A PILOT USE STUDY TO DETERMINE THE ABILITY OF A SPECIALLY DESIGNED GLOVE TO RELIEVE THE SYMPTOMS OF CARPAL TUNNEL SYNDROME

Report

CSRI Project No.: 00-223

April 13, 2001

for

Shock-Tek
21 Kerchival
Grosse Pointe, Michigan 48236

Conducted by:

California Skin Research Institute
A Division of DermTech International
15222-B Avenue of Science
San Diego, California 92128

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1.0 SUMMARY

California Skin Research Institute (CSRI) in San Diego, California conducted a study entitled "A Pilot Use Study To Determine The Ability Of A Specially Designed Glove To Relieve The Symptoms Of Carpal Tunnel Syndrome" for Shock-Tek Consultants in Clinton Township, Michigan. The study was designed to determine the ability of a specially designed glove to relieve the symptoms of carpal tunnel syndrome (CTS). The test article was identified as the Dr. Spitzer Impact Glove®.

Twenty-four subjects, nine males and fifteen females, (23-62 years of age) years of age) entered the study on January 20, 2001. Nine subjects, four males and five females (18-54 years of age) entered the study on January 27, 2001. Three subjects dropped from the study due to reasons unrelated to the study. Two additional subjects were excluded at the end of the study because of not meeting the inclusion/exclusion criteria. Twenty subjects, eight males and twelve females, (23-62 years of age) completed the study on February 3, 2001. Eight subjects, three males and five females (18-54 years of age) completed the study on February 14, 2001. A total of 28 subjects completed the study. There were no adverse events reported during the course of the study.

Each subject read and signed the Informed Consent Form and Medical Questionnaire on Visit 1 and was given the opportunity to have any questions answered. Each subject was given a copy of the Informed Consent, the Subjects Bill of Rights, the Subject Instructions and the Study Schedule.

Each subject was then screened by a physician, Jeffrey P. Sugar, D.O., using two diagnostic standards for CTS: the Tinel's Sign and Phalen's Test. The Tinel's Sign involves the physician gently tapping on the flexor surface of the wrist to check for tingling sensations in the digits while the Phalen's Test evaluates for CTS by volar flexing the wrists for one minute and noting when and if the onset of paresthesis occurred.

After diagnosis of CTS, each subject was placed either in Group A, the test group, which received the Dr. Spitzer Impact Glove or Group B, the control group, which received no glove. Subjects in the control group were advised to use the gloves they were currently using, if any. Subjects in both groups were instructed to wear their glove during their daily activities that involve impact to the hands. They were also instructed to remove their glove while sleeping. Both groups were instructed to continue their normal daily activities.

Each subject was instructed to report back to CSRI after one week of use. Each subject underwent a second physician's evaluation for pain, tingling and numbness as well as a self-evaluation. These evaluations were repeated again after two weeks of use. Subjects using the Dr. Spitzer Impact Glove were also asked to evaluate the glove on their final visit.

The physician evaluated both hands for numbness (Phalen's Test) and both wrists and elbows for CTS symptoms (Tinel's Sign). The Phalen's Test revealed, in the group wearing the glove, the majority of patients had their symptoms either getting better or remaining the same. These results were similar to that in the control group. The Tinel's Sign revealed a majority of patients had no CTS involvement in the elbows. The right and left wrists revealed CTS involvement in eleven out of fifteen subjects in the right wrist and eight out of fifteen subjects in the left wrist. In the right wrist four subjects showed improvement and seven subjects had symptoms that remained the same. In the left wrist, four subjects showed improvement in symptoms and four subjects remained the same.

All subjects in Group A completed self-evaluations and a questionnaire concerning of the Dr. Spitzer impact glove. Based on the 2-week self-assessment questionnaire, twelve out of fourteen subjects (86%) showed an improvement in their symptoms of pain, tingling and numbness, as well as their ability to carry out daily activities. Two subjects in test Group A (14%) reported their symptoms remained the same. One subject (7%) reported that the symptoms had worsened. Eight out of thirteen subjects (62%) in the control group, Group B, those that did not use the Dr. Spitzer impact glove, reported no change in their symptoms. Five subjects (38%) of the control Group B reported their symptoms had worsened. Two subjects (15%) reported symptoms had improved.

When subjects completed a written questionaire evaluating the Dr. Spitzer impact glove, two out of fifteen subjects (13%) stated they would definitely buy the glove. Ten out of fifteen (67%) stated they would probably buy it. One out of fifteen (7%) reported they would probably not buy the glove and two out of fifteen (13%) would definitely not buy it.

2.0 OBJECTIVE

To determine the ability of a specially designed glove to relieve the symptoms of carpal tunnel syndrome (CTS).

3.0 SPONSOR

Shock-Tek
21 Kerchival
Grosse Pointe, Michigan 48236

Telephone: (810) 286-3778
Fax: (810) 263-8230

Contact: Ron Cocquyt

4.0 INVESTIGATIVE ORGANIZATION

California Skin Research Institute
15222-B Avenue of Science
San Diego, California 92128

Phone: (858) 618-1328
Fax: (858) 618-1476

Investigator:	Jeffery P. Sugar, D.O., M.P.H.
Sub-Investigator:	Robert A. Harper, Ph.D.
Project Leader:	Zerla Bell, B.S.

5.0 PROTOCOL

The protocol was designed by the Investigative Organization and approved by the Sponsor.

6.0 SUBJECTS

Thirty-three subjects entered the study, and three subjects withdrew from the study due to reasons unrelated to the study. Two subjects were excluded at the end of the study and their data was not used because of not meeting the inclusion/exclusion criteria. Twenty-eight subjects, 11 males and 17 females (18 to 62 years of age) completed the study.

7.0 SCHEDULE

The study began on January 20, 2001 and completed on February 14, 2001.

8.0 PROTOCOL DEVIATIONS

Two subjects with hypothyroidism (Subject Nos. 5 and 6) were enrolled into the study. Hypothyroidism, when not properly medicated, can cause numbness in the hands. To avoid possibly confounding the data with this symptom, the data from these two subjects were excluded from the overall study results.

9.0 TEST ARTICLE

Dr. Spitzer glove was provided by the sponsor.

Product Name (as labeled)	Product Instructions
Dr. Spitzer Glove	Wear daily during normal daily activities. Remove for sleeping.

10.0 PROCEDURE

At the initial visit, the subjects completed and signed the Informed Consent and Medical Questionnaire. They were then given an opportunity for their questions and concerns to be addressed. The subjects were given a copy of the Informed Consent Form, the Research Subject's Bill of Rights, Study Instructions and Study Schedule.

The Investigator, Jeffery P. Sugar, D.O., M.P.H. then screened subjects, for the severity of the CTS symptoms using two diagnostic procedures. The Tinel's Sign involved the physician gently tapping on the flexor of the wrist to check for tingling sensations in the digits. The Phalen's Test evaluated for CTS was carried out by volar flexing the wrist for one minute and noting when and if the onset of parenthesis occurred.

Subjects were divided into two groups. The test group, Group A, was given the Dr. Spitzer glove and the control group, Group B, was untreated and did not receive a glove. Subjects in Group A were instructed to wear the glove during their daily activity that involved impact to the hands. They were instructed to remove the glove while sleeping. Subjects in the Group B were instructed to continue their daily activities as normal. Group B subjects were allowed to use their own glove, if they were currently using a glove.

The subjects reported back to CSRI after one week of use. Subjects were evaluated by the physician a second time and completed a self-evaluation. Evaluations rated pain,

tingling, and numbness (Appendix 1, under separate cover). The subjects reported back to CSRI for their final visit after two weeks of use. They were evaluated by the physician and were asked to complete a self-assessment questionnaire. The results are tabulated in Appendix II under separate cover. Each subject completed a Week 2 Self Assessment Questionnaire and the results are tabulated in Appendix III under separate cover. Subjects in Group A, the test group, were also given a questionnaire to rate the Dr. Spitzer Impact Glove. The results are tabulated in Appendix IV under separate cover.

11.0 ADVERSE EVENTS

The subjects reported no adverse events during the course of this study.

12.0 RESULTS AND CONCLUSION

The physician's clinical evaluations are found in Appendix I under separate cover. The data was evaluated only on those patients who had CTS symptoms at the baseline evaluation. The data below was derived by comparing symptoms at baseline with symptoms after two weeks.

Group A – Dr. Spitzer's Glove

Phalen's Test
The Phalen's Test was used by the physician to evaluate numbness in both hands for all subjects. Evaluations of the right hand for the test group of twelve subjects having symptoms at baseline showed symptoms in one subject (8%) worsened, seven remained the same (58%) and improved in four (33%). Evaluation of the left hand for ten evaluable subjects showed no subjects with symptoms worsening, six out of ten subjects (60%) with symptoms remaining the same and four out of ten subjects (40%) with symptoms improving.

Tinel's Sign
Tinel's Sign was used by the physician to evaluate CTS symptoms in both elbows and wrists of all the subjects. For the subjects using the glove, only four subjects out of fifteen had symptoms at baseline in the right elbow. Of the four subjects, one (25%) subject's symptoms improved and three (75%) subject's symptoms remained the same. On the left elbow, only three out of fifteen subjects had symptoms. Two (66%) of those subjects showed improvement and one (33%) remained the same.

The majority of subjects had CTS symptoms at baseline in their right and left wrists. In the right wrist, eleven of fifteen subjects had CTS symptoms. Four (36%) of these subjects showed improvement over the two weeks and seven (63%) of the subjects had symptoms which remained the same. In the left wrist, eight out of fifteen subjects had

baseline symptoms. Of the eight, four (50%) improved and four (50%) remained the same after two weeks of wearing the glove.

Group B – No Treatment

Phalen's Test

Using the Phalen's Test evaluate the right hand in the control group of thirteen subjects who did not use the glove, symptoms in the right hand worsened in two (15%) subjects, remained the same in five (38%) and improved in six (46%). Likewise, evaluations of the left hand for the control subjects revealed symptoms worsened in one (8%) subjects, remained the same in seven (54%) and improved in five (38%).

Tinel's Sign

For the subjects who did not use the glove, only three subjects out of thirteen had symptoms at baseline in the right elbow. Of the three subjects, one subject's symptoms became worse (33%) and two (66%) subject's symptoms remained the same. On the left elbow, only three out of thirteen subjects had symptoms and all three (100%) remained the same.

All the subjects in Group B had CTS symptoms at baseline in their right and left wrists. Two (15%) of these subjects showed improvement over the two weeks and 11 (85%) of the subjects had symptoms that remained the same. For the left wrist, four (31%) improved and nine (69%) remained the same after two weeks of wearing the glove.

Physician's Statement

"As an Occupational Medicine physician I treat multiple patients with CTS and Repetitive Stress Injuries. These gloves may be beneficial not only in CTS but also with RSIs which include: muscle strains, tendon overuse, trigger finger, and vibration injuries."

Self-Evaluation Questionnaire Results

Group A – Dr. Spitzer's Glove

All subjects in test Group A completed a self-evaluation questionnaire. Based on self-perception of percent improved at week two, twelve out of fifteen subjects (80%) perceived an improvement in their symptoms of pain, tingling and numbness, as well as their ability to carry out daily activities between 20 – 60 percent. Three subjects in test group (20%) reported their symptoms remained the same. Based on self-perception of percent worsened at week two, thirteen out of fifteen subjects (87%) perceived their symptoms as the same. Two subjects in test group (13%) reported their symptoms worsened between 1-20 percent.

Group B – No Treatment - Self-Evaluation Questionnaire Results

Based on self-perception of percent improved at week two, twelve out of thirteen subjects (92%) in the control Group B, those that did not use the Dr. Spitzer impact glove, reported no change in their symptoms. One subject (8%) of the control Group B reported their symptoms had improved between 1-20%. Based on self-perception of percent worsened at week two, nine out of thirteen subjects (69%) reported no change in their symptoms. Four subjects (31%) of the control Group B reported their symptoms had worsened between 1 – 60 percent.

Subject Glove Evaluation

Subject evaluation of the Dr. Spitzer impact glove concluded that two out of fifteen subjects (13%) would definitely buy the glove. Ten out of fifteen (67%) would probably buy it. One out of fifteen (7%) reported they would probably not buy the glove and two out of fifteen (13%) would definitely not buy it.

13.0 SIGNATURES

CALIFORNIA SKIN RESEARCH INSTITUTE

Submitted by:

Karen Regen 4/13/01

Zerla Bell, B.S. Date
Project Leader

Approved by:

Jeffrey P. Sugar, D.O., M.P.H. Date
Investigator

Robert A. Harper 4/13/2001

Robert A. Harper, Ph.D Date
Sub-Investigator

In accordance with the Standard Operating Procedures of CSRI, Quality Assurance conducted an audit of the study procedure, records and report. Quality Assurance has determined that corrective actions of any audit findings were completed with the exception of the protocol deviations listed in Section 8.0.

Approved by:

Diane S. DeVorn 4/13/01

Diane S. DeVorn, B.S. Date
Manager, Quality Assurance