

TRANSCUTANEOUS ELECTRICAL NERVE STIMULATORS
AND POSTARTHROTOMY PAIN

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CHAPTER 1

INTRODUCTION

Pain is man's oldest enemy. It has been described as "one of the most vexing and pervasive of all human problems" (Mitchell, 1973, p. 445). Man has searched for centuries for methods to reduce or alleviate pain, but thus far none have been found to be completely successful.

Providing comfort and facilitating the relief of pain have been reported as two of the major functions of nurses (Mitchell, 1973). To reduce the pain of patients, nurses have tried numerous modalities. Positioning, applying heat or cold, rubbing the back, supplying diversion and medicating are some of the many approaches attempted for pain reduction. Despite earnest efforts, the success of these methods is limited. Nurses usually resort to medicating the patient to relieve pain. However, the side effects of analgesics can on occasion be more destructive than useful. The entire medical field is aware of the need for a more effective pain-reducing technique and attempts are continually made to find better methods.

Modern investigative procedures by engineers have produced transcutaneous electrical nerve stimulators which

are rapidly becoming an acceptable pain reduction modality. The idea of using electricity to control pain is not new, but it has only been since 1970 that transcutaneous electrical nerve stimulators have been recognized as an effective, sophisticated technique (Lampe, 1978).

Recent studies reported that transcutaneous electrical nerve stimulators are both effective and safe when used to reduce pain (Lampe, 1978; VanderArk & McGrath, 1975). Could the transcutaneous electrical nerve stimulator be the answer for the historical problem of pain?

Problem of Study

Is there a difference in the amount of pain medicine used by male arthrotomy patients utilizing a transcutaneous electrical nerve stimulator and male arthrotomy patients not using a transcutaneous electrical nerve stimulator?

Justification of Problem

The nurse has more contact with the patient than any other member of the health team (McCaffery, 1972). Much of this contact time is spent attempting to control or alleviate pain. Many independent nursing interventions are used to help patients with pain. Among these are positioning, diversion, applying heat or cold, back rubbing, listening, and administering pain medications

(Mitchell, 1973). Although each of these techniques is helpful, none have been found to be completely effective. McCaffery (1972) also recommends the use of a variety of nursing activities for pain relief besides the use of analgesics.

Analgesics are drugs used to reduce pain. These drugs vary in potency, action, and composition. Basically, they can be classified as narcotic or non-narcotic. A narcotic is a depressant of the central nervous system with dependence-producing properties (Bergersen, 1973). Non-narcotics are all other analgesics. There are many side effects associated with analgesics. These include nausea and vomiting, constipation, postural hypotension, depression of respiration and coughing, behavioral changes, allergic reactions, development of a tolerance for or addiction to the drug (Bergersen, 1973). Despite the numerous side effects, these drugs are used because no other means have yet to be found totally effective in reducing pain.

Nurses, as well as the rest of the members of the medical field, continue searching for an alternative pain-reducing modality. The transcutaneous electrical nerve stimulator is a relatively new pain-reducing apparatus. Its effectiveness has just recently become known and its

use more widespread. This technique has many advantages over independent nursing interventions and medications (Lampe, 1978). The transcutaneous electrical nerve stimulator has been shown to be effective in reducing many types of pain. With use of the apparatus, pain was reduced for spinal surgery patients (Schuster & Infante, 1979), abdominal and thoracic surgery patients (VanderArk & McGrath, 1975), chronic pain patients (Bergman & Werblum, 1978), and others.

The side effects are very minimal when compared to those of the analgesics. No deaths or complications of existing conditions resulting from transcutaneous electrical nerve stimulators have been reported. The most commonly noted side effect is a skin reaction resulting from the electricity, tape, or conducting medium (Lampe, 1978).

The transcutaneous electrical nerve stimulator can be used by the individual after a training and instruction period by a nurse, physical therapist, physician, or other qualified health professional (Lampe, 1978). Usually a physician orders the apparatus and other professionals apply it and teach the patient self-application. Since the patient can operate it, the stimulator can be used at home and thereby shorten the length of time spent in the hospital for pain management.

To date, there have been no published studies of the effectiveness of transcutaneous electrical nerve stimulators on knee surgery patients. These patients do have severe postoperative pain compounded by immobility (Luckmann & Sorensen, 1974). A need exists for a way to reduce their pain and allow for early ambulation without the use of excessive narcotics. Whether or not the transcutaneous electrical nerve stimulator can fulfill this need should be determined and made known to the nursing profession.

Theoretical Framework

The gate-control theory of pain best explains how the transcutaneous electrical nerve stimulator (T.E.N.S.) is capable of relieving pain. This theory was first proposed by Melzack and Wall (1965), and later expanded by Melzack (1973). Basically the theory suggested that stimulation of the large fibers (nonpain fibers) inhibits the smaller pain carrying fibers in the spinal cord. Since the large myelinated fibers have a lower threshold to stimulation, they are more readily activated electrically and their impulses set a process in motion that tends to close the gate to information coming over the smaller pain fibers and the message of pain is blocked (Melzack, 1973).

Melzack and Wall's (1965) theory was derived from the function of three basic parts of the spinal cord system. These authors believed that stimulation of the skin evokes nerve impulses that are transmitted to those three areas: (a) the cells of the substantia gelatinosa in the dorsal horn, (b) the dorsal-column fibers that project toward the brain, and (c) the first central transmission (T) cells in the dorsal horn. Melzack and Wall's theory was based on the following three proposals:

1. The substantia gelatinosa functions as a gate control system that modulates the afferent patterns before they influence the T cells.

2. The afferent patterns in the dorsal column system act as a central control trigger which activates selective brain processes that influence the modulating properties of the gate control system.

3. The T cells activate neural mechanisms which comprise the action system responsible for response and perception.

Melzack and Wall (1965) defined the substantia gelatinosa as "densely packed cells that form a functional unit extending the length of the spinal cord" (p. 974). The substantia gelatinosa acts as the gate control system that modulates the synaptic transmission of nerve impulses

from peripheral fibers to central cells (Melzack & Wall, 1965).

Melzack and Wall (1965) reported three features of the afferent input that affect pain: (a) the ongoing activity which precedes the stimulus, (b) the stimulus-evoked activity, and (c) the relative balance of activity in large versus small fibers. The gate stays in an open position because of the ongoing activity of the small fibers which tend to be tonically active and adapt slowly. When the skin is stimulated, a relative increase of activity in the large fibers occurs which is greater than the small fiber activity. This stimulation fires the T cells and partially closes the presynaptic gate. The effects of the stimulation are determined by the total number of active fibers and frequencies of nerve impulses that they transmit and the balance of activity in large and small fibers (Melzack & Wall, 1965).

Melzack and Wall's (1965) theory explained the emotional component of pain through the concept of the central control trigger. The central nervous system can exert control over the sensory input through descending efferent fibers. Central activity may either open or close the gate thus allowing either more or less pain to be perceived. The central control trigger can be either the

dorsal-column-medial lemniscus system or the dorsolateral path.

The action system is triggered by the T cells once the integrated firing level exceeds a critical level. This action marks the beginning of the sequence of activities that occur when the body sustains damage (Melzack & Wall, 1965).

The gate-control system and the action system interact at various levels of the central nervous system and the sensory input may take place at any level. Because of this variability, pain interpretation can change continually or remain static (Melzack & Wall, 1965).

Howson (1978) suggested that the gate-control theory of pain can explain how transcutaneous electrical nerve stimulators reduce pain. The neural input from the stimulator is mediated through large diameter afferents which, when activated, close the gate and prevent smaller diameter afferent fiber transmittal of pain information to conscious levels (Howson, 1978).

Assumptions

The assumptions of this study were:

1. It was assumed that application of the transcutaneous electrical nerve stimulator activated the gate-control mechanism.

2. Most people in pain desire a reduction or alleviation of that pain.

3. All persons have similar nervous systems.

4. Pain is a usual result of knee surgery and the pain is most severe the first 48 hours after surgery.

5. All brands of transcutaneous electrical nerve stimulators are equally effective in reducing pain.

6. The amount of pain medication used was a measure of the amount of pain experienced by the patient.

Hypothesis

Male arthrotomy patients using a transcutaneous electrical nerve stimulator after reconstructive knee surgery will use less pain medication than postoperative male arthrotomy patients not using a transcutaneous electrical nerve stimulator.

Definition of Terms

For the purpose of this study, the following terms were utilized:

1. Transcutaneous electrical nerve stimulator (T.E.N.S.)--hand-held battery-operated pulse generator to which a pair of electrode-tipped wires can be attached. Applied to the skin overlying any painful area of the

body, these electrodes provide continuous mild electrical stimulation.

2. Arthrotomy (knee)--an operative procedure in which the knee joint is opened to repair damaged knee components such as the cartilages, ligaments, and tendons. This term excludes minor procedures performed by arthroscopy alone.

3. Pain medication--chemical compounds prescribed by physicians for the relief of pain: (a) Narcotics--depressants of the central nervous system with dependence-producing properties used for the relief of pain. Generally, narcotics are restricted by the federal narcotic law (Harrison Narcotic Act). Examples are: Demerol, Morphine, Codeine, Dilaudid, and Pantapone. (b) Non-narcotics--all other analgesics. Examples are: Darvocet N-100, Talwin, and Synalgos DC.

Limitations

The limitations of the study were:

1. Racial background was not a factor under consideration.
2. Educational background was not a factor taken into consideration.
3. Economic background was not controlled.
4. Religious background was not a factor under consideration.

5. The accuracy of the charting was a limitation.
6. The investigator's own errors when reviewing the charts was a limitation.

Summary

The transcutaneous electrical nerve stimulator may prove to be an effective and beneficial pain reduction technique. It has not previously been researched with postoperative knee surgery patients. This study attempted to study the transcutaneous electrical nerve stimulator as an alternative to medications for nurses striving to relieve the pain of knee surgery patients.

CHAPTER 2

REVIEW OF LITERATURE

The concept of pain has been of interest to man for centuries. Pain serves two valuable purposes--that of a danger signal and a diagnostic tool (Shealy, Burton, & Long, 1974). Besides these two purposes, pain has caused and continues to cause mankind much suffering and anxiety. This chapter explores the theories of pain, the relationship between surgery and pain, techniques to relieve pain, nursing research of pain-reducing treatments, the history of transcutaneous electrical nerve stimulation, and research studies.

Pain Theories

Through the years, several theories have been formed to explain the puzzle of pain. The most prominent pain theories include the specificity theory, pattern theory, gate-control theory, and the endorphin theory.

The specificity theory is also referred to as the traditional or "one-on-one" theory. It proposes that a free nerve ending is the probable pain end-organ and the pain signal is transmitted through a specific tract to a specific pain center located within the brain. This theory

has been unable to answer questions concerning distinguishing the degrees of pain or how emotions affect pain. No physical receptors have been found even through microscopes that are now available that can identify the nerve endings (Indeck & Printy, 1975; Mason, 1976; Siegele, 1974).

The pattern theory developed when the specificity theory failed to provide all the answers. This theory presented the idea that nerve firings form specific patterns which the brain decodes to interpret as pain, sensation, or variations of the two. This theory lost popularity when it could not explain why nerve fibers had such a high degree of specialization which was seen microscopically. This specialization would not be necessary if the nerve could fire varied signals to relate messages (Indeck & Printy, 1975; Mason, 1976; Melzack & Wall, 1965).

The gate-control theory was proposed by Melzack and Wall (1965). It has already been discussed in detail in the Theoretical Framework section of the current study. Briefly, the gate-control theory assumes that sensory nerve impulses travel from the nerve receptor to synapse in the grey matter of the dorsal horns of the spinal cords. The synapses act as gates which close to keep the impulses from reaching the brain or open to allow the impulses to

to ascend (West, 1981). Since its introduction in 1965, this theory has been studied and restudied in attempts to answer all questions about pain, its origin, and its cures. To date, this theory does not explain how pain can be suppressed for long periods of time (3-18 hours) after a relatively short (15-45 minutes) stimulation period (Mason, 1976). This theory is the explanation most often used to support transcutaneous electrical nerve stimulation as a pain-reducing technique.

The endorphin theory is the most recent theory having been developed within the last decade. The theory stated that there are specific sites to which opiate analgesics attach. These are found in multiple areas of the brain. Researchers reasoned that the brain would not have receptors for morphine-like substances unless it had a natural brain chemical that used those receptors. This chemical was searched for in hopes of finding the perfect analgesic. A polypeptide was found and called "enkephalin" from the Greek phrase "in the head." Later a larger polypeptide was found and called "endorphin," a combined form of the words "endogenous" and "morphine." This word is generally used to include all the opiate-like peptides. Research has yielded the following tentative conclusions about endorphins: Endorphins are located in the nerve fiber synapses,

they may relieve pain, people with increased pain thresholds have high endorphin levels, cutaneous stimulation and acupuncture increase endorphin levels, continuing pain may deplete endorphin levels, and endorphins may reduce depression (West, 1981).

Surgery and Pain

Pain is often an immediate concern when surgery is considered. People commonly believe that all surgical procedures are painful and that everyone will experience pain from surgery. However, both Keats (1967) and Bonica (1954) reported that not all postoperative patients complain of pain. Keats (1967) included all categories of postoperative patients and reported that 40% of all postoperative patients never complain of pain, 20% achieve relief of postoperative pain with placebos, 20% achieve relief of postoperative pain with 10 mg. or less of Morphine Sulfate, slightly more than 10% require over 10 mg. of Morphine Sulfate, and less than 10% never achieve pain relief postoperatively. Bonica (1954) supported Keats's findings and generally stated that about one-third of all postoperative patients do not experience pain. Keats (1956) also tried to correlate incidence and severity of postoperative pain with variables such as age, sex, type

and duration of anesthesia, previous surgical history, incidence and severity of preoperative pain, and personality disorders. No correlations could be found despite numerous attempts. Although Keats's (1956) findings showed that not all people have pain postoperatively, the data reiterated that approximately 60% of surgical patients do experience pain. Postoperative pain tends to be of short duration and acute in nature. The patient's response to surgery and postoperative pain is the result of a lifetime of experience, cultural and religious influences, learned responses to pain, and resources for coping with life (Sweeney, 1977).

Sweeney (1977) identified three types of postoperative pain--incisional, somatic, and visceral pain. Incisional pain arises from skin and mucous membranes. It is conducted by all diameter fibers but primarily A delta and C groups. Somatic pain is associated with muscles, tendons, ligaments, periosteum, cancellous bone, joints, and arteries. It is conducted by A, B, and C fibers. Visceral pain is associated with visceral organs, parietal peritoneum, or pleura. It is conducted by sympathetic nerves except for the vagus nerve (Sweeney, 1977). Incisional pain and somatic pain are the two types of most concern when dealing with postoperative orthopedic pain.

Relieving Pain

Man has sought to prevent pain for as long as pain has been known. Through the years, many techniques have been tried with various degrees of success.

Although new neurosurgical pain-relieving techniques have been improved in recent years, proper management of pain still remains largely conservative (Hachen, 1977-78). Conservative therapy includes analgesic medications, modulation of behavioral states (which includes suggestion, psychotherapy, hypnosis and alpha-feedback training), non-noxious peripheral counter-irritation (including acupuncture and cryoanalgesia), transcutaneous electrical stimulation, dorsal column stimulation, and nerve blocks. When conservative techniques fail to produce favorable results, the following surgical procedures can be considered: (a) peripheral neurectomy, (b) dorsal rhizotomy, (c) commissural myelotomy, (d) antero-lateral cordotomy, and (e) psychosurgery (Hachen, 1977-78).

Nursing Studies of Pain Reduction

Nurses are expected to evaluate the nature of and cause of a patient's pain, decide on the appropriate intervention, and determine the effectiveness of that action (Billars, 1970). Research on pain reduction was popular

during the late 1950s and continued through the latter part of the 1960s but has diminished considerably since that time (Sweeney, 1977). Nursing literature reports many suggested methods of reducing pain (Siegele, 1974; Stewart, 1976; Twedt, 1975), but actual nursing experiments are less abundant. Four such studies were found and will be related here.

Moss and Meyer (1966) reported an experiment they conducted to test pain reduction. Two groups were studied consisting of 25 patients each. For both groups, the nurse investigator approached the patient who complained of pain, stated she wanted to help relieve the pain, introduced relief methods such as repositioning, and stated she would return in 15 minutes. Patients in the experimental group were encouraged to choose one of the suggested relief methods. Patients in the control group were not involved in the decision of which relief method would be used. The investigator initiated the relief method suggested without input from the patient. All patients were questioned concerning level of pain 15 minutes after the first interaction. As hypothesized, the experimental group obtained a much higher degree of pain relief than did the control group. Moss and Meyer (1966) concluded that pain relief will be a consequence of the

interaction with a nurse depending upon how the interaction was initiated and how the patient is engaged in the decision making. Also, it was concluded that nursing care, when planned deliberately, can be effective in the relief of moderate pain (Moss & Meyer, 1966).

McBride (1967) studied the effect of three different nursing approaches on 21 general surgical patients. It was assumed that if the psychosomatic character of pain was assessed by exploring with the patient what his verbal and nonverbal behavior meant, a more appropriate nursing intervention would follow than if the patient was automatically given medication. The first approach was called Experimental Nursing and the investigator assessed what the patient meant by pain and ascertained his physical, intellectual, and emotional needs. Nursing intervention was provided based on the evaluation. Control Nursing I was the second approach. The investigator viewed patients' complaints as a request for pain medication. The patients initiated any discussion or questioning concerning their pain. Control Nursing II, the third approach, was given by the hospital staff nurses. The patients could respond in any way they felt appropriate but had to give a pain medication. The length of interaction varied among the three approaches. The Experimental Nursing approach took

from 7 to 25 minutes, the Control Nursing I approach took from 6 to 16 minutes, and the Control Nursing II approach took from 3 to 7 minutes. Relief from pain was measured by verbal statements, decreases in pulse and respiratory rates, and changes in nonverbal behavior. The Experimental Nursing group scored highest on all three measurements of pain relief. The Control Nursing I group was next, and the Control Nursing II group was lowest in the scoring. The findings seem to indicate that a nursing approach based on the psychosomatic view of pain is more effective than one which equates treatment of pain with simply giving medications (McBride, 1967).

Billars (1970) conducted research to determine if the suggestion of pain relief was a major variable in reducing pain. Patients were grouped into Groups A, B, and C. When the patients in Group A or B called for pain medication, nurses asked about the quantity of pain and suggested that a change in position "would probably relieve the pain." Group B patients were additionally told that the nurse would return in 10 minutes to take further action if needed for pain reduction. Group C patients were helped to change positions, but no positive suggestions were made. Each patient was re-evaluated in 10 minutes to determine if pain was reduced. Group A

reported the greatest relief, Group B was second, and Group C ranked lowest in pain relief. In retrospect, Billars (1970) determined that the assurance of further action if needed that was given Group B patients inhibited the effects of positive suggestion because it made patients doubt the effectiveness of relief from repositioning. Billars concluded that the suggestion of pain relief was a major variable in decreasing pain. Effectiveness of nursing measures can be increased with a suggestion that the action will help to reduce pain (Billars, 1970).

Diers, Schmidt, McBride, and Davis (1972) designed a clinical experiment with three treatment groups. There were 96 patients who asked for pain relief and were randomly assigned to one of the three groups. Three different nursing approaches were used. Group A patients were viewed by the nurse as feeling, thinking, and doing persons. Pain was viewed as a psychomatic phenomenon--partly physical, partly emotional, and partly cognitive. Group B patients were considered to be thinking and doing people. Pain was considered a physical entity, but patients could experience relief from pain if they were helped to analyze its causes and the best method to treat it. Group C patients were viewed as only doing people. Pain was mostly physical and the effort was to help the patients deal with

the physical aspects of the experience. The interaction consisted of the nurse administering the p.r.n. pain medication as ordered and spending about 15 minutes talking with the patient using the approach assigned. Both vital signs and verbal and nonverbal behavior were recorded at the beginning of the interaction, at the end of the interaction, and 1 hour later. As hypothesized, Group A received more relief than Group B, who in turn fared better than patients in Group C. The authors concluded that nursing approaches which take into account the "whole" patient--a feeling, thinking, and doing person--are more likely to produce pain relief than approaches which systematically eliminate one or more dimensions (Diers et al., 1972).

Flaherty and Fitzpatrick (1978) reported on the effectiveness of relaxation techniques to increase the comfort level of patients in their first postoperative attempt at getting out of bed. Forty-two patients were tested. All had had elective surgery. The experimental group patients were taught the relaxation techniques. Vital signs, subjective data, and amount of analgesics required were used to evaluate the results. The experimental patients reported significantly less incisional pain and body distress, and on the average went home approximately 2

days earlier than those patients not taught the relaxation exercises (Flaherty & Fitzpatrick, 1978).

The four studies presented indicate that the nursing intervention plays an important part in relieving a patient's pain. Even in the absence of medication, time spent talking with a patient increases the patient's comfort (McBride, 1967; Moss & Meyer, 1966).

History of Transcutaneous Electrical Nerve Stimulation

Transcutaneous electrical nerve stimulation was listed by Hachen (1977-78) as a conservative treatment modality for reducing pain. Using electricity to stop pain is not a new idea. Electricity was probably used by the Egyptians and Hippocrates himself, but the first written record of using electricity for pain reduction was in 46 A.D. when Seribonius Largus, a Roman physician and contemporary of Pliny, used the electric ray or torpedo fish for the treatment of headaches and gout. A jolt from the fish would apparently stun the area and relieve the pain often for hours (Shealy et al., 1974).

The field of neurophysiology was greatly expanded between 1745 and 1830 by two men and their discoveries. In 1745, Luigi Galvani (cited in Shealy et al., 1974) developed the Leyden jar and was able to demonstrate the

effect of direct current on the nervous system. Galvani (cited in Mason, 1976) applied electric currents to contract the muscles of frogs and sheep. Faraday (cited in Shealy et al., 1974) in the 1830s, discovered alternating currents. As a result of these two discoveries, physicians began showing great interest in the concept of electrical energy and by the late 19th century, this interest expanded to using man-made electrical energy for relieving pain (Shealy et al., 1974).

Man-made electrical devices were used to stimulate patients. Galvanic current was presented to the public and medical community as a cure for all ailments, including pain. Because there was no control over stimulation characteristics and inconsistent wave-forms, these early devices were found to be less than acceptable (Lampe, 1978).

Although real demonstrations of electricity's pain-relieving properties continued, the producers of the devices were claiming that "everything from pleurisy to piles, from chancre to cancer" could be cured by electricity (Shealy et al., 1974, p. 240). The manufacturers explained that the electricity subtracted the "irritones" and added "proctectones" to cure ailments. Eventually, manufacturers of the devices were accused of quackery and fraud, and

federal and medical agencies gradually forced numerous manufacturers out of business (Shealy et al., 1974).

There was one exception to the above. The Electreat, a battery-powered, hand-held device designed and patented in 1918 managed to survive by severely modifying its claims (Shealy et al., 1974).

In 1965, Melzack and Wall introduced the gate-control theory of pain. The theory seemed to provide an explanation for electricity altering pain perception. The theory prompted a rekindling of medical interest in electrical neuromodulation (Lampe, 1978).

In 1967, Mortimer and Shealy (cited in Lampe, 1978) developed the dorsal column stimulator for electrical stimulation. Shealy et al. (1974) suggested that in the dorsal column of the spinal cord where the large fibers are separated anatomically from the small fibers was the simplest place to try interrupting pain pathways with electricity. The electrodes of the dorsal column stimulator (DCS) had to be surgically implanted. Some patients found the electrical stimulation more unpleasant than the original pain. Shealy et al. (1974) decided to screen patients prior to implanting the dorsal column stimulator by using the Minnesota Multiphasic Personality Inventory (MMPI), psychiatric interviews, and testing pain

thresholds. An old Electreat was used transcutaneously to apply the electrical stimulation for the screening process. Shealy et al. (1974) found some pain was actually controlled enough by the Electreat during the screening process to avoid implanting the dorsal column stimulator.

By 1971, many neurosurgeons were using Electreats for screening for dorsal column stimulator candidacy and challenged engineers to develop a more up-to-date model. Many stimulators were developed which consisted of battery-operated pulse generators, a pair of cables, and a pair of electrodes to be applied to the skin. The stimulators varied in amplitude and frequency and outward appearance (Shealy et al., 1974).

Transcutaneous Electrical Nerve Stimulation Research Studies

Research on transcutaneous electrical stimulation is limited because of the newness of the concept and practice of electrical stimulation. Some studies have been published and a review of these follows.

Chronic Pain

Transcutaneous electrical nerve stimulation was originally used for chronic pain conditions. Four studies

were found to report research of transcutaneous electrical nerve stimulation and chronic pain.

Indeck and Printy (1975) researched 171 orthopedic pain patients with chronic pain and their response to transcutaneous electrical nerve stimulation. Treated either as in-patients or out-patients were 90 patients with low back syndrome, 31 with cervical syndrome, 32 with neck and headache pain, 8 with arthritis, 6 with phantom pain, and 4 with postherpetic neuralgia. A nurse was taught to apply the electrodes to the painful area and then instructed the patient self-application and how to control the amplitude, frequency, and duration of the stimulation to achieve comfort. After 24 hours, patients were grouped into one of the four following categories--unimproved, fair, good, or excellent. Category determination was primarily subjective. Classification depended upon the patient's subjective response to medication, tolerance to activity, and/or ability to work. If the patient improved in one category, he was considered "fair," improvement in two categories, "good," and if improvement was shown in all three categories, the patient was considered "excellent." Of the 90 patients with back pain, pain patterns had been experienced between 1 and 23 years. No correlation was found between the duration of symptoms

and success of the program. Of the 90 low back patients, 50 were "unimproved," 5 were considered "fair," 20 were "good," and 5 were "excellent." Of the 32 headache and neck pain patients, 14 were "unimproved," 4 were "fair," 10 were "good," and 4 were "excellent." Because the other three groups contained so few patients, results were not analyzed. Indeck and Printy (1975) summarized their efforts as: "This method appears to be useful for the relief of several types of pain seen in orthopedic practice, particularly pain unrelieved by many surgical approaches" (p. 309).

Hachen (1977-78) worked with transcutaneous electrical nerve stimulation at the Spinal Injuries Center in Geneva, Switzerland. Hachen evaluated 39 spinal cord injury patients suffering from chronic intractable pain of 6 to 35 months duration. Stimulation was applied for 6 consecutive hours. Pain relief was assessed by verbal and visual analogue scales and McGill's Pain Questionnaire. After 1 week, total or almost total relief was reported by 49% of the patients, moderate relief was reported by 41%, and no improvement was reported by 10%. At the 3-month follow-up, 28% reported total relief, 49% reported moderate relief, and 23% reported no improvement. Hachen reported

significant pain relief in approximately one-third of the cases.

Long (1977) reported results of transcutaneous electrical nerve stimulation performed at the University of Minnesota's pain treatment program, but no details of the experiment were provided. Psychogenic pain was not relieved and was commonly intensified by application of transcutaneous electrical nerve stimulators. Pain of central nervous system origin and peripheral nervous system origin of the neuropathic type rarely responded (diabetic and alcoholic neuropathies). The most impressive responses associated with electrical stimulation were pain of peripheral nerve injury, phantom limb, postherpetic neuralgia, and stump pain. Long suggested that 33% of patients admitted to chronic pain treatment centers require no direct therapy for pain other than transcutaneous electrical nerve stimulation.

Eriksson, Sjölund, and Nielzen (1979) reported their findings at the University of Lund in Sweden. There were 123 patients studied with chronic pain. The investigators used either traditional transcutaneous electrical nerve stimulators or acupuncture-like electrical nerve stimulators. Muscle nerves were activated at a low repetition rate with small trains of stimuli. Fifty-five of the 123

patients continued treatment 24 months later. Of the patients, 75% reported more than 50% pain relief as measured from visual analogue scales and half of these reported an increased social activity and a decrease of analgesic drug intake by more than 50%. Eriksson et al. (1979) concluded that peripheral conditioning stimulation is a valuable therapy in cases of chronic pain and that both conventional and acupuncture-like electrical nerve stimulation should be tried before considering implanting devices or destructive surgery.

Roberts (1979) first worked with thrombophlebitis patients and transcutaneous electrical nerve stimulation. This method of pain relief was tried because of its success with other painful disorders and its simple, non-invasive nature. After successful "trial runs," a study was conducted on 39 patients with thrombophlebitis. The average age of the patients was 47, and each had persistent thrombophlebitis in the lower extremities despite the use of medication and support hose. Occasions for treatment ranged from 1 to 17 therapy sessions with patients subjectively classifying their pain relief. Good to excellent relief of their pain was reported by 82% (32) of the patients. Fair results was reported by 8% (3) of the patients, and 10% (4) of the patients reported no relief.

Roberts (1979) summarized that transcutaneous electrical nerve stimulation afforded significant relief of the pain associated with acute and recurrent thrombophlebitis in 90% of the 39 patients treated. Transcutaneous electrical nerve stimulation can be given in conjunction with analgesics, anticoagulants, and supportive measures to achieve greater relief and mobility in patients.

Acute Pain

More recent studies related the value of transcutaneous electrical nerve stimulation with postoperative and/or acute pain. The following studies report these findings.

Cooperman, Hall, Sadar, and Hardy (1975) studied 50 adult patients who underwent abdominal operations through an upper midline incision. Twenty-six patients were randomly assigned to the experimental group who used working stimulators. Twenty-four patients were assigned to a control group who had placebo stimulators with no current. All patients were then classified based on their need and response to medication. Class 1 included patients who required no Demerol or an occasional dose of Valium in 24 hours. Class 2 included patients who required up to three Demerol doses per 24 hours. Class 3 included patients who

used more than three Demerol doses or objected to the stimulator. Cooperman et al. (1975) found pain relief was significantly better ($p < .008$) when stimulators with currents were used. Use of stimulators without currents resulted in $p < .2$. There was no significant difference in the incidence of postoperative atelectasis or ileus regardless of which stimulator was used. Age, sex, type, or length of operation were all insignificant. Of the cases, 77% had good to excellent results when stimulators with current were used. Of the patients with placebo stimulators, 34% received good results (Cooperman et al., 1975).

VanderArk and McGrath (1975) studied 100 patients between the ages of 13 and 87 who underwent abdominal or thoracic operative procedures. Patients were assigned randomly to either a control group (39 patients) or test group (61 patients). The control group members were given stimulators that did not contain batteries. Stimulation was scheduled for three times each day for 20 minutes with 4-hour intervals. Success was based on patients' subjective responses to stimulation and requests for medication. "Complete success" was the assigned category if greater than 50% relief was achieved and the patient asked for no pain medication. "Positive partial success" was assigned if patients experienced significant pain relief

and asked for minimal or no medication. "Negative partial success" was assigned if the patient experienced minimal or no relief from stimulation and asked for maximum medication. Of the 61 patients in the test group, 47 (77%) experienced pain relief. There was complete relief experienced by 25% of the patients, 31% had positive-partial relief, 21% had negative partial success, and 23% had failure. Thirty-two (83%) of the 39 control patients experienced no pain relief with the mock stimulation. Seven (17%) patients had some degree of relief with mock stimulation but had no objective information to support the claim of some relief. VanderArk and McGrath (1975) concluded that transcutaneous electrical nerve stimulation is an effective method of treatment that has many advantages over analgesic drugs.

Hymes, Raab, Yonehiro, Nelson, and Printy (1974) studied patients undergoing thoracotomies and major intra-abdominal procedures to test transcutaneous electrical nerve stimulation. There were 115 patients with stimulators compared to 154 patients in the control group without stimulators. Types of surgeries included cholecystectomies, thorocotomies, abdominal aortic procedures, colectomies, gastrectomies, bilateral nephrectomies, and splenectomies. The control group underwent the same surgeries with the

same surgeons but did not use stimulators. Age and sex distribution were the same in both groups. Results were reported in detail but basically there was no incidence of postoperative ileus in the treatment group; postoperative atelectasis was significantly reduced and length of stay in intensive care units was reduced an average of 1-1/2 days. The majority of the patients stated that their subjective perception of pain was reduced about 80% (Hyme et al., 1974).

Schuster and Infante (1979) worked with orthopedic patients to test the benefits of transcutaneous electrical nerve stimulation. The authors studied 26 patients in a control group and 26 patients in a test group (matched according to age, sex, and type of surgery). All patients had undergone a partial laminectomy, decompression laminectomy, spinal fusion, and/or iliac crest bone graft. The amount of analgesic intake postoperatively was used to determine the effectiveness of electrical stimulation. Patients in the test group ran the transcutaneous electrical nerve stimulators continuously for the first 18 hours and then as needed. A t test was used to compare results. Analysis revealed a much higher use of analgesics in the control group (Schuster & Infante, 1979).

This review of literature chapter attempted to relate knowledge and research concerning the transcutaneous electrical nerve stimulator and pain reduction. Sweeney (1977) stated: "There is a great need for nurses and other health professionals to conduct research on the alleviation of pain in the postoperative patient" (p. 344). Transcutaneous electrical nerve stimulation shows much potential for being a successful pain-reducing technique in the future.

CHAPTER 3

PROCEDURE FOR COLLECTION AND TREATMENT OF DATA

This study was an ex post facto type of research (Polit & Hungler, 1978). The independent variable (transcutaneous electrical nerve stimulators) could not be manipulated in this research because at this facility it is considered a physician's medical treatment. The subjects were not randomly assigned because their private physician might have objected to electrical stimulation. Data were collected by chart review. The design of this study was a static group comparison (Suchman, 1967). Two groups were compared--Group A having the transcutaneous electrical nerve stimulators, and Group B not having the transcutaneous electrical nerve stimulators. If Group A (the exposed group) showed a significantly higher incidence of the desired condition (requiring less pain medicine), it was assumed to be attributable to the exposure (the transcutaneous electrical nerve stimulator) (Suchman, 1967).

Setting

The setting for this research was the medical records department of a large, private general hospital located in the southern part of the United States. The hospital has approximately 1,200 patient beds, and 152 of these beds are allocated to the orthopedic service.

Population and Sample

The population consisted of all the medical records for male patients having arthrotomies for reconstructive knee surgery at this chosen hospital from January 1, 1980 through January 31, 1981. The sample was limited to charts of patients between the ages of 16 and 60 years undergoing arthrotomies for reconstructive knee surgery. The charts reflected that the patients had no previous experience with a transcutaneous electrical nerve stimulator. Charts of athletes were not included. The convenience technique of sampling was utilized to obtain 10 charts of patients meeting the criteria and using a transcutaneous electrical nerve stimulator (Group A) as well as 20 charts of patients meeting criteria and not using transcutaneous electrical nerve stimulators (Group B).

Protection of Human Subjects

To protect the rights of all individuals involved in this study, there was full compliance with the current rules and regulations of the Human Research Review Committee at Texas Woman's University (Appendix A) and the graduate school (Appendix B). Agency permission was also obtained (Appendix C). Since a chart review was utilized to obtain necessary data, no permission was requested from those individuals whose charts were used.

A potential risk existed to the agency in that it is the responsibility of the agency to assure anonymity for all patients. To minimize this risk, the following measures were taken: No names or identifying numbers were copied from the chart, and all data collection sheets were destroyed after the thesis was accepted by the university committee.

Instruments

A Transcutaneous Electrical Nerve Stimulator Study Data Collection Sheet (Appendix D) was designed by the researcher for data retrieval from the subjects' charts. Demographic material such as age, surgical procedure, and previous surgeries was obtained. A list of the pain

medications taken within 48 hours after surgery was obtained and totaled. The instrument had both face and content validity. Diers (1979) defined face validity as: "On inspection, the measure looks like it is a good indicator of the concept" (p. 230). Three faculty members of Texas Woman's University determined that the instrument does have face validity. Content validity means that the content of the measure can be justified from other evidence (Diers, 1979). Schuster and Infante (1979) stated that an exact measurement for pain has not yet been found. It was determined that the amount of pain medication taken postoperatively is probably as accurate a measurement as any other tool used to measure pain. Content validity of the instrument used for this study was based on the evidence presented by Schuster and Infante's (1979) research.

Data Collection

Data for this research were collected from the medical records of male arthrotomy patients whose knee surgery was performed between January 1, 1980 and January 31, 1981. After obtaining approval, medical records of patients meeting the criteria required were classified as Group A if a transcutaneous electrical nerve stimulator was used

for pain control after surgery. The medical records of patients not using a transcutaneous electrical nerve stimulator were classified as Group B.

The Transcutaneous Electrical Nerve Stimulator Study Data Collection Sheet devised for this study was used to collect data from the charts. The patient's age was obtained from the admission sheet. Whether or not the patient used a transcutaneous electrical nerve stimulator was discovered in the nurses' notes and/or physician's progress notes. Information concerning previous surgeries was found in either the nurse or physician history. The kind of surgery as well as the date and time was obtained from the surgical record. To obtain a list of pain medications used within 48 hours after surgery, the researcher reviewed nurses' notes appropriate for that time span.

Treatment of Data

The data collected were hand tabulated. A t test was used to compare the amount of medicine used by Group A to the amount used by Group B (Polit and Hungler, 1978). An average of the number of medicines used postoperatively by Group A was compared to the average number of medicines used by Group B. Demographic data were presented in tables

to determine if either Group A or Group B differed noticeably along the observed dimensions. The level of significance was set at .005 for this study.

CHAPTER 4

ANALYSIS OF DATA

An ex post facto research study was conducted to determine if patients using transcutaneous electrical nerve stimulation after arthrotomies for reconstructive knee surgery required less pain medication than those having similar surgery but not using electrical stimulation. The presentation of the data consisted of a description of the sample by age, type of surgery, and number of previous surgeries. The findings that related to both the study and the hypothesis follow.

Description of Sample

Ten charts of patients using transcutaneous electrical nerve stimulators postoperatively were reviewed. Twenty charts of patients not using transcutaneous electrical nerve stimulators after arthrotomies for reconstructive knee surgery were also reviewed. The ages of patients included in the study were limited from 16 years to 60 years. The stimulator group ranged from 19 to 58 years with the average being 33.3 years of age having a standard deviation of 16.4. The nonstimulator group ranged in age

from 16 to 59 years with the average being 28.8 years of age and having a standard deviation of 14.0.

The stimulator group was comprised of charts of four patients who had experienced an osteotomy, and five patients who had undergone ligament repairs. Two non-stimulator charts were matched to each stimulator group chart based on the surgical procedure. Therefore, the nonstimulator group was comprised of the charts of 8 patients who had undergone osteotomies, 2 patients who had had menisectomies, and 10 patients who had experienced ligament repairs. Table 1 presents the distribution of surgical procedures according to the number and group.

Table 1
Distribution of Surgical Procedures According
to Number and Group

	Stimulator Group	Nonstimulator Group
Osteotomies	4	8
Menisectomies	1	2
Ligament Repairs	5	10
Totals	10	20

n = 30.

Previous surgeries were recorded for each patient whose chart was utilized. Of the 10 charts of the stimulator patients, 4 had no previous surgery, 3 had undergone one surgery, 1 had experienced two previous surgeries, and 2 had three previous surgeries. Five of these patients had experienced knee surgery before this admission. Thirteen of the nonstimulator group charts revealed that the patients had not had any previous surgery. Two patients had each had one previous surgery, two had experienced two surgeries, and two more had experienced three previous surgeries. One patient had had five surgeries prior to this admission. Five of the nonstimulator group patients had also previously experienced knee surgery prior to this admission. Table 2 presents the number of previous surgeries.

Table 2

Number of Previous Surgeries According to Group

Group	None	One	Two	Three	Five
Stimulator	4	3	1	2	
Nonstimulator	13	2	2	2	1

n = 30.

Findings

Transcutaneous Electrical Nerve Stimulator Study

Data Collection Sheets were hand tabulated and then data were processed via computer. A t test was used to test the hypothesis that persons using a transcutaneous electrical nerve stimulator after arthrotomies for reconstructive knee surgery will use less pain medication than postarthrotomy reconstructive knee patients not using a transcutaneous electrical nerve stimulator. The stimulator group received pain medication on an average of nine occasions during the first 48 hours postoperatively. The nonstimulator group received pain medication on an average of 10.6 occasions during the first 48 hours postoperatively. There was no significant statistical difference in the amount of analgesics taken postoperatively by the two groups ($p = 0.17$) so the hypothesis as stated was not supported. Table 3 shows the number of occurrences pain medication was required by the patients in each group. No significant difference in the mean ages of the two groups was found ($p = .44$). There also was no significant difference in the number of previous surgeries experienced ($p = .64$).

Table 3
Number of Occurrences Pain Medication was
Required According to Group

Stimulator Group A (n = 10)		Nonstimulator Group B (n = 20)	
Mean	Standard Deviation	Mean	Standard Deviation
9.0	3.9	10.6	2.3

$$\underline{t} (28) = 1.43.$$

$$\underline{p} = 0.17.$$

A closer look at the data revealed some interesting findings. If the stimulator and nonstimulator groups could be further divided into Subgroup C (osteotomies and menisectomies) and Subgroup D (ligament repairs), the comparisons of the two groups changes. For Subgroup C, the mean number of occasions pain medicine was taken is 6.2 for the stimulator group and 10.7 for the nonstimulator group. This difference was significant ($\underline{p} = .005$) and revealed that when examining patients who had osteotomies and menisectomies, the stimulator group had fewer occasions of taking pain medication than those in the non-stimulator group who had the same surgeries.

When Subgroup D patients were separated and compared, no significant difference was found in the number of

occasions pain medication was taken. Therefore, there was no difference in the amount of pain medicine used by patients who had ligament repairs and used a transcutaneous electrical nerve stimulator and patients who had had a ligament repair and not used a transcutaneous electrical nerve stimulator. Table 4 presents the number of occurrences when pain medication was required by Subgroups C and D. Also, after being divided into Subgroups C and D, the ages were compared (see table 5).

Table 4

Number of Occurrences Pain Medication was
Required by Subgroups C and D

	Stimulator Group (<u>n</u> = 5)		Nonstimulator Group (<u>n</u> = 10)		Signifi- cance
	Mean	Standard Deviation	Mean	Standard Deviation	
Sub- group C	6.2	1.8	10.7	2.7	$t(13) =$ $\underline{3.38}$ $p = .005$
Sub- group D	11.8	3.4	10.5	1.9	$t(13) =$ $\underline{.96}$ $p = .35$

Table 5
Comparison of Ages in Subgroups C and D

	Stimulator Group (<u>n</u> = 15)		Nonstimulator Group (<u>n</u> = 15)	
	Mean	Standard Deviation	Mean	Standard Deviation
Subgroup C	45.8	14.5	38.1	14.2
Subgroup D	20.8	1.3	19.5	4.4

Summary of Findings

The findings of the study are summarized as follows:

1. The hypothesis that persons using a transcutaneous electrical nerve stimulator after arthrotomies for reconstructive knee surgery will use less pain medication than postarthrotomy knee patients not using a transcutaneous electrical nerve stimulator was not supported.
2. When analyzing the data according to the type of surgery performed, a significant difference was found between patients who had had osteotomies and menisectomies; however, no significant difference was found for patients having ligament repairs.

CHAPTER 5

SUMMARY OF THE STUDY

This study was conducted to determine if the use of transcutaneous electrical nerve stimulation reduces pain experienced after arthrotomies for reconstructive knee surgery. The basic research design was ex post facto, and a chart review was utilized to gather data. This chapter includes a summary of the study, discussion of the findings, conclusions and implication, and recommendations for further study.

Summary

The problem of this study was to determine whether or not there is a difference in the amount of pain medicine used by male arthrotomy patients utilizing a transcutaneous electrical nerve stimulator and male arthrotomy patients not using a transcutaneous electrical nerve stimulator. The theoretical framework for the study was Melzack and Wall's (1965) gate-control theory of pain. The study was conducted in the medical records department of a large, private general hospital located in the southern part of the United States. The data were obtained from charts of male arthrotomy patients between the ages of 16 and 60.

The following hypothesis was formulated for investigation: Male arthrotomy patients using a transcutaneous electrical nerve stimulator after reconstructive knee surgery will use less pain medication than male arthrotomy patients not using a transcutaneous electrical nerve stimulator. Data were collected by means of a chart review and recorded on Transcutaneous Electrical Nerve Stimulator Study Data Collection Sheets. A t test was utilized to test for significance of the amount of pain medicine taken by the stimulator and nonstimulator groups. Demographic data which related the subjects' ages, types of surgery, and number of previous surgeries were reported to further describe the sample. Findings of the study are summarized as follows:

1. There was no significant difference in the ages of the stimulator and nonstimulator groups ($p = .44$).
2. There was no significant difference in the number of previous surgeries experienced by the subjects of the stimulator and nonstimulator groups ($p = .64$).
3. There was no significant difference in the amount of pain medication taken postoperatively by the stimulator and nonstimulator groups ($p = .17$).

4. There was a significant difference in the amount of pain medication taken postoperatively by the subgroup composed of osteotomy and menisectomy patients ($p = .005$).

Discussion of Findings

Practical meaning and value may be derived from this study by the following interpretation of the results. Data from this study did not show transcutaneous electrical nerve stimulation to be effective in reducing postoperative pain despite previously reported studies which did show the transcutaneous electrical nerve stimulator to be effective (Cooperman et al., 1975; Hymes, et al., 1974; Schuster & Infante, 1979; VanderArk & McGrath, 1975). This discrepancy could be related to the small number of charts reviewed for the stimulator group patients (10 charts). Also, this study dealt with knee surgery patients and none of the previously mentioned studies involved any type of orthopedic surgery other than the back surgery studies by Schuster and Infante (1979). Pain from knee surgery could be different enough from other surgical pain to affect the usual response to transcutaneous electrical nerve stimulation. The results of this study could have also been affected by the lack of uniformity of postoperative transcutaneous electrical nerve stimulator management. Patients

were cared for by many different nurses and health professionals throughout their postoperative period. Each caregiver may have varied in approach and attitude towards the stimulators. As shown by Moss and Meyer (1966) and McBride (1967), the nurses' approach and interaction does affect the pain relief. Billars (1970) reported that the attitude of the nurse toward the pain relief measure does affect the patient. Therefore, if a nurse seemed extremely positive or skeptical as to the worth of transcutaneous electrical nerve stimulation, the patient might react in accordance.

Even though the ages of the stimulator and nonstimulator groups were not significantly different when viewed overall, there was a significant difference when the groups were further divided according to the surgical procedure. The stimulator group ligament repairs had a mean age of 21, and the nonstimulator group ligament repairs had a mean age of 19. This is considerably younger than the stimulator and the nonstimulator group osteotomies and menisectomies (mean of 38). Although no literature was found to confirm it, the younger patients who had ligament repairs might possibly have taken more pain medicine postoperatively due to lack of experience with painful occasions and curiosity about medication. When the younger

ligament repair patients were excluded from the calculations, data were significantly different for the remaining participants. When examining the osteotomy and menisectomy patients only, the patients using the transcutaneous electrical nerve stimulators requested significantly less medication than those not using the transcutaneous electrical nerve stimulators ($p = .005$).

The physiological theory behind the function of the transcutaneous electrical nerve stimulator is the gate-control theory of pain. Essentially, the neural input from the stimulator is mediated through large diameter afferents which, when activated, close the gate and prevent smaller diameter afferents from transmitting the pain information to conscious levels (Howson, 1978). When incomplete or no pain reduction is obtained by the transcutaneous electrical nerve stimulation, questions are raised:

1. Is the gate-control theory of pain invalid?
2. Do the transcutaneous electrical nerve stimulators actually function on the basis of the gate-control theory of pain?
3. Why does the transcutaneous electrical nerve stimulator not reduce pain for all patients?

4. Are there psychological aspects of pain reduction that were not considered in the study which may have affected the benefit of the transcutaneous electrical nerve stimulation?

The scope of this study provided insufficient data for the researcher to address any of these questions. However, the questions do indicate the need for further research on the gate-control theory of pain, the use of transcutaneous electrical nerve stimulation in pain reduction, and psychological aspects of pain control.

Conclusions and Implication

The following conclusions are based on the findings of the study:

1. Transcutaneous electrical nerve stimulation may possibly be effective in reducing pain of certain types of orthopedic surgeries but not be effective with all orthopedic surgeries.

2. The findings of this study do not support the gate-control theoretical framework.

3. The use of analgesics may not be an adequate measure of the degree of pain being experienced by the patient.

An implication that this study may have for nursing is that nurses should be knowledgeable and supportive

of pain-reducing techniques such as transcutaneous electrical nerve stimulation.

Recommendations for Further Study

Suggestions for further study include the following recommendations:

1. A similar study with a larger sample, randomly assigned, and subjects with only one type of surgical procedure could be conducted.
2. Further research on the validity of the gate-control theory of pain could be conducted.
3. Research dealing with psychological aspects of pain control could be conducted.

APPENDIX A

TEXAS WOMAN'S UNIVERSITY
Box 23717, TWU Station
Denton, Texas 76204

1810 Inwood Road
Dallas Inwood Campus

HUMAN SUBJECTS REVIEW COMMITTEE

Name of Investigator: Linda Sue Treadaway Henson Center: Dallas

Address: 8912 Westglen Date: 12/16/80

Dallas, Texas 75228

Dear Ms. Henson:

Your study entitled Effect of Transcutaneous Electrical Nerve

Stimulators on Postarthrotomy Pain

has been reviewed by a committee of the Human Subjects Review Committee and it appears to meet our requirements in regard to protection of the individual's rights.

Please be reminded that both the University and the Department of Health, Education, and Welfare regulations typically require that signatures indicating informed consent be obtained from all human subjects in your studies. These are to be filed with the Human Subjects Review Committee. Any exception to this requirement is noted below. Furthermore, according to DHEW regulations, another review by the Committee is required if your project changes.

Any special provisions pertaining to your study are noted below:

 Add to informed consent form: No medical service or compensation is provided to subjects by the University as a result of injury from participation in research.

 Add to informed consent form: I UNDERSTAND THAT THE RETURN OF MY QUESTIONNAIRE CONSTITUTES MY INFORMED CONSENT TO ACT AS A SUBJECT IN THIS RESEARCH.

____ The filing of signatures of subjects with the Human Subjects
Review Committee is not required.

____ Other:

XX No special provisions apply.

Sincerely,

Estelle D. Kurtz

Chairman, Human Subjects
Review Committee

at Dallas

PK/sml/3/7/80

APPENDIX B

TEXAS WOMAN'S UNIVERSITY

DENTON, TEXAS 76204

THE GRADUATE SCHOOL

February 16, 1981

Mrs. Linda Sue Treadaway Henson
8912 Westglen
Dallas, Texas 75226

Dear Mrs. Henson:

I have received and approved the Prospectus for your research project. Best wishes to you in the research and writing of your project.

Sincerely yours,

A handwritten signature in cursive script that reads "Robert S. Pawlowski".

Robert S. Pawlowski
Provost

RP:d1

cc Ms. Kathryn Jane Dawson
Dr. Anne Gudmundsen
Graduate Office

APPENDIX C

TEXAS WOMAN'S UNIVERSITY
COLLEGE OF NURSING

AGENCY PERMISSION FOR CONDUCTING STUDY*

THE _____

GRANTS TO LINDA SUE HENSON, R.N.

a student enrolled in a program of nursing leading to a Master's Degree at Texas Woman's University, the privilege of its facilities in order to study the following problem.

Does the transcutaneous electrical nerve stimulator reduce the amount of pain medication used by postarthrotomy knee patients? A chart review is planned to compare the amount of analgesics used by knee surgery patients with and without transcutaneous electrical nerve stimulators.

The conditions mutually agreed upon are as follows:

1. The agency (~~may~~) (may not) be identified in the final report.
2. The names of consultative or administrative personnel in the agency (~~may~~) (may not) be identified in the final report.
3. The agency (wants) (~~does not want~~) a conference with the student when the report is completed.
4. The agency is (willing) (~~unwilling~~) to allow the completed report to be circulated through interlibrary loan.
5. Other _____

Date: 11-19-80

Linda Henson
Signature of Student

Signature of Agency Personnel

Jane Dawson
Signature of Faculty Advisor

*Fill out & sign three copies to be distributed as follows:
Original - Student; First copy - Agency; Second copy - TWU College of Nursing.

APPENDIX D

Date and time

Pain medication taken within the first 48 hours after surgery:

[illegible]

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