary cost besides materials lies in tooling for the rigid frame. By keeping complex geometry all on one side, the frame can be thermoformed as opposed to injection molded. This cuts the tooling costs in half. The cost of tooling must then be amortized over the number of units sold. Commercial viability depends on achieving a product volume that justifies the tooling.

Project Planning

Project planning is the final step in the front-end process of concept development. The goal is to create a detailed development schedule that minimizes development time and identifies the necessary resources required to complete the project. Fabrication of an α

prototype TENS knee immobilizer moved from conception through completion in four months. A refined α prototype was completed in six months. Proper scheduling coupled with early identification and allocation of resources made such an aggressive schedule possible.

4.2.2 System-level Design

System-level design seeks to define product architecture & subsystems. The knee immobilizer can be broken into five subsystems: the rigid frame, the elastic knee cover, the electrodes, flex circuitry, and the modular control device. Section 4.1.1 discussed the control device. This section focuses on the development of the other four subsystems. The functional requirements of each are given, and the evolution from concept through full specification is detailed. The section concludes with the integration of all five subsystems into a final product.

The Rigid Frame

The rigid frame is the structural basis of the product concept. As such, it must serve a variety of functional requirements. These include:

1. Knee immobilization
2. Attachment point for both the elastic knee cover and the modular control device
3. Routing of flex circuitry from control device to electrodes

The rigid frame developed in an analytically iterative fashion. The key issues addressed were material selection and visual styling. As discussed previously, economic success depended on fabrication from stock plastics. This required that the frame be designed with significant load bearing capability. However, visual appeal was equally important since this is a consumer, as well as a medical, product. Figure 30 illustrates the difficulties of fabricating with plastics as opposed to composites or metals.

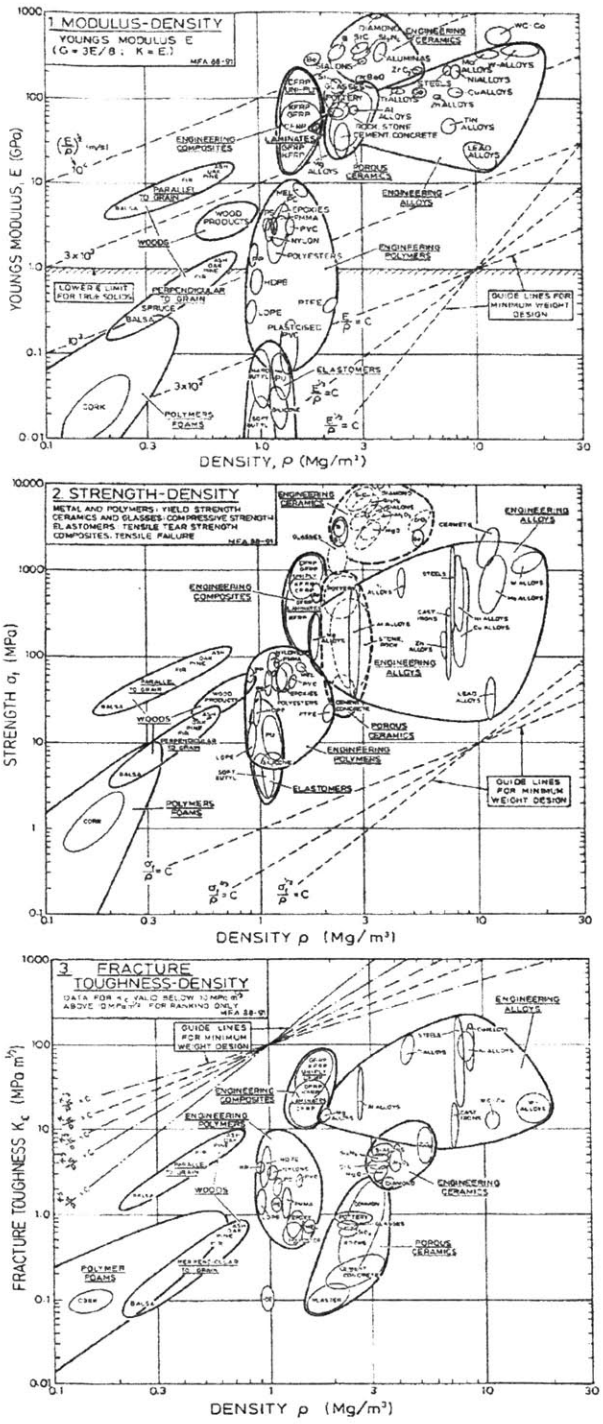


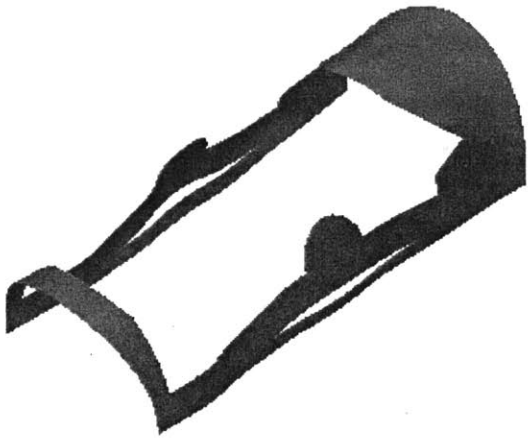
Figure 30

Material properties of engineering materials.
(From Ashby, M. F. Materials Selection in Mechanical Design. Copyright 1992 M.F. Ashby. Publ. by Butterworth-Heinemann Ltd.; Oxford [29; App. C: pp. 7, 9, 11].)

The comparatively low density of the engineering polymers makes them attractive. However, their other properties (Young's Modulus, strength, fracture toughness, etc.) pose serious challenges. Computer-aided design (CAD) models of various frame shapes were created to address both strength and styling issues. The strength characteristics of each frame were evaluated with the spreadsheet models developed previously (see *Concept Selection* in Section 4.2.1). The spreadsheets set minimum values for the salient material properties and checked those values against approximately 30 polymers under consideration for fabrication of the frame. In an iterative manner, strength balanced against visual appeal was achieved. Figure 31 chronologically shows several of the frames that were evaluated and the final chosen frame.

Evolution of the TENS Knee Immobilizer Frame

Frame 1



Frame 2

Frame 3

Frame 4

Frame 5

Frame 6

Frame7

Frame 8

Frame 9

Frame 10

Frame 11

Frame 12 (Chosen Design)

Figure 31

Evolution of the TENS knee immobilizer frame.

Development began with a very basic frame shape (frame 1). Semicircles located at the midpoint increased the moment of inertia while also providing a visual reference for centering the device over the knee. Stress calculations showed that this design had several shortcomings, especially related to torsional stiffness. It also lacked visual flare. Frame 2 was an early attempt to improve aesthetics, but it too was unsatisfying.

Frame 3 departed dramatically from the first two designs. It sought to address the torsional stiffness issues while sustaining a significant moment of inertia at the midpoint. It also greatly upped the visual ante. The molded oval around the knee increased structural integrity in the vicinity of the midpoint, but the removal of members running down the side of the leg decreased torsional stability near the ends. Frame 4 resolved this problem by combining frames 1 and 3, thereby gaining the strength advantages of both. Frames 5 and 6 reintroduced the circle at the midpoint. This increased the safety factor in bending, the most probable failure loading, by increasing the moment of inertia at the critical point. Although frame 5 passed the spreadsheet tests, the unbalanced look of the semicircle was not visually pleasing. Also, the full circle of frame 6 increased the safety factor even further. The hole at the circle's center decreased mass without affecting inertia, and it provided a point to attach the electrodes to the flex circuitry. This will be developed in greater detail during the discussion of those subsystems.

Frame 6 came very close to being selected as the final design. Visual and strength characteristics had been delicately balanced, and the frame could be fabricated from stock plastics. However, design for manufacturing showed that more work was necessary. As the frame shape evolved, more and more of the top of the leg was covered. In order to limit tooling costs, only a limited number of sizes are to be fabricated. For these limited sizes to fit all legs, very little customization can be tolerated. As more of the leg is covered, the same immobilizer fits a smaller and smaller range of leg sizes. More work was therefore necessary to open up the top surface of the leg while maintaining strength and visual appeal.

Frame 7 was basically a beefed-up version of the original frame. Although it showed much improvement over frame 1, it shared many of its shortcomings. Frame 8 reintegrated the oval of frame 3, but stretched it so that less of the leg was covered. Frame 9 continued this process. Frame 10 tried to open the oval up into more of a square shape that would cover as little of the leg as possible. The square shape becomes the side members that run the length of the leg. This design lacked torsional stiffness and appeared flimsy to several people that viewed it. However, it did open up the top of the leg and would be able to withstand significant bending loads. Frame 11 solved the torsional stiffness problem and removed the flimsy look. Frame 12, the final chosen design, simply balanced the contour of the top and bottom of frame 11. Frame 12 is resistant to yielding, fracture, torsion, and buckling, as well as fatigue, creep, etc. Figure 32 shows top, front, side, and isometric views of the chosen frame.

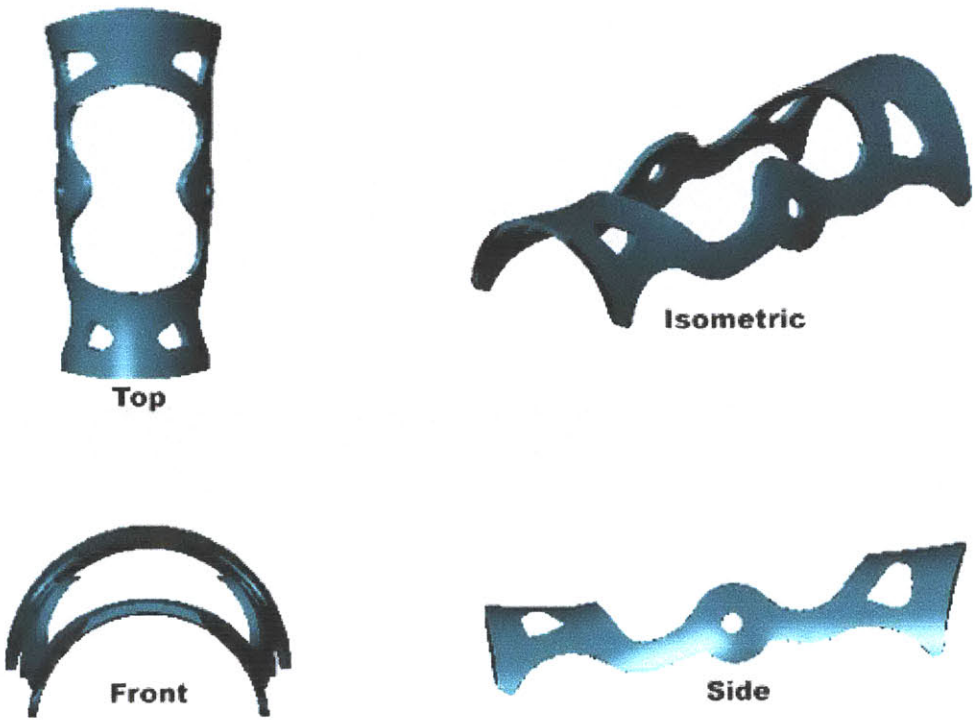


Figure 32

Four views of the chosen frame.

A short list of acceptable polymers was drawn up. Based on biocompatibility, cost, and workability, polypropylene was chosen from that list.

Two final element of the frame subsystem were left to specify:
1. The method of tightening when attached to the leg
2. The contact layer to be placed between the plastic frame and the leg

Four 2" wide straps will be used to tighten the immobilizer. These straps will run through eight D-rings with chafes riveted to the frame. Several different materials were examined for the contact layer. A foam adhesive padding was chosen for its ease of attachment, lightweight, low cost, and comfort in use.

The Elastic Knee Cover

The key purpose of the knee cover subsystem is to place the electrodes at the proper nerve endings around the knee. Thus, its functional requirements are:
1. Conform to the shape of the knee
2. Precisely and accurately align electrodes
3. Allow for electrode disposal
4. Remain comfortable over extended periods of treatment

Electrodes are disposable. Depending on which type is used, they last from one to several treatments. The conductive hydrogel eventually degrades and new electrodes are necessary. It must therefore be possible to attach and remove electrodes from the elastic knee cover. The original plan was to embed flex circuitry between two pieces of the elastic material. The electrodes would then be attached to the knee cover and circuitry by metal snaps placed at the proper locations. However, preliminary prototyping showed that flex circuitry will not conform to the shape of the knee. The design was modified so that short wires would connect the electrodes to the flex circuitry at about the midpoint of the knee brace frame. This reintroduced the question: "How do electrodes attach to the elastic knee cover in an attractive, fast, and highly repeatable fashion?" Velcro was chosen for its versatility.

Two more questions remained:
1. What elastic material will the knee cover be fabricated from?
2. How does the knee cover attach to the rigid frame?

Several materials were tested in response to the first question including several thicknesses of neoprene, elastic, and several weights of Lycra Spandex. Heavyweight Spandex offered the proper level of resistance to stretch and it is very comfortable over long periods of time, as attested by the proliferation of Spandex sportswear.

The second question was very important because the knee cover needed to be washable. A permanent attachment was therefore undesirable. The job required some sort of hook that would be highly reliable but also easily removable. The hook needed to be very inexpensive and easy to attach to both fabric and plastic. Coat hooks and eyes were selected. The hook end is sewn into the fabric while the eye is riveted to the frame.

The basic shape of the Spandex knee cover with electrodes is seen in Figure 33.

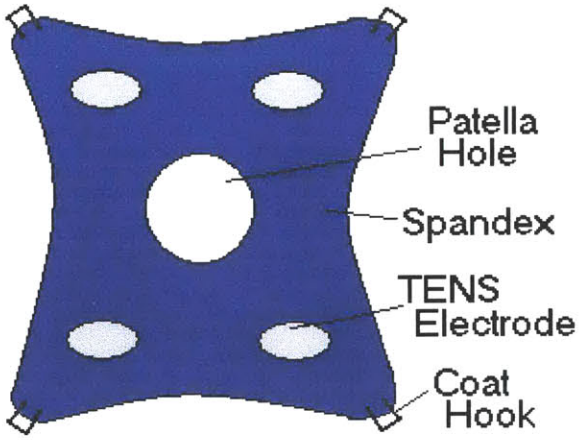


Figure 33

Layout of the elastic knee brace cover.

The Electrodes

TENS electrodes are essentially a commodity item. They are available in many shapes, sizes, and styles. This study did not seek to alter their basic design. Beyond the functional requirements of standard TENS electrodes, which include a conductive hydrogel adhesive layer and an electrical contact, the TENS knee immobilizer electrodes must:

1. Have a Velcro backing for attachment to the Spandex knee cover
2. Allow for attachment to flex circuitry.

The first requirement is straightforward and simple to accomplish. The second allows for product differentiation and the creation of renewable income. A unique connection method that differs from existing electrodes means that consumers must buy electrodes specifically manufactured for this device. This allows profit to be made from a secondary market on top of the sale of the initial device in a manner similar to disposable razor blades. It also means that the initial selling price of the knee immobilizer can be lower as costs can be recouped from the electrodes, which are very inexpensive to manufacture.

The chosen product strategy was electrodes sold in sets of two. Each pair of electrodes is joined at a male 2-pin Molex connector. In this manner, the two electrodes on the lateral aspect of the knee are joined, and the two electrodes on the medial aspect of the knee are joined. A female Molex connector will be located on each side of the rigid frame near the midpoint. The electrodes plug into these female connectors and are then connected via flex circuitry to the modular control device. Molex connectors are very robust and simple to use.

Flex Circuitry

The key functional requirements of the flex circuitry subsystem are:

1. Connect the modular control device to the TENS electrodes
2. Make the TENS knee immobilizer essentially wireless

The second requirement means that exposed wires are kept to a minimum. As discussed previously, the initial design called for the flex circuitry to be embedded in the Spandex knee cover. A schematic of the initial concept is seen in Figure 34.

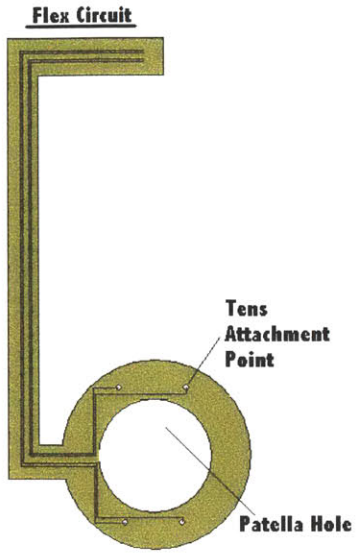


Figure 34

Initial flex circuitry concept.

Preliminary prototyping showed that this design would be ineffective because it would not conform to the shape of the knee. In the modified design, the flex circuitry only runs along the oval of the rigid frame. At the top, it connects via the 8-pin interconnect to the modular control device. At the ends it connects via a pair of female 2-pin Molex connectors to the electrodes. It is sandwiched between the frame and its foam lining and is not visible to the patient. Figure 35 presents the modified design.

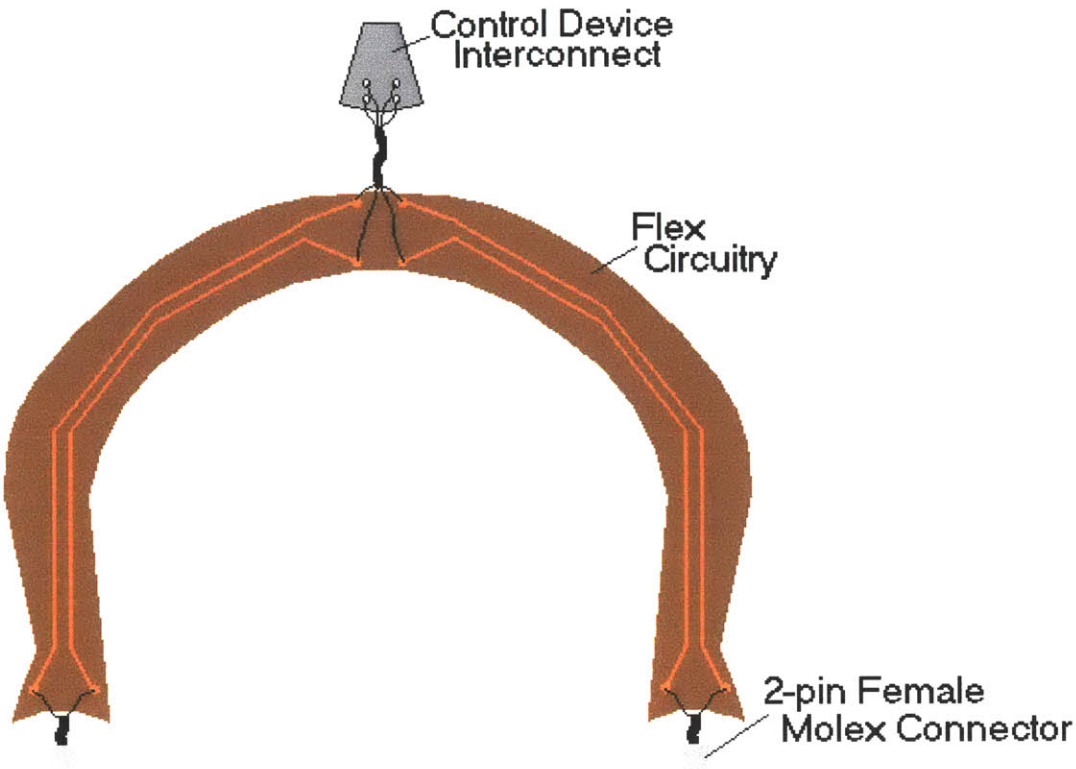


Figure 35

Final flex circuitry concept.

Each of the five subsystems has now been discussed. A flow chart for assembly of the final product completes subsystem design. Figure 36 presents this flow chart.

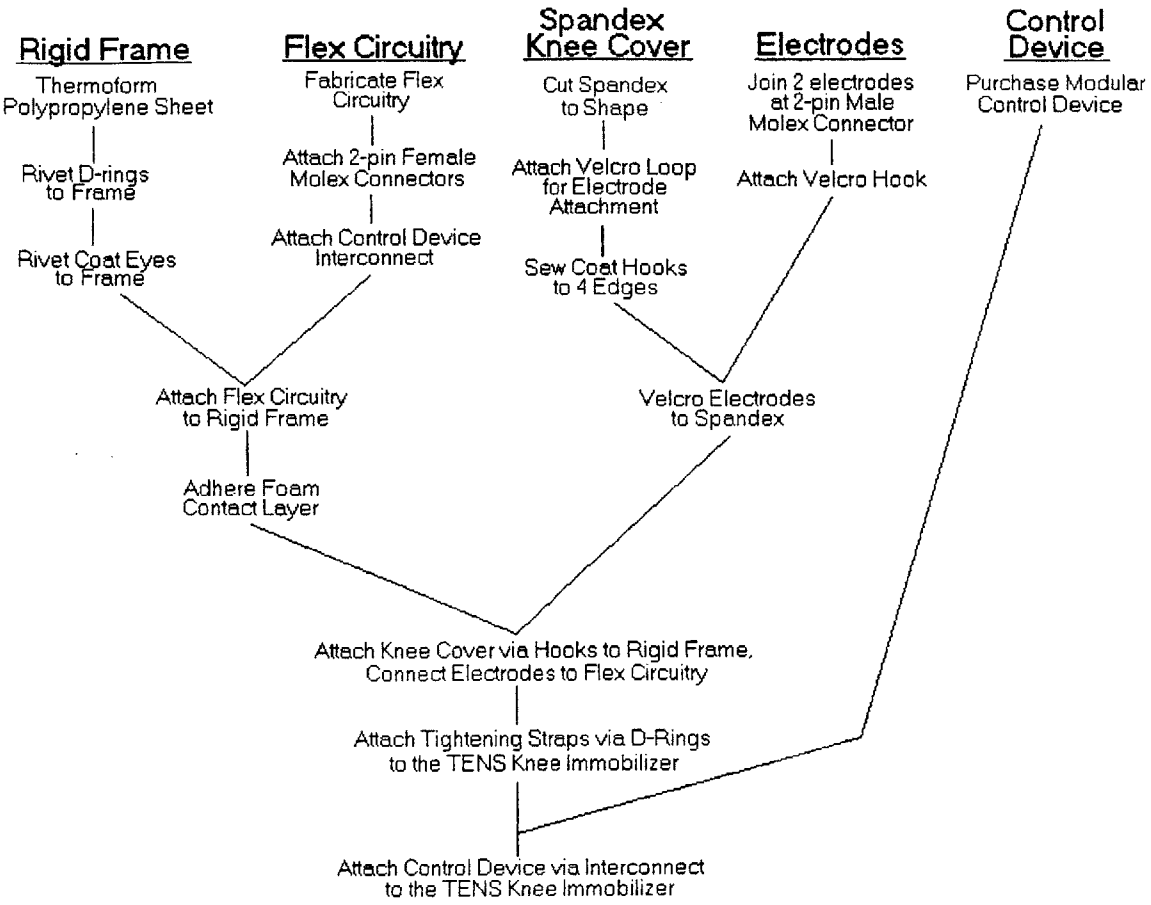


Figure 36

Assembly flowchart.

Figure 37 is a CAD drawing of the final device.

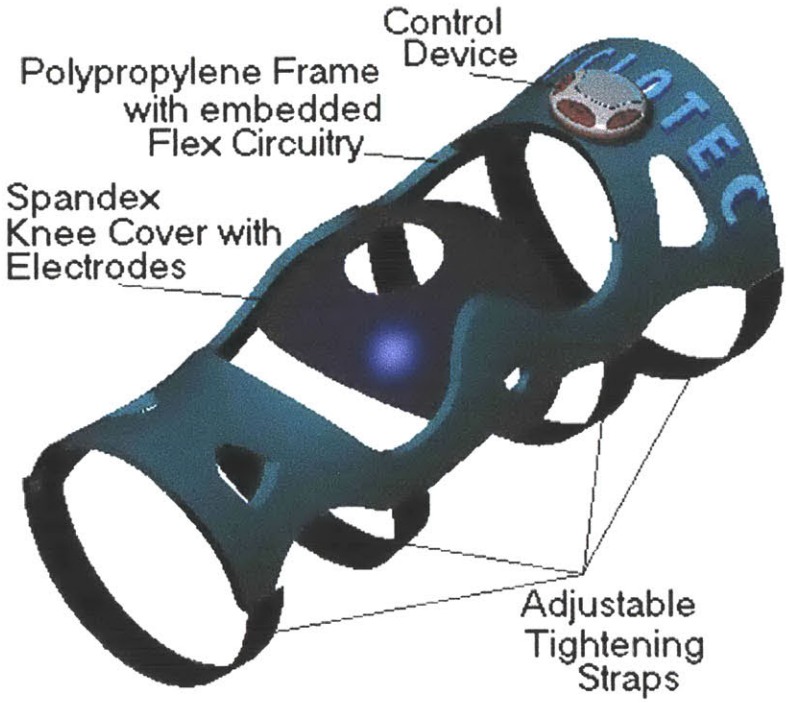


Figure 37

Rendering of the assembled TENS knee immobilizer.

4.2.3 Detail Design

Detail design involves specification of final geometry, material selection, and a list of outsourced parts. It is alternatively known as design for manufacturing. Most of the aspects of detail design were discussed in Section 4.2.2 during the explanation of each subsystem. It is of particular importance to note that all complex geometry lies on one side of the rigid frame. It can therefore be thermoformed and requires only one mold. This greatly decreases manufacturing costs. Also note that the frame is fabricated from polypropylene, an inexpensive stock plastic. The materials list provided in Table 14 in conjunction with Figure 36 shows which parts are outsourced and which are fully or partially fabricated.

4.2.4 Testing & Refinement

The end goal of this study was the production of α prototype orthopedic TENS devices. Future work will test and refine these prototypes, and lead to production models. An α prototype is made from the same parts as the final device, but the parts are not necessarily fabricated in the same manner. For example, the cost of tooling for the rigid frame could not be justified solely for prototypes. An alternative method of fabrication was therefore developed. The α prototyping techniques for each subsystem are discussed herein.

The Rigid Frame
To ensure that visual aspects and user interface issues had been properly addressed, an initial frame was fabricated from low temperature thermoplastics that could be deformed in hot water. Although this frame did not nearly possess the strength characteristics of polypropylene, it served as an effective visual model for evaluating industrial design issues. Once remaining concerns had been resolved, work began on fabrication of a rigid frame.

A plaster cast was created of this author's leg. This created a negative of the leg. A hardening silicone rubber was poured into the plaster cast to create a positive. The rubber positive was used as a mold around which a ¼" sheet of polypropylene was thermoformed. The thermoformed sheet was then cut to the proper shape. The frame was produced for only a few thousand dollars. Purchased D-rings and coat eyes were riveted at the proper points. Flex circuitry was attached. The foam contact layer was adhered. Finally, tightening straps were inserted through the D-rings.

The Spandex Knee Cover
Heavyweight Spandex was cut to the proper shape. Coat hooks were sewn into the edges and Velcro was attached at the proper points.

The Electrodes
Standard electrodes were joined together at a 2-pin male Molex connector. Velcro was attached to the nonconductive surface.

Flex Circuitry
Flex circuitry was fabricated by standard methods. A template was made from which the circuitry was produced. 2-pin female Molex connectors were soldered to the two ends, and the control device interconnect was soldered to the top.

The Control Device
The control device was developed concurrently. For testing purposes, a functional LabView emulator which could be connected to orthopedic TENS devices was created. However, prototyping of the actual control device was outside the scope of this study. Sufficed to say that aluminum molds were made for injection molding its plastic parts, and electronics were fabricated in limited numbers.

The five subsystems were integrated into the α prototype seen in Figure 38.

Figure 38

Four views of the TENS knee immobilizer α prototype.

The view marked "Bottom" has two of the tightening straps removed in order to make the knee cover subsystem more visible.

Figure 39 illustrates the Molex connection between the electrodes and the flex circuitry, as well as the interconnect point between the flex circuitry and the control device. Figure 40 focuses on the knee cover subsystem and shows the Spandex attachment to the rigid frame. It also demonstrates how the electrodes are fastened to the Spandex. Finally, Figure 41 shows the tightening straps and the prototype in use.

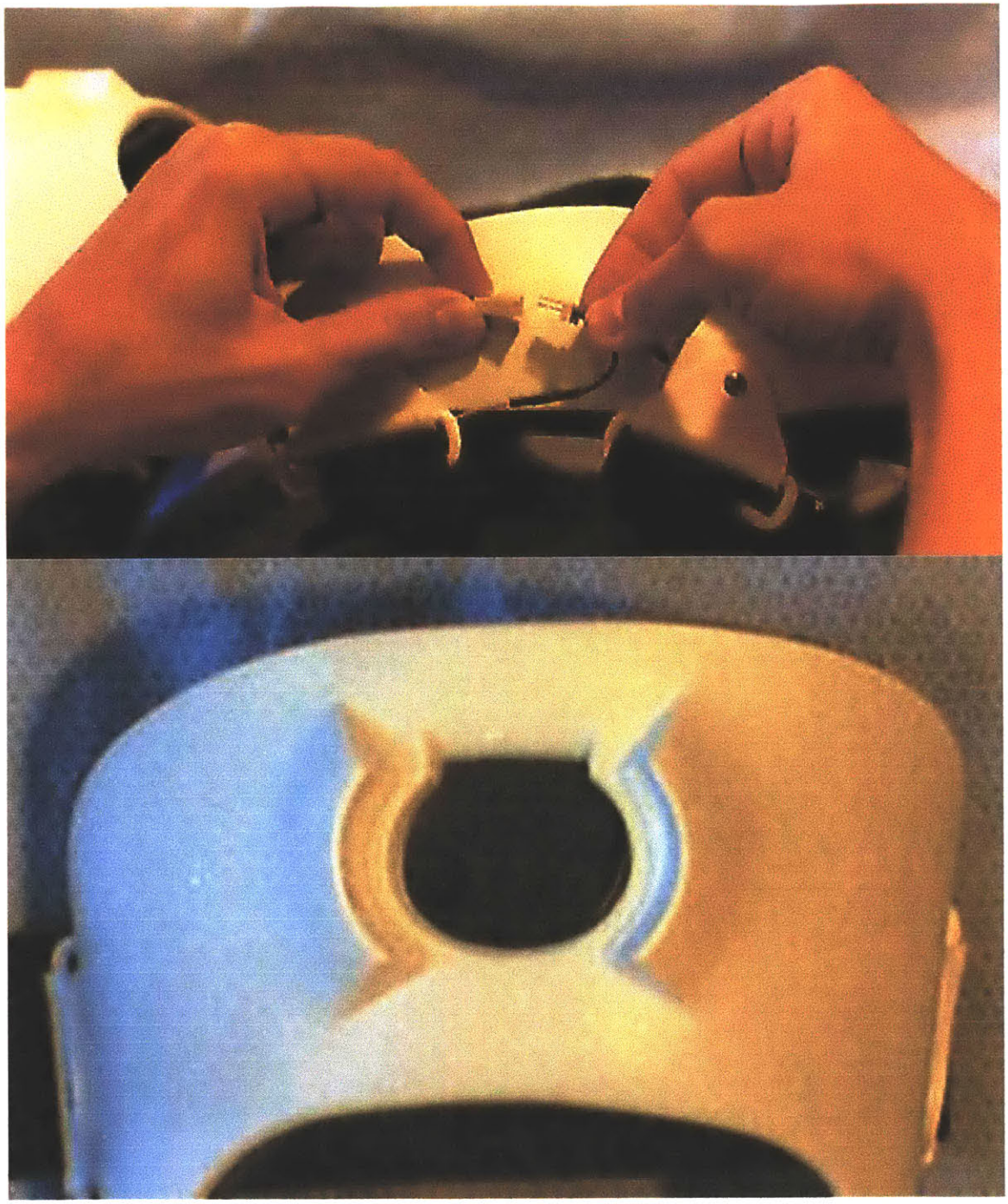


Figure 39

Flex circuitry connections. The top picture shows the Molex connection between the electrodes and the flex circuitry. The bottom picture shows the interconnect point between the flex circuitry and the control device.

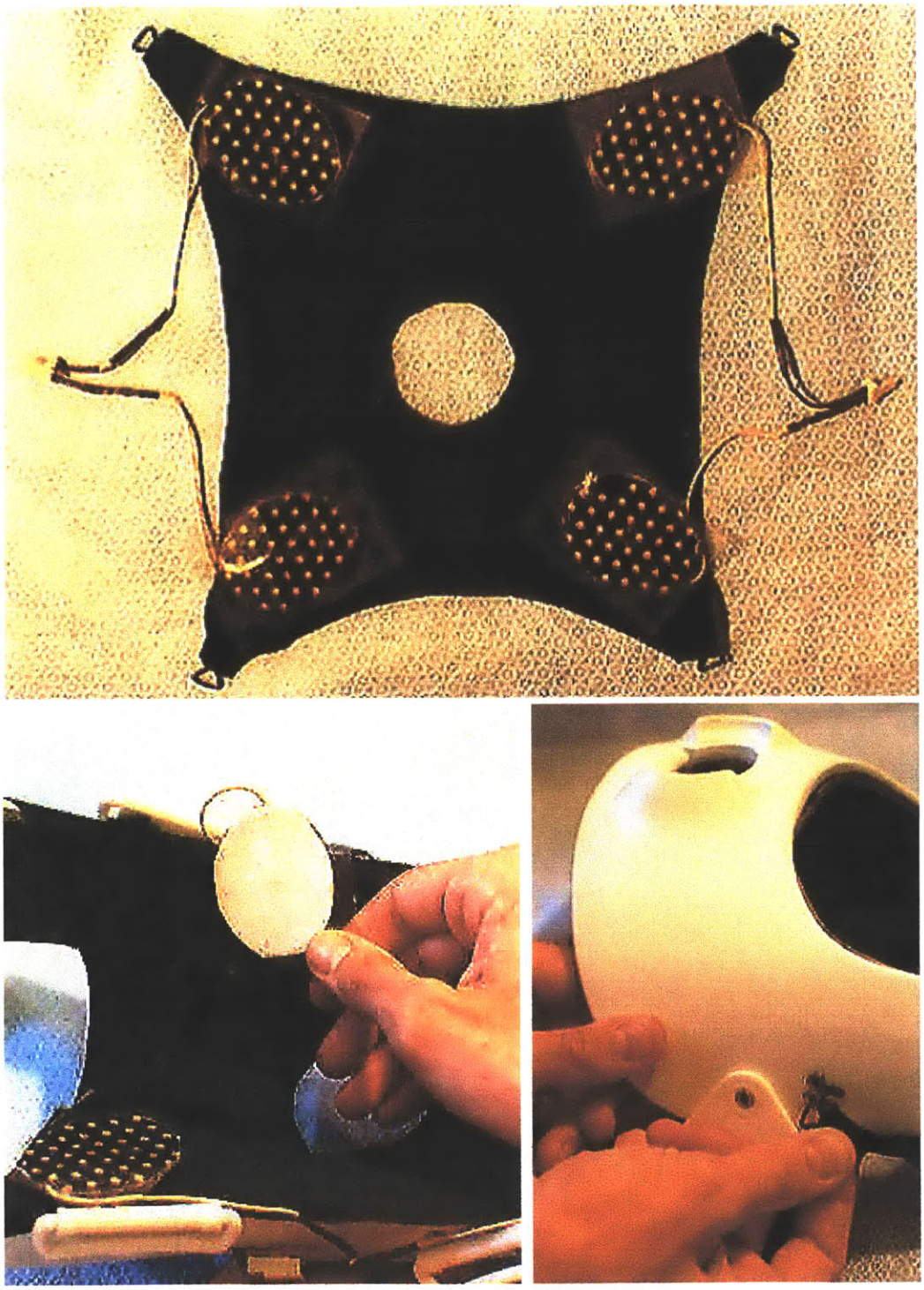


Figure 40

Spandex knee cover. The top picture shows the knee cover subsystem unattached to the rigid frame. The bottom left picture demonstrates the Velcro connection between the electrodes and the knee cover. The bottom right picture illustrates the coat hook and eye connection between the knee cover and the frame.

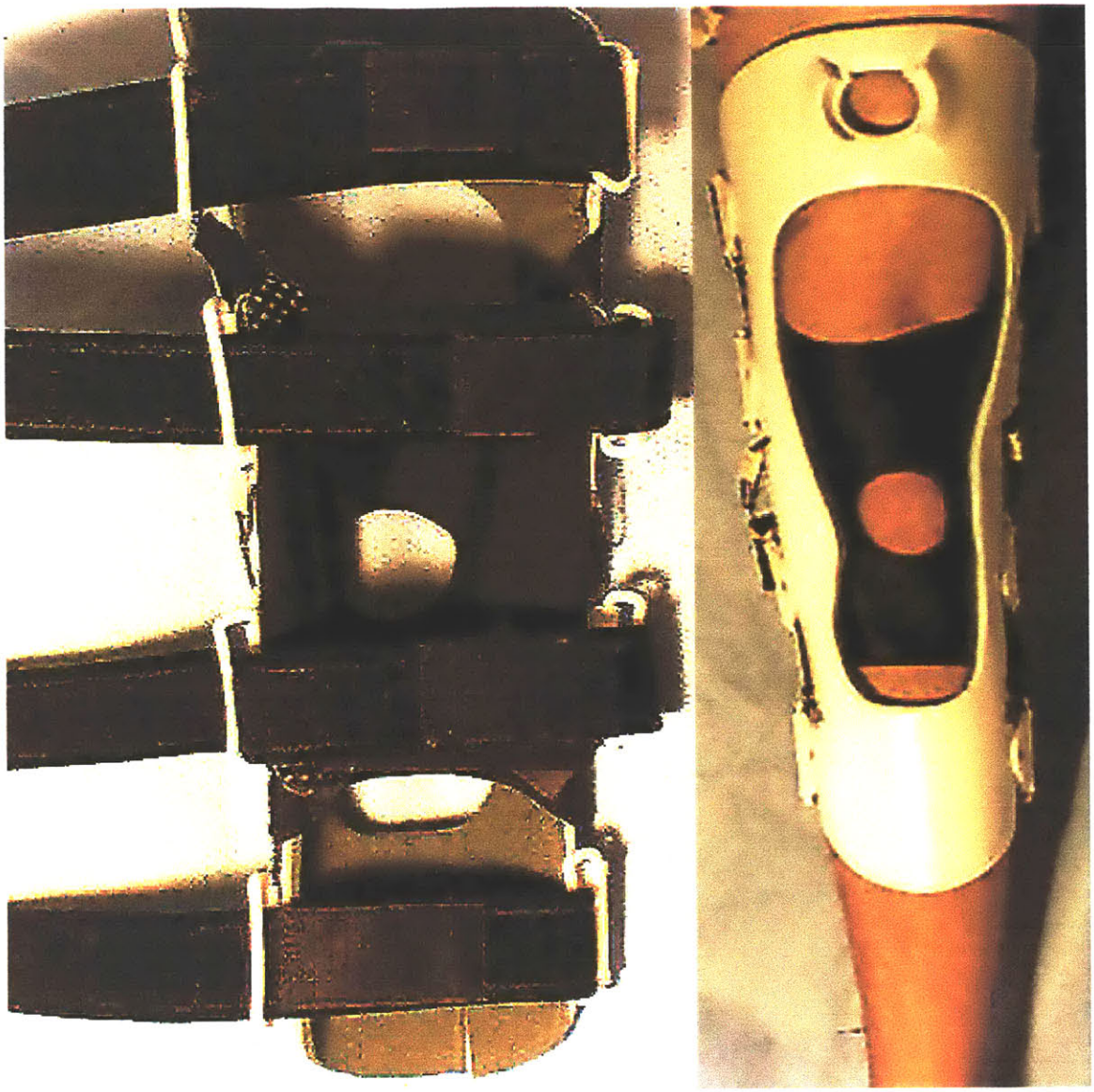


Figure 41

The TENS knee immobilizer in use. The picture on the left shows the four Velcro tightening straps. The picture on the right shows the prototype being worn.

Initial testing results are very positive, especially related to the strength characteristics of the frame. The functional performance of the prototype is currently being tested against the target specifications. This process will lead to improvements integrated into β prototypes and, eventually, production models.

4.2.5 Production Ramp-up (Future Work)

Production ramp-up is the last step in a development effort. The TENS knee immobilizer has not reached this stage yet. Further testing is required before full production can begin. A significant investment in tooling and manufacturing facilities will be necessary.

4.3 TENS Wrist Splint

In addition to the knee immobilizer, a TENS wrist splint was developed for the treatment of acute wrist pain. It too incorporates the modular technology described in Section 4.1. This section again applies a structured design process to the development of an orthopedic TENS device. It also explains the functional characteristics of the TENS wrist splint in significant detail.

4.3.1 Concept Development

Concept development begins with a mission statement that explicitly defines the goal, the market, any assumptions, and people with a stake in the development effort. Table 15 is the mission statement for the TENS wrist splint.

Table 15
Mission statement for a TENS wrist splint.

Product Description	An orthopedic wrist splint with embedded TENS technology for relief of the symptomatic aspects of pain.
Primary Market	• Acute wrist pain sufferers (post op., soft tissue damage, etc.)
Secondary Market	• Chronic wrist pain sufferers
Assumptions	• Incorporates platform control device • Embedded TENS technology • Limits wrist mobility
Stakeholders	• Patient • Medical suppliers (retailers) • Healthcare professionals (doctors, physical therapists, etc.) • Sales • Service • Production • Legal (patents, etc.)

Once the mission statement was in place, customer needs were established. Information was gathered from clinicians, benchmarking, and personal interviews. This led to the customer needs of Table 16.

Table 16
Weighted customer needs for a TENS wrist splint.

Number		Need	Rank
1	The device	restricts wrist motion.	5
2	The device	keeps fingers unencumbered.	5
3	The device	alleviates pain.	5
4	The device	is safe with few side effects.	5
5	The device	aligns electrodes precisely & accurately.	4
6	The device	keeps electrodes in close contact with the skin.	4
7	The device	fits snugly and comfortably.	4
8	The device	is water resistant.	3
9	The device	can be easily cleaned.	3
10	Electrodes	can be easily replaced.	4
11	The device	is compact.	4
12	The device	is inexpensive.	5
13	The device	exhibits modern industrial design.	3
14	The device	minimizes entangling wires.	4
15	The device	actively counters accommodation.	3
16	The user	can alter stimulation parameters.	4
17	The device	maintains power for several hours of use.	4
18	The device	is easy to put on and take off.	3
19	The device	has an intuitive fastening method.	4
20	Control device	is easily accessible.	3
21	The device	batteries can be easily changed.	3
22	The device	remains at a comfortable temp. after prolonged use.	3
23	The device	is elastic.	2
24	The device	is impact resistant.	4
25	The device	requires limited doctor visits.	4

Note the similarities between Tables 10 and 16. Most all of the needs concerned with TENS technology are seen in both lists. Many of the issues concerned with fit and comfort also appear twice. However, the importance rankings for some of the same needs are different.

Target specifications proceed from Table 16. Table 17 establishes metrics mapped from the customer needs.

Table 17
TENS wrist splint metrics.

Metric #	Need #s	Metric	Rank	Units
1	1	Range of motion of wrist	5	ang. deg.
2	2, 6, 11	Length of splint past knuckle joints	5	cm
3	3	Change in pain pre- to post-treatment	5	% (subj.)
4	4	Patients exhibiting skin burns or irritation	5	%
5	5	Avg. distance from target nerve	4	cm
6	5,6	Avg. amt. Of electrode in contact with skin	4	%
7	7	Device is comfortable	4	subj.
8	8	Time submerged before loss of function	3	s
9	9	Time to clean	3	s
10	10	Time to replace electrodes	4	s
11	11	Max. Thickness	4	cm
12	12	Unit Manufacturing Cost	5	US$
13	13	Exhibits modern design	3	subj.
14	14	Max. length of any exposed wire	4	cm
15	15	Intensity increase during modulation treatment	3	mA
16	16	Intensity range	4	mA
17	16	Frequency range	4	Hz
18	16	Pulse width range	4	μs
19	17	Time to battery failure in worst case mode	4	hrs.
20	18	Time to put on or remove device	3	s
21	19	The device has an intuitive fastening method.	4	subj.
22	20	Time to activate control device & begin use	3	s
23	21	Time to change batteries.	3	s
24	22	Mean temperature of device after 1 hour of use	3	°C
25	24	3 meter drop test	4	Boolean
26	25	Avg. # of doctor visits to gain proficiency	4	Numeric

Once again, several metrics were generated that primarily focused on the TENS control module and were nearly independent of the wrist splint. These (metrics 16-18) were not assigned target values. Also note that customer need #23 was not mapped to a metric. Elasticity is an independent variable, which can be specified during material selection. Generally, specifications are only set for dependent variables. They help to identify trade-offs inherent in each decision the development team makes.

These metrics were then assigned target values. Benchmarking of competitive products informed the process by establishing what was realistically achievable and what minimum standards had to be met. As with the knee immobilizer, wrist splints with embedded TENS technology are not yet available in the market place. However, benchmarking in several related areas provided a great deal of information. Various methods of pain relief were examined to determine what advantages TENS offers, as

discussed in Section 2.2.3. Several TENS stimulators were also examined to determine strengths, weaknesses, operating parameters, etc. Section 4.1.1 reviewed much of this information. Finally, wrist splints, braces, and immobilizers were studied to learn more about the marketplace and to provide feasible values for several metrics in Table 17.

The working principle behind most all wrist splints is the same. A metal stay, usually aluminum, is bent to the contour of the underside of the wrist and palm. The stay is then encased in a cloth material, which wraps around the hand and is fastened shut. The splint limits wrist extension and flexion.

The key differences between models lie in material selection of the cloth, and location and method of fastening. Fastening is usually done with either string or Velcro. Closure occurs either on the topside of the wrist or on the thumb side of the hand. Some models are made of an elastic material that comes in one piece and is simply pulled on over the hand and into position. Another, less common, wrist splint is made out of molded plastic. The plastic is contoured to the shape of the wrist, and a metal stay is not used. Plastic splints are used when more immobilization is necessary. Figure 42 shows examples of several different wrist splints.

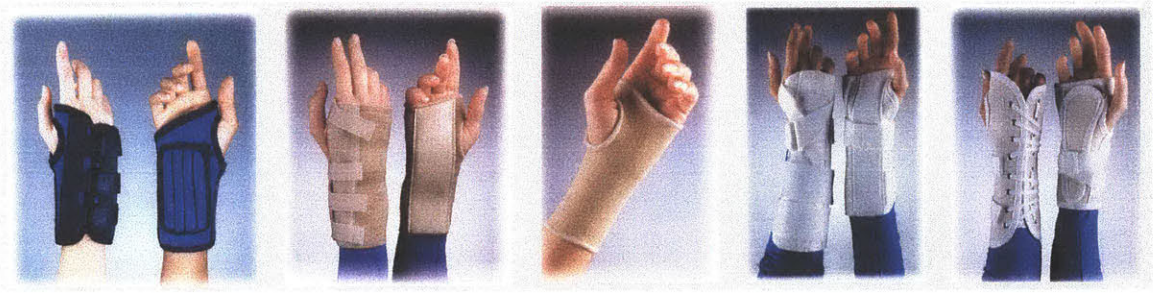


Figure 42

Different types of wrist splints.
(From F*L*A Orthopedics' "Orthopedic and Bracing Product Guide")

The first picture shows a Velcro top closure wrist splint made from neoprene. The second exhibits Velcro side closure and is fabricated from elastic. The third is a seamless pullover model, again from elastic. The fourth is molded vinyl. The last picture illustrates closure with string as opposed to Velcro.

From benchmarking data and a variety of other sources, target specifications were set. They are listed in Table 18.

Table 18
TENS wrist splint target specifications.

Metric #	Need #s	Metric	Rank	Units	Marginal Value	Ideal Value
1	1	Range of motion of wrist	5	ang. deg.	<50°	<30°
2	2, 6, 11	Length of splint past knuckle joints	5	cm	<2	<0
3	3	Change in pain pre- to post-treatment	5	% (subj.)	>30	>70
4	4	Patients exhibiting skin burns or irritation	5	%	<5	<2
5	5	Avg. distance from target nerve	4	cm	<2	0
6	5,6	Avg. amt. of electrode in contact with skin	4	%	>80	>90
7	7	Device is comfortable	4	subj.	>7/10	>9/10
8	8	Time submerged before loss of function	3	S	>15	>60
9	9	Time to wipe clean	3	S	<180	<60
10	10	Time to replace electrodes	4	S	<120	<60
11	11	Max. Thickness	4	cm	<2	<1
12	12	Unit Manufacturing Cost	5	US$	<12	<10
13	13	Exhibits modern design	3	subj.	>7/10	>9/10
14	14	Max. length of any exposed wire	4	cm	<5	<3
15	15	Avg. intensity increase during modulation treatment	3	mA	<30	0
16	16	Intensity range	4	mA	*NA	NA
17	16	Frequency range	4	Hz	NA	NA
18	16	Pulse width range	4	μs	NA	NA
19	17	Time to battery failure in worst case mode	4	hrs.	>12	>24
20	18	Time to put on or remove device	3	s	<60	<30
21	19	The device has an intuitive fastening method.	4	subj.	>7/10	>9/10
22	20	Time to activate control device & begin use	3	s	<120	<60
23	21	Time to change batteries.	3	s	<60	<30
24	22	Mean temperature of device after 1 hour of use	3	°C	<80	<70
25	24	3 meter drop test	4	Boolean	Pass	Pass
26	25	Avg. # of doctor visits to gain proficiency	4	Numeric	<2	0

*NA = Not Applicable

Generate Product Concepts

Product concept generation sought to meet as many of the ideal values of the target specifications as possible in an attractive and innovative product. Figure 43 provides the pertinent TENS stimulation sites for the treatment of acute wrist pain.

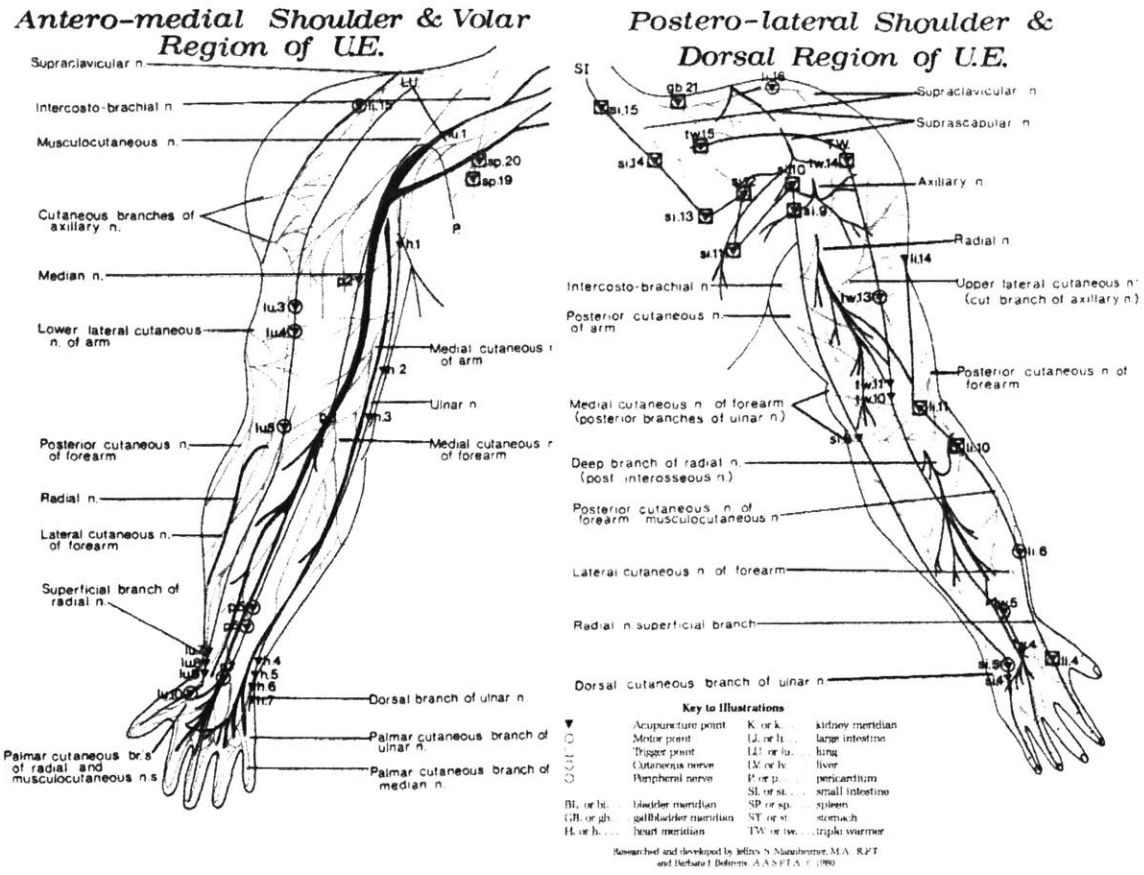


Figure 43

Optimal TENS stimulation sites and major nerves of the upper extremity.
(Adapted from Mannheimer, J. S. & Lampe, G. N.
Clinical transcutaneous electrical nerve stimulation, 8th ed.
Copyright 1988 by FA Davis Co.; Philadelphia, PA [10; pp. 301, 310, 314].)

For the relief of wrist pain, TENS seeks to stimulate the points marked lu7-9 and h4-7 on the medial aspect and si5 on the lateral aspect. Table 19 lists the details of these points.

Table 19
Optimal stimulation sites for TENS electrodes.
(Adapted from Mannheimer, J. S. & Lampe, G. N.
Clinical transcutaneous electrical nerve stimulation, 8th ed.
Copyright 1988 by FA Davis Co.; Philadelphia, PA [10; pp. 311, 313, 316].)

Location	Superficial Nerve Branch	Acupuncture Point	Segmental Level
Just lateral to radial artery from 1st volar crease to just above radial styloid	Lateral cutaneous nerve of forearm communicating with superficial radial nerve	LU 7-9	C5-7 C6-8
Ulnar aspect of wrist lateral to flexor carpi ulnaris (FCU) tendon from 1½" above 1st volar wrist crease to pisiform bone.	Ulnar nerve and its palmar cutaneous branch	H 4-7	C7-T1
In depression between pisiform bone and ulnar styloid	Dorsal and palmar cutaneous branches of ulnar nerve	SI 5	C7-T1

A TENS wrist splint poses a much simpler design problem than the TENS knee immobilizer. As with the immobilizer, the key benefits over a standard wrist splint used in conjunction with a standard TENS stimulator lie in the minimization (elimination?) of entangling wires and in the precise and accurate positioning of TENS electrodes without the help of a skilled clinician. Once again, concept generation focused on seamless integration of TENS technology into a device similar to existing splints. Specifically, it focused on hiding all wires and properly aligning electrodes.

Concept generation examined the existing products to determine how they could be modified to fit the needs of this study. Pull-on models were quickly deemed impractical because the hydrogel electrodes would stick to your fingers while putting it on. Proper electrode alignment would be difficult. Models fastened at the top or sides took advantage of many of the benefits found in the Spandex knee cover. The electrodes could easily be attached to the proper points when the splint is laid open. Then, when it is put on and tightened, the electrodes are held at the proper locations. Velcro. or even snap electrical contacts connected to wires placed between two pieces of elastic material, could attach the electrodes. The wires could then be routed to the control device interconnect which would sit on top of the hand when the splint is worn. No wires would be exposed and the electrodes would accurately and precisely be in position. Preliminary concepts based on this electrode placement/wiring method were created for both top and side closure models. Figure 44 shows the preliminary sketch for the top closure concept. The splint is seen lying flat when not worn.

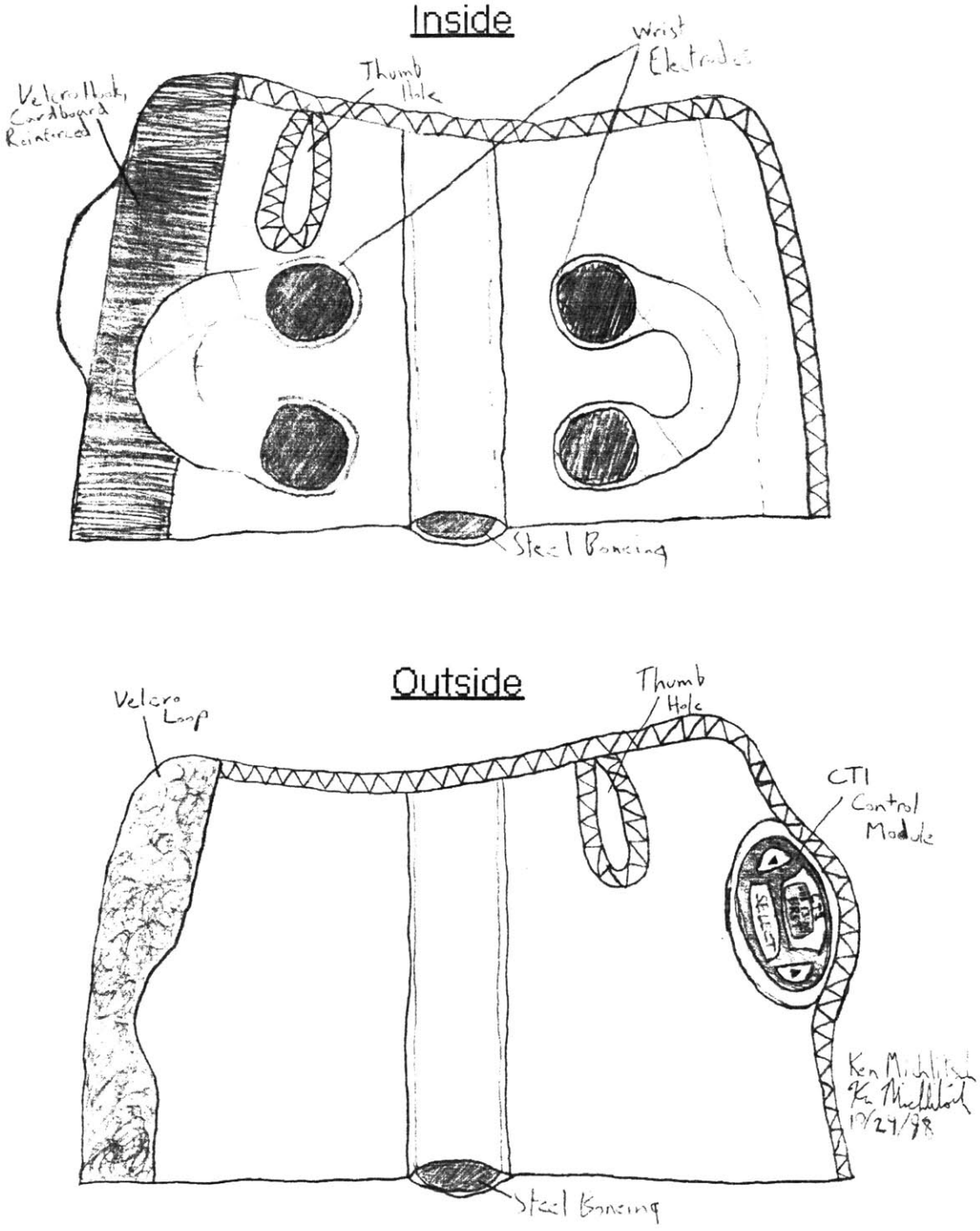


Figure 44

Preliminary TENS wrist splint concept with top closure.

The electrodes snap into position, and the modular control device is attached at the side out-flaring containing the interconnect. No wires are seen, and an aluminum stay (incorrectly marked here as steel boneing) located between the two pieces of elastic material accomplishes wrist stabilization. Figure 45 shows an isometric drawing of the concept in use.

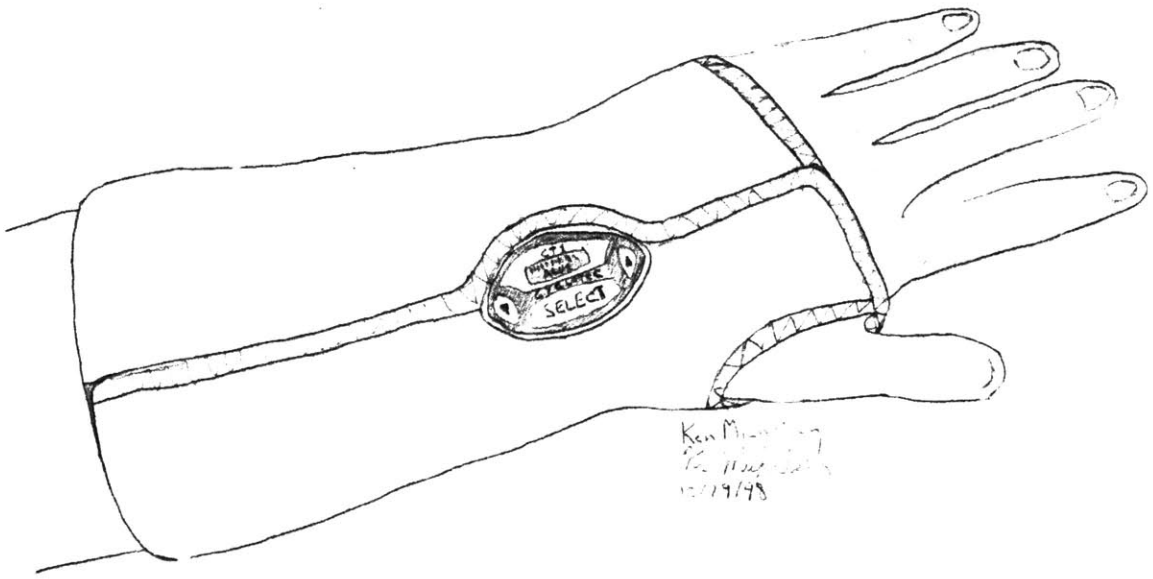


Figure 45

Isometric drawing of the TENS wrist splint concept in use.

Concept Selection

The top and side closure concepts were systematically evaluated to determine feasibility and scoring against target specifications. Evaluation criteria included:

1. Elimination of exposed wires
2. Precision and accuracy of electrode placement
3. Ease of handling and use
4. Ease of manufacture

To evaluate trade-offs, preliminary prototypes for each concept were fabricated and tested. Electrodes were taped to the proper positions on a standard top closure splint and on a side closure splint. A paper cut out the size of the control device was also taped at the proper location on each splint. Each was then put on and taken off several times to evaluate electrode positioning and comfort. To stimulate the proper points in Figure 43, the electrodes must wrap around the sides of the wrist when worn. Side closure splints do not provide a simple attachment point for the electrodes on the thumb side of the hand. The top closure concept was therefore selected for further development.

Refinement of Specifications

After concept selection, target specifications are reevaluated in light of the chosen concept. Metric #23, time to change batteries, was no longer relevant as additional batteries would not be used. The ideal value of metric #14, maximum length of any exposed wire, was reset to zero. Other metrics remained relevant and attainable.

Economic Analysis

There was much less potential for cost variation in the fabrication of the TENS wrist splint in comparison with the knee immobilizer. Except for the aluminum stay, splints are hand stitched from soft splinting materials (foams, cloths, Velcro, elastic, etc.). Tooling costs are at a minimum while direct labor costs comprise a significant percentage of the unit manufacturing cost. Therefore, it is important to minimize the number of hand-cut patterns and the amount of sewing necessary. Table 20 provides the final parts list for the TENS wrist splint. Most of these materials did not change between the concept selection phase and α prototype phases. Thus, a realistic cost estimate was obtained early in development.

Table 20

TENS wrist splint final parts list.

Item	Quantity	Approx. Retail Cost	
1/8"*8"*11" Neoprene	1	$6.40	
1/8"*6"*11" Neoprene	1	$4.80	
1" Wide Velcro Hook and Loop	8"	$1.80	
#3 Sew-on Nickel Snaps	4	$0.55	
Wire	30"	$0.25	
Thread	10'	$0.20	
1"*6.75" Al Stay	1	$0.25	<== Rough Estimate
Stiffener with Flex Circuitry	1	$0.25	<== Rough Estimate
Approx. Retail Material Cost =		*$14.50*	*(Doesn't include electrodes)*

Using a 3x markup for retail as a baseline, materials (including outsourced parts) should cost in the ballpark of $5. In order to achieve the ideal value of less than $10 for unit manufacturing costs; conversion costs, distribution, warranties, etc., cannot exceed roughly $5, or 50% of the manufacturing costs. The primary cost next to materials is labor. By minimizing the number of pattern pieces and the amount of sewing required, labor costs will be kept to a minimum. Because the product does not require large up-front tooling investments, profitability can be obtained with much lower volumes than those required for the knee immobilizer.

Project Planning

The last step in the front-end process of product development is project planning. The first TENS wrist splint was taken from mission statement to α prototype in the span of 2½ months. Aggressive and thorough planning allowed rapid turnaround.

4.3.2 System-level Design

The wrist brace can be broken into four subsystems: the splint, the electrodes, wiring, and the control device. The control device has already been discussed in some detail. This section lists the functional requirements of the first three subsystems and the evolution of each from concept to full specification. Finally integration of the four subsystems into a final product is addressed.

The Splint

The splint is the structural piece of the product concept. Its functional requirements include:

1. Attachment point for both electrodes and the modular control device
2. Restriction of wrist mobility
3. Routing wires from the control device to electrodes

These functional requirements are actually addressed in the product concept. Electrodes snap into place at the proper locations and the control device interconnect sits on top of the wrist for easy connection of the controls module and intuitive activation of the device. An aluminum stay at the bottom of the wrist restricts mobility. The main body consists of two pieces. Wires are routed from the interconnect to the snap points between these two pieces. A Velcro top closure was chosen over string because Velcro allows easier access to the electrodes and is less cluttering. Therefore, system-level design primarily consisted of material selection, specification of snap size and method of attachment to the splint, and styling.

Splints are fabricated from a variety of elastic materials. 1/8" thick neoprene was chosen for its cushioning capabilities. For comfort's sake, it's important that the patient not feel the wires running between the two pieces of the main body. Neoprene provides the necessary padding to dissipate the sensation.

Snap specification was equally straightforward. Electrodes are currently available with size #3 male snaps. Therefore, sew-on, size #3 female snaps will be sewn into the proper locations on the splint.

The wrist splint allows significant latitude for product differentiation through styling. Various industrial design concepts were drawn up and evaluated. Figure 46 presents several concepts.

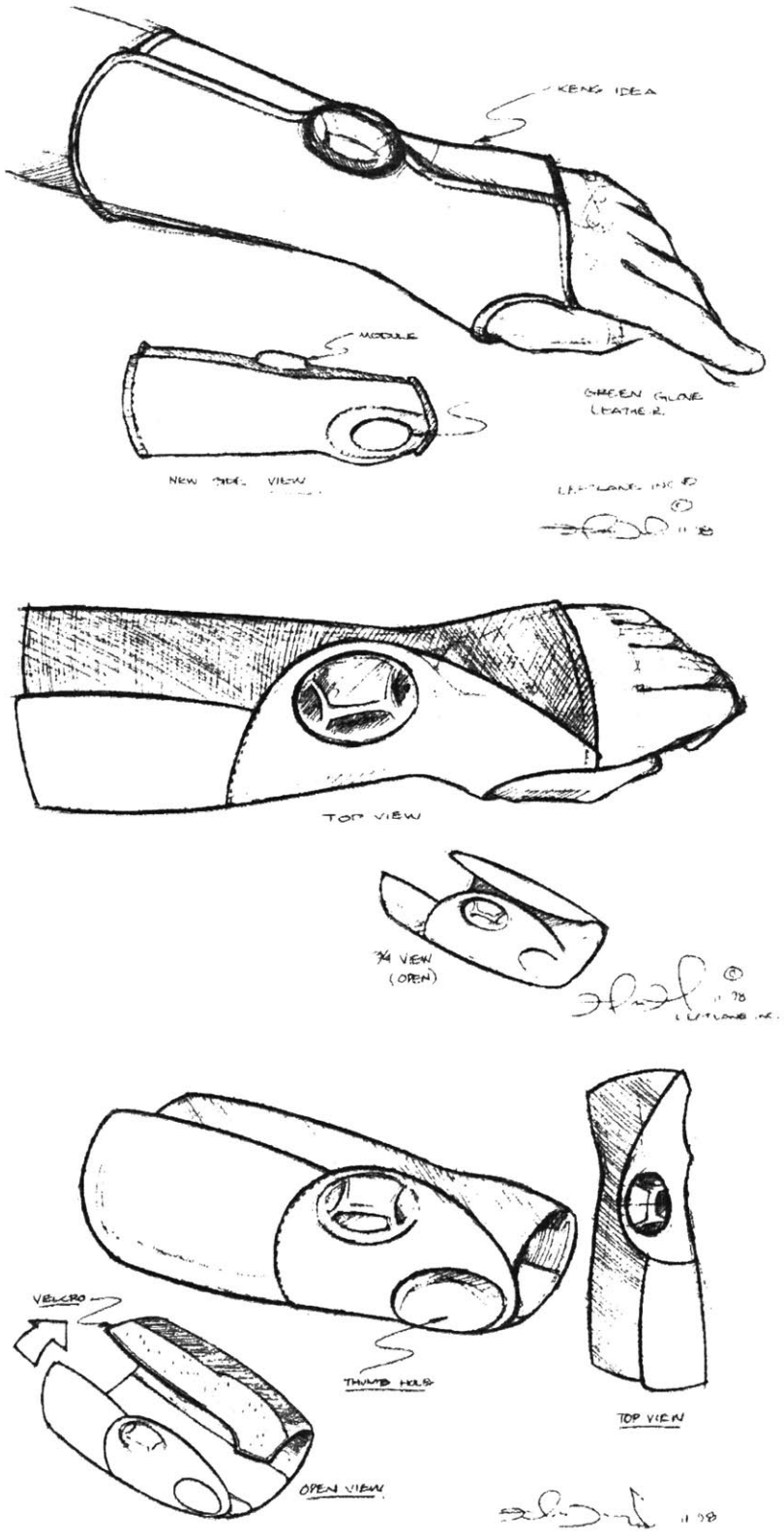


Figure 46

Various industrial design concepts for the TENS wrist splint.
(Sketches by Frank Tyneski, Industrial Designer.)

Styling was specified, and Figure 47 shows an assembly drawing of the splint subsystem.

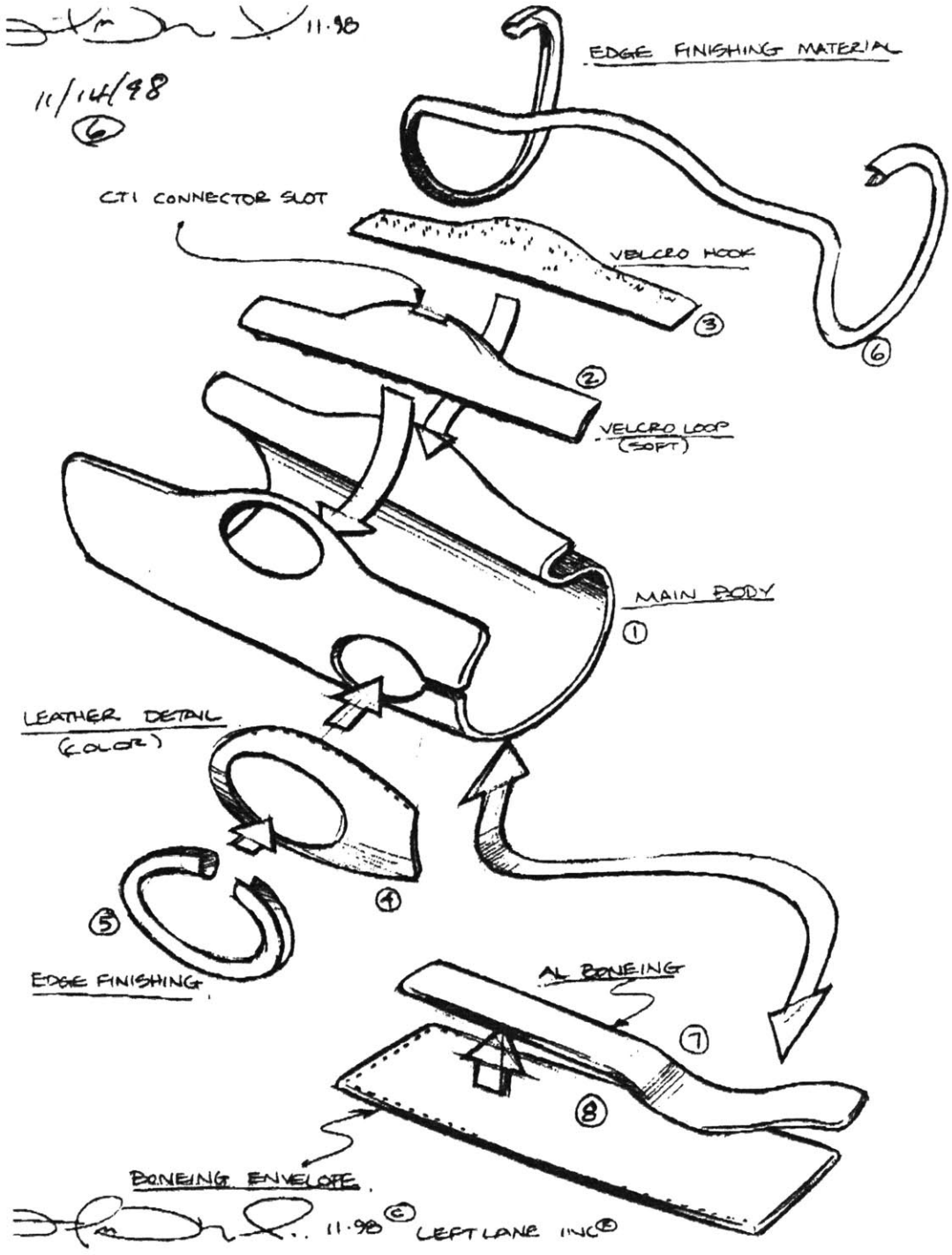


Figure 47

Assembly drawing of the splint subsystem.
(Sketch by Frank Tyneski, Industrial Designer.)

The Electrodes

The electrodes subsystem consists exclusively of the electrodes. The only functional requirement unique from standard electrodes is:

1. Allow for snap attachment to TENS wrist splint

Standard snap electrodes with #3 male snaps were chosen.

Wiring

The functional requirements for wiring are:

1. Connect the modular control device to the TENS electrodes
2. Make the TENS wrist brace essentially wireless

The first requirement is met by soldering a wire to each of the female snaps before sewing them into the splint subsystem. The other end of each wire is then attached to the control device interconnect located on top of the splint when worn. By sandwiching the wires between two pieces of neoprene, the patient sees no exposed wires, and the second requirement is fulfilled.

Each of the four subsystems has now been discussed. The final step in subsystem design is the creation of a flow chart for assembly of the final product. Figure 48 presents this chart.

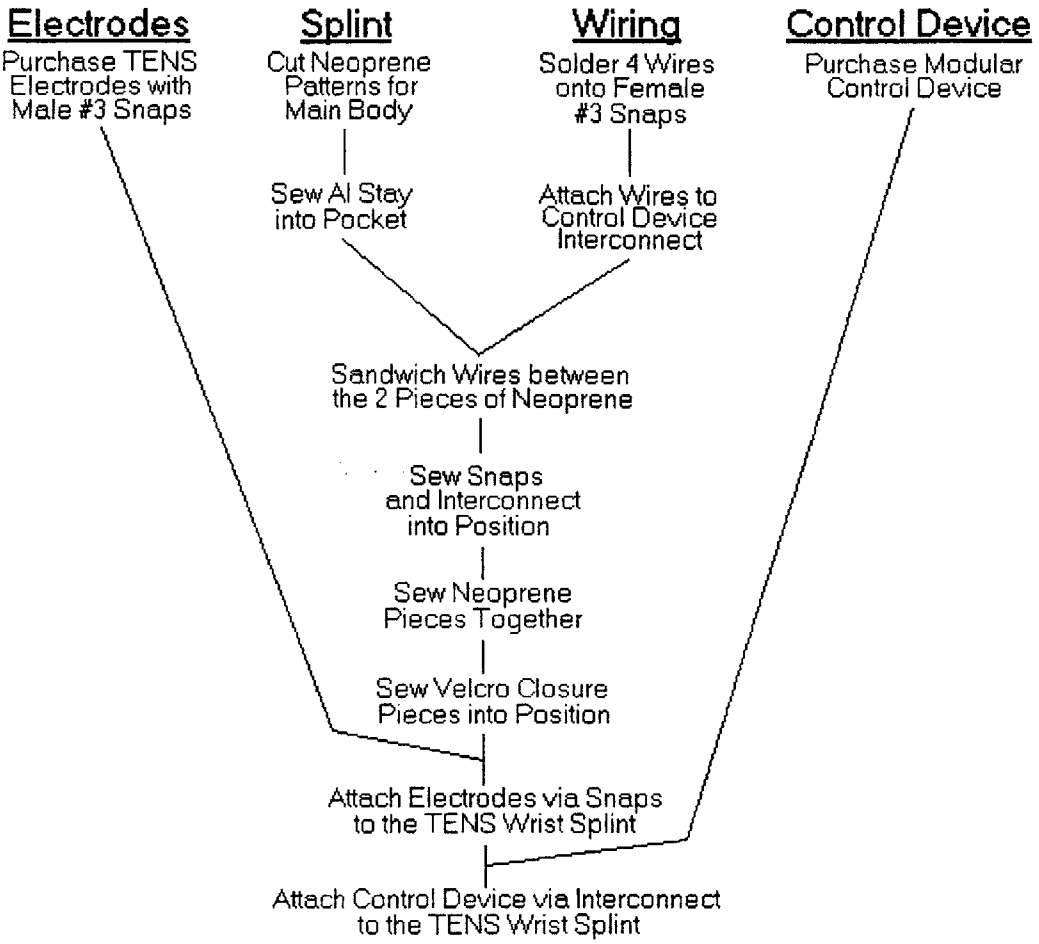


Figure 48

Assembly flowchart.

4.3.3 Detail Design

As with the knee immobilizer, most of the aspects of detail design were discussed in the previous discussion during the explanation of each subsystem. Since manufacturing will occur in a very low technology manner, design for manufacturing must focus on reducing pattern pieces and assembly sewing. This is discussed in somewhat more detail in the next section. The materials list of Table 20 in conjunction with Figure 48 shows which parts are outsourced, and which are fully or partially fabricated.

4.3.4 Testing & Refinement

This study sought to create α prototype orthopedic TENS devices for the treatment of acute pain. Future work will test and refine these prototypes in preparation for mass production. An α prototype is made from the same parts as the final device, but the parts are not necessarily fabricated in the same manner. A β prototype is made from the same

parts fabricated in the same manner. The TENS wrist splint is nearly a β prototype. Only the wiring subsystem was fabricated in a different manner than the anticipated production model. The prototyping techniques for each subsystem are discussed herein.

The Splint

To fully understand the pertinent manufacturing methods, an established splint manufacturer fabricated the splint subsystem and completed final assembly. The manufacturer identified ways to reduce the amount of material used and the amount of stitching required for assembly. Fabrication occurred as illustrated in Figure 48.

The Electrodes

Electrodes were purchased from an outside vendor.

Wiring

Wires were hand soldered to the snaps and interconnect. In production, this process will be automated.

The Control Device

The control device was developed concurrently. For testing purposes, a functional LabView emulator which could be connected to orthopedic TENS devices was created. However, prototyping of the actual control device was outside the scope of this study. Sufficed to say that aluminum molds were made for injection molding its plastic parts, and electronics were fabricated in limited numbers.

The four subsystems were integrated into the α prototype seen in Figure 49.

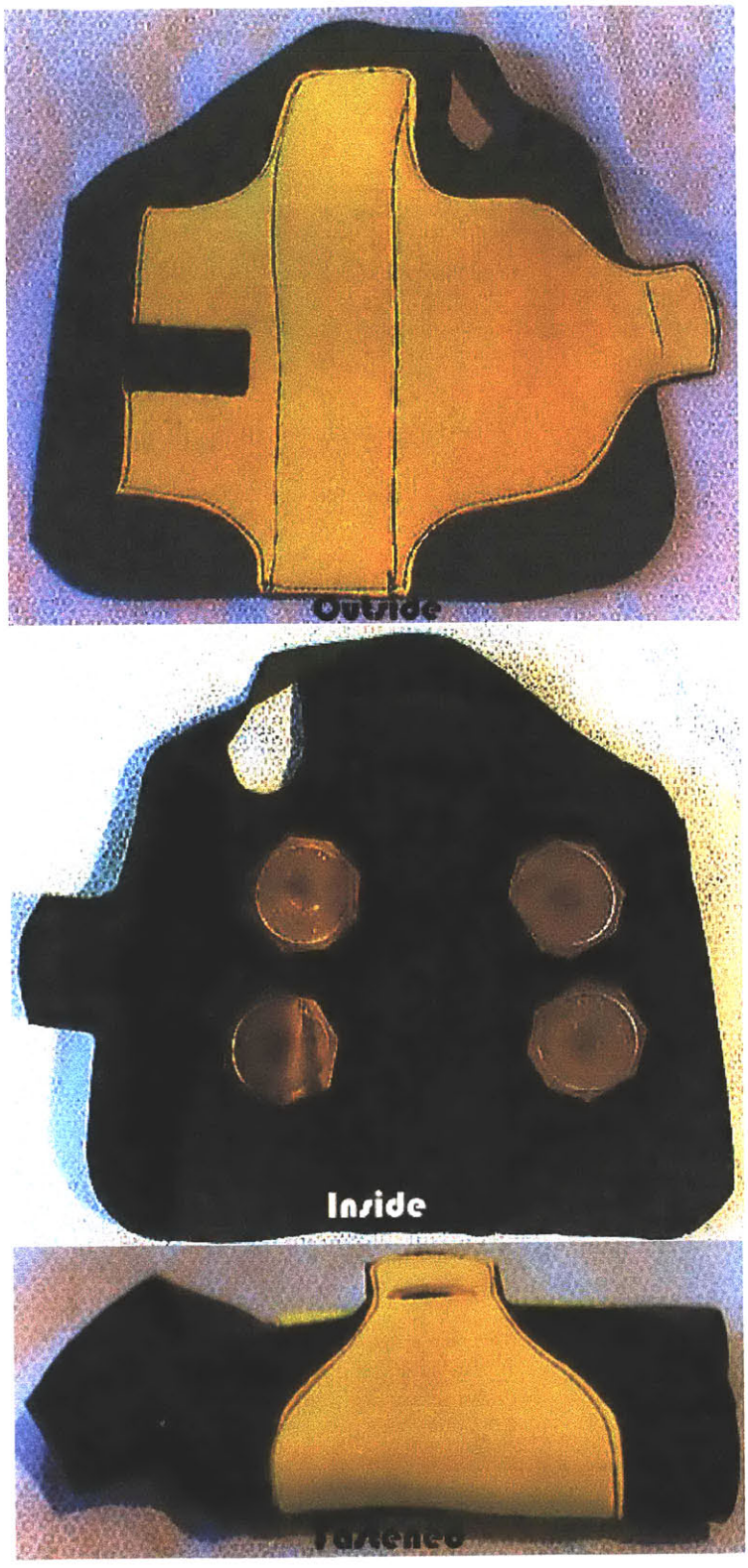


Figure 49

Three views of the TENS wrist splint α prototype.

Figure 50 illustrates the snap attachment between the electrodes and the wrist splint, and the interconnect point between the control device and the splint. Figure 51 demonstrates the Velcro top closure and the splint in use.

Figure 50

Wiring connections. The top picture shows the snap attachment between the electrodes and the wrist splint. The bottom picture shows the interconnect point between the splint and the control device.

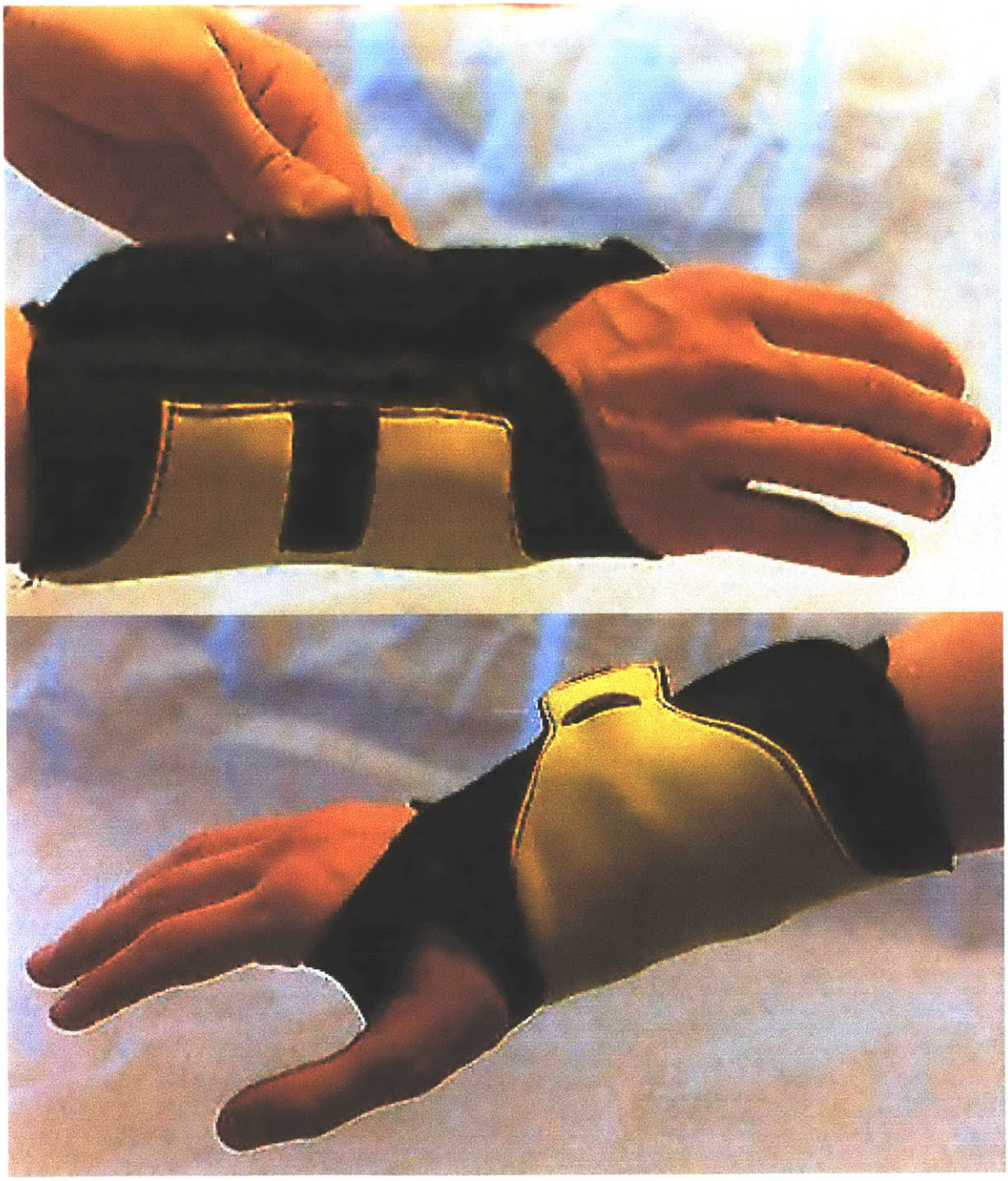


Figure 51

The TENS wrist splint in use. The top picture shows the Velcro top closure. The bottom picture shows the prototype being worn.

Initial testing results are very positive, especially related to wire management, electrode alignment, and ease of use. The color scheme is being reworked and further styling

changes may be incorporated. Functional performance is now being tested against the target specifications. This process will lead to improvements seen in β prototypes and, eventually, production models.

4.3.5 Production Ramp-up (Future Work)

The last step in a development effort before product launch is production ramp-up. The TEN wrist brace has not reached this stage to date. Further testing is required before full production can begin.

Chapter 4 has illustrated the application of a structured design process to a real-world problem – the development of orthopedic TENS devices for the treatment of acute pain. The successful fabrication of α prototype TENS knee immobilizers and wrist braces was outlined. Chapter 5 summarizes the study and details future work.

5.0 CONCLUSIONS & FUTURE WORK

A structured design process was successfully applied to the development of innovative orthopedic TENS devices for the treatment of acute pain. A modular design that allows a standardized controls and battery package to be used in a variety of splints, braces, and immobilizers was developed. Prototype knee immobilizers and wrist splints with integrated TENS technology were created as platforms to test modularity and to serve as proofs of concept.

TENS is an attractive alternative to conventional methods of relief for the symptomatic aspects of pain. Drug therapy can be highly addictive with severe side effects while surgical procedures are even more drastic, can lead to debilitation, and are often ineffective. TENS has been proven safe with minimal side effects. Its contraindications are few and clinical trials have shown that it can help a significant percentage of people that needlessly suffer from pain.

Traditionally, TENS has been used as a pain modulation technique in the treatment of chronic pain. However, research suggests that TENS is most effective in early treatments and when applied close to the onset of pain. It is therefore perhaps better suited to the modulation of acute pain. Acute pain sufferers represent a much larger patient population than chronic sufferers.

Acute pain sufferers have different needs than those with chronic pain. They generally live more active lifestyles and require therapies sympathetic to their needs. Currently available TENS devices are often unwieldy and counterintuitive. Advances in battery technology and microprocessing capability have made possible user-friendly, essentially wireless TENS devices that limit impact and interference with a patient's lifestyle.

A new and innovative modular TENS control device has been developed and was adopted as the platform from which an entire product line will follow. The product line focuses on three areas of concurrent development: 'Band-Aid™' TENS devices; remotely operated TENS devices; and orthopedic braces, splints, and immobilizers with integrated TENS technology. This study focused on the final area. Specifically, α prototype knee immobilizers and wrist splints were developed. The devices were presented herein from problem statement through prototype in relation to the structured design process. The major steps in the process are concept development, system-level design, detail design, testing and refinement, and production ramp-up. Methodologies for each step were provided in the context of application to the orthopedic TENS devices. Thereby, this paper serves as a case study in the application of a structured design process to a real-world problem.

Fully physical α prototype TENS knee immobilizers and wrist braces were created. Future work must now focus on testing and refinement. This work will lead to improvements seen in β prototypes. The long-term goal is production ramp-up and product launch. Work must also focus on other orthopedic TENS devices, as well as the areas of concurrent development. This will eventually lead to an entire product family

aimed at relief of the symptomatic aspects of acute pain. The structured design process in place will provide a solid framework for these efforts.

I'd like to close with a quote from Kaplan, et al.; a group that clinically evaluated a TENS device designed for a specific patient population. Kaplan states that if a TENS device is safe, easy, and comfortable to use, it will be used by patients for longer periods and will be more effective: "...by listening to the patient's needs, compliance and hence treatment results can be improved."[30]

6.0 ACKNOWLEDGMENTS

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Patents are pending on much of the material contained herein.

7.0 REFERENCES

1. Melzack, R. and P.D. Wall, *Pain Mechanisms: A New Theory.* Science, 1965. **150**(3699): p. 971-979.
2. Ganong, W.F., Review of Medical Physiology. 18 ed. 1997, Stamford, Connecticut: Appleton & Lange. 829.
3. Rattay, F., Electrical nerve stimulation : theory, experiments and applications. 1990, New York: Springer-Verlag. 264.
4. Ottoson, D. and T.T. Lundeberg, Pain treatment by TENS, transcutaneous electrical nerve stimulation : a practical manual. 1988, New York: Springer-Verlag. 130.
5. Walton, L., Essentials of Neurology. 6th ed. 1989, New York: Churchill Livingstone. 339.
6. Doctor, J.N., An evaluation of transcutaneous electrical nerve stimulation TENS for the treatment of pain related to a spinal cord injury. Thesis in Clinical Psychology. 1996, University of California, San Diego & San Diego State University: San Diego, CA. 155.
7. Sjoelund, B.H. and M.B.E. Eriksson, *Relief of pain by TENS : transcutaneous electrical nerve stimulation.* 1985, Chichester ; New York: Wiley. 116.
8. Conybeare's Textbook of Medicine. 16th ed., ed. Mann, W.N. 1975, Edinburgh, UK: Churchill Livingstone.
9. Gardner, E., Fundamentals of Neurology. 4th ed. 1963, Philadelphia and London: Saunders.
10. Mannheimer, J.S. and G.N. Lampe, Clinical transcutaneous electrical nerve stimulation. 8 ed. 1988, Philadelphia: F.A. Davis Co. 636.
11. Slavkin, H.C., *What we know about pain.* Journal of the American Dental Association, 1996. **127**: p. 1536-1541.
12. Wall, P.D. and W.H. Sweet, *Temporary Abolition of Pain in Man.* Science, 1967. **155**: p. 108-109.
13. Jenkner, F.L., Electric Pain Control. 1995, New York: Springer-Verlag. 233.
14. Myklebust, J.B., Neural stimulation. Vol. 1. 1985, Boca Raton, Fla.: CRC Press.
15. Abram, S.E., *Advances in Chronic Pain Management since Gate Control.* Regional Anesthesia, 1993. **18**: p. 66-81.
16. Garrison, D.W. and R.D. Foreman, *Decreased activity of spontaneous and noxiously evoked dorsal horn cells during transcutaneous electrical nerve stimulation (TENS).* Pain, 1994. **58**: p. 309-315.
17. Ten Vaarwerk, I.A.M., W.J. Meyler, and M.J.L. Dejongste, *Transcutaneous electrical nerve stimulation for the control of pain.* Pain Clinic, 1995. **8**: p. 63-71.
18. Feigenbaum, E., *Transcutaneous electrical nerve stimulation for acute pain treatment for ambulatory patients.* 1984, Rockville, MD & Springfield, VA: US Dept. of Health and Human Services, Public Health Service, Office of the Assistant Secretary for Health, National Center for Health Services Research; Available from National Technical Information Service.
19. Ishimaru, K., K. Kawakita, and M. Sakita, *Analgesic effects induced by TENS and electroacupuncture with different types of stimulating electrodes on deep tissues in human subjects.* Pain, 1995. **63**: p. 181-187.
20. Sluka, K.A., *et al., Treatment with either high or low frequency TENS reduces the secondary hyperalgesia observed after injection of kaolin and carrageenan into the knee joint.* Pain, 1998. **77**: p. 97-102.
21. Sjoelund, B.H. and M.B.E. Eriksson, *Endorphins and Analgesia Produced by Peripheral Conditioning Stimulation,* in *Advances in Pain Research and Therapy*, J.J. Bonica, Editor. 1979, Raven Press: New York.
22. Hardy, P.A.J., *Studies of the mechanism of transcutaneous electrical nerve stimulation using thermal thresholds and skin thermography.* Pain Clinic, 1993. **6**: p. 233-239.
23. *TENS for chronic low-back pain.* Lancet, 1991. **337**(8739): p. 462.
24. Liu, J. and C.W.Y. Hui-Chan. *Do the effects of repetitive transcutaneous electrical nerve stimulation TENS on experimental pain cumulate over time?* in *23rd Annual Meeting of the Society for Neuroscience.* 1993. Washington, DC: Society for Neuroscience Abstracts.
25. Ulrich, K.T. and S.D. Eppinger, Product Design and Development. 1995, New York: McGraw-Hill, Inc. 289.

26. Repperger, D.W., *et al.*, *Microprocessor based spatial TENS transcutaneous electric nerve stimulator designed with waveform optimality for clinical evaluation in a pain study.* Computers in Biology and Medicine, 1997. **27**: p. 493-505.
27. *TENS research in Russia.* 1998, Biofil Ltd., RFNC-VNIIEF: Sarov, Nizhni Novgorod Region, Russia.
28. Repperger, D.W., C.C. Ho, and C.A. Phillips, *Clinical short-wire TENS transcutaneous electric nerve stimulator study for mitigation of pain in the Dayton VA Medical Center.* Journal of Clinical Engineering, 1997. **22**: p. 290-297.
29. Ashby, M.F., Materials Selection in Mechanical Design. 1995, Oxford, England: Butterworth-Heinemann Ltd. 362.
30. Kaplan, B., *et al.*, *Clinical evaluation of a new model of a transcutaneous electrical nerve stimulation device for the management of primary dysmenorrhea.* Gynecologic and Obstetric Investigation, 1997. **44**: p. 255-259.

8.0 BIBLIOGRAPHY

Abram, S.E., *Advances in Chronic Pain Management Since Gate Control.* Regional Anesthesia, 1993. **18**: p. 66-81.

Ashby, M.F., Materials Selection in Mechanical Design. 1995, Oxford, England: Butterworth-Heinemann Ltd. 362.

Chabal, C., *et al. Long-term transcutaneous electrical nerve stimulation TENS use: Impact on medication and physical therapy utilization and costs.* in *Annual Meeting of the American Society of Regional Anesthesia.* 1997. Atlanta, Georgia: Regional Anesthesia.

Devulder, J., M. De Laat, and G. Rolly, *Dual channel electrostimulation in pain.* Acta Neurologica Belgica, 1998. **98**(2): p. 195-8.

Deyo, R.A., *et al., A Controlled Trial of Transcutaneous Electrical Nerve Stimulation (TENS) and Exercise for Chronic Low Back Pain.* New England Journal of Medicine, 1990. **322**(23): p. 1627-34.

Doctor, J.N., An evaluation of transcutaneous electrical nerve stimulation TENS for the treatment of pain related to a spinal cord injury. Thesis in Clinical psychology. 1996, University of California, San Diego & San Diego State University: San Diego, CA. p. 155.

Eriksson, E., *The scientific basis of rehabilitation.* American Journal of Sports Medicine, 1996. **24**: p. S25-S27.

Feigenbaum, E., *Transcutaneous electrical nerve stimulation for acute pain treatment for ambulatory patients.* 1984, Rockville, MD & Springfield, VA: US Dept. of Health and Human Services, Public Health Service, Office of the Assistant Secretary for Health, National Center for Health Services Research ; Available from National Technical Information Service.

Foster, N.E.L., *et al. Transcutaneous electrical nerve stimulation: Effect of manipulation of stimulation parameters upon two models of experimental pain in humans.* in *Scientific Meeting of the Physiological Society.* 1996. London, England: Journal of Physiology (Cambridge).

Ganong, W.F., Review of Medical Physiology. 18 ed. 1997, Stamford, Connecticut: Appleton & Lange. 829.

Gardner, E., Fundamentals of Neurology. 4th ed. 1963, Philadelphia and London: Saunders.

Garrison, D.W. and R.D. Foreman, *Decreased activity of spontaneous and noxiously evoked dorsal horn cells during transcutaneous electrical nerve stimulation TENS.* Pain, 1994. **58**: p. 309-315.

Hardy, P.A.J., *Studies of the mechanism of transcutaneous electrical nerve stimulation using thermal thresholds and skin thermography.* Pain Clinic, 1993. **6**: p. 233-239.

Ishimaru, K., K. Kawakita, and M. Sakita, *Analgesic effects induced by TENS and electroacupuncture with different types of stimulating electrodes on deep tissues in human subjects.* Pain, 1995. **63**: p. 181-187.

Jenkner, F.L., Electric Pain Control. 1995, New York: Springer-Verlag. 233.

Kaplan, B., *et al., Clinical evaluation of a new model of a transcutaneous electrical nerve stimulation device for the management of primary dysmenorrhea.* Gynecologic and Obstetric Investigation, 1997. **44**: p. 255-259.

Liu, J. and C.W.Y. Hui-Chan. *Do the effects of repetitive transcutaneous electrical nerve stimulation TENS on experimental pain cumulate over time?* in *23rd Annual Meeting of the Society for Neuroscience*. 1993. Washington, DC: Society for Neuroscience Abstracts.

Lowe, A.S., *et al. The effects of transcutaneous electrical nerve stimulation TENS parameters upon bilateral nerve conduction, mechanical pain and tactile thresholds in humans.* in *The Physiological Society Scientific Meeting*. 1996. Edinburgh, Scotland: Journal of Physiology (Cambridge).

Conybeare's Textbook of Medicine. 16th ed., ed. Mann, W.N. 1975, Edinburgh, UK: Churchill Livingstone.

Mannheimer, J.S. and G.N. Lampe, Clinical transcutaneous electrical nerve stimulation. 8 ed. 1988, Philadelphia: F.A. Davis Co. 636.

Melzack, R. and P.D. Wall, *Pain Mechanisms: A New Theory.* Science, 1965. **150**(3699): p. 971-979.

Myklebust, J.B., Neural stimulation. Vol. 1. 1985, Boca Raton, Fla.: CRC Press.

Myklebust, J.B., Neural stimulation. Vol. 2. 1985, Boca Raton, Fla.: CRC Press.

Ottoson, D. and T.T. Lundeberg, Pain treatment by TENS, transcutaneous electrical nerve stimulation : a practical manual. 1988, New York: Springer-Verlag. 130.

Rattay, F., Electrical nerve stimulation : theory, experiments and applications. 1990, New York: Springer-Verlag. 264.

Repperger, D.W., *et al., Microprocessor based spatial TENS transcutaneous electric nerve stimulator designed with waveform optimality for clinical evaluation in a pain study.* Computers in Biology and Medicine, 1997. **27**: p. 493-505.

Repperger, D.W., C.C. Ho, and C.A. Phillips, *Clinical short-wire TENS transcutaneous electric nerve stimulator study for mitigation of pain in the Dayton VA Medical Center.* Journal of Clinical Engineering, 1997. **22**: p. 290-297.

Schade, J.P. and D.H. Ford, Basic Neurology: An Introduction to the Function and Structure of the Nervous System. 1967, Amsterdam, Netherlands: Elsevier Publishing Company. 373.

Sjoelund, B.H. and M.B.E. Eriksson, *Endorphins and Analgesia Produced by Peripheral Conditioning Stimulation*, in *Advances in Pain Research and Therapy*, J.J. Bonica, Editor. 1979, Raven Press: New York.

Sjoelund, B.H. and M.B.E. Eriksson, Relief of pain by TENS : transcutaneous electrical nerve stimulation. 1985, Chichester ; New York: Wiley. 116.

Slavkin, H.C., *What we know about pain.* Journal of the American Dental Association, 1996. **127**: p. 1536-1541.

Sluka, K.A., *et al., Treatment with either high or low frequency TENS reduces the secondary hyperalgesia observed after injection of kaolin and carrageenan into the knee joint.* Pain, 1998. 77: p. 97-102.

Ten Vaarwerk, I.A.M., W.J. Meyler, and M.J.L. Dejongste, *Transcutaneous electrical nerve stimulation for the control of pain.* Pain Clinic, 1995. **8**: p. 63-71.

Thoden, U., *Methods: Transcutaneous electrical nerve stimulation (TENS) in pain therapy.* 1993.

Ulrich, K.T. and S.D. Eppinger, Product Design and Development. 1995, New York: McGraw-Hill, Inc. 289.

Urasaki, E., *et al., Effect of transcutaneous electrical nerve stimulation TENS on central nervous system amplification of somatosensory input.* Journal of Neurology, 1998. **245**: p. 143-148.

Verdouw, B.C., *et al., Long-term use and effectiveness of transcutaneous electrical nerve stimulation in treatment of chronic pain patients.* Pain Clinic, 1996. **8**: p. 341-346.

Wall, P.D. and W.H. Sweet, *Temporary Abolition of Pain in Man.* Science, 1967. **155**: p. 108-109.

Walsh, D.M., G.D. Baxter, and J.M. Allen. *The effects of transcutaneous electrical nerve stimulation TENS upon unilateral nerve conduction, mechanical pain and tactile thresholds in humans.* in *Scientific Meeting of the Physiological Society.* 1997. Dublin, Ireland: Journal of Physiology (Cambridge).

Walton, L., Essentials of Neurology. 6th ed. 1989, New York: Churchill Livingstone. 339.

Novel Research Applications for TENS use. 1998, Biofil Ltd., RFNC-VNIIEF: Sarov, Nizhni Novgorod Region, Russia *TENS for chronic low-back pain.* Lancet, 1991. **337**(8739): p. 462.

Possible Remote Communication Schemes for Transcutaneous Electrical Nerve Stimulation. 1998, Biofil Ltd., RFNC-VNIIEF: Sarov, Nizhni Novgorod Region, Russia.

TENS research in Russia. 1998, Biofil Ltd., RFNC-VNIIEF: Sarov, Nizhni Novgorod Region, Russia.

TENS Patent Background. 1998, Biofil Ltd., RFNC-VNIIEF: Sarov, Nizhni Novgorod Region, Russia.