THE EFFECTS OF A CARPOMETACARPAL THUMB ORTHOSIS ON PINCH STRENGTH, SELF-REPORTED ACTIVITIES OF DAILY LIVING AND PAIN IN OSTEOARTHRITIS

A THESIS

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BY

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To the Dean of Graduate Studies and Research:

I am submitting herewith a thesis written by Joyce Geralyn Kraenzle entitled "The Effects of a Carpometacarpal Thumb Orthosis on Pinch Strength, Self-Reported Activities of Daily Living, and Pain in Osteoarthritis". I have examined the final copy of this thesis for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Master of Arts in Occupational Therapy.

Jean Spencer, Ph.D., OTR
Major Professor

We have read this thesis
and recommend its acceptance:

Accepted:

Leslie M Thompson
Dean of Graduate Studies
and Research

Dedication

I dedicate this thesis to my parents who have given me the opportunity, confidence and support to pursue the ideas and to accomplish the goals that made this project possible.

Acknowledgement

Completion of this tremendous project was possible only through the invaluable assistance of others. Therefore, I would like to acknowledge the assistance of the staff at the Arthritis Institute, especially Louis Berman, M.D. and Benjamin Cohen, M.D. for their support of occupational therapy in the treatment of rheumatological diseases. I am grateful to the administration at HCA Center for Health Excellence for use of the outpatient facility and equipment. I greatly appreciate my boss, Pamela Massey, M.S., P.T. who has been understanding and encouraging throughout my pursuit of higher education. I would like to thank Jean Spencer, Ph.D., O.T.R. whose enthusiasm for research and unending guidance eased my graduate school anxieties. A special acknowledgement goes to Patrick Plenger, Ph.D. for his willingness, time and brilliance in assisting with the statistical analysis of data. Finally, I would like to thank a few of my personal friends, especially Mrs. Mildred Brown, Lea Ann Motycka, Laurie Parrish and Bernie and Vion Schram for their support and prayers during the difficult times.

Abstract

The Effects of a Carpometacarpal Thumb Orthosis on Pinch Strength, Self-Reported Activities of Daily Living and Pain in Osteoarthritis.

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This project investigates the effects of splint intervention on pinch strength, activities of daily living (ADL) and pain in persons with osteoarthritis at the thumb carpometacarpal (CMC) joint. Eight female subjects were evaluated for dominant hand involvement. Using a small-n design, baseline levels across variables were obtained using objective measures and self-report questionnaires. A thumb orthosis was fabricated to support the CMC joint while allowing hand function. Pinch strength, ADL performance and pain were reassessed at one, two and six week post-intervention intervals to determine the effects of treatment. Subject graphs, summary tables, repeated measures ANOVA and correlations were computed to analyze data. Results revealed significant effects upon lateral pinch strength, ADL performance and pain at six weeks post-intervention. No correlation was found among variables

of percentage time splints were worn and its beneficial effects which suggests changes in splint wearing protocols prescribed by therapists.

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CHAPTER I

Introduction

Osteoarthritis (OA), the oldest and most common rheumatic disease, affects about 16 million Americans and is a major cause of chronic disability (Arthritis Foundation, 1986; Swanson & Swanson, 1985). Characteristics of this progressive entity include loss of articular cartilage, osteophyte formation at the joint margins and synovitis which is usually seen in the advanced stage (Schumacher, Klippel & Robinson, 1988). Although the disease commonly affects people over 60 years of age, many experience the symptoms of OA before age 40 as a result of joint injury or overuse (Arthritis Foundation, 1986). A greater incidence appears to be linked with repetitive trauma which suggests a relationship between osteoarthritic joint changes and occupational stress (Acheson, 1966; Lawrence, 1969). One study reports increased severity of OA in the dominant hand of its subjects (Acheson, Chan & Clemett, 1970).

Degenerative changes commonly invade the proximal and distal interphalangeal finger joints as well as the carpometacarpal (CMC) joint at the base of the thumb (Schumacher et al, 1988). In some instances, the affected

thumb may become the only symptomatic indication of OA. As it accounts for 45% of hand function and provides for diverse mobility at the CMC joint, the thumb is subsequently subject to a significant amount of occupational stress (Melvin, 1989). In a study of 70 patients with disabling OA of the hand, Swanson et al (1985) found pain and swelling at the base of the thumb to be common complaints. These symptoms, as well as CMC joint instability, crepitation, loss of motion, deformity and decreased strength were found to be aggravated by repetitive pinch motions. Therefore, as osteoarthritic disease develops in the CMC joint, individuals may avoid functions of prehension during daily activities (Swanson, 1972).

Statement of the Problem.

The role of occupational therapy in managing individuals with rheumatic disease involves the prevention of functional disability and the improvement of daily activity performance (Arthritis Health Professions Task Force, 1986). As a primary therapeutic means of preserving thumb integrity in OA, individually fabricated orthoses have been utilized by occupational therapists. Specifically, the use of thumb-stabilizing CMC splints has been reported to restore thumb stability while providing symptomatic relief (Swezey, 1978; Fess, 1981; Melvin, 1987; Malick, 1980). One such orthosis was designed by Melvin to provide stabilization,

relieve pain and reduce inflammation at the CMC thumb joint while increasing hand function. Melvin and Carlson-Rioux subsequently conducted an efficacy study which concluded that the splint had a causative effect on decreasing pain in the CMC joint and demonstrated a high rate of wearer compliance (Brown, 1989). Reportedly, the splint also allowed patients to maintain hand function. However, the available literature failed to empirically support this latter claim and lacked an examination of the splint's effect on pinch strength and performance of daily living activities. Furthermore, the generalizeability of pain reduction in patients from one study to similar populations remains unknown.

Purpose of the Study.

The purpose of this investigation was to determine the effects of a CMC thumb orthosis on pinch strength, performance of daily activities and pain in patients with osteoarthritis. It was the researcher's expectation that pinch strength would be increased, performance of daily activities enhanced and that pain would be reduced with the application and use of this orthotic device over time.

CHAPTER II

Review of the Literature

The literature describes a number of similarly designed thumb orthoses for the treatment of basal joint involvement in OA. In 1981, Ellis advocated the use of a thumb post splint for pain relief while enabling patients to perform daily tasks such as writing. Seeger (1984) recommended a functional thumb splint which relieved pain in the CMC and/or metacarpophalangeal (MCP) joints. Another orthotic variation increased function of the thumb by reducing pain and correcting early boutonniere deformity at the base and interphalangeal (IP) joints (Gruen, 1980). Similarly, a light fiberglass splint was described by Parry (1981) to rest the CMC joint while enabling finger flexion of the thumb for hand function. However, these reports lack empirical evidence that pain is actually diminished and hand function is preserved or increased. In an overview of orthotic advances in rheumatological splinting, Merritt (1987) concluded that more research is needed to determine the functional effects of orthoses on the degenerated joint. It thus becomes apparent that the efficacy study of the thumb orthosis on pain and patient compliance, conducted by Melvin

and Carlson-Rioux, remains exclusive at this time. Due to her explicit detail in thumb assessment, splint fabrication and follow-up, Melvin's evaluation procedures, orthotic design and treatment program were utilized in this study (1989).

Strength.

Several investigations have addressed the effect of splints on hand strength. In 1969, Gault and Spyker studied the outcome of joint immobilization in rheumatoid arthritis using a plaster of paris resting hand splint and a sling. Results showed inconsistent changes in grip strength from patient to patient during a four week period post-fitting. In a study of 92 patients with rheumatoid arthritis (RA), Anderson and Maas (1987) found no immediate effect of wrist splinting on grip strength. Biddulph (1981) measured grip and pinch strengths in 22 patients with painful wrists, eight of which had RA. Results showed a decrease in grip and pinch strengths immediately following splint application, after which a substantial increase in both measures was seen at day 10 post-fitting. Likewise, a demonstrable improvement in grip and pinch strengths was identified in three women with RA fitted with static wrist splints as described by Backman and Deitz (1988). In summary, the literature contains a substantial amount of information regarding grip and pinch strength improvement with use of wrist splints for persons

with RA. Unfortunately, the effects of thumb orthoses on hand strength in osteoarthritis is relatively unknown. In the researcher's experience, patients have reported basal thumb pain interfering with pinch strength during activity. Therefore, lateral and three-point pinch strengths specifically related to thumb function were chosen as outcome measures as they require thumb adduction, opposition and applied force to the index and middle fingers for prehension (Parry, 1981).

Activities of Daily Living.

In measuring functional status of individuals with rheumatic disease, the literature describes a variety of assessment scales and functional indices. Gresham (1987) highlighted traditional approaches including physical exam, mobility, activities of daily living (ADL), upper extremity function and global assessment instruments and subsequently suggested future research be aimed toward a consensus in this area. In the comparison of five health status instruments used in arthritis research, Liang, Larson, Cullen and Schwartz (1985) concluded that no single instrument performed better than the others. However, self-report ADL questionnaires, advocated by Brooks et al (1988), were found to be sensitive and reliable assessment and monitoring devices of clinical status in OA. In identifying an outcome

measure of ADL for the investigation at hand, two specific arthritis questionnaires were further explored.

The Arthritis Impact Measurement Scale (AIMS) questionnaire has been proven to be a practical, reliable and valid measure of health status for a mixed arthritis population. Its use was recommended for evaluating outcomes of arthritis interventions (Meenan, Gertmen & Mason, 1980). Additionally, the modified Stanford Health Assessment Questionnaire (MHAQ), which was devised from the Health Assessment Questionnaire (HAQ) by reducing the number of ADL items from 20 to 8, was found to obtain very similar information using fewer questions without significant concern for which eight activities were chosen (Pincus, Summey, Soraci, Wallston & Hummon, 1983). Unfortunately, application of the AIMS and MHAQ to specific functions of the thumb CMC joint was found to be limited. Therefore, an adapted questionnaire based on these scales was devised by the researcher for this investigation.

Pain.

As the major symptom of rheumatic disease, pain must be directly measured in order to demonstrate the outcome of treatment. Description, number and visual analog systems have become three methods of expressing pain severity (Huskisson, 1982). Descriptive scales have reportedly posed limitations in the quantity, definition and ranked order of

descriptors. Likewise, numerical scales have presented problems with a subject's number preferences which skew the distribution of results. In contrast, the visual analog scale has proven to be a sensitive, reproducible, widely applicable and valid means of measuring pain severity (Dickson & Bird, 1981; Huskisson, 1982). In a study conducted by Callahan, Brooks, Summey and Pincus (1987), the visual analog scale appeared to provide useful data in assessing pain in people with RA. Furthermore, the visual analog pain scale was utilized by Brooks, Callahan and Pincus (1988) in an ADL questionnaire for patients with OA and seemingly provided a reliable measure of clinical status. As this study aimed to determine the effects of an orthotic device on the subjective experience of pain, the visual analog scale was used as an outcome measure.

CHAPTER III

Methodology

Research Design.

A small-n design was used in this study. Unlike the traditional experimental design which requires a large number of subjects assigned to experimental and control groups, the small-n model is able to identify change on an individual basis with baseline data serving as the patient's own control. Unfortunately, information gathered from experimental group comparison may not be as useful clinically due to rigid and controlled set-up which limits application to direct patient care. In contrast, the small-n design incorporates empirical procedures into the practice arena with the ability to determine the efficacy of intervention. Typically, subsequent withdrawal of the treatment establishes greater credibility in the intervention. However, withdrawal from treatment, especially when effective, was felt to be both unethical and undesirable in direct patient care. Therefore, the AB or baseline-intervention variation was chosen as an ideally suited, small-n design for this project (Ottenbacher & York, 1984).

Subjects.

All subjects were referred to occupational therapy at the Arthritis Institute at HCA Center for Health Excellence in Houston, Texas. Although it was initially intended that ten subjects would be used for the study, sample size was reduced to eight due to the limited patient volume presenting with this condition over time. Those selected for the study included the first eight people who met the following criteria, outlined on the Subject Criteria Form (see appendix A):

(a) male or female between ages 30 and 70;

(b) diagnosed with osteoarthritis by a board certified rheumatologist;

(c) reported pain at the thumb CMC joint of the dominant hand with movement and/or at rest;

(d) exhibited a positive grind test for CMC involvement when evaluated by the same registered occupational therapist for all subjects. (The positive grind test elicited pain or crepitus in the CMC joint when the first metacarpal head was pressed into the trapezium bone and gently rotated. Crepitus was defined as a grating or crunching sensation or sound which occurred during joint or tendon motion.) (Melvin, 1989);

(e) demonstrated no active thumb interphalangeal joint inflammation when assessed clinically for pain, swelling, redness and motion;

(f) not currently using a thumb orthosis and must not have used one during the previous six months;

(g) agreed to participate in the study by signing an informed consent;

(h) may have exhibited additional CMC joint symptoms which included: limited retroversion or extension movements, muscle weakness or atrophy secondary to disuse, CMC joint squaring due to osteophyte formation, localized tenderness, aching, swelling, redness or instability.

All eight subjects were female with ages ranging from 36 to 70 years and mean age of 56.4 years. From the time they were screened for the study, two of the subjects had experienced onset of symptoms within one month, three subjects between one month and one year, one subject between one and two years and two subjects between 5 and 10 years. Six of the eight or 75% of the sample were right hand dominant. All subjects reported pain at the base of the thumb with activity, and five also reported pain occurring at rest. One subject, who had been wearing a thumb orthosis that had broken within the previous six months, was included in the study due to recurring, severe pain at the CMC joint. The subjects'

occupations included two nurses, three retirees, one housewife and two clerical personnel. Leisure activities included gardening, sewing, needlework, cooking, reading, painting, crafts and traveling. During the six week program, six of the subjects reportedly took pain and/or anti-inflammatory drugs approximately twice daily as prescribed by their physician. The use of these medications was monitored for consistency throughout the six weeks as control for this variable in influencing outcome.

Instrumentation.

Lateral and three-point pad pinch strengths were measured using a calibrated pinch gauge. Lateral pinch was tested where the thumb pad touches against the radial aspect of the index finger. Three-point pinch was assessed where the thumb, index and middle finger pads come together. The average of three trials for each prehension pattern was calculated and recorded on the Data Collection Form (see appendix B). Average scores for lateral and three-point pinch strengths were charted daily on a data graph for each subject.

The ADL questionnaire was adapted from the AIMS and MHAQ to provide eight activities directly applicable to thumb function. The first four activities were taken from the MHAQ and the following two items were adapted from the dexterity subgroup of the AIMS. The last two functional tasks were

chosen by the researcher based upon reports from previous patients experiencing basal thumb pain during activity. The first three assessment scales, which measure levels of difficulty, satisfaction and need for assistance during activity performance were taken directly from the MHAQ. The fourth scale, addressing the level of pain during performance, was derived from Callahan et al. (1987) and chosen by the researcher to determine the splint's ability to relieve pain during specific tasks. Information regarding pain and functional capacity in ADL was gathered from the questionnaire in the following manner:

1. Subjects were requested to rate their level of difficulty in performing each of eight tasks by checking one of four choices: "without any difficulty," "with some difficulty," "with much difficulty" or "unable to do." Responses were rated 4, 3, 2 and 1 respectively. The total ADL difficulty score was derived by summing ratings from all eight activities per day. Each score was charted daily on individual subject graphs during the six week program.
2. Level of satisfaction in the ability to perform each of these same activities was determined by choosing one of the following categories: "very satisfied," "somewhat satisfied," "somewhat

dissatisfied" or "very dissatisfied." Responses were rated 4, 3, 2 and 1 respectively. The total ADL satisfaction score was derived by summing ratings from all eight activities each day. Daily ADL satisfaction scores were charted on subject graphs during the six week period.

3. To determine need for help during each of these tasks, subjects were requested to choose one of two responses: "do not need help" or "need help." Although it was described by the therapist how "do not need help" and "need help" were to be distinguished, subjects appeared to be confused with the type of help required (ie. from another person, the other hand or an assistive device). Due to the high variability in interpretation across subjects, data from this scale were not computed.

4. In assessing how often it is painful to execute each of the eight activities, subjects were asked to check one of four responses: "never," "sometimes," "most of the time" or "always." Responses were again rated 4, 3, 2 and 1 respectively and summed across all eight tasks to produce a total ADL pain score per day. Scores

were plotted on subject graphs throughout the six weeks.

5. The visual analog pain scale was comprised of a horizontal line measuring 10 centimeters in length with descriptors at its ends representing the extremes of pain. Subjects were asked to mark the line at a point which corresponded to their daily level of pain. The visual analog (VA) pain score was derived by measuring the distance in millimeters between the subject's mark and the end point of severe pain. This number was then divided by three in order to determine a score which was comparable to strength and ADL performance graph scores. Likewise, VA pain scores were plotted daily on subject graphs for six weeks.

High questionnaire scores were therefore desirable across all scales, indicating low difficulty, high satisfaction, and low pain outcome measures. To determine adequate design, this particular questionnaire was pilot tested on three patients previously treated for thumb CMC joint involvement prior to initiating its use for this project (see appendix C).

Procedures.

Patients who agreed to participate in this study signed an informed consent form during a regular visit to the

Arthritis Institute (see appendix D). Upon meeting the outlined criteria as determined by the occupational therapist, subjects completed an initial questionnaire with assistance to become acquainted with its format. For the gathering of baseline information, each patient was provided with five identical, blank questionnaires and instructed to complete one daily, over a five consecutive day period, at the same time each day when pain was felt to be most severe for them. Questionnaires were to be completed without viewing previous scores (Jacobsen, 1965).

During a scheduled appointment approximately one week later, subjects returned their questionnaires to the therapist. At that time, each patient was evaluated for pinch strength of the affected thumb in a standardized manner. The average of three trials was recorded as pre-orthotic values for each prehension type. All subjects were then measured for and fitted with a custom made, thumb CMC orthosis as described by Melvin (1989). A thermoplastic material with high contourability in 1/16" thickness was used for splint fabrication. The orthosis was fitted to restrict motion at the CMC and MCP joints, allow function of the wrist, thumb IP and index MCP joints and to maintain the thumb in palmar abduction. The thumb MCP joint was splinted to permit writing and pinch functions during the fitting.

Immediately following splint application and while wearing it, each subject was reassessed for pinch strengths which were recorded as post-orthotic values. Splint precautions were assessed individually for pressure, skin irritation, rubbing and joint mobility. Written wearing instructions were provided to include day and night splint usage for three weeks, followed by an additional three weeks of wear only when pain made it necessary, during activity and/or at rest. Subjects were given a Splint-Wear Diary Form to record periods of time that the splint was actually worn during the six week program (see appendix E).

At the end of the first week post-orthotic fitting and while wearing the splint, patients were clinically reassessed for pinch strength and values were recorded. During five consecutive days of the second week post-fitting, at the same time each day when pain was usually most severe, subjects completed a questionnaire to rate pain and ADL status while wearing the orthosis. At the end of the second week, subjects returned the questionnaires, were measured for pinch strength, and values were recorded. At six weeks post-fitting, a final questionnaire was completed and pinch strength was reassessed. Splint-Wear Diary Forms were collected to determine actual time the splints were worn during the project.

CHAPTER IV

Results

Graphic Analysis of Change in Study Variables Over Time.

Persons advocating use of small-n research designs recommend the use of graphs in order to visually present and analyze data over time. Individual graphs were therefore created to present each subject's data for strength, ADL performance and pain over a six week period. The averaged values for lateral and three-point pinch strengths were plotted prior to the intervention, immediately following the intervention and at one week, two week and six week post-intervention intervals. Strength values ranged from a low of 4.66 to a high of 17.33 pounds. Total scores for ADL difficulty, ADL satisfaction, ADL pain and visual analog scale pain from eleven questionnaires completed by each subject were individually plotted at five baseline days, at five days during the second week post-intervention and at six weeks post-intervention. ADL performance scores ranged from a low of 8 to a high of 32. Visual analog (VA) pain measures were converted to obtain graph scores comparable to ADL scales. This was done by determining the distance in millimeters between the subject's pain mark and the "severe

pain" end of a 10-centimeter line and dividing this number by three. VA pain scores subsequently ranged from severe pain at O to no pain at 33.3 (see graphs 1-8, appendix F).

Visual inspection of these eight graphs revealed a high degree of variability over time for each subject as well as across subjects. Lateral and three-point pinch strength values generally tended to decline immediately following splint intervention. For three subjects, the highest strength value appeared to be at two weeks with a slight decrease in strength seen at six weeks post-intervention. In contrast, either a plateau effect or an increased value was noted in five subjects at six weeks. Overall, lateral pinch strength showed greater values over three-point pinch strength in seven of eight subjects at six weeks post-intervention.

Similarly, there appeared to be a demonstrable improvement in ADL difficulty, satisfaction and pain between baseline and two week post-intervention intervals for six of eight subjects. Subjects #4 and #5 showed variable improvement between these time intervals. As may be expected, ADL satisfaction levels tended to correspond to levels of ADL difficulty and pain and were generally the lowest ADL values during baseline measures. In contrast, difficulty levels tended to be the highest ADL values during baseline. During the second week post-intervention interval,

ADL scores began to converge in seven of eight subjects as compared to baseline values. Nonetheless, at six weeks, all eight subjects displayed improvement in overall ADL performance beyond pre-intervention status.

Pain, measured by the visual analog scale, exhibited a high degree of variability during baseline and two week post-intervention measures. Moreover, it did not demonstrate a close relationship to ADL pain scores. However, the trend showed VA pain steadily decreased overall at six weeks post-intervention for seven of eight subjects.

A final graph, plotted with the mean values of pinch strength, ADL performance and VA pain from all eight subjects, was formulated to gain perspective on overall group response to splint intervention. Lateral pinch strength mean values steadily increased from baseline through six week intervals. In contrast, mean values for three-point pinch strength decreased from baseline to immediate post-intervention, increased at one week and two week intervals, then decreased slightly at six weeks post-treatment. All ADL performance and VA pain mean values were consistently higher at two week over baseline measures. At six weeks, ADL mean scores appeared to plateau, but the mean value of VA pain showed greatest improvement over all previous VA measures (see graph 9, appendix F).

Descriptive Data on Study Variables Over Time.

In order to see how ratings for self-reported ADL performance varied over time, mean values were computed representing the number of times each rating was chosen across all eight subjects. Ratings of 4, 3, 2 and 1 ranged from no problem to maximal difficulty, dissatisfaction or pain during ADL performance, respectively. Thus, high scores indicated low difficulty, high satisfaction and low pain. These values were entered into summary tables for ADL difficulty, satisfaction and pain with comparisons over baseline, two week and six week post-intervention time frames (see table 1). Clearly, the highest ratings of 3 and 4 were more frequently chosen at two week and six week time intervals over baseline for all ADL scales.

Table 1

Changes Over Time in ADL Ratings.

	Ratings	Baseline	Two Weeks	Six Weeks
ADL	4	6.875	20.50	23.125
Difficulty	3	18.875	14.75	13.75
Scale	2	12.75	4.125	2.50
	1	1.50	0.625	0.625
ADL	4	5.75	21.375	21.875
Satisfaction	3	7.875	10.25	12.50
Scale	2	12.00	6.00	3.75
	1	14.375	2.375	1.875
ADL	4	4.375	18.00	20.625
Pain	3	15.875	14.50	14.375
Scale	2	8.250	5.375	3.125
	1	11.50	2.125	1.875

Note. Data represent mean values for the number of times each rating was chosen across all subjects at baseline, two week and six week post-intervention intervals. Ratings of 4 indicate low difficulty, high satisfaction and low pain.

Likewise, mean values were determined for VA pain measures of 0 (no pain) to 10 (severe pain) represented on a 10-centimeter line where subjects placed a mark corresponding

to their level of pain. As with ADL performance, pain levels decreased over time from baseline to six week intervals (see table 2).

Table 2

Changes Over Time in Pain.

	Baseline	Two Weeks Post-Intervention	Six Weeks Post-Intervention
Visual Analog Pain Scale	4.975 cm.	1.875 cm.	0.838 cm.
	0 = no pain		severe pain = 10

Note. Data represent mean values in centimeters where subjects placed a mark corresponding to their level of pain at baseline, two weeks and six weeks post-intervention.

An additional table was provided to summarize the mean percentage of time subjects actually wore their splint during the entire six weeks. These data were collected on diary forms by the subjects themselves. Whereas subjects were requested to wear their splint all the time during the first three weeks, actual time averaged from 74% to 84%. During the second three week period, subjects could wear their

splint when they felt they needed it. Average time the splint was actually worn was 26% to 41% (see table 3).

Table 3

Changes Over Time in Splint Wear.

	Week					
Actual Splint Wear	1	2	3	4	5	6
Average Percentage of Time	74%	82%	84%	41%	34%	26%
Average Hours Per Day	17.8	19.7	20.0	9.8	8.2	6.2

Note. Data represent mean percentages of time splints were actually worn during the six week program.

Statistical Analysis of Change in Study Variables Over Time.

In order to look for significance of changes over time, especially from baseline to treatment, repeated measures analyses of variance (ANOVA) were computed across measures for lateral and three-point pinch strengths, ADL performance and VA pain. Pair wise comparisons were computed to compare pre-orthotic and each successive post-orthotic value. Mean, standard deviation and F values as well as significance levels can be seen in table 4.

Table 4

Changes in Pinch Strength.

		Post-Intervention			
Variable	Baseline	Immediate	One Week	Two Weeks	Six Weeks
Lateral Pinch Strength					
M	9.435	9.559	10.704	11.081	11.580
SD	2.754	2.140	1.957	2.145	2.883
F		8.45645	.00023	1.01902	12.68224
Signif		.023*	.988	.346	.009**
Three-Point Pinch Strength					
M	9.288	7.939	10.123	11.123	10.935
SD	3.576	2.271	2.354	2.595	2.480
F		16.02958	.56653	1.40287	3.26758
Signif		.005*	.476	.275	.114

Note. Data represent repeated measures ANOVA for pinch strength and pair wise comparisons between baseline and each successive post-intervention strength value.

*$p \leq .05$. **$p \leq .01$.

A significant difference between pre- and post-intervention values was noted for lateral pinch strength measures

immediately following orthotic intervention ($p=.023$) and at six weeks post-intervention ($p=.009$). However, the degree of change among mean values at baseline and immediate post-treatment was not meaningful. A significant difference for three-point pinch was only seen immediately following orthotic intervention ($p=.005$).

Likewise, a repeated measures ANOVA for ADL difficulty, satisfaction, pain and VA pain were computed among measures at baseline day #5 and each successive post orthotic value. Baseline day #5 was used for this test because subjects were felt to be more accustomed to using the questionnaire over previous days resulting in the most stable and accurate pre-intervention measure. Mean, standard deviation, F values and significance levels were identified (see table 5).

Table 5

Changes in ADL Performance and VA Pain.

Scale	Baseline	Post-Intervention					
		Two Weeks					Six Weeks
	day #5	#1	#2	#3	#4	#5	
ADL Difficulty							
M	22.00	26.125	27.375	27.00	26.875	27.625	27.875
SD	4.567	3.944	3.998	4.690	4.998	3.962	3.603
F		.2879	15.1250	5.4967	1.9470	13.9622	32.8301
Signif		.608	.006**	.052	.206	.007**	.001**
ADL Satisfaction							
M	16.875	23.750	27.50	26.250	26.375	26.750	26.875
SD	7.453	7.741	4.567	5.625	5.605	4.528	4.824
F		1.1045	25.9531	30.5842	27.7956	34.2347	70.00
Signif		.328	.001**	.001**	.001**	.001**	.000**
ADL Pain							
M	18.375	25.00	25.750	25.750	25.625	26.250	26.750
SD	6.781	5.606	5.874	5.120	5.680	5.092	5.676
F		.6176	13.440	9.600	17.6458	16.7470	17.8641
Signif		.458	.008**	.017*	.004**	.005**	.004**

(Table continues)

Scale		Post-Intervention					
	Baseline	Two Weeks					Six Weeks
	day #5	#1	#2	#3	#4	#5	
Visual Analog Pain							
M	14.625	28.250	28.416	25.917	25.791	27.083	30.541
SD	8.093	3.384	3.829	8.398	6.407	8.011	4.486
F		3.0883	4.1959	.9091	3.0674	3.3273	33.7673
Signif		.122	.080	.372	.123	.111	.001**

Note. Data represent repeated measures ANOVA for ADL performance and VA pain. Pair wise comparisons between baseline day #5 and each successive post-intervention ADL and pain value were computed. ADL scores ranged from 8=low to 32=high performance. VA pain values (converted) ranged from 0=severe pain to 33.3=no pain.

*$p \leq .05$. **$p \leq .01$.

A significant effect was recognized for days #2 and #5 during the second week post-intervention for ADL difficulty, satisfaction and pain measures ($p \leq .01$). Values on days #3 and #4 of that week were also significant for ADL satisfaction and pain ($p \leq .05$). Moreover, significant differences were found for all measures of ADL performance and VA pain at six weeks ($p \leq .01$).

Changes in Ratings for Specific Activities.

Specific responses regarding the eight activities of daily living on the self-report questionnaire were further

analyzed across subjects to identify which activities showed most improvement following splint application. Measures at baseline day #5 were chosen as stable and accurate pre-intervention data. Measures at day #2 of the second week were selected due to significant ANOVA results previously described. Six week post-intervention scores were also included in the analysis. Mean values were computed for self-report ratings, which ranged 4 to 1, with 4 indicating normal status and 1 the poorest status. The total number of subjects who rated themselves normal on individual activities was determined and compared across time (see table 6).

Table 6

Changes in ADL Ratings for Specific Activities Over Time.

Individual Activity Performance	ADL Difficulty		ADL Satisfaction		ADL Pain		Total No. of Normal Values	Percentage of Normal Activity
	Mean	No. of Normal Values	Mean	No. of Normal Values	Mean	No. of Normal Values		
Baseline day #5								
a. dress self	3.125	3	2.25	2	2.375	1	6	
b. lift cup to mouth	2.75	0	1.875	0	2.25	0	0	
c. open jars	2.50	2	1.625	1	1.875	1	4	
d. turn faucet on/off	2.75	2	2.25	2	2.50	2	6	15%
e. write with pen	3.125	2	2.50	1	2.625	1	4	
f. turn key in lock	2.75	0	2.00	0	2.375	0	0	
g. pick up coin	2.50	1	2.125	2	2.125	1	4	
h. use scissors	2.62	1	2.25	2	2.25	1	4	
							28	
Second week, day #2								
a. dress self	3.375	3	3.50	5	3.25	3	11	
b. lift cup to mouth	3.75	6	3.75	6	3.25	3	15	
c. open jars	3.125	3	3.125	3	2.75	3	9	
d. turn faucet on/off	3.25	4	3.375	6	3.25	3	13	53%
e. write with pen	3.625	6	3.625	6	3.50	6	18	
f. turn key in lock	3.625	5	3.625	5	3.25	4	14	
g. pick up coin	3.50	4	3.50	4	3.375	4	12	
h. use scissors	3.125	3	3.00	3	3.125	3	9	
							101	
Six Weeks								
a. dress self	3.50	4	*3.50	5	3.25	4	13	
b. lift cup to mouth	*3.875	7	*3.75	6	*3.50	5	18	
c. open jars	3.00•	3	*2.875•	3	*3.125	3	9	
d. turn faucet on/off	3.625	6	3.125•	3	3.375	4	13	55%
e. write with pen	3.50•	5	*3.625	5	3.375	5	15	
f. turn key in lock	3.50•	4	*3.375•	4	*3.375	3	11	
g. pick up coin	*3.50	4	*3.375•	4	*3.625	5	13	
h. use scissors	3.375	4	*3.25	5	3.125	4	13	
							105	

Note. Mean values at baseline day #5, at second week post-intervention, day #2 and at six weeks post-intervention for self-report ratings on individual activities of daily living across ADL difficulty, satisfaction and pain scales from questionnaires. The range of ratings for ADL performance was 4 to 1, with 4 indicating normal status and 1 the poorest status. Total number of subjects was 8. Number of subjects with normal values was summed at each time interval and across each ADL scale. Percentage of normal activity performance was calculated for each time interval.

• = decreased mean values by .25 or .125 from 2nd week interval; mean = .179.
* = improved mean values by $\geq$1.0 over baseline interval; mean = 1.25.

Clearly, difficulty and pain levels decreased as satisfaction levels increased (that is, all measures moved toward normal function) across all eight activities from baseline to second week intervals. Normal value ratings across difficulty, satisfaction and pain scales increased from a total of 28 at baseline to a total of 101 (out of 192 possible if all eight subjects would have rated themselves "normal" on all eight activities across the three scales) at second week post-intervention. This indicates that 15% of activity performance was considered normal at baseline whereas activity performance during the second week was 53% normal when rated subjectively on the questionnaire. At six weeks post-intervention, all ratings were improved over baseline and most ratings continued to increase from second week levels. Activities which decreased at six weeks from second week measures across two of three ADL scales included opening jars, writing and turning a key in a lock. However, activities which showed most improvement across two or three ADL scales from baseline measures included lifting a cup, opening jars, turning a key and picking up a coin. Overall, normal activity performance at six weeks further improved to 55% which resulted in a 40% gain over baseline ratings when considering the splint's influence on difficulty, satisfaction and pain during ADL.

Relationships Among Study Variables.

Pearson product moment correlations were computed to determine relationships among variables across time. Variables included in the first analysis consisted of percentage time splints were actually worn and values of lateral and three-point pinch strength across one week, two week and six week intervals. Mean and standard deviation values were calculated for all subjects. Lateral pinch strength values were correlated significantly with three-point pinch strength values across weeks one, two and six as shown in tables 7 and 8.

Table 7

Mean Values of Strength and Splint Wear Variables Over Time.

	Post-Intervention		
Variable	M at One Week	M at Two Weeks	M at Six Weeks
% Time Splint Worn	.8526	.8244	.2596
Lateral Pinch Strength	10.7038	11.0813	11.5800
Three-Point Pinch Strength	10.1225	11.1225	10.9350

Table 8

Relationships Among Strength and Splint Wear Variables Over Time.

Variable	% Time Splint Worn	Lateral Pinch Strength	Three-Point Pinch Strength
	One Week Post-Intervention		
% Time Splint Worn	1.0000	.1473	.1810
Lateral Pinch Strength	.1473	1.0000	.8432**
Three-Point Pinch Strength	.1810	.8432**	1.0000
	Two Weeks Post-Intervention		
% Time Splint Worn	1.0000	.0733	.1867
Lateral Pinch Strength	.0733	1.0000	.9092**
Three-Point Pinch Strength	.1867	.9092**	1.0000
	Six Weeks Post-Intervention		
% Time Splint Worn	1.0000	-.5599	-.6322
Lateral Pinch Strength	-.5599	1.0000	.9200**
Three-Point Pinch Strength	-.6322	.9200**	1.0000

Note. Pearson product moment correlations among variables of splint wear, lateral pinch strength and three-point pinch strength across all subjects at one, two and six week post-intervention intervals.

** $p \leq .01$

The second analysis consisted of splint wearing time variables which were an average of the first two weeks and an average of the last three weeks. Correlations were computed among variables of percent average time splints were actually worn, values of lateral and three-point pinch strength, values of ADL difficulty, satisfaction and pain and VA pain measures across two week and six week intervals. Values for mean and standard deviation were determined. Significant relationships were identified among lateral and three-point pinch values as well as among ADL difficulty, satisfaction and pain measures across two week and six week time intervals (see tables 9 and 10).

Table 9

Mean Values of all Variables Over Time.

	Post-Intervention	
Variable	M at Two Weeks	M at Six Weeks
% Average Time Splint Worn	.8383	.3354
Lateral Pinch Strength	11.0813	11.5800
Three-Point Pinch Strength	11.1225	10.9350
ADL Difficulty	27.6250	27.8750
ADL Satisfaction	26.7500	26.8750
ADL Pain	26.2500	26.7500
Visual Analog Pain Scale	27.0800	30.5388

Table 10

Relationships Among All Variables Over Time.

Variable	% Avg. Time Splint Worn	Lateral Pinch Strength	Three Point Pinch Strength	ADL Difficulty	ADL Satisfaction	ADL Pain	VA Pain
			Two Weeks Post-Intervention				
% Avg. Time Splint Worn	1.0000	.0670	.1451	.5649	.6171	.4090	.2361
Lateral Pinch Strength	.0670	1.0000	.9092**	-.3210	-.4095	-.2946	-.2343
Three Point Pinch Strength	.1451	.9092**	1.0000	-.2381	-.2746	-.3093	.0598
ADL Difficulty	.5649	-.3210	-.2381	1.0000	.9736**	.9330**	.1873
ADL Satisfaction	.6171	-.4095	-.2746	.9736**	1.0000	.8706**	.2265
ADL Pain	.4090	-.2946	-.3093	.9330**	.8706**	1.0000	.0567
VA Pain	.2361	-.2343	.0598	.1873	.2265	.0567	1.0000
			Six Weeks Post-Intervention				
% Avg. Time Splint Worn	1.0000	-.4542	-.5280	-.3232	-.2283	-.4818	-.1210
Lateral Pinch Strength	-.4542	1.0000	.9200**	-.3724	-.4887	-.1757	-.0999
Three Point Pinch Strength	-.5280	.9200**	1.0000	-.1684	-.3366	-.0770	-.1461
ADL Difficulty	-.3232	-.3724	-.1684	1.0000	.9278**	.8924**	.3289
ADL Satisfaction	-.2283	-.4887	-.3366	.9278**	1.0000	.8910**	.6132
ADL Pain	-.4818	-.1757	-.0770	.8924**	.8910**	1.0000	.5090
VA Pain	-.1210	-.0999	-.1461	.3289	.6132	.5090	1.0000

(Table continues)

Note. Pearson product moment correlations among variables of splint wear, pinch strength, ADL performance and VA pain across all subjects at two and six week post-intervention intervals. Two week splint wear value is an average of the first and second weeks. Six week splint wear value is an average of the fourth, fifth and sixth weeks.

** $P \leq .01$

CHAPTER V

Discussion

These data indicate that subjects having osteoarthritis in the CMC joint of the thumb benefitted from splint intervention with increased pinch strength, improved ADL performance and decreased pain over a six week period. As one may expect, graphs illustrated tremendous variability for each subject and across subjects, probably due to the varying severity, duration and unpredictable nature of the disease as well as the intersubject differences of occupation and lifestyle. Two subjects, for example, exhibited severe disease symptoms which warranted arthrodesis surgery at the CMC joint, which was undertaken following their participation in the study. Occupations of four subjects required direct and constant physical use of the hands which placed specific forces upon the thumbs. Consistent use of pain and anti-inflammatory medications was monitored throughout the study to rule out their potential effects on outcome measures.

The objective measures of pinch strength revealed trends which were fairly consistent across subjects. Values which decreased slightly immediately following intervention

were probably due to unfamiliarity with the splint. Three-point pinch strength values were significantly correlated with lateral pinch. However, lateral pinch values showed greater improvement over three-point pinch at six weeks suggesting greater splint stability during lateral pinch motions over time. This is probably due to the fact that lateral pinch requires less motion at the CMC joint away from the hand, while three-point pinch places the thumb in a maximally abducted position, causing more strain at that joint.

The subjective measures of ADL difficulty, satisfaction and pain showed greater variability on graphs within and across subjects than was expected during baseline intervals, which again may be due to subject differences. During post-intervention intervals, however, graphed ADL measures were more similar, apparently due to splint intervention. Significant effects were consistently identified at day #2 of the second week post-intervention across ADL difficulty, satisfaction and pain scales. This might suggest that subjects require at least a week to become familiar with the splint and to appreciate its benefits during daily tasks. ADL satisfaction and pain showed significant effects throughout the second week, suggesting a direct relationship between decreased pain and increased satisfaction. However, significant effects for ADL difficulty were inconsistent

during week #2 suggesting that difficulty level may vary with use of the splint. At six weeks, ADL difficulty, satisfaction, pain and VA pain continued to be significantly different than pre-treatment measures, suggesting that function continued to improve over time. Furthermore, ADL difficulty, satisfaction and pain were significantly correlated, indicating that as difficulty and pain decreased, satisfaction level increased, as was expected.

It is interesting to note, however, that ADL pain and VA pain showed inconsistent relationships when measures were inspected on graphs. Moreover, VA pain exhibited no significant correlation with ADL difficulty, satisfaction and pain scales overall. It is suspected that ADL pain represents an acute onset of pain directly related to a specific activity whereas VA pain signifies the varying level of dull, aching pain which is characteristic of chronic disease. Two types of arthritis pain exist and therefore require individual methods of assessment. The ADL performance scale seems to directly measure joint pain, whereas the VA scale appears to measure pain related to the disease process. Additionally, individual differences in pain tolerance and one's ability to cope with pain most likely increases variability in the results.

The summary graph and data tables further support the splint's effect on strength, ADL performance and pain. Mean

value increments plotted over time provide evidence for improved scores following splint intervention. Likewise, individual ratings for ADL performance and VA pain derived from the self-report questionnaires indicated overall performance and pain benefits.

When analyzing changes in kinds of activities over time, subjective ratings clearly identified greater improvement during activities that required grasp and release, pad to pad pinch, gripping, twisting and lateral pinch motions. The splint apparently provides more stability for applied strength during these hand functions. Measures which decreased slightly from second to six week intervals were most likely due to the reduction in splint wearing time from 82% to 26%. Turning faucets on and off was the only activity that showed no significant improvement over time. This was probably due to removal of the splint to avoid losing its shape in hot water, thus necessitating splint removal during water related activities.

The percentage of time splints were actually worn during the entire six weeks was also presented in a summary table. During the first three weeks when the splint was to be worn all the time, subjects actually wore it between 74% and 84% of the time, or 17.8 to 20 hours per day. Subjects reported reasons for not wearing it which included "didn't want other people to see it, might lose job, couldn't do some

activities with it on, didn't always have pain so didn't need it, and sometimes caused skin irritation." During the second three weeks, when subjects were instructed to wear it as needed, the splint was actually worn between 26% and 41% of the time, or 6.2 to 9.8 hours per day. Interestingly, the percentage of time splints were worn showed no significant correlation with strength, ADL performance and VA pain measures. The splint's effect, therefore, may not have been due to the number of hours it was worn but rather to the fact that it was worn at the appropriate time during activities which placed maximum stress upon the joint. Subsequently, if the splint was not needed during a light activity such as reading, it was easily removed. Furthermore, splint wear may have increased one's awareness of thumb arthritis, thus enhancing the use of joint protection techniques during activities. Splint wear for joint support during stressful activities while permitting use of the hand justifies the consideration of this device as a functional splint. Thus, availability and appropriate use of the splint during activity may be more important issues than patient compliance with a rigid splint wearing schedule. Patient involvement in the splint wearing decision, which provides a sense of control over one's disease, may further influence wearer compliance and enhance splint benefits.

It is important to acknowledge that there may be alternative explanations for the documented improvements in pinch strength, ADL performance and pain. This may have included the Hawthorne effect where subjects performed better while in the study or the increased awareness prompted by use of the diary. However, there is anecdotal evidence from comments made by subjects that the splint itself was helpful. Ethical reasons did not permit withdrawal of the splint which would have allowed a more definitive analysis of cause and effect.

CHAPTER VI

Implications

Future Research.

Although this investigation has revealed meaningful and useful information involving a small subject population across a six-week period, a number of limitations exist. In the presented study, baseline intervals were equal across subjects such that all received splint intervention at the same point in time. Subsequently, the question arises whether or not time is an influencing factor on outcome. Ideally, a small-n design consists of multiple baseline phases such that intervention is staggered across subjects, thus providing further evidence to support the effect of intervention. Furthermore, the follow-up period was limited to six weeks post-intervention. One may question how these effects vary over a greater length of time. A splint study constituting multiple baseline phases with a follow-up period greater than six weeks is therefore recommended for future research.

Surprisingly, there seemed to be no significant relationship between splint wearing time and its beneficial effects. Additional studies placing splint wearing time as

an independent variable are indicated to determine specific time frames which produce optimal splint benefits.

This investigation was further limited by the small number of subjects presenting with osteoarthritis at the thumb CMC joint. Consequently, results may not be generalizeable to all subjects with osteoarthritic thumb involvement. Likewise, a finite sample of daily living activities was utilized to measure hand function while wearing the splint. Thus, the effect of the orthosis upon all other hand activities is unknown. Therefore, a study comprised of a larger subject population and involving a comprehensive sample of hand activities would provide information regarding the generalizeability of the splint's effects across a broader arena of hand function. This would further equip therapists with a better understanding of splint care for persons suffering with arthritis.

The present study identified inconsistencies in splint wearing time across subjects. Several reasons for this variability in compliance were described. It would be of interest to know, more specifically, what factors influenced subjects to wear or not to wear their splints. With increased awareness of these factors, therapists could provide qualitative improvement in the fabrication and fitting of orthotic devices as well as in patient education.

The analysis of data from this investigation identified no relationship among variables of ADL pain and pain measured on the VA scale. Differences between these pain types and their impact on functional performance were suggested. Future research is recommended to more clearly define these differences in arthritis pain and the specific impact of pain upon quality of life during functional activity performance.

Finally, from a study which utilizes self-report and objective measures of gathering data, one may question the relationship among subjective and objective variables on outcome. When provided with an objective measure of progress, for example, do patients subjectively rate themselves with a higher level of performance? In contrast, when scoring themselves higher in functional performance, do subjects put greater effort into an objective test of progress? Research to determine how subjective and objective measures of treatment outcome are related would further benefit practitioners who utilize a variety of testing procedures.

Clinical Practice.

In arthritis care, the benefits of splinting vary among patients as was seen in this study. The decision to splint painful joints is a difficult one. A variety of factors influence this decision-making process as well as the success of orthotic intervention. The unpredictable course of these

diseases hinders the level and type of splint benefits expected among patients. Individual characteristics, such as whether or not one will actually wear the splint, the understanding of its purpose, the level of coping with one's disease, disability and pain, knowledge of disease, attitude, support systems, self-image as well as how one receives reactions from others during home, work and leisure activities make a significant impact upon the success of orthotic interventions. Additionally, the practitioner's method of presenting treatment, as well as splint making techniques, attitude, competence level and expectations for success further influence the patient's acceptance or rejection of orthotic devices. Overall, therapists must consider these factors when orthotic intervention is indicated in arthritis care.

It is worthy to note that two of the eight patients decided to pursue arthrodesis surgery despite improvement with use of the splint. This raises the question whether or not splint intervention was the treatment of choice for patients with severe disease. Based on the clinical judgement of this author, it is felt that orthotic treatment provides a conservative means of managing disease symptoms. With use of the splint, patients are given additional time to make decisions involving joint surgery. Therefore, splinting

is felt to be a beneficial and recommended intervention for individuals with severe disease.

Results of this study demonstrated no relationship between the amount of time splints were worn and their beneficial effects. This suggests that the availability and appropriate use of the splint may be more important than the specific number of hours per day or days per week it is worn. One may further question the prescription of initial three week splint wear versus splint use as needed throughout the entire program. Therefore, in prescribing splint wearing protocols, a greater emphasis might need to be placed on teaching the patient why and when to wear the device rather than just to wear it a particular amount of time. Patient education may even include self-assessment techniques to determine which activities require stress-related thumb motions at the CMC joint. In this way, the patient becomes responsible for the splint wearing-time decision, is more likely to wear the splint as needed during stressful tasks and subsequently experiences greater benefits during daily functional activities. Further research comparing rigid splint wearing protocols to splint wear as needed based on patient education would provide useful information to therapists prescribing orthotic devices.

Two different types of arthritis related pain appeared to be measured during this investigation. Splint

intervention significantly effected joint pain during activity performance rather than pain characteristic of the disease process. In view of this, therapists must provide realistic expectations of splint benefits to patients prior to treatment. People with arthritis should not be led to believe that orthotic devices will improve chronic disease pain, but rather expect the splint to relieve acute pain in specific joints during stressful activities.

Indirect benefits also result from splint intervention in arthritis care. Now that the patient wears an orthotic device on the hand, awareness of the arthritic condition as well as the need to carry out joint protection techniques are hopefully enhanced throughout the day. The splint is more likely to remind the patient to follow through with the entire arthritis program consisting of medications, modalities, exercise, nutrition and rest.

In summary, results obtained from this study support continued use of the CMC thumb orthosis for the improvement of pinch strength, ADL performance and pain for persons afflicted with osteoarthritis. Continued investigations involving splint intervention further enrich the literature with evidence for the utilization and beneficial effects of orthotic treatment in future health care.

References

1. Acheson, R. M. (1966). The New Haven Surgery of Joint Diseases: selection of study. In Population Studies of the Rheumatic Diseases, Proceedings of the Third International Population Symposium.

2. Acheson, R. M., Chan, Y. K., and Clemett, A. R. (1970). Distribution and Symptoms of Osteoarthritis in the Hands with Reference to Handedness. Annals of Rheumatic Disease, 29, 275-286.

3. Anderson, K., and Maas, F. (1987). Immediate Effect of Working Splints on Grip Strength of Arthritic Patients. Australian Occupational Therapy Journal, 34, 26-31.

4. Arthritis Foundation (1986). Medical Information Series: Osteoarthritis. Atlanta, Georgia.

5. Arthritis Health Professions Task Force for the Commission on Practice (1986). Roles and Functions of Occupational Therapy in the Management of Patients with Rheumatic Diseases. American Journal of Occupational Therapy, 40(12), 825-829.

6. Backman, C. L., and Deitz, J. C. (1988). Static Wrist Splint: Its Effect on Hand Function in Three Women with Rheumatoid Arthritis. Arthritis Care and Research, 1(3), 151-160.

7. Biddulph, S. L. (1981). The Effect of the Futuro Wrist Brace in Painful Conditions of the Wrist. South African Medical Journal, 60, 389-391.

8. Brooks, R. H., Callahan, L.F., and Pincus, T. (1988). Use of Self Report Activities of Daily Living Questionnaires in Osteoarthritis. Arthritis Care and Research, 1(1), 23-31.

9. Brown, E. J. (1989, October). [Interview with Jeanne Melvin, author of Rheumatic Disease: Occupational Therapy and Rehabilitation]. In Advance for Occupational Therapists, p. 13.

10. Callahan, L. F., Brooks, R. H., Summey, J.A., and Pincus, T. (1987). Quantitative Pain Assessment for Routine Care of Rheumatoid Arthritis Patients, Using a Pain Scale based on ADL and a Visual Analog Pain Scale. Arthritis and Rheumatism, 30(6), 630-636.

11. Dickson, J. S., and Bird, H. A. (1981). Reproducibility Along a 10 cm Vertical Visual Analogue Scale. Annals of Rheumatic Disease, 40, 87-89.

12. Ellis, M. (1984). Splinting the Rheumatoid Hand. In C. B. Wynn Parry (Ed.), The Hand (pp.673-696). Clinic in Rheumatic Diseases: Vol. 10. London: W.B. Saunders Co.

13. Fess, E. (1981). Hand Splinting: Principles and Methods. St. Louis: C. V. Mosby.

14. Gault, S. J., and Spyker, J. M. (1969). Beneficial Effects of Immobilization of Joints in Rheumatoid and Related Arthritides: A Splint Study Using Sequential Analysis. Arthritis and Rheumatism, 12(1), 34-44.

15. Gresham, G. E. (1987). Traditional Approaches to Functional Assessment in Arthritis. Journal of Rheumatology, 15(40), 11-14.

16. Gruen, H. (1980). Splinting in the Rheumatic Diseases. In G. Ehrlich (Ed.), Rehabilitation Management of Rheumatic Conditions (pp. 243-251). Baltimore, MD: Williams and Wilkins.

17. Huskisson, E. C. (1982). Measurement of Pain. Journal of Rheumatology, 9(5), 768-769.

18. Jacobsen, M. (1965). The Use of Rating Scales in Clinical Research. British Journal of Psychiatry, 111, 545-546.

19. Lawrence, J. S. (1969). Generalized Osteoarthritis in a Population Sample. American Journal of Epidemiology, 90, 381-389.

20. Liang, M. H., Larson, M. G., Cullen K. E. and Schwartz, J. A. (1985). Comparative Measurement Efficiency and Sensitivity of Five Health Status Instruments for Arthritis Research. Arthritis and Rheumatism, 28(5), 542-547.

21. Malick, M. H. (1980). Manual on Static Hand Splinting, (4th ed.). Pittsburgh, PA: Harmarville Rehabilitation Center, Inc.

22. Meenan, R. F., Gertman, P. M., and Mason, J. H. (1980). Measuring Health Status in Arthritis. Arthritis and Rheumatism, 23(2), 146-152.

23. Melvin, J. (1987). Rheumatic Disease: Occupational Therapy and Rehabilitation. Philadelphia: F. A. Davis.

24. Melvin, J. (1989). Rheumatic Diseases in the Adult and Child: Occupational Therapy and Rehabilitation, (3rd ed.). Philadelphia: F. A. Davis.

25. Merritt, J. L. (1987). Advances in Orthotics for the Patient with Rheumatoid Arthritis. Journal of Rheumatology, 15(14), 62-66.

26. Ottenbacher, K., and York, J. (1984). Strategies for Evaluating Clinical Change: Implications for Practice and Research. American Journal of Occupational Therapy, 38(10), 647-659.

27. Parry, W. (1981). Rehabilitation of the Hand. London: Butterworth and Co.

28. Pincus, T., Summey, J. A., Soraci, S. A., Wallston, K. A., and Hummon, N. P. (1983). Assessment of Patient Satisfaction in ADL using a Modified Stanford Health Assessment Questionnaire. Arthritis and Rheumatism, 26(11), 1346-1353.

29. Schumacher, H. R., Klippel, J. H., and Robinson, D. R. (Eds.). (1988). Primer on the Rheumatic Diseases, (9th ed.). Atlanta, GA: Arthritis Foundation.

30. Seeger, M. S. (1984). Splints, Braces and Casts. In G. Riggs and E. Gall (Eds.), Rheumatic Diseases: Rehabilitation and Management, (pp. 151-172). Stoneham, MA: Butterworth Publishers.

31. Swanson, A. (1972). Disabling Arthritis at the Base of the Thumb. Journal of Bone and Joint Surgery, 54, 456-471.

32. Swanson, A. B. and DeGroot Swanson, G. (1985). In L. Sokoloff (Ed.), Clinics in Rheumatic Diseases, Vol. II. London: W. B. Saunders Co.

33. Swezey, R. L. (1978). Arthritis: Rational Therapy and Rehabilitation. Philadelphia: W.B. Saunders Co.

APPENDICES

APPENDIX A

Subject Criteria Form

Subject Criteria Form

Code # _____ Date _____

Occupation_____

Male/Female Age_____ Onset of Symptoms_____

Leisure Activities_____

Diagnosed with OA by a board certified rheumatologist? yes/no

Thumb pain: at rest? _____ with activity? _____

Hand dominance: right/left Which thumb is painful?_____

Grind Test: positive/negative Crepitation? yes/no

Thumb IP involvement: active/inactive

pain?_____ swelling?_____

redness?_____ ROM?_____

Use of thumb orthosis currently? yes/no _____

during past 6 months? yes/no _____

Additional CMC joint symptoms:

limited CMC retroversion or extension?_____

muscle weakness or atrophy?_____

CMC joint squaring?_____

localized tenderness?_____

aching?_____

swelling?_____

redness?_____

instability?_____

Therapist_____

APPENDIX B

Self-Report ADL Questionnaire

SELF REPORT ADL QUESTIONNAIRE

Initial_____
Pre-intervention #_____
Post-intervention #_____
Date_____ Time_____

Patient Code #_____

The questions below concern your symptoms and daily activities. Please answer each question as it relates to your normal method of performance.

Please (✓) the one best answer to the questions below:

AT THE PRESENT TIME, are you able to:	Without ANY difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do
a. Dress yourself including tying shoelaces and doing buttons?	_____	_____	_____	_____
b. Lift a full cup to your mouth?	_____	_____	_____	_____
c. Open jars which have been previously opened?	_____	_____	_____	_____
d. Turn faucets on and off?	_____	_____	_____	_____
e. Write with a pen or pencil?	_____	_____	_____	_____
f. Turn a key in a lock?	_____	_____	_____	_____
g. Pick up a coin from a table?	_____	_____	_____	_____
h. Cut with a scissors?	_____	_____	_____	_____

AT THIS TIME, how satisfied are you with your ability to:	VERY satisfied	SOMEWHAT satisfied	SOMEWHAT dissatisfied	VERY dissatisfied
a. Dress yourself including tying shoelaces and doing buttons?	_____	_____	_____	_____
b. Lift a full cup to your mouth?	_____	_____	_____	_____
c. Open jars which have been previously opened?	_____	_____	_____	_____
d. Turn faucets on and off?	_____	_____	_____	_____
e. Write with a pen or pencil?	_____	_____	_____	_____
f. Turn a key in a lock?	_____	_____	_____	_____
g. Pick up a coin from a table?	_____	_____	_____	_____
h. Cut with a scissors?	_____	_____	_____	_____

Do you need help TODAY to:	Do not need help	Need help
a. Dress yourself including tying shoelaces and doing buttons?	_____	_____
b. Lift a full cup to your mouth?	_____	_____
c. Open jars which have been previously opened?	_____	_____
d. Turn faucets on and off?	_____	_____
e. Write with a pen or pencil?	_____	_____
f. Turn a key in a lock?	_____	_____
g. Pick up a coin from a table?	_____	_____
h. Cut with a scissors?	_____	_____

How often is it PAINFUL for you to:	NEVER	SOMETIMES	MOST OF TIME	ALWAYS
a. Dress yourself including typing shoelaces and doing buttons?	_____	_____	_____	_____
b. Lift a full cup to your mouth?	_____	_____	_____	_____
c. Open jars which have been previously opened?	_____	_____	_____	_____
d. Turn faucets on and off?	_____	_____	_____	_____
e. Write with a pen or pencil?	_____	_____	_____	_____
f. Turn a key in a lock?	_____	_____	_____	_____
g. Pick up a coin from a table?	_____	_____	_____	_____
h. Cut with a scissors?	_____	_____	_____	_____

How much pain do you have at the base of your thumb TODAY? Place a mark on the line below to indicate how severe your pain is:

no pain |——————————————————————————| severe pain

Please write below all the drugs or medicines you presently take for the treatment of your Osteoarthritis (including aspirin and medicine bought without prescription):

Name of drug or medicine	Dose	How many per day	How helpful is it? alot	some	none	Side effects? yes	no
1. _____	___	_____	___	___	___	___	___
2. _____	___	_____	___	___	___	___	___
3. _____	___	_____	___	___	___	___	___
4. _____	___	_____	___	___	___	___	___

APPENDIX C

Data Collection Form

DATA COLLECTION FORM

Code No.	Inform Consent	Initial Ques.	Pre-tx Ques. (5)	Interv. Date	Pre-orthotic Values	Immed. Post-ortho. Values	Immed V-A	1 Week Post-orth. Values	1 Week V-A	2 Week Ques. (5)	2 Week Post-ortho. Values	6 Week Ques.	6 Week Post-ortho. Values
1.					lat.	lat.		lat.			lat.		lat.
					3-pt.	3-pt.		3-pt.			3-pt.		3-pt.
2.					lat.	lat.		lat.			lat.		lat.
					3-pt.	3-pt.		3-pt.			3-pt.		3-pt.
3.					lat.	lat.		lat.			lat.		lat.
					3-pt.	3-pt.		3-pt.			3-pt.		3-pt.
4.					lat.	lat.		lat.			lat.		lat.
					3-pt.	3-pt.		3-pt.			3-pt.		3-pt.
5.					lat.	lat.		lat.			lat.		lat.
					3-pt.	3-pt.		3-pt.			3-pt.		3-pt.
6.					lat.	lat.		lat.			lat.		lat.
					3-pt.	3-pt.		3-pt.			3-pt.		3-pt.
7.					lat.	lat.		lat.			lat.		lat.
					3-pt.	3-pt.		3-pt.			3-pt.		3-pt.
8.					lat.	lat.		lat.			lat.		lat.
					3-pt.	3-pt.		3-pt.			3-pt.		3-pt.
9.					lat.	lat.		lat.			lat.		lat.
					3-pt.	3-pt.		3-pt.			3-pt.		3-pt.
10.					lat.	lat.		lat.			lat.		lat.
					3-pt.	3-pt.		3-pt.			3-pt.		3-pt.

APPENDIX D

Informed Consent

INFORMED CONSENT

I hereby give my consent to be involved in the following investigation:

(1) I understand that I will be participating in a 6 week study that is designed to evaluate how a thumb splint for the treatment of arthritis effects the pain, pinch strength and performance of daily activities of my dominant hand. I understand that this splint is a commonly used and well-known form of therapeutic treatment for thumb arthritis. During the first 3 week period, I will be asked to wear the splint all day and night. During the second 3 week period, I will be asked to wear the splint as needed for thumb pain. I understand that I will be asked to fill out a brief, 15-minute questionnaire on 12 separate days requesting information on my pain level and activity performance. I understand that I will be asked to attend four-60 minute therapy sessions during which my splint will be made and checked for adjustments, my pinch strength will be measured and my splint program reviewed. I understand that I will be asked to keep a written account of splint wearing time during the entire 6 weeks. I understand that this entire treatment program will be directed by Joyce Kraenzle who is a registered occupational therapist and a TWU graduate student. Dr. Jean Spencer is research advisor of this study and a faculty member at TWU.

(2) I understand that the splint will be custom-molded to the joint at the base of my thumb. I understand that the splint is intended to limit normal movement. I understand that there are some risks associated with this study. Although it should be comfortable to wear if fitted properly, it is possible that the splint may possibly cause excessive swelling, red pressure areas, skin irritations, stiffness and/or achiness. I understand that it is my responsibility to report any of these problems to the therapist so that my splint can be adjusted for improved comfort. Although the splint is intended to decrease thumb pain, improve pinch strength and make my daily activities easier to perform, I understand that the splint may increase my thumb pain, decrease my pinch strength and may make some activities more difficult to perform. If pain increases, pinch strength decreases and/or daily activities become more difficult to perform, I understand that I can choose to remove the splint at any time to alleviate these problems. Another possible risk of this study is loss of confidentiality. Measures are described below to protect confidentiality.

(3) I understand that the wearing of this splint is intended to relieve my thumb pain, increase my pinch strength and improve my ability to perform daily activities. In addition to these personal benefits, I understand that the results of this study will provide information about the effects of a splint currently used in the treatment of the thumb involved with arthritis.

(4) I understand that applicable, alternative procedures for pain relief include the applications of heat and cold, medications taken by mouth and/or injected directly into the joint and commercially available, pre-fabricated thumb splints.

(5) I understand that my confidentiality will be protected through a number coding system so that my name will not appear on any data collected in this study. I further understand that the results will be reported anonymously without using names of subjects.

(6) I understand that my participation in this study is done on a voluntary basis and that I am free to withdraw at any time without penalty.

(7) I understand that Texas Woman's University or HCA Center for Health Excellence in Houston, Texas will provide no compensation or medical treatment related to risks associated with this study. First aid treatment will be available.

(8) I understand that I may contact the researcher or the research advisor at any time if I have pertinent questions and/or concerns. These persons are Joyce Kraenzle, student researcher, at (713) 796-1389 or Dr. Jean Spencer, research advisor, at (713) 794-2131.

Signature_____ Date_____

Witness_____ Date_____

APPENDIX E

Splint-Wear Diary Form

SPLINT-WEAR DIARY FORM

Code #_____
Date of splint fabrication_____
Week #_____

Place a (✓) or (o) in each space to indicate the times of each day you wore or did not wear your splint. Place the number of hours you wore your splint during the night in the space provided at the bottom of each column.

(✓) = splint on (o) = splint off

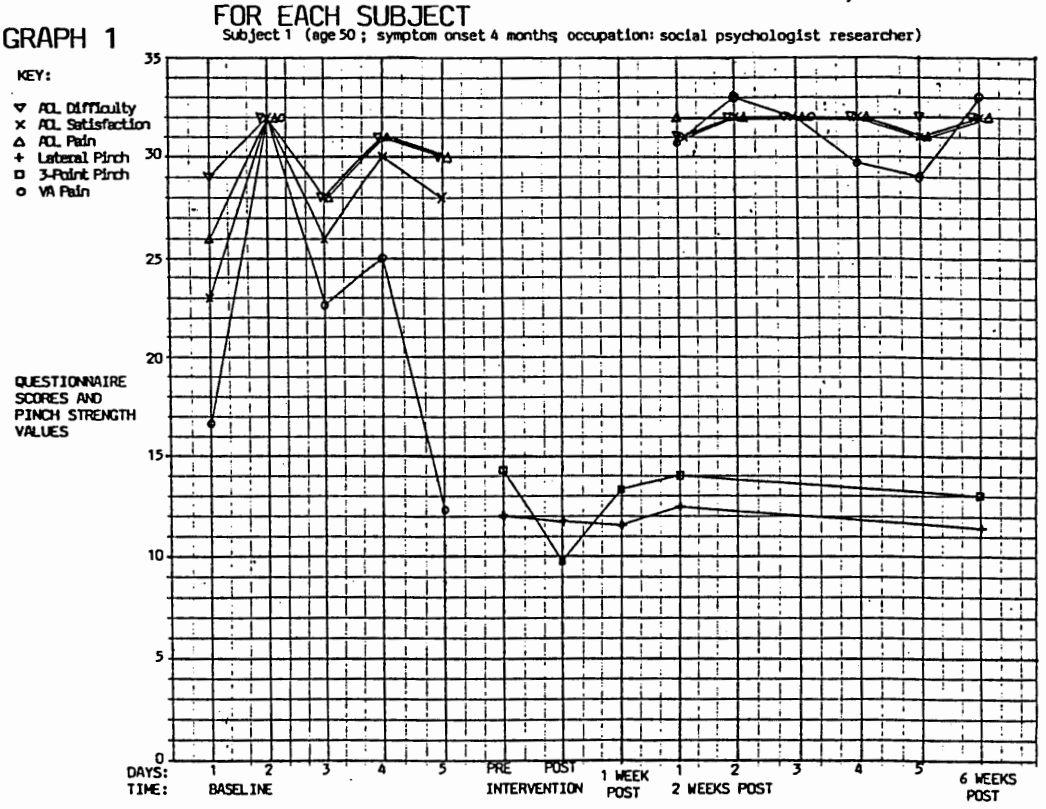
Date							
Day of week							
6:00 am							
7:00							
8:00							
9:00							
10:00							
11:00							
12:00 noon							
1:00 pm							
2:00							
3:00							
4:00							
5:00							
6:00							
7:00							
8:00							
9:00							
10:00							
Total # of hours worn at night							

APPENDIX F

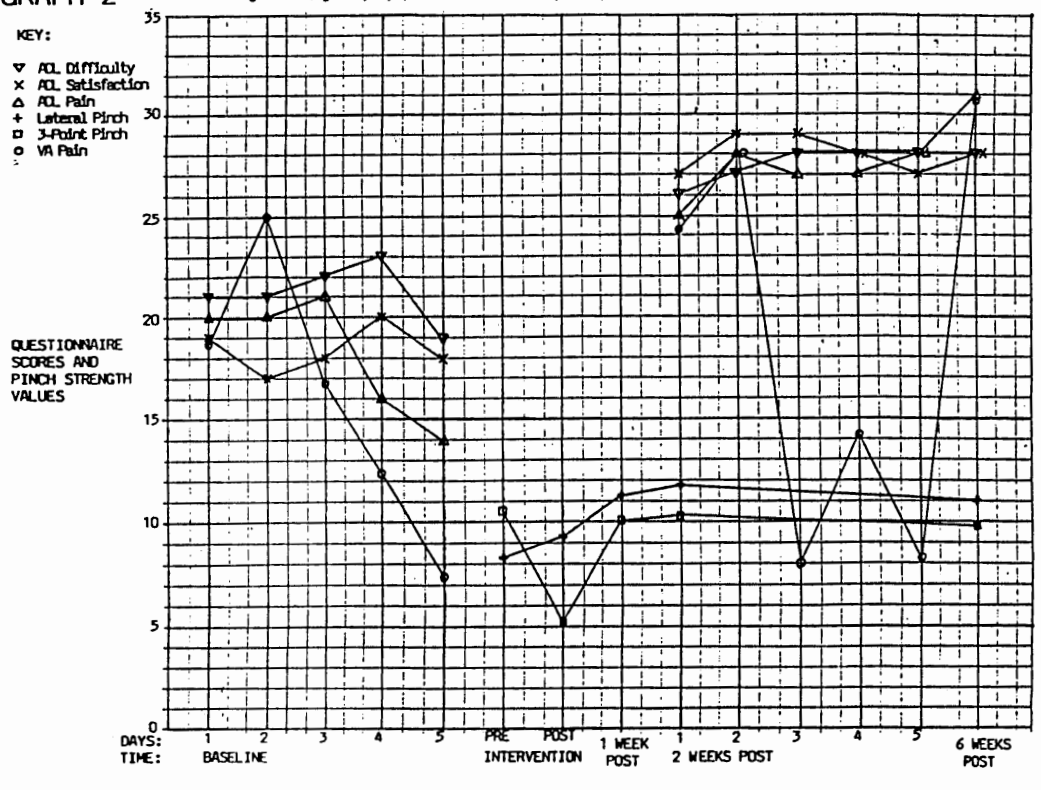
Subject Graphs

GRAPHS 1-8: CHANGE IN ALL STUDY VARIABLES OVER TIME; VALUES FOR EACH SUBJECT

GRAPH 1

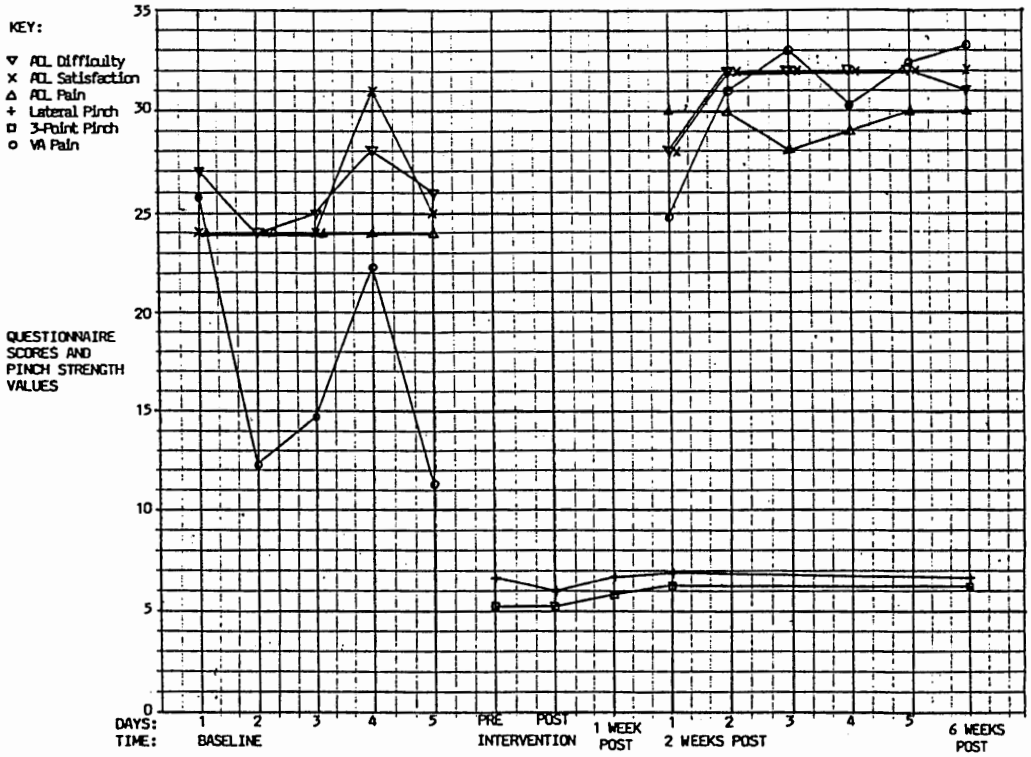


GRAPH 2



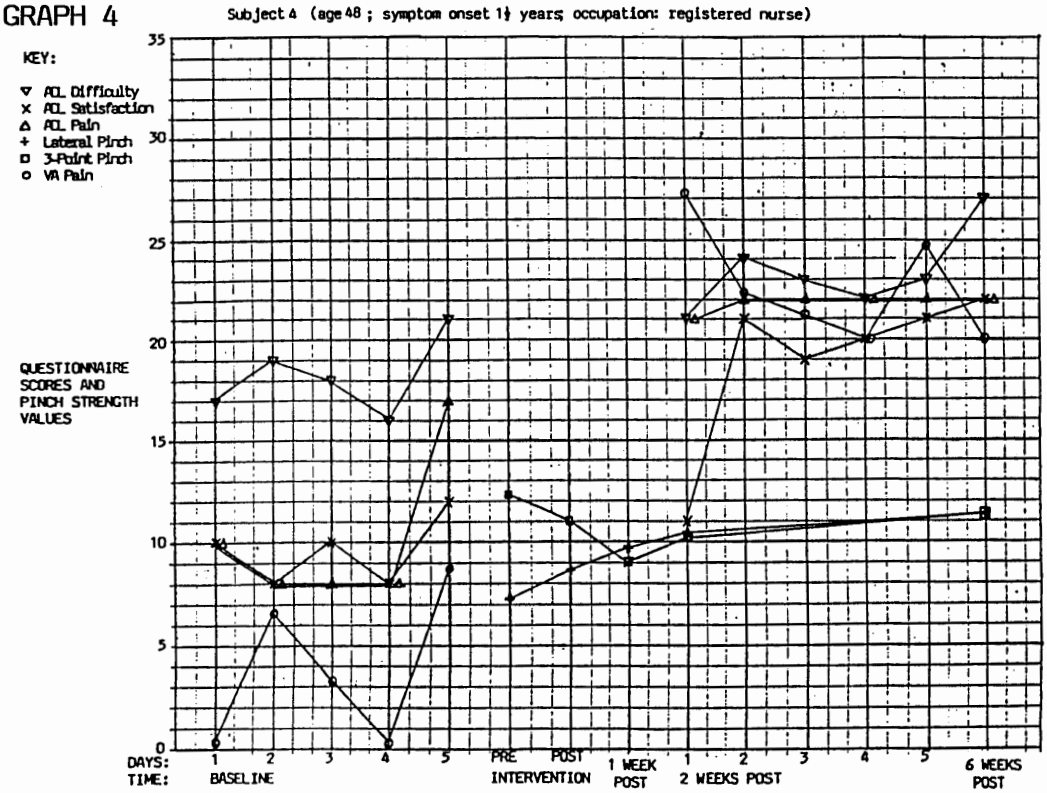
GRAPH 3

Subject 3 (age 70 ; symptom onset 1 week ; occupation: retired)



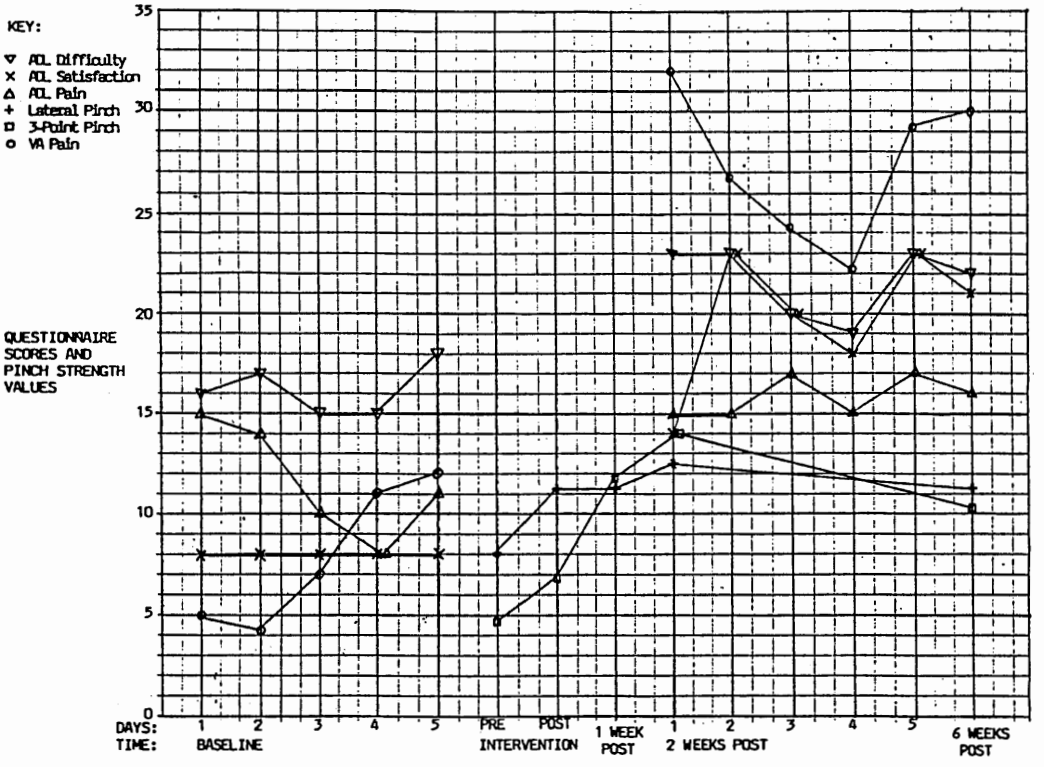
GRAPH 4

Subject 4 (age 48 ; symptom onset 1½ years; occupation: registered nurse)



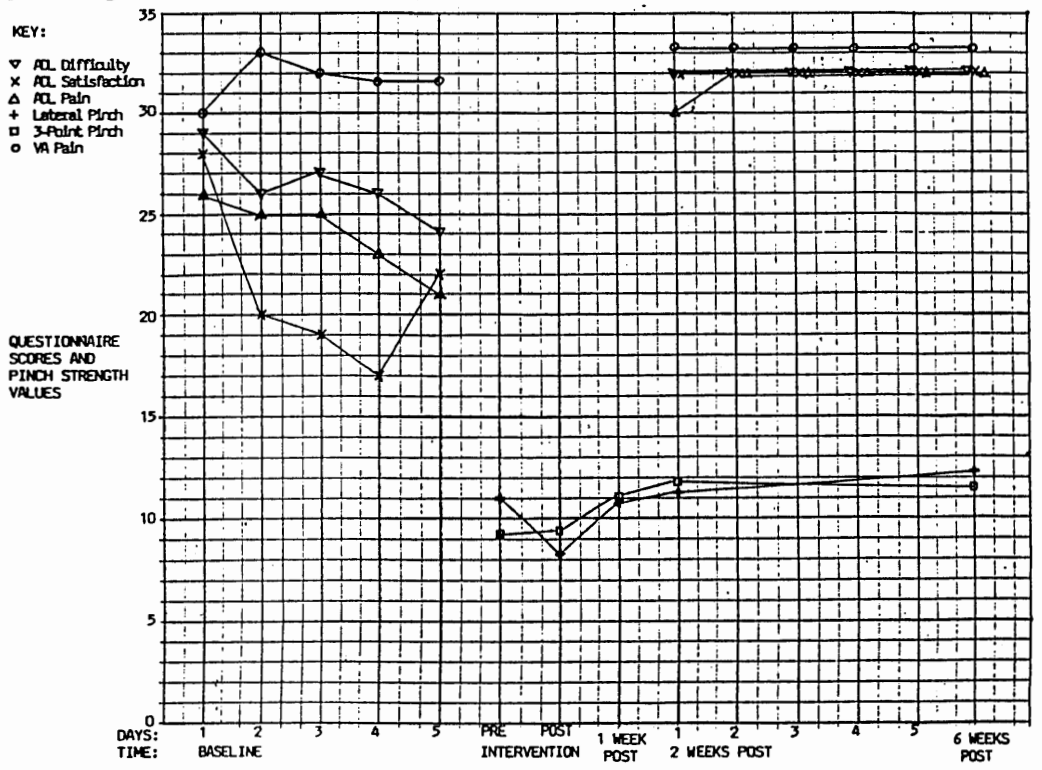
GRAPH 5

Subject 5 (age 49; symptom onset 7 years; occupation: registered nurse)



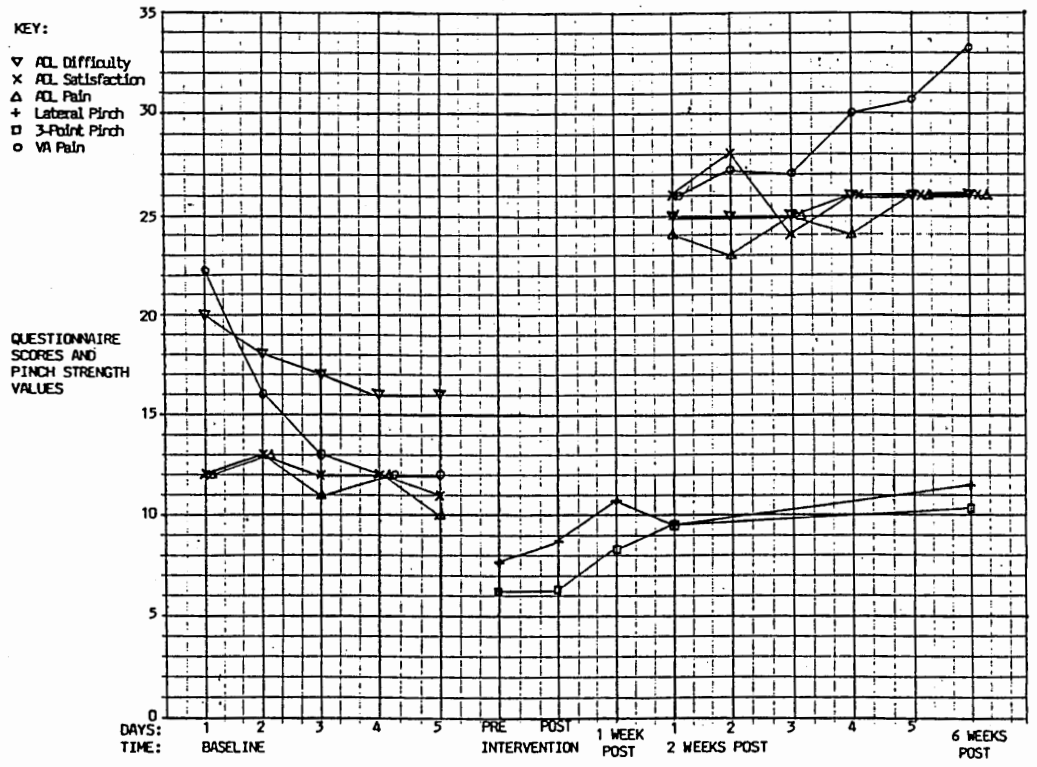
GRAPH 6

Subject 6 (age 64; symptom onset 1 month; occupation: retired)



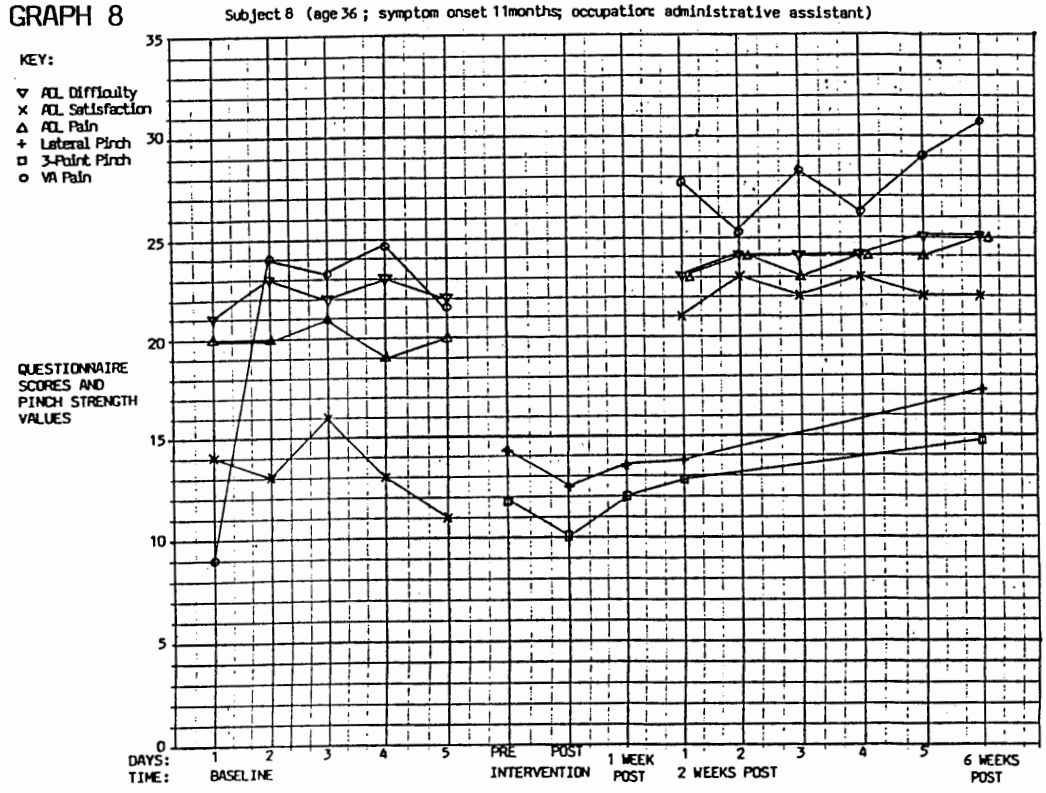
GRAPH 7

Subject 7 (age 69 ; symptom onset 8 years ; occupation: retired secretary)

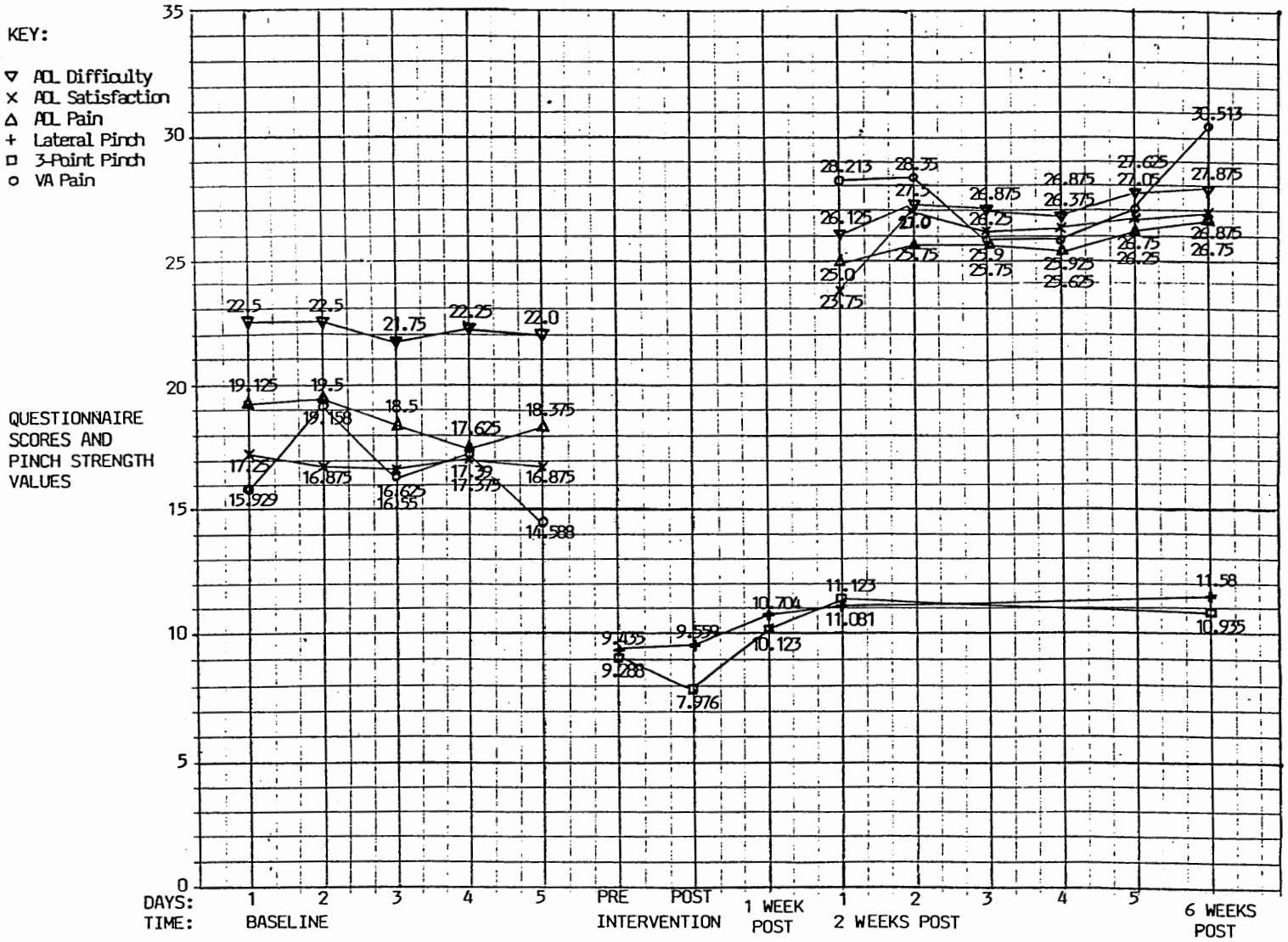


GRAPH 8

Subject 8 (age 36 ; symptom onset 11 months; occupation: administrative assistant)



GRAPH 9: CHANGE IN ALL STUDY VARIABLES OVER TIME; MEAN VALUES OF ALL SUBJECTS



APPENDIX G

Approval Letters

THE **ARTHRITIS** INSTITUTE
at the HCA Center for Health Excellence

May 10, 1990

Leslie Thompson, Ph.D.
Dean of Graduate Studies and Research
Texas Woman's University
Box 22479
TWU Station
Denton, Texas 76204

Dear Dr. Thompson,

We, at the HCA Center for Health Excellence, have reviewed and approved this research prospectus entitled "The Effects of a Carpometacarpal Thumb Orthosis on Pain, Pinch Strength and Self-Reported Activities of Daily Living in Osteoarthritis" to be conducted by Joyce G. Kraenzle, B.S., O.T.R. at the Arthritis Institute in Houston, Texas beginning in June, 1990.

Louis Berman, M.D.
Medical Director, Arthritis Institute

Daniel Morrison, M.D.
Medical Director, Rehabilitation Services

Larry Pollock, Ph.D.
Clinical Director, Rehabilitation Services

Pamela Massey, M.S., P.T.
Program Director,
Rehabilitation Services and
Arthritis Institute

Janet Matthews
Assistant Administrator,
HCA Center for Health Excellence

7800 Fannin, Suite 102, Houston, Texas 77054 • (713) 796-9900

LARRY POLLOCK, PH.D. AND ASSOCIATES
NEUROPSYCHOLOGY

2646 SOUTH LOOP WEST, SUITE 220
HOUSTON, TEXAS 77054
(713) 661-4961 — FAX (713) 432-1746

May 31, 1990

Leslie Thompson, Ph.D.
Dean of Graduate Studies and Research
Texas Woman's University
Box 22479
TWU Station
Denton, Texas 76204

Dear Dr. Thompson:

This letter is to confirm that the Institutional Review Board at Medical Center Hospital, Houston, Texas reviewed Joyce Kraenzle's research proposal entitled "The Effects of a Carpometacarpal Thumb Orthosis on Pain, Pinch Strength and Self-Reported Activities of Daily Living in Osteroarthritis". We understand that this research will be conducted in connection with her Master's Thesis. After reviewing her proposal, we approved it as meeting all FDA requirements for protecting the rights of human subjects. Ms. Kraenzle may proceed with her research project at her discretion.

Sincerely,

Larry Pollock

Larry Pollock, Ph.D.
Chairman, Institutional Review Board

TEXAS WOMAN'S UNIVERSITY
DENTON DALLAS HOUSTON
HUMAN SUBJECTS REVIEW COMMITTEE - HOUSTON CENTER

HSRC APPROVAL FORM

Name of Investigator(s): JOYCE G. KRAENZLE, B.S., O.T.R.

Social Security Number(s): 494-58-4387

Address: 7747 CAMBRIDGE

HOUSTON, TEXAS 77054

Dear: _____

Your study entitled: THE EFFECTS OF A CARPOMETACARPAL THUMB ORTHOSIS ON PAIN, PINCH STRENGTH AND SELF-REPORTED ACTIVITIES OF DAILY LIVING IN OSTEOARTHRITIS.

(The applicant must complete the top portion of this form)

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

Please be reminded that both the University and the Department of Health and Human Services regulations typically require that signatures indicating informed consent be obtained from all human subjects in your study. These are to be filed with the Human Subjects Review Committee Chairman. Any exception to this requirement is noted below. Furthermore, according to HHS regulations, **another review by the HSRC is required if your project changes or if it extends beyond one year from this date of approval.**

Any special provisions pertaining to your study are noted below:

_____ Add to informed consent form: "I understand that the return of my questionnaire constitutes my informed consent to act as a subject in this research".

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

_____ Other: see attached sheet.

_____ No special provisions apply.

Sincerely,

William R. Gould, Ph.D.
Chairman, HSRC - Houston Center

6-28-89
Date

HSRC Fall, 1989