USER SATISFACTION, FUNCTIONABILITY, GRIP STRENGTH, AND PINCH STRENGTH ASSOCIATED WITH A PROTOTYPE SPLINT

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PREFACE

This thesis is the outcome of a functional design project for a Functional Design course. The search for a more comfortable and effective functional hand and /or wrist splint resulted in the development of a prototype functional splint. A few studies have investigated the perceived comfort and effectiveness of functional hand and /or wrist splints. This work was an attempt to determine the perceptions of comfort and effectiveness of a prototype splint. Chapter I is a review of problems and medical conditions that require the use of a functional splint, different kinds of splints, and purpose, objectives, hypotheses, and limitations of the study.

Chapter II investigates the causes of hand and/or wrist orthopedic dysfunction, available treatments, clothing comfort, grip strength, pinch strength, and previous studies. Chapter III includes process, testing procedures and outcomes that resulted in the development of the prototype functional hand and/or wrist splint, testing and evaluation of the prototype splint, the experimental protocol for the evaluation of the prototype splint, and the statistical analyses. Chapter IV is the manuscript that is being prepared for submission to "Arthritis Care and Research" and Chapter V encompasses summary conclusions, and recommendations.

Findings of this study indicate that the prototype splint was a comfortable and highly effective. The results presented here emphasis the fact that use of functional splint is very task specific.

This work is the pinnacle of a five-year endeavor during which I have benefited from the help of many individuals and overcome many impediments. However, I am mostly indebted to Dr. Donna Branson, my advisor. I wish to express my sincere gratitude to Dr. Branson, without whose continuous support and concern this work would have not been possible. I appreciate Dr. Janice Park and Dr. Bert Jacobson for their participation in my committee and their help and guidance. I also thank Dr. Lary Claypool for excellent advice in statistical analysis. In addition, I appreciate Dr. Mark Munson for providing the orthopedic expertise, which was an essential part of this study.

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CHAPTER I

INTRODUCTION

Hand movement is very important in daily life. When there are problems with the hand and/or wrist, day-to-day activities are difficult to accomplish. Arthritis, fluid accumulation (edema) due to hemodialysis (Kulick, 1996), sudden weight gain like pregnancy (Tapley, Weiss, and Morris, 1985), overuse syndromes such as carpal tunnel syndrome (CTS), tenosynovitis of the dorsal wrist extensor compartments and flexor tendons of the wrist, and trigger finger (Verdon, 1996) are examples of problems that can be encountered with the hand and/or wrist. These problems lead to loss of time from work, medical and vocational rehabilitation expenses, and loss of productivity (Louis, Calkins, and Harris, 1996). In general, these problems are managed through medical treatments accompanied with a therapeutic regimen.

Overuse syndromes such as CTS, arthritis, and injuries of the hands and/or wrists are treated with standard drug therapy and joint protection (Weinstock, 1993). Standard treatment includes rest, non-steroidal anti-inflammatory drugs (NSAIDs), and corticosteroid injection (Verdon, 1996). Joint protection may be accomplished by placing the hand and/or wrist in a "non-deforming position" (Weinstock, 1993), or by using splints or orthopedic devices to limit or immobilize the hand and/or wrist (Sailer, 1996).

There are many different types of custom-designed and ready-to-wear hand and/or wrist splints (Anderson and Maas, 1987). Soft and hard splints are used to immobilize the hand and/or the wrist of individuals with arthritis and to alleviate the symptoms of arthritis by reducing the stress on the damaged joint (Callinan and Mathiowetz, 1996). Dynamic and static splints are used after surgery and implantation. The dynamic splint allows active flexion of the digits and facilitates achievement of the correct posture. The static splint is used at night (Stirrat, 1996). The commercial static wrist extensor orthoses, also known as the functional or working orthoses, (Anderson and Maas, 1987), is designed to support the wrist and facilitate the functional use of the hand (Stern, 1996).

Hand and/or wrist splints decrease inflammation, reduce pain, protect wrist joints, provide support, reduce stiffness, and prevent deformity (Falconer, 1991). However, individuals with problematic hands and/or wrists show low compliance with wearing hand and/or wrist splints (Callinan and Mathiowetz, 1996). Poor compliance with wearing hand and/or wrist splints is thought to be due to a number of reasons that include discomfort, low wearing tolerance (Callinan and Mathiowetz, 1996), interference with function, poor appearance, and failure to reduce pain (Hicks, Leonard, Nelson, Fisher, and Esquenazi, 1989).

Background Information

A number of studies have investigated the effectiveness of different kinds of splints (Gumpel and Cannon, 1981; Anderson et al., 1987; Nordenskiold, 1990; Feinberg, 1992; Stern, 1996; Stern et al. 1996; and Callinan et al., 1996). However, only a few studies have investigated the comfort aspect of the functional hand and/or wrist splints. The Callinan and Mathiowetz (1996) study indicated that individuals with rheumatoid arthritis preferred soft hand resting splints to the hard ones. Stern et al. (1997) concluded that satisfaction with a splint depended on its therapeutic effect, comfort, and ease of use. They suggested that patients' satisfaction could be maximized by improving the likelihood of appropriate fit and comfort through availability of several styles of functional splints.

Due to personal rheumatoid arthritis experience and difficulty in finding an effective and comfortable functional hand and/or wrist splint, the researcher became interested in functional splints. As a requirement for a functional design class, the researcher developed a prototype functional hand and/or wrist splint using the functional design process as given in Watkins (1984). The prototype was designed to provide greater comfort as well as a more pleasing appearance than existing functional hand and/or wrist splints.

Purpose

The purpose of this study was to evaluate the perceived comfort and the effectiveness of a prototype functional hand and/or wrist splint through a four-week wear study.

Objectives of the Study

The objectives of the study included the following:

1. Administer a "Pre-Test Questionnaire" to obtain subjects' perceptions of their existing splints.
2. Administer grip strength and pinch strength tests on subjects, while they were

wearing their current splints.

3. Have subjects complete a "Daily splint evaluation" log during the four-week wear test period.
4. Administer a "post-test questionnaire" to obtain subjects' perceptions of the prototype splint following the four week wear test.
5. Administer grip strength and pinch strength tests on subjects at the end of the study, after they wore the prototype splints for four weeks.
6. Determine perceived comfort and effectiveness of the prototype splint as compared with subjects' perception of comfort and effectiveness of their existing splints.
7. Determine if a relationship between perceived comfort and perceived effectiveness of the prototype splint exist.

Hypotheses

Ho1: There will be no significant differences between subjects' comfort perceptions regarding their existing splints and the prototype splint.

Ho2: There will be no significant difference in grip strength associated with wearing the existing splint and the prototype splint.

Ho3: There will be no significant difference in pinch strength associated with wearing the existing splint and the prototype splint.

Ho4: There will be no significant differences between perceived effectiveness of the existing splints and the prototype splint where perceived effectiveness included ease of donning and doffing and effectiveness while performing activities of daily living.

Limitations of the study

1. Only nine volunteer subjects participated in the study.
2. Subjects have not been chosen based on a specific disease that causes hand and or wrist orthopedic dysfunction.
3. Subjects have not been chosen based on a specific type or brand of splint that they were using.
4. A control group was not used for this study.
5. The effect of taking medication were not controlled nor considered as part of this study.

CHAPTER II

LITERATURE REVIEW

There is limited literature related to this topic. Researching the available resources resulted in the following information. This chapter investigated six topics: causes of hand and/or wrist orthopedic dysfunction, available treatments, clothing comfort, grip strength, pinch strength, and previous studies.

Causes of Hand and/or Wrist Orthopedic Dysfunction

The effective use of the hand and/or wrist in everyday activity depends on anatomic integrity, muscle strength, coordination, mobility, sensation, age, sex, and mental state (Jebsen, Taylor, Trieschmann, Trotter, and Howard, 1969). A wide variety of conditions (e.g., rheumatoid arthritis, post-traumatic arthritis, osteoarthritis, septic arthritis, carpal instability, spasticity, and various inflammatory arthritides) can cause chronic pain and loss of function in the wrist and hand (Murray, 1996).

Rheumatoid arthritis (RA) is a chronic, systemic, and progressive disease that causes pain and inflammation within the joints, especially joints of the hands and feet (Milazzo, 1979). In progressive RA, 95% of the patients develop arthritic symptoms in the wrist (Blank and Cassidy, 1996). Research indicates women are affected three times more than men (Jayson and Dixon, 1984).

Overuse syndromes, repeated strain and cumulative trauma on a specific body part, usually affect the neck, shoulder, elbow, wrist, and hand (Verdon, 1996). These syndromes affect the wrist, primarily in the form of work-related carpal tunnel syndrome (CTS) (Verdon, 1996). Fifteen percent of the workers who are at risk for overuse syndromes can develop CTS (Masear, Hayes, and Hyde, 1986) and the risk of developing tendinitis doubles in these situations (Moore, 1992).

In addition, injuries to the neurologic or musculoskeletal parts of the upper extremity can cause weakness and/or pain that may result in impairment and disability (Janda, Geiringer, Hankin, and Barry, 1987).

Available Treatments

Impaired hand and/or wrist function may be improved by physical therapy, medication, and joint protection through splinting (Jebsen et al., 1969). Medication includes non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroid injection, and rest (Verdon, 1996). To protect the affected joint, the hand and/or wrist maybe placed in a "non-deforming position" (Weinstock, 1993). A splint or orthopedic device may also be used to limit or immobilize the hand and/or wrist (Sailer, 1996).

The main reason for splinting is to modify or minimize drag (any factor preventing a joint's free motion in response to a muscle contraction), facilitate better function (Ouellette, 1991), provide rest, prevent or correct deformity, provide support, and stabilize the affected joint in a functional position to facilitate movement in other joints (Lawton, 1974). Functional splints align, stabilize, decrease or increase a joint's action, facilitate specific hand functions or tasks, and relieve pain caused by performing functional activities (Falconer, 1991). Functional wrist splints have been recommended by occupational therapists for treatment of RA and other similar hand and/or wrist disorders (Anderson et al., 1987). Splints are designed to facilitate the function of muscles and joints in a mechanically correct position when there are damaged joints (Falconer, 1991).

Functional splints come in a wide variety of styles and materials. The most common design features in these splints are a gauntlet style glove in a fabric (usually from elasticized materials) and a removable volar metal stay, which supports the wrist and hand (Stern, 1996). This type of wrist splint is recommended by occupational therapists when there is no need for custom fitting, moderate wrist movement is allowed, and wrist support is required instead of wrist immobilization (Melvin, 1989). The appropriate commercial wrist splints offer the patient a sufficient and effective treatment for weakness, temporary wrist pain, or mild inflammation while providing the splinted hand with functional use (Melvin, 1989).

Clothing Comfort

There is a large body of literature linking to comfort in general and textile related comfort. Human comfort is defined by Sontag (1985-1986) as a "mental state of ease of well-being, a state of balance or equilibrium that exists between a person and the environment" (p. 10). Slater's definition of comfort indicates "comfort is a pleasant state of physiological, psychological and physical harmony between a human being and the environment" (1985, p. 4). According to Branson and Sweeney (1991), the complex phenomenon of clothing comfort for an individual wearing a specific ensemble under specific environmental conditions is the result of interaction among a number of physical and non-physical variables. They defined clothing comfort as a "state of satisfaction indicating physiological, social-psychological, and physical balance among a person, his/her clothing, and his/her environment." (1991, p. 99).

Hatch, Markee, and Maibach (1992) in their paper " Skin response to fabric: A review of studies and assessment methods" investigated the response of human skin to fabric when skin is in contact with fabric. Based on this study, skin and fabric create a thermal and sensorial state of comfort that maintains an individual's physical health state. Health is defined by the World Health Organization as "a state of complete physical, mental, and social well being." (Hatch et al. 1992).

Hatch et al. (1992) stated that clothing comfort and clothing health form a continuum with a state of comfort and health at the extreme left, different degrees of discomfort (like feeling cool or warm, or feeling prickliness or roughness, or psychological uneasiness) at the center, and an unhealthy state at the extreme right. They explained that an unhealthy state is the result of failure of the body and fabric regulatory mechanisms to prevent hypothermia or burn injury, as well as skin reaction to chemicals absorbed from fabrics.

Researchers have demonstrated that different variables relative to the person, clothing, and environment influence perception of clothing comfort. Clothing thermophysiological comfort studies may investigate the relationship of garment variables, such as fabric structure, finish, fiber content, and garment design to moisture and heat retention and/or transfer to subjects' physiological and behavioral response in a given environment or several environments.

On the other hand, clothing contact comfort research has investigated fabric variables and their relationship to perceive unpleasant sensations such as rough, prickly, sticky, and clammy (Hatch et al. 1992). Hollies, Custer, Morin, and Howard (1979) developed a psychological scale and protocol to examine relationships between fabric structure, perceived contact comfort, and environmental parameters. They measured human perception of contact comfort by rating the intensity of comfort sensations like rough, loose, picky, heavy, clingy, staticy, damp, and clammy when humidity and exercise were manipulated. Hollies and his colleagues (1979) used male and female subjects while wearing two different kinds of shirts and jeans to illustrated details of the human perception approach to comfort. Their statistical analyses demonstrated that cotton garments provided better comfort.

Pontrelli's (1977) "Comfort Gestalt" model listed a number of parameters that he considered causes of experiencing comfort or discomfort. These parameters were grouped under three following distinct categories: 1) a combination of the physical environmental variables including: fabric transport properties, person activity level, and clothing, 2) a combination of psycho-physiological variables like state of being, occasion and end-use of clothing, tactile aesthetic, etc., and 3) stored modifiers that included elements of an individual's past experiences, expectations, and fantasies. According to Pontrelli, the comfort gestalt implied that feeling of comfort or discomfort hinged upon the interactions between physical, physiological and psychological stimuli and the conscious and subconscious stored modifiers of an individual.

Fourt and Hollies (1970) believed comfort included three separate entities of the person, the environment, and clothing. They viewed clothing as an extension of the body or as a part of the environment that a person consciously selects and adjusts to provide comfort and protect the human body from adverse environmental effects. Sontag (1985-1986) on the other hand, used a human ecological approach (Bubolz, Eicher, and Sontag, 1979) to model impact of the attributes of the person, clothing, and environment on comfort perception and behavioral response. She depicted the triad as three concentric circles with relevant attributes listed in each circle, and a two-way arrow representing the interaction between the person, the clothing, and the environment, for example a change in environment conditions would cause a physiological response and most likely a behavioral response.

Sweeney and Branson (1990a, 1990b) used psychophysical methods to investigate the relationship between moisture stimulus intensity and perceived moisture intensity on an area of subjects' upper back through application of wetted fabric swatches. They demonstrated that psychophysical scaling is another tool for investigating clothing comfort.

Grip Strength

Napier defined (1956) prehensile movements as seizing and holding of an object by wrapping the hand around it. He divided prehensile movements into power and precision grip. Power grip happens when an object is held in a clamp. Precision grip occurs when an object is pinched between the thumb and the fingers. Functional activities often involve both grips. He further indicated that the size and shape of the object and the nature of the intended use determined the grip.

Hand grip was used as a means of determining strength by Sargent for the first time in 1880 (Schmidt and Toews, 1970). Since then, grip strength has been associated with physical fitness, hand dominance, and normal growth (Everett and Sills, 1952). In addition, the hand-grip test has been used to determine severity of injuries to upper extremity as well as restoration of grip strength through rehabilitation programs (Schmidt and Toews, 1970).

Kirkpatrick (1956, p.286) outlined grip strength as: "(1) Grip is a force. (2) Grip is not pressure. (3) The measurement of grip must be in force units such as the pound or the gram." Grip strength is a measurement that is used to evaluate the effectiveness of treatment of individuals with hand dysfunction (Flood-Joy and Mathiowetz, 1987). Among the various types of measuring instruments that have been used to quantify grip strength, the Jamar dynamometer is the most accurate and has the highest reliability (Mathiowetz, Weber, Volland, and Kashman, 1984). Grip strength is influenced by a number of variables related to subjects, equipment, and the design of the experiment.

Subject Variables

Grip strength is affected by a number of subject variables including body position, sincerity of effort, age, the sex of the subject, hand dominance, body weight, and height.

Body Position

The effect of body position has been investigated by several studies. Teraoka's (1979) research results indicated that grip strength was significantly stronger in standing position than sitting and significantly stronger in sitting position than supine. On the other hand, Mathiowetz, Rennells, and Donahoe (1985) study demonstrated that grip and pinch strengths of the right hand were significantly stronger with elbow flexed at 90 degrees as oppose to a fully extended elbow. Woody and Mathiowetz (1988) reported a significantly stronger key pinch strength while subjects' forearms were in mid-position between pronation and supination versus the fully pronated position.

Other studies researched the effect of wrist position on the grip strength. There was no significant difference in grip strength with wrist in neutral, 15 or 30 degrees of extension, according to Kraft and Detels (1972). However, they reported when the wrist was flexed at 15 degrees, scores were significantly lower. Pryce's (1980) findings indicated that grip strength scores from the 15-degree flexed position and the 30-degree ulnar deviation position were significantly lower than scores from the other seven wrist positions between neutral and ulnar deviation, and fifteen degrees each side of neutral in volar and dorsiflexion. Apfel (1986) noticed that during the testing period, 29 out of 30 subjects used the flexed position spontaneously. She also found that subjects showed 28 to 38 percent higher scores in key pinch when their thumb interphalangeal joint was flexed versus extended. Findings of these studies demonstrate the need for using a standardized body position while measuring grip and pinch strengths.

Sincerity of Effort

Studies show contradicting results on sincerity of effort. Stokes (1983) tested his subjects at five handle settings to demonstrate that grip strength measurement can objectively document real loss of grip as oppose to fictitious loss. His results indicated that subjects with true grip weakness had a slightly skewed bell-shaped curve for both the injured and uninjured hand. While subjects with fictitious grip weakness had a straight line curve for the fictitiously weak hand and a bell-shaped curve for the uninjured hand. However, the Niebuhr and Marion (1987) study showed significant differences between the sincere and fictitious condition and between handle positions. In addition, their results did not confirm Stokes' findings that subjects faking a weak grip had equal grip strength for the five handle positions.

Age

Several studies suggested that the relationship between hand strength and age is curvilinear. From 6 to 19 years of age, hand strength increased rapidly (Mathiowetz, Wiemer et al., 1986). Hand strength peaked from 20 to 50 years of age and gradually declined after the peak (Montoye and Lamphiear, 1977; Fike and Rousseau, 1982; Mathiowetz, Kashman, et al., 1985). It peaked most commonly in the 30 to 34 year old age group (Mathiowetz, Kashman, et al. 1985). It seams that age is an important variable that should be considered when measuring grip and pinch strengths.

Sex of the Subject

Researchers also investigated the effect of subjects' sex on hand strength. In general, males have stronger hand strength than females (Mathiowetz, Kashman, et al., 1985 and Mathiowetz, Wiemer, et al., 1986). Robertson and Deitz (1988) found no significant difference in grip strength of 3 to 5½ years old boys and girls. However, boys from 6 to 13 years old generally had slightly stronger hand strength than girls of the same age group (Mathiowetz, Wiemer, et al., 1986; Ager, Olivett, and Johnson, 1984; and Jones, 1947). The differences between male and female hand strength increased rapidly from 14 to 20 years and from 20 to 50 years, males were stronger than females by 40 to 70 percent, according to Mathiowetz, Kashman, et al., 1985 and Mathiowetz, Wiemer, et al., 1986. The difference in males' and females' hand strength gradually declined from age 50 and above (Mathiowetz, Kashman, et al., 1985). As a result, sex of the subject is a variable that must be taken into account in measuring hand strength.

Hand Dominance

The effect of hand dominance on grip and pinch strengths has been treated differently by various researchers. As Kellor, Frost, Silberberg, Iversen, and Cummings (1971) indicated, there is no accepted universal method of determining hand dominance. They believed that there is a continuum of dominance from pure right to pure left with different graduations and combinations in between. Some studies used hand dominance data as dominance/non-dominance (Schmidt and Toews, 1970; Lunde, Brewer, and Garcia, 1972; Swanson, Matev, and Groot, 1970; Thorngren and Werner, 1979). Other studies ignored the hand dominance issue and reported data as right/left (Kellor, et al., 1971; Fike and Rousseau, 1982; Mathiowetz, Kashman, et al., 1985; Teraoka, 1979; Mathiowetz, Wiemer, et al., 1986). However, there are some studies that analyzed the right-hand scores and left-hand scores separately (Mathiowetz, Kashman, et al., 1985; Weiss and Flatt, 1971; Burmeister, Flatt, and Weiss, 1974; Fullwood, 1986).

Body Weight and Height

Variables of body weight and height have a positive relationship with hand strength (Schmidt and Toews, 1970; Lunde, et al., 1972; and Fullwood, 1986). According to Lunde et al. (1972), as height and weight increased, grip strength increased. However, height and weight accounted for a relatively small percentage of the variability. Therefore, height and weight are not very important variables in measuring hand strength.

Equipment Variables

Grip strength is affected by equipment variables such as handle spacing of the adjustable handle dynamometer. The handle spacing of the adjustable dynamometers is an essential element in grip strength measurement. The Niebuhr and Marion (1987), Fess (1982), and Bechtol (1954) studies indicated that at the second or third handle position from the inside, subjects' scores were the highest. Evidence indicates that handle position must be controlled when measuring grip strength.

Experiment Design Variables

Variables involved in the design of the experiment have the potential to impact the grip strength. These variables include multiple trials within a session, multiple sessions (test-retest reliability), and multiple raters (interrater reliability).

Multiple Trials Within a Session

The issue of multiple trials within a session deals with fatigue effect. Several studies indicated that fatigue does not have an impact on hand strength (George, 1970;

Jerslid, 1932; Newman, D., Pearn, Barnes, Young, Kehoe, and Newman, J., 1984). While Reddon, Stefanyk, Gill, and Renney (1985) reported that non-dominant hand grip strength of six men and six women declined significantly over 10 trials, this decline was relatively small. Mathiowetz (submitted for publication) examined the effects of completing three trails of grip, tip pinch, key pinch, and palmar pinch measurements on fatigue of 49 normal and 49 disabled subjects. He concluded that even though there were statistically significant differences within the three trial measurements, the differences in means were so small that they did not have practical significance. Although there might be a small fatigue effect over multiple sessions it does not appear to have practical significance.

Multiple Sessions (Test-retest Reliability)

Several studies investigated effects of multiple sessions (test-retest reliability). Mathiowetz, et al. (1984) tested grip strength with the Jamar dynamometer, and tip, key, and palmar pinch strengths with the B&L Engineering pinch gauge three times at standard positioning and instructions. They used means of three trials that resulted in the highest test-retest reliability, ranging from .81 to .93 while using only one trial resulted in the lowest test-retest reliability (.52 to .86). Woodard (1988) used the same conditions and equipment as Mathiowetz, et al. (1984) except he used the digital Jamar dynamometer for the grip strength test. Using the mean of three trials, he achieved .95 test-retest reliability. It appears that using the mean of three trials is a good trade-off between acceptable test-retest reliability and economy of time.

Multiple Raters (Interrater Reliability)

Mathiowetz, et al. (1984) used the standard Jamar dynamometer and the B&L Engineering pinch gauge and measured the grip and pinch strength of 27 individuals. The results indicated that the interrater reliability between two raters was very high (.979 to .999) which implied minimal variability between the raters. Consequently, based on this study, when standards procedures are followed, multiple raters are not significant variables in hand strength measurement.

Pinch Strength

The American Society of Hand Therapists (ASHT) has identified three types of pinch strengths palmar pinch, key pinch, and tip pinch (Fess and Moran, 1981). Palmar (three-jaw chuck) pinch is thumb pad to pads of the index and middle fingers. Key (lateral) pinch is pad of the thumb against the lateral part of middle phalanx of the index finger. Tip (two-point) pinch is thumb tip to index finger tip.

There are only a few instruments to measure pinch strength; however, Mathiowetz, et al. (1984) found the pinch gauge produced by B&L Engineering to be the most accurate. Pinch strength is influenced by the same variables as grip strength.

Previous Studies

The effectiveness and comfort of different kinds of splints have received limited attention from researchers. Gumpel and Cannon (1981) compared two kinds of ready-made, lightweight, fabric hand and/or wrist splints (Futuro and Spencer) in terms of support, suitability for daily routine, comfort, and ease of donning and doffing. Sixteen patients with RA were assigned to the two splints for the same period of time according to a pre-determined randomized order. Results indicated no difference between the two splints in regard to support, comfort, and ease of donning and doffing. Both splints interfered almost equally with some daily routines with the Futuro splint doing marginally better.

Anderson and Maas (1987) theorized that splinting of the dominant and non-dominant hands of patients with RA would reduce pain, and as a result, grip strength would increase. The Ritchie Rating Scale ranging from 0 to 3 was used to measure the wrist-pain level. Ninety-two volunteer female RA patients were randomly assigned to one of five independent groups (four splinting groups and a control group). Four splinting groups were fitted for four kinds of working splints (dorsal, palmar, gauntlet, and elastic ready-made) and grip strength for the dominant and non-dominant hands was measured (using a modified sphygmomsnometer). The results showed some pain reduction in both hands, but it was not statistically significant and there was no immediate increase in grip strength regardless of the type of splint.

Biddulph (1981) studied the effect of the Futuro wrist splint on the grip and pinch strengths of 22 subjects with osteoarthritis, rheumatoid arthritis, tenosynovitis, and gout of the wrist. On the first day of the study, grip and pinch strengths were measured for both the unsplinted hand and the hand wearing the Futuro splint. After ten days of using the Futuro splint, a third grip strength measurement was taken. A dynamometer obtained from Asimow Engineering was used for all three sets of measurements. The initial splinted grip and pinch strengths decreased from the unsplinted grip and pinch strengths.

After ten days of splint use, the post splinted grip and pinch strengths increased by almost 23.7% and 14.8% of the initial non-splinted grip and pinch strengths measurements, respectively.

In his investigation, Nordenskiold (1990) studied the effect of two types of soft volar wrist splints on pain, grip strength and function of splinted dominant hand. The research results indicated that application of splints significantly reduced pain when the three standardized ADL tasks were performed. The three ADLs included: 1- setting a breakfast table for two people (standing and walking), 2- filling a glass with milk from a full carton (sitting), 3- vacuuming a floor without a rug for three minutes with one hand (walking). Findings also showed that use of both splints significantly increased the pain-free grip strength.

Kjeken, Moller, and Kvien (1995) compared the effect of the Rehband elastic wrist splint on pain, motion, and wrist function of 36 subjects who used the splint during two standardized tasks performance compared to the control group consisting of 33 subjects. The two standardized tasks were pouring a glass of water from a one-liter carton and cutting three slices of brown cheese. Six months of splint use improved wrist function, reduced pain, and increased grip and pinch strength by 24% and 11% respectively.

Stern, Ytterberg, Krug, Mullin et al. (1996) investigated the immediate and short-term effects of using three types of commercial wrist splints (Roylan, Futuro #33, and AliMed Long) on function and grip strength of 36 RA patients. Grip strength of the splinted and non-splinted dominant-hand was measured at initial exposure to the splints (all three splints) and after one-week of use. All subjects used all three splints. The results indicated that all three splints reduced grip strength during first wear. After a one-week adjustment period, Roylan wearer's grip strength was the same for splinted and non-splinted hand. The other two splints yielded significantly lower grip strength than those wearing Roylan and continued to reduce grip strength. Subjects indicated the Roylan was more comfortable than the other two splints.

Stern, Ytterberg, Krug, and Mahowald (1996) compared the effect of wearing three styles of commercial hand and/or wrist splints (Roylan, Futuro, and AliMed Long) on finger dexterity and hand function of the dominant hand of 42 subjects with RA. Splinted and non-splinted dominant hands were tested for finger dexterity and hand function at the initial setting and after using each splint for one-week. Two sub-tests from the Purdue Pegboard Test and the Jebsen-Taylor Hand Function Test were used for finger dexterity and hand function, respectively. The results indicated that all three splints significantly and similarly reduced finger dexterity and hand function.

Stern (1996) compared the effects of five styles of functional wrist splints (Roylan, Futuro, AliMed Long, AliMed Short, and LMB) on grip strength and finger dexterity of 23 right-hand-dominant women with no upper extremity dysfunction. The Purdue Pegboard's unimanual sub-test was used to measure finger dexterity and a Jamar hydraulic dynamometer was used to measure grip strength. Results showed finger dexterity due to wearing the Futuro, AliMed Short, Roylan, and LMB splints did not significantly differ from finger dexterity of the unsplinted hand. AliMed Long splint reduced finger speed in comparison with speeds afforded by LMB splints and the unsplinted hand. Grip strength was not significantly different from the unsplinted hand for the Rolyan splint. Other four splints reduced grip strength in comparison with the Rolyan splint and the unsplinted hand.

The Pagnotta, Baron, and Korner-Bitensky (1998) study investigated the effect of wearing a wrist splint (Futuro) on work performance, hand dexterity, and pain during task performance. Two tasks (one simulating the use of shears, the other the use of a screwdriver) were used to measure splinted and non-splinted hand work performance. Splinted and non-splinted hand dexterity was measured using the Jebsen Hand Function Test. Pain was measured before and after work performance using a 10-cm horizontal visual analog scale. The results showed splint wear significantly reduced pain. Also, splint-wear decreased work performance, its effect on work performance was highly task specific.

Although several studies investigated the effectiveness of splints on pain and compliance, few studies considered the comfort aspect of the splint. This is important because discomfort could affect splint wearers' compliance of a given regimen. Different variables relative to the person, clothing, and the environment influence perception of clothing comfort. According to Branson and Sweeney (1991), the complex phenomenon of clothing comfort for an individual wearing a specific ensemble under specific environmental conditions is the result of interaction among a number of physical and non-physical variables.

Callinan and Mathiowetz (1996) noticed patients' comfort and wearing tolerance impacted compliance; therefore, the splint materials were crucial elements for an effective treatment. They compared the effect of soft and hard resting hand and/or wrist splints on hand pain and function. The Arthritis Impact Measurement Scales 2 (a self-administered questionnaire for arm and hand function), a pain localization diagram, a calibrated Jamar dynamometer, and a daily diary (of splint wear, medication, morning stiffness, and level of activities) were used for the above purpose. The researchers also determined the effect of splint preference and comfort on compliance through a subjective splint rating form. Findings indicated resting hand and/or wrist splints reduced pain and RA patients preferred the soft splints and were more compliant.

Forty-two RA patients were studied by Stern et al. (1997) to examine their preference patterns for three commercial hand and/or wrist splints (Futuro, AliMed Long, and Roylan). Subjects used each of three splints for one week while there was a one-week wash out period between each week of use. They used each splint at least four hours a day while performing functional tasks for five out of seven days and completed a daily "splint diary." In order for subjects to compare and contrast the three splints, a private semi-structured interview was conducted at each subject's final session. Results indicated splints were deemed to provide comfort and a sense of security during functional tasks only if they were comfortable and well fitting. No single splint was suitable for all subjects; therefore, researchers concluded satisfaction with a splint rested on its therapeutic effect, comfort, and ease of use. They suggested that patients' satisfaction could be maximized by improving the likelihood of appropriate fit and comfort through availability of several styles of functional splints.

This study investigated the perceived comfort and the effectiveness of a prototype functional hand and/or wrist splint through a four-week wear study.

CHAPTER III

METHODOLOGY

The purpose of this study was to investigate the perceived effectiveness and comfort of a prototype functional hand and/or wrist splint for people with hand and/or wrist problems. This chapter has three major components: a description of the process, testing procedures and outcomes that resulted in the development of the prototype functional hand and/or wrist splint, testing and evaluation of the prototype splint, and the statistical analyses used to determine significance.

Development of the Prototype Functional Hand and/or Wrist Splint

Seven steps of the design process as given in Watkins (1984), were used to develop the prototype splint. In step one, *request made,* problem was identified as discomfort associated with functional hand and/or wrist splints. In step two, *design situation explored,* good quality information was gathered quickly and easily to better define the problem. This task was accomplished through literature review, interview with splint users, and brainstorming. In step three, *problem structure perceived,* data were obtained using research methods for a market analysis, user survey, and textile tests to answer specific questions in support of designing functional splints.

In step four, *specifications described,* the desired characteristics for a prototype splint were described. In step five, *design criteria established,* an interaction matrix was created to identify the conflicting specifications. Then, design criteria were ranked according to their importance and accommodations for conflicting specifications were considered. In step six, *prototype developed,* the prototype splint was designed using findings in the previous steps. In step seven, *prototype evaluation,* the prototype splint was evaluated against the product specifications. However, the prototype splint's functional effectiveness and comfort were evaluated by a wear test study that is the subject of this research.

The prototype splint consists of two layers of fabrics. The following test methods were performed on two candidate fabrics suitable for the exterior fabrics and six candidate fabrics suitable for the interior fabric layer to evaluate the selected candidate fabrics for this project:

- AATCC Test Method 135-1973, Dimensional Changes in Automatic Home Laundering of Durable Press Woven or Knit Fabrics,
- AATCC Test Method 61-1975, Colorfastness to Washing, Domestic; and Laundering, Commercial: Accelerated,
- ASTM Designation: D 3884 - 92, Standard Test Method for Abrasion Resistance of Textile Fabrics (Rotary Platform, Double-Head method),
- Laboratory Test Methods for Measuring Wicking.

Fabric for the exterior layer was selected based on the results from the textile tests. Specifically, a 100% cotton denim twill weave had a better abrasion resistance and color fastness to washing than the other candidate fabric. The selection of the interior fabric was based on the results of wicking and dimensional stability tests. A jersey knit, 2% nylon and 48% polyester blend, had better wickability and greater dimensional stability.

Figures 1 and 2 illustrate the design of the prototype functional hand and/or wrist splint. The closure system includes a Velcro strip, 2" x 4", which is covered with a layer of fabric to prevent it from attaching to the surrounding surface. A double fold bias tape binds all edges of the splint. The palmar section of the splint includes a padded pocket, which houses the removable volar stay. In addition, the LMB-blend splinting material, a blend of plastic and rubber, is used to make the volar stay. Typically, the volar stay is made of metal. The advantage of the LMB-blend material is that it is malleable when placed in hot water, thus allowing a custom fit for a subject's hand. The LMB-blend material has small holes (two millimeters in diameter) spaced two and a half centimeters from each other (Figure 3). According to product literature, these holes facilitate perspiration transfer. Figure 4 shows a cross-section of the padded volar pocket that houses the removable volar stay. The length of the volar stay does not extend beyond the palmar crease.

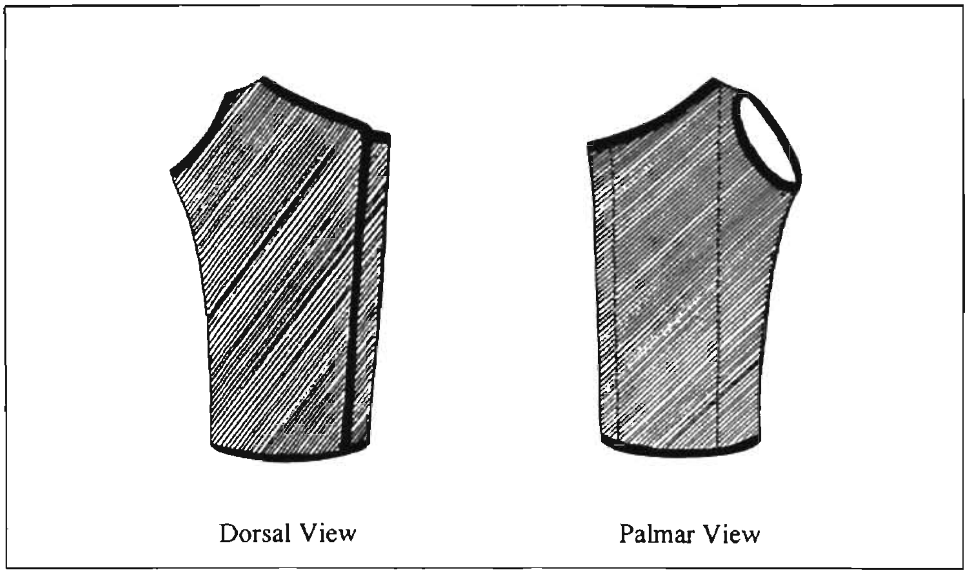

Figure 1, Dorsal & Palmar View of the Prototype Functional Hand and/or Wrist Splint

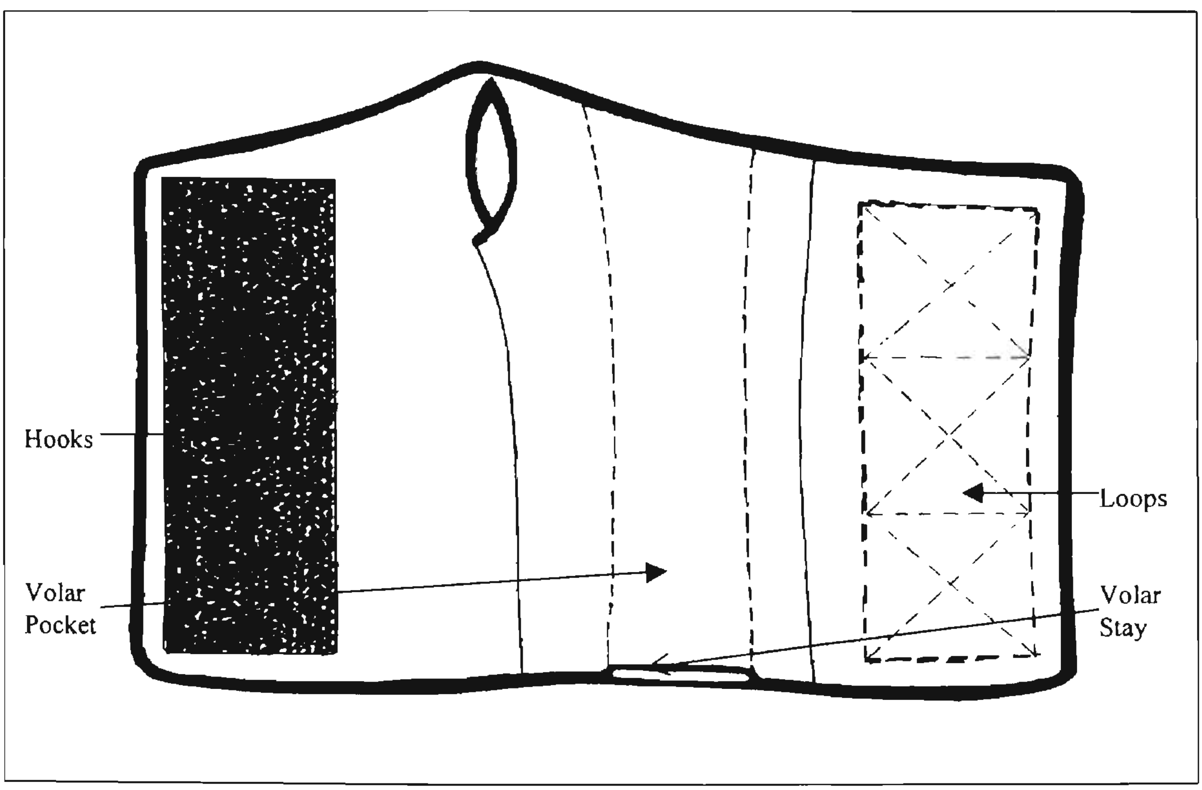

Figure 2, Inside View of the Prototype Functional Hand and/or Wrist Splint

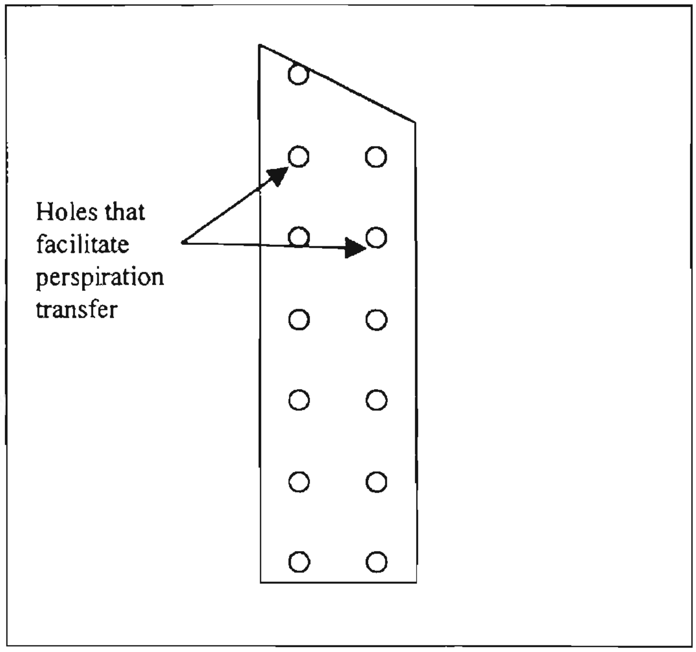

Figure 3. Front View of the Thermoplastic Volar Stay

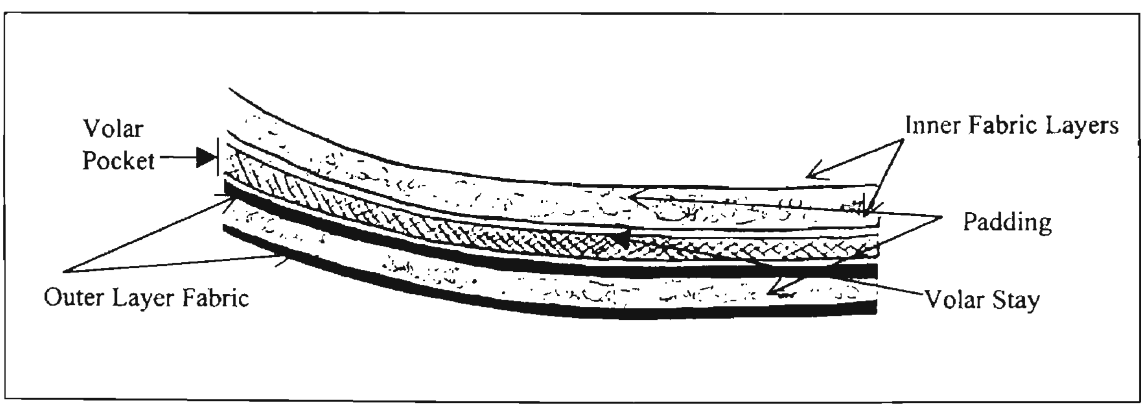

Figure 4, A Cross Sectional View of the Volar Pocket Section

Testing and Evaluation of the Prototype Functional Hand and/or wrist Splint

Human Subjects Review Board

Approval from the Oklahoma State University Institutional Review Board (IRB) for human subjects was obtained.

Sample

A convenience sample of nine subjects (eight females and one male) with hand and/or wrist problems, which used a functional splint due to a physician recommendation, wear-tested the prototype splint. Age of the subjects ranged from about 17 to over 50. The majority of the subjects used a splint for less than a year to two years. Subjects were solicited through posting ads (Appendix A) in different departments at Oklahoma State University, visiting various local factories, e-mailing OSU employees, networking with friends and acquaintances for help in identifying individuals who used a functional splint, and advertising in a local newspaper. Interested individuals contacted the researcher and set up an initial appointment.

Pre-Wear Test Procedures

At the initial meeting the researcher reviewed the purpose of the study and asked subjects, who met the criteria for participation, to sign the "Consent Form for Subjects Accepted for Splint Study" (Appendix B). The "Subject Information Card" (Appendix C) was then given to each subject and they were asked to complete the form. This form provided information on the subjects' medical backgrounds and demographic information. Subjects then answered a "Pre-Test Questionnaire" (Appendix D). This questionnaire determined subjects' perceptions about the splints that they were currently using.

Following the completion of the paperwork (signing the consent form, filling out the information card, and answering the Pre-Test Questionnaire), the maximum grip strength was assessed between 4:00 and 8:00 in the evening, according to Bechtol (1954) findings. Grip strength of the splinted hand (only dominant hand if both hands were splinted)[1] was measured three times by a Jamar dynamometer, and the results were documented. Pinch strength of the splinted hand (only dominant hand if both hands were splinted) was evaluated using a B&L Engineering pinch gauge.

Each subject's hand that required a splint (dominant hand if both hands were splinted) was measured for a custom fitted prototype functional hand and/or wrist splint. A custom-designed splint was made for each subject and was examined by a physician for appropriate angle (angle of the volar stay was set at 30° extension) of the thermoplastic volar stay. Proper fit of the splint was determined by the researcher.

<u>Independent Variables</u>

The independent variables included the prototype splint and the existing splints.

[1]. Typically, the dominant hand is the hand requiring a splint. In the event that the non-dominant hand is the splinted hand, then the splinted hand was tested. If both hands are splinted the dominant hand was tested.

Dependent Variables

The dependent variables of perceived comfort, ease of donning and doffing, allergic reaction, perspiration absorption, and movement limitation due to the prototype splint were investigated. Data on this set of variables was obtained using data gathered from the "Daily Splint Evaluation" (Appendix E) log for the four-week wear study as well as data from the "Pre and Post-Test Questionnaires" (Appendixes D & F, respectively).

Both pre -and post- grip and pinch strengths of the splinted hand were measured three times and results were recorded. Average of each of the three trails was used as the maximum grip and pinch strength measurements. Effectiveness of the functional prototype splint was assessed by comparing pre-and post-grip and pinch strength tests data.

Experimental Protocol

Upon Dr. Munson's approval of the custom fitted splint, the study began. Subjects wore the prototype hand and/or wrist splint for four weeks at least four hours a day while performing activities of daily living (e.g., dressing, grooming, preparing food, house keeping, driving, writing, and typing or word processing). Subjects were instructed not to use their existing splints during the wear study. After performing activities of daily living with the prototype splint, subjects filled out a "Daily Splint Evaluation" log (Appendix E). During the four-weak period, the researcher contacted the subjects to make sure they were not encountering any problems. At the end of four weeks, the researcher contacted the subjects and set up an appointment for conducting the post- grip and pinch strength tests. Subjects were allowed to keep their prototype splint at the end of the tests.

The American Society of Hand Therapists (ASHT) recommended the use of the second handle position of the dynamometer to evaluate grip strength (Fess and Moran, 1981). According to ASHT recommendation, the subjects were seated with their shoulder adducted and neutrally rotated, elbow flexed at 90° and the forearm and wrist in neutral position. Due to ASHT recommendation, the grip strength was measured in three successive trials and the mean of three measurements was used as the grip strength measurement. These procedures were followed for both the pre-and post-grip strength sets of measurements.

ASHT recommended the same arm positioning as grip strength for the three kinds of pinch strength measurements and the use of the mean of three successive trial as the pinch strength measurement. Pinch strength was determined according to the ASHT's recommendations for both the pre-and post-pinch strength sets of measurements.

Statistical Analysis

The ANOVA procedure for a randomized block design with sub-sampling was used to analyze the five-point response data. Since there were two treatment conditions, the paired t-test was used.

CHAPTER IV

MANUSCRIPT

Objective. To compare the effectiveness and perceived comfort associated with wearing a prototype splint with the effectiveness and perceived comfort of subjects' existing splints.

Methods. Nine subjects with different kinds of hand and/or wrist problems, who were using a functional splint based on a physician recommendation, participated in the wear study of a prototype splint. Grip and pinch strengths of the subjects' dominant-hands were measured at the beginning of the study. After 28 days of wearing the prototype splint, grip and pinch strengths of the dominant-hand were re-measured. Pre-and-post-Test questionnaires and a daily log were used to investigate perceived effectiveness and comfort of the currently used and the prototype splints.

Results. The prototype splint was perceived as more comfortable (means = 2.00), cooler (mean = 3), lighter (mean = 1.88), easier to doff (mean = 1.11), and subjects' hands sweat less during wear (mean = 3) (Table 1). Grip and key pinch strengths increased significantly (mean = 21.34 and mean = 7.20). There was no significant difference between the two treatments for palmar and tip pinch strengths. No significant difference was observed concerning perceived effectiveness of the prototype splint and the existing splint for Activities of Daily Living (ADLs). The effect of splinting on work performance was highly task specific.

Conclusions. Since the prototype splint increased grip strength for all subjects, it is recommended that a larger study with a controlled group be implemented.

INTRODUCTION

Hand function is crucial in day-to-day living. When there are problems with the hand and/or wrist like arthritis, fluid accumulation (edema) due to hemodialysis (Kulick, 1996), sudden weight gain like pregnancy (Tapley, Weiss, and Morris, 1985), overuse syndromes such as carpal tunnel syndrome (CTS), tenosynovitis of the dorsal wrist extensor compartments and flexor tendons of the wrist, and trigger finger (Verdon, 1996), it is difficult to accomplish activities of daily living (ADLs).

These medical conditions often result in loss of work time, medical and vocational rehabilitation expenses, and loss of productivity (Louis, Calkins, and Harris, 1996). In general, medical treatments accompanied with a therapeutic regimen are used to manage these problems. Standard drug therapy and joint protection are the treatments prescribed for overuse syndromes such as CTS, arthritis, and other injuries of the hands and/or wrists (Weinstock, 1993). Standard treatment includes rest, non-steroidal anti-inflammatory drugs (NSAIDs), and corticosteroid injection (Verdon, 1996). Joints can be protected by placing the hand and/or wrist in a "non-deforming position" (Weinstock, 1993), or by using splints or orthopedic devices to limit or immobilize the hand and/or wrist (Sailer, 1996).

There are many different types of custom designed and ready-to-wear hand and/or wrist splints (Anderson and Maas, 1987). Soft and hard splints are used to immobilize the hand and/or the wrist of individuals with arthritis and to alleviate arthritis symptoms by reducing the stress on the damaged joint (Callinan and Mathiowetz, 1996). After surgery and implantation, dynamic and static splints are used to allow active flexion of the digits and to facilitate achievement of the correct posture (Stirrat, 1996). The commercial static wrist extensor orthoses, also known as the functional or working orthoses, (Anderson and Maas, 1987), is designed to support the wrist and facilitate the functional use of the hand (Stern, 1996). Functional wrist splints have been recommended by occupational therapists for treatment of RA and other similar hand and/or wrist disorders (Anderson et al., 1987).

There is a limited amount of literature concerning the effectiveness and comfort of different kinds of splints. Gumpel and Cannon (1981) compared two kinds of ready-made, lightweight, fabric hand and/or wrist splints (Futuro and Spencer) in terms of support, suitability for daily routine, comfort, and ease of donning and doffing. Results indicated no difference between the two splints in regard to support, comfort, and ease of donning and doffing. Both splints interfered almost equally with some daily routines with the Futuro doing marginally better.

Anderson and Maas (1987) theorized that splinting of the dominant and non-dominant hands of patients with RA would reduce pain, and as a result, grip strength would increase. The Ritchie Rating Scale, ranging from 0 to 3, was used to measure the wrist-pain level. Ninety-two volunteer female RA patients were randomly assigned to one of five independent groups (four splinting groups and a control group). Four splinting groups were fitted for four kinds of working splints (dorsal, palmar, gauntlet, and elastic ready-made) and grip strength for the dominant and non-dominant hands was measured (using a modified sphygmomsnometer). The results showed some pain reduction in both hands, but it was not statistically significant and there was no immediate increase in grip strength regardless of the type of splint.

Biddulph (1981) studied the effect of the Futuro wrist splint on the grip and pinch strengths of 22 subjects with osteoarthritis, rheumatoid arthritis, tenosynovitis, and gout of the wrist. On the first day of the study, grip and pinch strengths were measured for both the unsplinted hand and the hand wearing the Futuro splint. After ten days of using the Futuro splint, a third grip strength measurement was taken using a dynamometer obtained from Asimow Engineering. The initial splinted grip and pinch strengths decreased from the unsplinted grip strength. After ten days of splint use, the post splinted grip and pinch strengths increased by almost 23.7% and 14.8% of the initial non-splinted grip strength measurement, respectively.

In his investigation, Nordenskiold (1990) studied the effect of two types of soft volar wrist splints on pain, grip strength and function of splinted dominant hand. The research results indicated that application of splints significantly reduced pain when three standardized ADL tasks were performed. The three ADLs included: 1- setting a breakfast table for two people (standing and walking), 2- filling a glass with milk from a full carton (sitting), and 3- vacuuming a floor without a rug for three minutes with one hand (walking). Findings also showed that use of both splints significantly increased the pain-free grip strength.

Kjeken, Moller, and Kvien (1995) compared the effect of the Rehband elastic wrist splint on pain, motion, and wrist function of 36 subjects who used the splint during two standardized tasks performance compared to the control group consisting of 33 subjects. The two standardized tasks were pouring a glass of water from a one-liter carton and cutting three slices of brown cheese. Six months of splint use improved wrist function, reduced pain, and increased grip and pinch strength by 24% and 11%.

Stern, Ytterberg, Krug, Mullin et al. (1996) investigated the immediate and short-term effects of using three types of commercial wrist splints (Roylan, Futuro #33, and AliMed Long) on function and grip strength of 36 RA patients. Grip strength of the splinted and non-splinted dominant-hand was measured at initial exposure to the splints and after one week of use. All subjects used all three splints. The results indicated that all three splints reduced grip strength at the initial exposure. After a one-week adjustment period, Roylan splint users' grip strength was the same for the splinted and non-splinted hand and wearing the other two splints had significantly lower grip strengths as compared to the unsplinted hand. Subjects indicated that the Roylan splint was more comfortable than the other two splints as well.

Stern (1996) compared the effects of five styles of functional wrist splints (Roylan, Futuro, AliMed Long, AliMed Short, and LMB) on grip strength and finger dexterity of 23 right-hand-dominant women with no upper extremity dysfunction. The Purdue Pegboard's unimanual sub-test was used to measure finger dexterity and a Jamar hydraulic dynamometer was used to measure grip strength. Results showed finger dexterity due to the Futuro, AliMed Short, Roylan, and LMB splints did not significantly differ from that of the unsplinted hand. The AliMed Long splint reduced finger speed in comparison with speeds afforded by LMB splints and the unsplinted hand. Roylan grip strength was not significantly different from the unsplinted hand and the other four splints reduced grip strength in comparison with Roylan and the unsplinted hand.

The Pagnotta, Baron, and Korner-Bitensky (1998) study investigated the effect of wearing a wrist splint (Futuro) on work performance, hand dexterity, and pain during task performance. Two tasks (one simulating the use of shears, the other the use of a screwdriver) were used to measure splinted and non-splinted hand work performance. Splinted and non-splinted hand dexterity was measured using the Jebsen Hand Function Test. Pain was measured before and after work performance using a 10-cm horizontal visual analog scale. The results showed splint wear significantly reduced pain. Also, splint-wear decreased work performance and its effect on work performance was highly task specific.

Although several studies investigated the effectiveness of splints on pain and compliance, few studies considered the comfort aspect of the splint. This is important because discomfort could affect patients' compliance of a given regimen. Different variables relative to the person, clothing, and the environment influence perception of clothing comfort. According to Branson and Sweeney (1991), the complex phenomenon of clothing comfort for an individual wearing a specific ensemble under specific environmental conditions is the result of an interaction among a number of physical and non-physical variables.

Callinan and Mathiowetz (1996) noticed patients' comfort and wearing tolerance impacted compliance; therefore, the splint materials were crucial elements for an effective treatment. They compared the effect of soft and hard resting hand and/or wrist splints on hand pain and function. The Arthritis Impact Measurement Scales 2 (a self-administered questionnaire for arm and hand function), a pain localization diagram, a calibrated Jamar dynamometer, and a daily diary (of splint wear, medication, morning stiffness, and level of activities) were used for the above purpose. The researchers also determined the effect of splint preference and comfort on compliance through a subjective splint rating form. Findings indicated that both soft and hard resting hand and/or wrist splints reduced pain, but RA patients preferred the soft splints and the patients were more compliant with the regimen.

Forty-two RA patients were studied by Stern et al. (1997) to examine their preference patterns for three commercial hand and/or wrist splints (Futuro, AliMed Long, and Roylan). Subjects used each of the three splints for one week while there was a one-week wash out period between each week of use. They used each splint at least four hours a day while performing functional tasks for five out of seven days and completed a daily "splint diary." In order for subjects to compare and contrast the three splints, a private semi-structured interview was conducted at each subject's final session. Results indicated that splints were deemed to provide comfort and a sense of security during functional tasks only if they were comfortable and well fitting. No single splint was suitable for all subjects; therefore, researchers concluded satisfaction with a splint rested on its therapeutic effect, comfort, and ease of use. They suggested that patients' satisfaction could be maximized by improving the likelihood of appropriate fit and comfort through availability of several styles of functional splints.

Purpose. This study investigated the effectiveness and the perceived comfort and effectiveness of a prototype functional hand and/or wrist splint through a four-week wear study. The following questions were addressed in this research.

1. Is there a significant difference between subjects' comfort perceptions regarding their existing splints and the prototype splint?

2. Is there a significant difference in grip strength associated with wearing the existing splints and the prototype splint?

3. Is there a significant difference in pinch strength associated with wearing the existing splints and the prototype splint?

4. Is there a significant difference between perceived effectiveness of the existing splints and the prototype splint where perceived effectiveness included ease of donning and doffing and effectiveness while performing ADL?

SUBJECTS AND METHODS

Prototype Splint. The perceived effectiveness and comfort associated with wearing a prototype splint as compared with the perceived effectiveness and comfort of wearing existing splints were investigated in this wear study. A prototype splint was developed to address the comfort problems associated with functional splints available in the market place. The prototype splint consisted of two layers of fabrics, selected based on results from textile tests. A 100% cotton denim fabric was chosen for the exterior fabric layer and a jersey knit, 52% nylon/ 48% polyester blend, was selected for the interior fabric. The prototype splint's closure system included a Velcro strip covered with a layer of fabric. The palmar section of the splint housed the removable LMB-blend volar stay (a malleable blend of plastic and rubber with holes designed to facilitate perspiration transfer).

Subjects. A convenience sample of nine volunteer subjects, with hand and/or wrist problems, who used a functional splint due to a physician recommendation, wear-tested the prototype splint. Compiled data from the "Subject Information Card" (Appendix C) showed that almost 22% of the subjects were under the age of 20, 22% were 20-29, 33% were 30-39, and 22% were 50 or older. All of the subjects were Caucasian and 89% were female.

Almost 45% of the subjects were diagnosed with CTS, 22% with tendinitis, 11% with arthritis, and 33% with other kinds of disorders (spinal cord injury and osteoarthritis) (Appendix G, Table 1). Eighty-nine percent indicated they suffered from pain, 78% had swelling, 67% felt weakness, 56% experienced numbness, and 45% had stiffness in their hands and/or wrists (Appendix G, Table 2). Almost 22% experienced symptoms in their right hand, 22% in left hand, and 33% in both hands (Appendix G, Table 3). Almost 45% had symptoms in their right wrists, 22% in their left wrists, and 22% in both wrists (Appendix G, Table 3). Eighty-nine percent of the subjects were right-handed.

Eighty-nine percent of the subjects reported their occupations involved repetitive motion all the time. Seventy-eight percent of subjects indicated that they used a hand and/or wrist splint and 22% used a splint sometimes. Forty-five percent used the splints on their right hands, 22% on their left hands, and 33% on both hands. Forty-five percent reported using a splint for less than a year, 22% for 1-2 years, 22% for 3-4 years, and 11% for 5-10 years (Appendix G, Table 5).

Protocol. Subjects completed a "Pre-Test Questionnaire" (Appendix D) at their initial meeting with the researcher. The instrument was designed to determine subjects' perceptions about the splints that they were currently using. Grip and pinch strengths of the splinted dominant hand were measured with subjects wearing their own splints. Each subject's hand that required a splint (only the dominant hands if both hands were splinted) was measured for a custom fitted prototype functional hand and/or wrist splint. A custom-designed splint was made for each subject and was examined by a physician for appropriate angle (angle of the volar stay was set at 30° extension) of the thermoplastic volar stay. Proper fit of the splint was determined by the researcher.

Subjects wore the prototype hand and/or wrist splint for four weeks at least four hours a day while performing activities of daily living (e.g., dressing, grooming, preparing food, house keeping, driving, writing, and typing or word processing). Every day, after performing activities of daily living with the prototype splint, subjects completed a "Daily Splint Evaluation" log (Appendix E). At the end of four weeks, grip and pinch strength were re-measured while subjects were wearing the prototype splint. Subjects also answered a "Post-Test Questionnaire" (Appendix F) to determine their perceptions about the prototype splint. They were allowed to keep their prototype splints at the end of the tests.

Instruments. To measure maximum grip strength, a Jamar dynamometer was used. A B&L Engineering pinch gauge was used to measure pinch strength. The second handle position of the dynamometer and the standard body positioning for grip strength measurements approved by the American Society of Hand Therapists (Fess & Moran,

1981) were used. To achieve the maximum grip and pinch strengths, time of the tests were set between 4:00 and 8:00 in the evening (Bechtol, 1954). Verbal instructions recommended by Mathiowetz (1990) were used while measuring the grip and pinch strength. To obtain the maximum grip and pinch strengths for each subject, the mean of three successive trials was calculated. Grip and pinch strengths were measured in kilograms.

The researcher specifically developed the "Subject Information Card", the "Pre-and/Post-Test Questionnaires", and the "Daily Splint Evaluation" log for this study. The "Pre-and/Post-Test Questionnaires" included part of Stern, Ytterberg, Krug, and Mahowald (1996) instrument for "orthoses influence on daily tasks." The "Pre-Test Questionnaire" also included questions concerning extent of splint usage in ADLs, theraputic effects of splints, length of the volar stay, comfort, temperature, hand sweat, skin irritation and abrasion, ease of donning and doffing, lightness of the splint, pain reduction or prevention, activities that splints were used for and activities that performed without a splint, color, and style of splints. In addition, the "Post-Test Questionnaire" included the same questions as the "Pre-Test Questionnaire", questions in regard to frequency and method of cleaning, as well as the price range that respondents were willing to pay for a prototype splint. An example of the "Subject Information Card", the "Pre-and/Post-Test Questionnaires", and the "Daily Splint Evaluation" log are given in appendixes C, D, E, and F.

RESULTS

The design of the experiment was a randomized block design with sub-sampling. Therefore, the ANOVA procedure for a randomized block design with sub-sampling was used to analyze the data. Since there were two treatment conditions, the paired t-test was used. Three measurements were taken for the grip and pinch strength measurements and an average was calculated. All of the hypotheses in the study were investigated separately.

1. Is there a significant difference between subjects' comfort perceptions regarding their existing splints and the prototype splint? Seven identical items from the pre-and post-test questionnaires were used to compare comfort perceptions regarding the existing splints and the prototype splint. Table 6 shows means, standard deviations, and the probability level, for four of the seven items with a five-point response scale. Examination of the means given in Table 6 shows that the prototype splint was perceived as more comfortable, cooler, lighter, and subjects perceived that their hands sweat less during wear. Paired t-tests indicated that the observed differences were statistically significant for two of the four, i.e. temperature and hand sweat. Overall satisfaction was also significantly higher for the prototype splint.

Table 6

Seven items with a yes/no response scale (three of the above seven items and four additional items) asked various questions regarding whether the splints prevented or reduced pain, caused skin irritation, enhanced or inhibited making a fist, and were used while performing ADLs. As Table 7 shows, subjects perceived the prototype splint more favorably on three of the seven items. The prototype splint inhibited making a fist less than the existing splints. It caused no skin abrasion or skin irritation. With both splints about 1/3 of the subjects removed their splints to perform some activities. For word processing, writing, washing, driving, eating, cooking, grooming, sleeping, and dressing, subjects removed their existing splints. They removed the prototype splint for word processing, writing, washing, driving, eating, cooking as well as using a wheelchair.

Table 7

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2. *Is there a significant difference in grip strength associated with wearing the existing splints and the prototype splint?* Initial grip strength measurements ranged from 0.41 Kg. to 35 Kg. After wearing the prototype splint for four weeks, a second set of grip strength measurements were taken and ranged from 3 to 41.33 Kg. Every subject's second set of grip strength measurements increased over the initial grip strength (Appendix G, Table 4).

Table 8 presents the means, standard deviations, and probability value for grip strength. The mean grip strength associated with the prototype was 21.34 Kg. and 14.87 Kg. for the existing splints. Paired t-test found this difference to be significant as Table 3 shows.

Table 8

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3. Is there a significant difference in pinch strength associated with wearing the existing splints and the prototype splint? There are three types of pinch strength measurements. Palmar pinch is thumb pad to pads of the index and middle fingers. Key pinch is pad of the thumb against the lateral part of middle phalanx of the index finger. Tip pinch is thumb tip to index finger tip. Three pinch strength measurements associated with the prototype and the existing splints were compared. Examination of the means given in Table 8 indicated that pinch strengths taken after wearing the prototype splint were stronger than after wearing the existing splints. Paired t-tests showed that the observed differences were statistically significant for one of the three pinch strength measurements, i.e. key pinch (Table 8).

4. Is there a significant difference between perceived effectiveness of the existing splints and the prototype splint where perceived effectiveness included ease of donning and doffing and effectiveness while performing ADLs? Means given in Table 6 shows that the prototype splint was perceived as easier to don and doff. The paired t-test indicated significant differences between the prototype and existing splints for donning.

A comparison of means of "splint helpfulness" while performing ADLs for the existing and prototype splints showed no significant difference for seven of eight listed ADLs (Table 9). Observed differences for typing were significant ($P = 0.05$, Table 9). The reason that subjects used the existing splints more than the prototype splint for typing could be due to the slope of the prototype splint's volar stay. The slope of the prototype splint's volar stay was fixed at 30° angle in order to keep this variable constant. Perhaps the slope of the volar stay should be adjusted at an angle that keeps the wrist in a neutral position between 15° to 30° of extension (Kraft and Detels, 1972), to facilitate typing by the splint user. Based on the researcher's personal experience, a volar stay with a 30° angle is not necessarily a comfortable position for a problematic wrist. Thus, the volar stay's angle should be adjusted at an angle between 15° to 30° of extension that is comfortable for that specific splint user. Nevertheless, for activities like dressing, grooming, eating, and house keeping, subjects used the prototype splint more often than the existing splints.

Table 9

Scrutiny of Table 10 on the frequency of the therapeutic effects that splints provide indicated that more subjects perceived the prototype splint as therapeutic in terms of stimulating circulation, relieving stress and pain, increasing range of motion, and containing body heat.

Table 10

Comparison of the extent of splint usage while performing ADLs is shown in Table 11. Paired t-test showed that the observed differences were not statistically significant for nine of the ten listed activities. The prototype splint was used more often for dressing ($P = 0.06$, Table 11).

Table 11

Subjects were overall significantly more satisfied with the prototype splint than the existing splints (P = 0.04, Table 6). The prototype splint had a mean of 1.6 vs. a mean of 2.4 for the existing splints (on a five-point scale where 1= excellent, 2 = good, 3 = fair, 4 = poor, and 5 = unsatisfactory).

DISCUSSION

Findings indicated subjects perceived the prototype splint to be more comfortable than their existing splints. They perceived the prototype splint to be cooler, lighter, and they perceived that their hands sweat less when they wore the prototype splint. This is in accordance with the conclusion by Stern et al. (1997), that only comfortable and well fitting splints provide comfort. The fact that the prototype splint was custom-fitted might be a reason that it was perceived by subjects as more comfortable than the existing splints. Other influential factors could be the kinds of fabrics that were used, structure of the volar pocket, volar stay, or a combination of any or all of these elements. Callinan's and Mathiowetz's (1996) findings showed that a more comfortable resting soft splint was preferred to the hard resting splint by subjects. Because these researchers found that a more comfortable splint increased subjects' compliance, the importance of features that enhance comfort was demonstrated. Thus, the present study's findings maybe influential in increasing compliance.

The data indicated a statistically significant increase in grip strength due to wearing the prototype splint. This finding is in agreement with results by Biddulph (1981), Nordenskiold (1990), and Kjeken et al. (1995) who found an increase in grip strength due to use of a splint. The studies by Stern, Ytterberg, Krug, and Mahowald (1996), and Stern (1996) did not find an increase in grip strength. However, the design of these studies and the variables examined were different. Yet, all of the studies focused on increasing grip strength due to splint use. Thus, repeating this research with a larger number of subjects and a control group would be an important step for validating the present study's results.

This study used a B&L Engineering pinch gauge and measured three types of pinch strength (palmar, key, and tip) between 4 p.m. and 8 p.m., when according to Bechtol (1954) grip strength reaches its maximum strength. The statistical analysis showed that key pinch strength was significantly stronger after wearing the prototype splint (P = 0.01). Increases in the other two types of pinch strength were not statistically significant. Only two other studies were located that examined pinch strength. The Biddulph (1981) study did not indicate the type of the pinch strength measurement or the time of measuring pinch strength. He used grip and pinch dynamometers obtained from Asimow Engineering and reported an increase of 14.8% in pinch strength after ten days of using the Futuro splint. Kjeken et al. (1995) measured pinch grip between 10 a.m. and 3 p.m., using a Mannerfelt Intrinsicmeter, in which the subjects used only their thumbs, index, and middle fingers (palmar pinch). Results indicated an increase of 11% in pinch strength. Since the measurements were taken at different times with different instruments, it is not possible to compare the results.

Perceived effectiveness data indicated that subjects perceived the prototype splint to be more effective in terms of ease of doffing. The majority of subjects perceived the prototype splint to be more effective in terms of preventing pain and containing body heat. Even though there was no significant difference between the prototype and the existing splints in terms of suitability for ADLs and reducing pain, the prototype splint marginally performed better than existing splints.

The "Post-Test questionnaire" also included questions on color, style, frequency and method of cleaning, as well as the price range that respondents were willing to pay for a the prototype splint. Almost 70% of the subjects were satisfied with the color of the prototype splint and 30% did not care. All of the subjects liked the style of the prototype splint and 90% indicated they would continue to wear the prototype splint. Almost 45% were willing to pay between $15 to $20 for this splint.

Due to the limited number of subjects, it was not possible to categorize subjects based on the type of their existing splints. It would be interesting to repeat this study while using a specific kind of commercial functional splint to see whether an increase in grip strength would be found again. Other scenarios that could be investigated include: experimenting for a longer period of time with a larger and equal number of subjects from each sex and a control group, using a different angle for the volar stay, and comparing the effect of a metal volar stay with the effect of the LMB splinting material volar stay.

TABLES

Table 6

Means, Standard Deviations, & P-Values for Subjects' Perceptions of Comfort Variables for Existing Splints & Prototype Splint

	Existing Splint		Prototype Splint		
Items	Means	SD	Means	SD	P-Values
Overall splint comfort (a)	2.88	1.26	2.00	1.11	0.10
Temperature (b)	2.22	0.83	3.00	0.00	0.02
Hand sweat (c)	1.90	1.26	3.00	1.41	0.05
Lightness of splint (d)	2.22	1.30	1.88	0.92	0.54
Easy to put on splint (e)	2.22	0.97	1.4	0.72	0.08
Easy to taking off (f)	2.11	1.26	1.11	0.33	0.05
Overall satisfaction (g)	2.4	0.72	1.6	0.5	0.04

(a) On a 5-point response scale with 1 = very comfortable and 5 = very uncomfortable
(b) On a 5-point response scale with 1 = too warm and 5 = too cool
(c) On a 5-point response scale with 1 = always and 5 = never
(d) On a 5-point response scale with 1 = very light and 5 = very heavy
(e) On a 5-point response scale with 1 = very easy and 5 = very difficult
(f) On a 5-point response scale with 1 = very easy and 5 = very difficult
(g) On a 5-point response scale with 1 = excellent, 2 = good, 3 = fair, 4 = poor, and 5 = unsatisfactory

Table 7

Frequency Table for Yes/No Items

	Existing Splint			Prototype Splint	
	Yes	No	Missing*	Yes	No
Inhibit making a fist	33.3%	44.4%	22.2%	33.3%	66.7%
Cause skin irritation	22.2%	77.8%		00.0	100%
Cause skin abrasion	11.1%	87.8%		00.0	100%
Used splint to perform ADLs	77.8%	22.2%		66.7%	33.3%
Removed splint to perform ADLs	66.7%	33.3%		66.7%	33.3%
Prevent Pain	88.9%	11.1%		55.6%	44.4%
Reduce Pain	88.9%	11.1%		66.7%	33.3%

* Missing = Missing data

Table 8

Means, Standard Deviations, and P-Values of Grip & Pinch Strength with Existing Splints & Prototype Splint in Kilograms

	Existing Splint		Prototype Splint		
Items	Means (Kg)	SD	Means (Kg)	SD	P-Values
Grip Strength	14.87	10.624	21.34	10.035	0.0012
Key Pinch Strength	6.09	3.124	7.20	3.128	0.0128
Palmar Pinch Strength	6.24	2.954	6.90	2.835	0.2359
Tip Pinch Strength	5.157	2.570	5.79	2.445	0.1976

Table 9

Comparison of "Splint Helpfulness" While Performing ADLs for Existing & Prototype Splints

	Existing Splint		Prototype Splint		
Items	Means*	SD	Means*	SD	P-Values
Dressing	4.1	1.61	3.9	1.61	0.64
Grooming	4.4	1.23	3.9	1.69	0.30
Eating	3.4	1.74	3.0	1.32	0.53
Preparing Food	3.8	1.64	3.8	1.71	1.00
House Keeping	2.9	1.53	2.1	1.61	0.27
Driving	2.8	1.78	3.6	2.06	0.45
Writing	3.3	1.58	3.6	1.11	0.52
Typing	1.9	1.16	3.4	1.66	0.05

* On a 5-point response scale where:
a = help a lot
b.= help a little
c.= interfere a little
d. = interfere a lot
e. = I don't take care of my own.......

Table 10

Frequency Table for Yes/No Therapeutic Effects that Splints Provide

	Existing Splint		Prototype Splint	
Items	Yes	No	Yes	No
Support	100%	00.0%	100%	00.0%
Massage	00.0%	100%	00.0%	100%
Stimulate Circulation	00.0%	100%	11.1%	88.8%
Relieve Stress & Pain	66.6%	33.3%	77.7%	22.2%
Increase Range of Motion	00.0%	100%	22.2%	77.7%
Contain Body Heat	22.2%	77.7%	77.7%	22.2%

Table 11

Comparison of Extent of Splint Usage While Performing ADLs for Existing & Prototype Splints

	Existing Splints	Prototype Splint	
Items	Means*	Means*	P-Value
Dressing	4.4	3.7	0.06
Grooming	4.4	4.1	0.52
Eating	3.9	2.9	0.12
Preparing Food	4.2	3.6	0.24
House Keeping	3.2	3.2	1.00
Driving	2.9	3.1	0.73
Writing	3.4	2.6	0.15
Typing	1.9	1.9	1.00
Gardening	4.0	4.3	0.52
Sewing	4.4	4.0	0.10

* Five-point response scale with 5 = never and 1 = always

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CHAPTER V

SUMMARY AND RECOMMENDATIONS

Hands and or wrists could be effected with medical conditions that could result in loss of work time and productivity, and medical and rehabilitation expenses (Louis, Calkins, and Harris, 1996). In general, these problems are managed through medical treatments accompanied with a therapeutic regimen. Overuse syndromes such as CTS, arthritis, and injuries of the hands and/or wrists are treated with standard drug therapy and joint protection (Weinstock, 1993). Standard treatments includes rest, non-steroidal anti-inflammatory drugs (NSAIDs), and corticosteroid injection (Verdon, 1996). Joint protection may be accomplished by using splints or orthopedic devices to limit or immobilize the hand and/or wrist (Sailer, 1996).

There are many different types of custom-designed and ready-to-wear hand and/or wrist splints (Anderson and Maas, 1987) such as soft and hard splints, dynamic and static splints, and commercial static wrist extensor splints that are also known as functional or working splints. Functional splints are designed to support the wrist and facilitate the functional use of the hand (Stern, 1996). These splints purport to decrease inflammation, reduce pain, protect wrist joints, provide support, reduce stiffness, and prevent deformity (Falconer, 1991).

However, individuals with problematic hands and/or wrists show low compliance with wearing splints due to a number of reasons such as discomfort, low wearing tolerance (Callinan and Mathiowetz, 1996), interference with function, poor appearance, and failure to reduce pain (Hicks, Leonard, Nelson, Fisher, and Esquenazi, 1989).

Because of personal experience with rheumatoid arthritis and difficulty in finding an effective and comfortable functional hand and/or wrist splint, the researcher became interested in functional splints and as a requirement for a functional design class, developed a prototype functional hand and/or wrist splint. The prototype was designed to provide greater comfort as well as a more pleasing appearance than existing functional hand and/or wrist splints. The purpose of this study was to evaluate the effectiveness, perceived comfort and the perceived effectiveness of a prototype functional hand and/or wrist splint through a four-week wear study.

This study's objectives included an examination of subjects' perceived comfort and effectiveness of their existing splints and the prototype splint and a comparison of grip and pinch strength of the existing and prototype splints. It was hypothesized that there would be a significant difference between subjects' perceptions of comfort and effectiveness of their existing splints and the prototype splint. It was also hypothesized that there would be a significant difference between grip and pinch strength associated with wearing the existing splints and the prototype splint.

Testing Protocol

The research took place at the College of Human Environmental Sciences in Oklahoma State University during the end of fall semester of 1998 and the spring semester of 1999. Nine individuals with hand and/or wrist problems, who used a functional splint due to a physician recommendation, solicited through posting flyers, advertising in a local newspaper, visiting various local factories, e-mailing, and networking to identify qualified individuals, served as subjects.

An initial session with each subject included gathering demographic and medical background information. Also, subjects' perceptions about their existing splints were obtained through completion of a "Pre-Test Questionnaire." Then, maximum grip and pinch strength measurements of the dominant splinted hand were obtained between 4:00 p.m. and 8:00 p.m. Finally, each subject's hand that required a splint (only dominant hand if both hands required splints) was measured for a custom fitted prototype functional hand and/or wrist splint. A custom-designed splint was made for each subject and was examined by a physician for appropriate angle (angle of the volar stay was set at 30° extension) of thermoplastic volar stay. Appropriate fit was determined by the researcher.

Subjects used the prototype for four weeks at least four hours a day while performing ADLs (e.g., dressing, grooming, preparing food, house keeping, driving, writing, and typing or word processing). Every day, they completed a "Daily Splint Evaluation" log after performing ADLs. At the end of four weeks, grip and pinch strength were re-measured while subjects were wearing the prototype splint. Subjects also answered a "Post-Test Questionnaire" to determine their perceptions about the prototype splint. The "Pre-and/Post-Test Questionnaires" included part of Stern, Ytterberg, Krug, Mullin et al. (1996) instrument for "orthoses influence on daily Tasks." The "Pre-Test Questionnaire" also included questions concerning extent of splint usage in ADLs, theraputic effects of splints, length of the volar stay, comfort, temperature, hand sweat, skin irritation and abrasion, ease of donning and doffing, lightness of the splint, pain reduction or prevention, activities that splints were used for and activities that performed without a splint, color, and style of splints. In addition, the "Post-Test Questionnaire" included the same questions as the "Pre-Test Questionnaire", questions in regard to frequency and method of cleaning, as well as the price range that respondents were willing to pay for a prototype splint. The subjects were allowed to keep their prototype splints at the end of the tests.

Conclusions

Results showed subjects perceived the prototype splint to be more comfortable, cooler, lighter, and subjects' hands sweat less during wear as compared to their existing splints. Subjects perceived the prototype splint more favorably on preventing or reducing pain, causing skin irritation, and inhibiting making a fist.

Paired t-test found a significant difference in the mean grip strength associated with the prototype and existing splints. Paired t-tests showed that the observed differences in one of the three pinch strength measurements were statistically significant (key pinch).

The paired t-test showed that the prototype splint was perceived as easier to doff Than the existing splints. Subjects used the prototype splint more often than they had used their existing splints for activities like dressing, grooming, eating, and house keeping.

Subjects perceived the prototype splint to be more therapeutic in terms of stimulating circulation, relieving stress and pain, increasing range of motion, and containing body heat. A comparison of the extent of splint usage while performing ADLs showed that the observed differences were not statistically significant for nine of the ten listed activities. The exception was dressing that the prototype splint was used significantly more often than the existing splints. Subjects were overall significantly more satisfied with the prototype splint than their existing splints.

Recommendations for Future Research

The following suggestions for future research were recommended:

1. Conduct a similar investigation for a longer period of time with a larger number of subjects and a control group to rule out the possibility of the Hawthorne effect.
2. Conduct an investigation with equal number of subjects from each sex to examine if gender makes a difference.
3. Design a study to examine whether a different angle for the volar stay would be more comfortable and effective.
4. Design a study to compare the effect of a metal volar stay with the effect of the LMB splinting material volar stay.
5. Conduct an investigation to compare the effect of the prototype splint with a specific kind of commercial functional splint.
6. Conduct an investigation that controls the effect of taking medication.
7. Explore the long-term effect of wearing the prototype splint as a means to prevent development of CTS in individuals who are involved with repetitive motions in their activities.

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APPENDIXES

APPENDIX A

Do you fit these qualifications?

- **suffering from any kind of hand and/ or wrist problems**
- **using a functional hand splint due to a physician recommendation**

Then Oklahoma State University, the Department of Design, Housing & Merchandising

is

Looking for you

- **DHM is conducting research which will involve wearing a prototype splint for four weeks.**
- **Subject will be supplied with a custom-made prototype splint that will be checked by Dr. Mark Munson.**
- **Subject needs to complete a "Daily splint evaluation" log each day that he / she wears the splint.**
- **Subject needs to complete a pre-and post-questionnaire.**
- **Subject will be given grip strength and pinch strength tests before and after using the prototype splint.**
- **Subject will be permitted to keep the prototype splint after he/ she has completed all parts of the study.**

Interested individuals can contact Elaheh at 744-5035 (from 8-5pm) or elaheh@okstate.edu

APPENDIX B

CONSENT FORM FOR SUBJECTS ACCEPTED FOR SPLINT STUDY

- "I, ________________________________,understand that Elaheh Amouzadeh, has developed a prototype splint under Dr. Donna Branson's (Oklahoma State University, Department of Design, Housing, & Merchandising) direction.

- This was done as part of an investigation entitled User satisfaction, functionability, grip strength, and finger dexterity associated with a prototype splint.

- The purpose of this investigation is to evaluate the effectiveness and comfort of the prototype splint.

- Confidentiality of records will be maintained by using the mean data, at no time will an individual's responses be given, and records and data will be kept in a locked file that only the researcher will have access to.

- I understand that I will be supplied with a custom-made prototype splint that will be checked by Dr. Mark Munson.

- I understand that I will need to wear the prototype splint for four weeks, at least four hours a day, while I am performing activities of daily living (e.g., dressing, grooming, preparing food, house keeping, driving, writing, typing or word processing).

- I understand that I will need to complete a "Daily splint evaluation" log each day that I wear the splint.

- I understand that I will need to complete a pre- and post-questionnaire.

- I understand that I will be given grip strength and pinch strength tests before and after using the prototype splint.

- I understand that I will be permitted to keep the prototype splint after I have completed all parts of the study.

- I understand that my participation is voluntary, that there is no penalty for refusal to participate, and that I am free to withdraw my consent and participation in this project at any time without penalty after notifying Elaheh Amouzadeh.

- I understand that if I experience any discomfort while using the prototype splint I should contact Dr. Mark Munson at 743-3212 or Dr. Branson at 744-5035 (9:00-5:00) or 624-0945. I may also contact Gay Clarkson, IRB Executive Secretary, 305

Whitehurst, Oklahoma State University, Stillwater, OK 74078; telephone number: (405) 744-5700.

I have read and fully understand the consent form. I sign it freely and voluntarily. A copy has been given to me.

Date: ______________________ Time: ____________________(a.m./p.m.)

Signed: ____

Signature of Subject

____

Person authorized to sign for subject, if required

I certify that I have personally explained all elements of this form to the subject or his/her representative before requesting the subject or his/her representative to sign it."

Signed: ____

Project Director or his/her authorized representative

APPENDIX C

SUBJECT INFORMATION CARD

Name ______________________ Date ______________ Subject # ________

Please, answer every question by circling the appropriate answer(s):

1. What is your occupation? ______________________________

2. In your occupation, to what extent do you perform repetitive motions with your hands and wrists?

Always				Never
1	2	3	4	5

3. Have you been diagnosed with any of the following conditions of the hand &/or wrist by a physician? (Circle all that apply)

   a. Arthritis
   b. Carpal Tunnel Syndrome
   c. Tendenitis
   d. Other ______________________

4. What are your symptoms?

   a. Pain
   b. Numbness
   c. Stiffness
   d. Weakness
   e. Swelling
   f. Others ______________________

5. Do you have any symptoms in your hands? a. Yes b. No

6. If yes, where? a. Right hand b. Left hand c. Both

7. Do you have any symptoms in your wrists? a. Yes b. No

8. If yes, where? a. Right wrist b. Left wrist c. Both

9. Which hand do you use the most?
   a. Right hand b. Left hand c. Both equally

10. Are you presently using a hand and/or wrist splint or orthopedic device?
    a. Yes b. No c. Sometimes

11. If yes, what type?

    a. Stretch lycra
    b. Elasticized
    c. Heavy duty
    d. Leather
    e. Custom made
    f. Other ______________________

12. If you use a splint or orthopedic device, on which hand do you use it?

    a. Right hand b. Left hand c. Both

13. How long have you been using a hand and/or wrist splint or orthopedic device?

a. Less than one year c. 3-4 years e. Other ________
b. 1-2 years d. 5-10 years

14. When you work, on a typical work day, how often do you use your splint or orthopedic device?

Always				Never
1	2	3	4	5

15. When involved in leisure activities or hobbies (such as gardening), how often do you use your splint or orthopedic device?

Always				Never
1	2	3	4	5

16. What is your age range?

a. 20-29 c. 40-49
b. 30-39 d. 50 and over

17. What is your gender? a. Male b. Female

18. What is your race?

a. Caucasian c. American Indian
b. African-American d. Other ________________

19. What is your education level?

a. Less than 8th grade
b. 1-3 years of high school
c. High school diploma or equivalent
d. 1-3 years of college
e. BS degree or equivalent
f. Graduate degree or professional degree
g. Vocational school
h. Other ________________

20. Height ________________

21. Weight ________________

APPENDIX D

PRE-TEST QUESTIONNAIRE

Please, answer the following questions about the splint that you are using at the present. There are no right or wrong answers to the questions. Most of the questions can be answered with a simple check (X). Please answer every question.

1. How did you get your splint or orthopedic device?

   a. It was purchased from a drug store or other store
   b. It was purchased from a rehabilitation center, a clinic, or a doctor's office
   c. It was custom made
   d. Other (please explain) _______________

2. Was your splint **adjusted** by your physician?

   a. Yes (explain) _________________________
   b. No (explain) _________________________

3. In your activities of daily living to what extent do you perform each of the following activities while wearing a splint?

	Always				Never
a. Dressing	1	2	3	4	5
b. Grooming	1	2	3	4	5
c. Eating	1	2	3	4	5
d. Preparing food	1	2	3	4	5
e. House keeping	1	2	3	4	5
f. Driving	1	2	3	4	5
g. Writing	1	2	3	4	5
h. Typing or word processing	1	2	3	4	5
I. Gardening	1	2	3	4	5
j. Sewing	1	2	3	4	5

4. Does your splint or orthopedic device provide the following? (Circle **all** that apply)

   a. Support
   b. Massage
   c. Stimulate circulation
   d. Relieve stress & pain
   e. Increase range of motion
   f. Contain body heat
   g. Other ______________

5. Does your splint have a volar metal stay?
   a. Yes b. No c. Do not know

6. Does the length of the volar metal stay inhibit your ability to make a fist?
   a. Yes b. No

7. Rank the overall comfort level of your splint or orthopedic device?

Very comfortable				Very uncomfortable
1	2	3	4	5

8. Is your splint:

Too warm				Too cool
1	2	3	4	5

9. To what extent does your hand sweat during wear?

Always				Never
1	2	3	4	5

10. Does the splint cause you any skin irritation?
    a. Yes b. No

11. Does the splint cause you any skin abrasion?
    a. Yes (explain)
    b. No (explain)

	Very easy				Very difficult
12. How easy is putting on the splint?	1	2	3	4	5
13. How easy is taking off the splint?	1	2	3	4	5

14. When you are wearing the splint does it feel;

Very light				Very heavy
1	2	3	4	5

15. When you dress, does the splint:
    a. help a lot
    b. help a little
    c. interfere a little
    d. interfere a lot

e. I don't dress myself

16. When you take care of your daily grooming (for example, brushing your teeth, brushing or combing your hair) does the splint:
    a. help a lot
    b. help a little
    c. interfere a little
    d. interfere a lot
    e. I don't take care of my own grooming

17. When you eat your meals (for example, cutting your meat, using a utensil, drinking from a glass), does the splint:
    a. help a lot
    b. help a little
    c. interfere a little
    d. interfere a lot
    e. I don't feed myself

18. When you prepare food for meals or snacks, does the splint:
    a. help a lot
    b. help a little
    c. interfere a little
    d. interfere a lot
    e. I don't prepare my own meals or snacks

19. When you do work around the house (for example, dusting, vacuuming, taking out trash) does the splint:
    a. help a lot
    b. help a little
    c. interfere a little
    d. interfere a lot
    e. I don't do housework

20. When you drive a car, does the splint:
    a. help a lot
    b. help a little
    c. interfere a little
    d. interfere a lot
    e. I don't drive

21. When you write with a pencil or pen, does the splint:
    a. help a lot
    b. help a little
    c. interfere a little
    d. interfere a lot

e. I don't write with a pen or pencil

22. When you type or do word processing, does the splint:
   a. help a lot
   b. help a little
   c. interfere a little
   d. interfere a lot
   e. I don't type

23. During the past week, did you ever put on the splint to help you perform an activity?
   a. Yes   b. No

24. If yes, for what activities did you put on the splint?

____

____

25. During the past week, did you ever take the splint off to help you perform an activity?
   a. Yes   b. No

26. If yes, during what activities did you remove the splint and why?
   Activity:
   Reason for removing splint:

____

27. Did you ever put the splint on to prevent pain?
   a. Yes   b. No (skip #28)

28. If you answered "yes" to #27, how successful was the splint at preventing pain?

very successful				very unsuccessful
1	2	3	4	5

29. Did you ever put the splint on because you were in pain at that time.
   a. Yes   b. No

30. If you answered yes to #29, how successful was the splint at reducing the pain?

very successful				very unsuccessful
1	2	3	4	5

31. What color is your splint?
  a. Black d. White
  b. Beige e. Other ______
  c. Navy blue

32. Are you satisfied with the color of your splint or orthopedic device?
  a. Yes c. Do not care
  b. No

33. If not what color would you prefer? ____________

34. How do you clean your splint or orthopedic device?
  a. Wash it in a washing machine
  b. Use a clean cloth
  c. Other ___________

35. How often do you clean your splint?
  a. Weekly c. Monthly
  b. Bimonthly d. Seldom

36. Rate your splint on your overall satisfaction.

Excellent Good Fair Poor Unsatisfactory

37. Comment: ____

____

____

Thank you for taking part in this survey.

APPENDIX E

Name ______________
Subject # ______________

DAILY SPLINT EVALUATION - DAY 1

This study is designed to obtain users' evaluations of a prototype functional hand splint under actual wearing conditions. Please wear this splint seven consecutive days for at least four hours while performing your usual activities of daily living (e.g., eating, grooming, preparing food, driving, writing,.........). Please, complete the daily evaluation log below. Fill in the date and time of day, list each activity that you perform while wearing the splint. After each activity, please answer yes or no to the six items shown on the chart, i.e. comfort, ease in putting on and taking off, whether you noticed any allergic reaction, and whether hand perspiration was absorbed by the splint. Lastly, did the splint limit your hand and wrist movement? Please, note the time that you took the splint off. Your participation in this wear study is greatly appreciated.

Date	Time of putting on	Activity	Comfort able		Easy to put on		Easy to take off		Allergic reaction		Absorbs perspiration		Limits movement		Time of taking off
			Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	

APPENDIX F

POST-TEST QUESTIONNAIRE

Please answer the following questions about the splint that you have worn this past week. There are no right or wrong answers to the questions. Most of the questions can be answered with a simple check (X). Please answer every question.

1. In your activities of daily living to what extent do you perform each of the following activities while wearing a splint?

	Always				Never
a. Dressing	1	2	3	4	5
b. Grooming	1	2	3	4	5
c. Eating	1	2	3	4	5
d. Preparing food	1	2	3	4	5
e. House keeping	1	2	3	4	5
f. Driving	1	2	3	4	5
g. Writing	1	2	3	4	5
h. Typing or word processing	1	2	3	4	5
I. Gardening	1	2	3	4	5
j. Sewing	1	2	3	4	5

2. Did the splint provide the following? (Circle **all** that apply)
   a. Support
   b. Massage
   c. Stimulate circulation
   d. Relieve stress & pain
   e. Increase range of motion
   f. Contain body heat
   g. Other ____________

3. Did the length of the volar stay inhibit your ability to make a fist?
   a. Yes   b. No

4. Rank the overall comfort level of the splint?

Very comfortable				Very uncomfortable
1	2	3	4	5

5. Was the splint:

Too warm				Too cool
1	2	3	4	5

6. To what extent did your hand sweat during wear?

Always				Never
1	2	3	4	5

7. Did the splint cause you any skin irritation?
   a. Yes (explain) ____________
   b. No (explain) ____________

8. Did the splint cause you any skin abrasion?
   a. Yes   b. No

	Very easy				Very difficult
9. How easy is putting on the splint?	1	2	3	4	5
10. How easy is taking off the splint?	1	2	3	4	5

11. When you are wearing the splint does it feel

Very light				Very heavy
1	2	3	4	5

12. When you dressed, did the splint:
    a. help a lot
    b. help a little
    c. interfere a little
    d. interfere a lot
    e. I don't dress myself

13. When you took care of your daily grooming (for example, brushing your teeth, brushing or combing your hair) did the splint:
    a. help a lot
    b. help a little
    c. interfere a little
    d. interfere a lot
    e. I don't take care of my own grooming

14. When you ate your meals (for example, cut your meat, used a utensil, drank from a glass), did the splint:
    a. help a lot
    b. help a little
    c. interfere a little
    d. interfere a lot
    e. I don't feed myself

15. When you prepared food for meals or snacks, did the splint:
    a. help a lot
    b. help a little
    c. interfere a little
    d. interfere a lot
    e. I don't prepare my own meals or snacks

16. When you worked around the house (for example, dusting, vacuuming, taking out trash) did the splint:
    a. help a lot
    b. help a little
    c. interfere a little
    d. interfere a lot
    e. I don't do housework

17. When you drove a car, did the splint:
    a. help a lot
    b. help a little
    c. interfere a little
    d. interfere a lot
    e. I don't drive

18. When you wrote with a pencil or pen, did the splint:
    a. help a lot
    b. help a little
    c. interfere a little
    d. interfere a lot
    e. I don't write with a pen or pencil

19. When you typed or did word processing, did the splint:
    a. help a lot
    b. help a little
    c. interfere a little
    d. interfere a lot
    e. I don't type

20. During the past week, did you ever put on the splint to help you perform an activity?

a. Yes b. No

21. If yes, for what activities did you put on the splint?

---

22. During the past week, did you ever take the splint off to help you perform an activity?

a. Yes b. No

23. If yes, during what activities did you remove the splint and why?

Activity:

Reason for removing splint:

---

24. Did you ever put the splint on to prevent pain?

a. Yes b. No (skip #25)

25. If you answered "yes" to #24, how successful was the splint at preventing pain?

very successful				very unsuccessful
1	2	3	4	5

26. Did you ever put the splint on because you were in pain at that time?

a. Yes b. No

27. If you answered yes to #26, how successful was the splint at reducing the pain?

very successful				very unsuccessful
1	2	3	4	5

28. Were you satisfied with the color of the splint?

a. Yes b. No c. Do not care

29. If not what color would you prefer?-- ________

30. Do you like the style of the splint?

a. Yes b. No

31. If not, what would you like to change about it?

---

32. Rate the splint on your overall satisfaction.

Excellent Good Fair Poor Unsatisfactory

33. Would you continue to wear this splint?
   a. Yes   b. No

34. How much would you be willing to pay for this splint?
   a. $ 15-20
   b. $ 21-25
   c. $ 26-30

35. Did any of your friends or family members show any interest in the splint?
   a. Yes   b. No

36. Comment: ____
____
____

Thank you for taking part in this survey.

APPENDIX G

Table 1

Conditions that Subjects were Diagnosed by a Physician

Conditions	Frequency	Percentage
CTS	4	44.4%
Tendenitis	2	22.2%
Arthritis	1	11.1%
Others	3	33.3%

Table 2

Frequency and Percentage of Symptoms Experienced by Subjects

Symptoms	Frequency	Percentage
Pain	8	88.9%
Swelling	7	77.8%
Weakness	6	66.7%
Numbness	5	55.6%
Stiffness	4	44.4%
Other	1	11.1%

Table 3

Frequency and Percentage of Hand and/or Wrist Symptoms

Symptoms in hands &/or wrists	Frequency	Percentage
No hand	2	22.2%
Right hand	2	22.2%
Left hand	2	22.2%
Both hands	3	33.3%
No wrist	1	11.1%
Right wrist	4	44.4%
Left wrist	2	22.2%
Both wrists	2	22.2%

Table 4

Grip Strength Means with Existing Splints & Prototype Splint in Kilograms

Subjects	Existing Splint	Prototype Splint
1	6.33 (Kg)	18.50 (Kg)
2	35.00 (Kg)	41.33 (Kg)
3	3.83 (Kg)	13.66 (Kg)
4	0.41 (Kg)	3.00 (Kg)
5	10.50 (Kg)	22.50 (Kg)
6	19.66 (Kg)	25.00 (Kg)
7	16.83 (Kg)	20.33 (Kg)
8	17.08 (Kg)	22.16 (Kg)
9	24.16 (Kg)	25.58 (Kg)

Table 5

Frequency and Percentage of Hand and/or Wrist Splint Usage

	Frequency	Percentage
Subjects used splint	7	77.7%
Used splint on right hand	4	44.4%
Used splint on left hand	2	22.2%
Used splint on both hands	3	33.3%
Used splint for < 1 yr	4	44.4%
Used splint for 1-2 yr	2	22.2%
Used splint for 3-4 yr	2	22.2%
Used splint for 5-10 yr	1	11.1%

Table 6

Key Pinch Strength Means with Existing Splints & Prototype Splint in Kilograms

Subjects	Existing Splint	Prototype Splint
1	4.36 (Kg)	5.58 (Kg)
2	11.08 (Kg)	12.66 (Kg)
3	4.06 (Kg)	7.00 (Kg)
4	0.10 (Kg)	0.33 (Kg)
5	4.08 (Kg)	6.58 (Kg)
6	7.86 (Kg)	8.58 (Kg)
7	7.41 (Kg)	7.58 (Kg)
8	7.58 (Kg)	8.36 (Kg)
9	8.25 (Kg)	8.16 (Kg)

Table 7

Palmar Pinch Strength Means with Existing Splints & Prototype Splint in Kilograms

Subjects	Existing Splint	Prototype Splint
1	4.83 (Kg)	6.00 (Kg)
2	10.83 (Kg)	10.75 (Kg)
3	3.16 (Kg)	7.08 (Kg)
4	1.61 (Kg)	0.41 (Kg)
5	4.08 (Kg)	5.50 (Kg)
6	7.53 (Kg)	8.33 (Kg)
7	8.25 (Kg)	7.33 (Kg)
8	6.50 (Kg)	7.66 (Kg)
9	9.38 (Kg)	9.06 (Kg)

Table 8

Tip Pinch Strength Means with Existing Splints & Prototype Splint in Kilograms

Subjects	Existing Splint	Prototype Splint
1	3.33 (Kg)	5.50 (Kg)
2	10.33 (Kg)	9.66 (Kg)
3	4.08 (Kg)	6.91 (Kg)
4	0.75 (Kg)	1.00 (Kg)
5	4.16 (Kg)	4.41 (Kg)
6	6.50 (Kg)	8.66 (Kg)
7	5.91 (Kg)	5.83 (Kg)
8	5.66 (Kg)	5.01 (Kg)
9	5.66 (Kg)	5.16 (Kg)

Table 9

Frequency Table for Yes/No Item Activities which Subjects Used a Splint

	Existing Splint	Prototype Splint
Word Processing	44.4%	44.4%
Writing	11.1%	11.1%
Driving	22.2%	11.1%
Moving	22.2%	11.1%
Shopping	11.1%	
Basketball	11.1%	
Kayaking	11.1%	
Gardening	11.1%	
Using mouse	11.1%	
Cleaning		11.1%
Farm work		11.1%

Table 10

Frequency Table for Yes/No Item for Activities which Subjects Removed their Splints

	Existing Splint	Prototype Splint
Word Processing	22.2%	11.1%
Writing	22.2%	33.3%
Washing	11.1%	11.1%
Driving	11.1%	11.1%
Eating	11.1%	22.2%
Cooking	11.1%	11.1%
Grooming	11.1%	
Sleeping	11.1%	
Dressing	11.1%	
Cleaning		11.1%
Farm work		11.1%
Using a wheelchair		11.1%

Table 11

Percentage of the Prototype Splint Effectiveness in Performing Daily Tasks

Activities	Comfortable	Absorb Perspiration	Limitation
Housework	94.33%	82.70%	32.70%
Typing	64.63%	25.61%	68.29%
Writing	76.67%	53.70%	87.80%
Moving	100.0%	75.00%	12.50%
Driving	63.27%	65.31%	65.31%
Eating	87.50%	52.78%	41.67%
Cooking	50.00%	44.44%	72.22%
Grooming	55.56%	50.00%	100.0%
Sleeping	98.08%	96.15%	46.15%
Sewing	83.33%	66.67%	66.67%
Sign Language	100%	100.0%	66.67%

APPENDIX H

OKLAHOMA STATE UNIVERSITY
INSTITUTIONAL REVIEW BOARD
HUMAN SUBJECTS REVIEW

Date: 04-06-98 **IRB #: HE-98-077**

Proposal Title: USER SATISFACTION, GRIP STRENGTH, AND FINGER DEXTERITY ASSOCIATED WITH A PROTOTYPE SPLINT

Principal Investigator(s): Donna H. Branson, Elaheh Amouzadeh

Reviewed and Processed as: Expedited

Approval Status Recommended by Reviewer(s): Approved

ALL APPROVALS MAY BE SUBJECT TO REVIEW BY FULL INSTITUTIONAL REVIEW BOARD AT NEXT MEETING, AS WELL AS ARE SUBJECT TO MONITORING AT ANY TIME DURING THE APPROVAL PERIOD.
APPROVAL STATUS PERIOD VALID FOR DATA COLLECTION FOR A ONE CALENDAR YEAR PERIOD AFTER WHICH A CONTINUATION OR RENEWAL REQUEST IS REQUIRED TO BE SUBMITTED FOR BOARD APPROVAL.
ANY MODIFICATIONS TO APPROVED PROJECT MUST ALSO BE SUBMITTED FOR APPROVAL.

Comments, Modifications/Conditions for Approval or Disapproval are as follows:

Signature: John H. Wycoff Date: April 9, 1998

Chair of Institutional Review Board

cc: Elaheh Amouzadeh

VITA

Elaheh Amouzadeh

Candidate for the Degree of

Master of Science

Thesis: USER SATISFACTION, FUNCTIONABILITY, GRIP STRENGTH, AND PINCH STRENGTH ASSOCIATED WITH A PROTOTYPE SPLINT

Major Field: Design, Housing and Merchandising

Professional Experience: Graduate Research and Teaching Assistant, Department of Design, Housing & Merchandising and Department of Economics, Oklahoma State University, Stillwater, Oklahoma.

Education: Received Master of Science Degree in Economics from Oklahoma State University, Stillwater, Oklahoma, May 1992; Received Bachelor of Science Degree in Economics May 1989; completed requirements for the Master of Science Degree in Design, Housing and Merchandising, Oklahoma State University, Stillwater, Oklahoma in July 1999.

Honors: Phi Kappa Phi Honor Society, Beta Gamma, Golden Key National Honor Society, Sigma Honor Society, Kappa Omicron Nu National Honor Society, Recipient of "Senior Economic Scholastic Award," March 1989, Recipient of Duck Woo Nam and Richard and Maxine Leftwich Fellowship Award.