



Introduction

Nucap Medical Inc. would like to introduce you to SpiderTech[™] Therapy. SpiderTech[™] Therapy is an innovative functional therapeutic approach to modulate pain and myofascial dysfunction through the use of specialized pre-cut, pre-packaged and ready to apply kinesiology taping applications using the original Nitto Denko tape from Japan. SpiderTech[™] applications designed to improve application efficiency and are therapeutic consistency for progressive clinicians utilizing kinesiology taping as a part of their patient management strategies. The use of SpiderTech[™] applications results in a simple and effective approach to pain reduction and improved activity regardless of the clinician's professional designation. SpiderTech[™] therapy was designed to be a synergistic and complimentary addition to any form of patient centered care.

There are different therapeutic mechanisms involved in the application of SpiderTech[™] as an intervention depending on how it is applied: 1) Improving microcirculatory fluid flow is achieved when using Microcirculatory Applications; 2) Improving static and dynamic postures and preventing potentially harmful ranges of motion are achieved when Structural Applications are implemented, where the tape is stretched and not the muscle; and 3) The most utilized and commonly accepted therapeutic effect is through sensori-motor mechanisms potentially resulting in neuroplastic changes through sensory gating, which in essence reduces pain and restores proper muscle activation. This is achieved primarily through the use of Neurosensory Applications, where the muscle (tissue) is stretched and not the tape.

The use of Kinesiology tape in its original roll format has been in use for approximately 30 years with impressive clinical results treating muscle injuries, joint strains, and neurological disorders along with both conservative and post-surgical rehabilitation. SpiderTech[™] is the evolution of this clinically proven therapy with the development of pre-engineered therapeutic applications which require no cutting.

Pain is the main condition that SpiderTech[™] is used to manage. Pain is the common component to all neuro-musculoskeletal conditions that result in movement dysfunction and disease. Pain results in adverse effects on muscle activation and tone. Current research has now shown us that acute pain and chronic pain are distinct entities physiologically, neuroanatomically, and psychologically. Chronic pain is not just acute pain that occurs over a long period of time, but rather a disease that has developed though biochemical and anatomical changes in the peripheral and central nervous systems.

Ongoing pain is associated with widespread neuroplastic changes at multiple levels within the nervous system including primary afferent neurons within the spinal cord, brainstem, thalamus, limbic system and cortex. Many of these changes

occur through the processes of neuroplasticity. Neuroplasticity is characterized by the ability of our nervous system to adapt and change in response to the demands placed on it. Plasticity responses are characterized by changes over time and the potential for reversibility. Neuroplastic changes are a crucial component of the conversion of acute pain into chronic pain and thus equally important with the reversal of such conditions. When a patient undergoes chronic sensitization the pain pathways and processing centers become conditioned to maintain their post-injury activity long after the insulting trauma has passed and the tissue has, for all intensive purposes, healed. Since plasticity is dependent on input, the continuous input provided by wearing SpiderTech[™] applications on a daily basis can provide the stimulus necessary to create positive neuroplastic changes required to return the body to an optimally functioning machine, free of pain and dysfunctional movement.

Two main neurogenic reactions have been identified in response to pain, muscle inhibition and increased muscle tone. This is a pain evasion strategy to prevent further damage being inflicted on the injured or involved muscle and/or joint structure. However, complications arise when the prolonged experience of pain leads to a decrease in neuromuscular efficiency and compensatory mechanisms in movement patterns and hence neuromuscular control that can lead to an increased likelihood of further trauma. Decreased neuromuscular efficiency leads to compensation and substitution patterns which increases the mechanical stress and loads experienced by the muscles and joints involved. Recent studies have shown that there is an alteration in EMG activity not only in the primary muscle experiencing pain but in all of the synergist as well. On top of this finding is the revelation that there are different recruitment patterns depending on the type of muscle activation ²⁰.

The response of the central nervous system (CNS) to painful stimuli is complex, but motor changes have consistently been demonstrated and seem to be influenced by higher centers consistent with a change in the transmission of the motor command and thus a muscles function. Injuries therefore result in a change in the transmission of the commands for muscle activation and timing. Early research and theories focused on changes in strength and endurance while current research has focused on how pain alters the timing of muscle activation and movement patterns.

How does wearing SpiderTech[™] Applications affect the pain pathways?

All SpiderTech[™] Applications are intended to be worn for up to five (5) days. The sustained stimulus of the tape on the skin results in the activation of epidermal and dermal mechanoreceptors mainly Merkel cells via the transmission of afferent input through A-beta fibers, resulting in a decrease in the patient's perception of pain (A-delta and C-fibres) due to sensory gating mechanisms at the spinal cord level.

The decrease in pain signaling into the CNS restores normal muscular activation, the end result being improved functional muscle and joint stability. For a better appreciation of the neurological mechanisms that are involved with SpiderTech and SpiderTape please read "Foundations for Therapeutic Effectiveness of SpiderTech Kinesiology Taping".

In conclusion we can see that understanding the mechanisms of neuro-sensory rehabilitation and plasticity which is vital to creating successful treatments for musculoskeletal functional impairments. In addition, the use of kinesiology tape in either roll or pre-cut format can provide a crucial means to access the necessary mechanisms to reverse chronic sensitization and pain induced muscle inhibition.

Clinical Evaluation of SpiderTech™ Applications

General Product Description

SpiderTech[™] is a professionally engineered pre-cut elastic adhesive tape available in the following different shape variants that are designed for the different areas of the body:

SpiderTech™ Applications and tape are available in the four different colours: Beige, Red, Blue and Black.



SpiderTech[™] Pre-Cut Applications are made with with raw tape material from the original kinesiology taping manufacturer from Japan, Nitto Denko.

Nitto Denko kinesiology taping products were engineered to mimic the thickness, weight and elasticity of human skin. It is made from high-grade 100% cotton material with a 100% acrylic adhesive. There is no Latex in the product therefore making it hypoallergenic. The tape is water-resistant and breathable, and is recommended to be worn for approximately 5 days before re-applying an application when necessary.

The tape is designed to be worn on the skin even during strenuous exercise, and adheres well to the body without irritation in the majority of patients, typically not leave any residue when removed. The tape material has moderate elasticity, which matches the same basic elasticity found in human skin, allowing it to work within the patient's natural range of motion. This provides support and stability, without adversely affecting movement.

Composition of the SpiderTech[™] Applications

- Material: 100% cotton elastic fabric
- Adhesive: Poly-acrylic adhesive
- Release Liner: Silicone coated paper

Due to the special characteristics of the material, activities of daily life such as sports and leisure are unrestricted and can be supported by the application of the SpiderTech[™] products. The nature of the applications allows the user to shower or bath without having to change the support.

The benefits of the tape can be evident immediately or within the first couple of days wearing the application depending on the condition. For some special injuries, a longer continuous application may be necessary to demonstrate positive effects. The SpiderTech[™] applications should be applied by a trained professional, or for long-term therapy the patient may be trained to self administer.

The tape is frequently used for sprains and strains, as well as, injury prevention and protection.

Evaluation of Clinical Effectiveness of Taping in Various Areas Research

Literature Search

In order to validate the clinical validity of SpiderTech[™] a literature search was conducted using the international database MEDLINE, the online NCBI library, accessible online journals and the internet. Keywords used were among others:

- Medical Taping
- Kinesiology Tape
- Kinesio- Therapy
- Clinical Efficacy of Taping
- Side Effects

Several papers were selected based on:

- Qualified abstract review
- Material used
- Applicability and availability

All literature articles are published in international well-known scientific journals. The authors are experts within their respective specialty and in the scientific areas of biomedical research. The results of the literature review are summarized in the following.

Introduction to the Taping method of "Kinesio"/ "Kinesiology"

Taping is widely used in the field of rehabilitation as both a means of treatment and prevention of sports-related injuries.¹⁻⁶ The essential function of most tape is to provide support during movement. Some believe that tape serves to enhance proprioception and, therefore, to reduce the occurrence of injuries.⁷⁻⁹ The most commonly used tape applications are done with non-stretch tape. The rationale is to provide protection and support to a joint or a muscle.^{10, 11} Utilizing Leukotape and CoverRoll stretch tape, investigators have shown clinical improvement in patients with grade III acromioclavicular separations, anterior shoulder impingement, and hemiplegic shoulders.^{2, 12, 13}

In recent years, the use of "Kinesiology Tape" has become increasingly popular in North America and Europe. This special "Kinesiology Tape" was developed in the 1970's by a Japanese chiropractor Dr. Kenzo Kase. The development of Kinesiology tape was engineered to mimic the qualities of human skin. It has roughly the same thickness as the epidermis and can be stretched between 130% and 140% of its resting length longitudinally. The application techniques were developed through the use of Applied Kinesiology testing, which logically gave the therapy and material its name. Kase et al have proposed several benefits, depending on the amount of stretch applied to the tape during application: (1) to provide a positional stimulus through the skin, (2) to align facial tissues, (3) to create more space by lifting fascia and soft tissue above the area of pain/ inflammation, (4) to provide sensory stimulation to assist or limit motion, and (5) to assist in the removal of edema by directing exudates toward a lymph duct.¹⁴ Some of these concepts have yet to be proven, but for a contemporary understanding of the mechanisms which SpiderTech Pre-Cut Applications and Tape work, please see "Foundations for Therapeutic Effectiveness of SpiderTech Kinesiology Taping.

Kinesiology Tape manufactured by Nitto Denko, the material used for all the SpiderTech[™] Applications and for Tape is unique in several respects when compared to most commercial brands of tape. It is latex free and the adhesive is 100% acrylic and heat activated. The 100% cotton fibers allow for evaporation and quicker drying. This allows the tape to be worn in the shower or pool without having to be reapplied. Lastly, the prescribed wear time for one application is longer, usually four (4) to five (5) days. The tape can be applied to virtually any part of the body in order to manage condition that are associated with pain and dysfunction of the neuromusculoskeletal (NMSK) system.

Clinical Studies in published literature

The clinical information on this special kind of tape application suggests improved function, pain, stability, and proprioception in pediatrics and patients with acute patellar dislocation, stroke, ankle and shoulder pain, and trunk dysfunction. The respective information comes from case series and pilot studies, the most important of which are summarized in the following:

The effect of Kinesio-Taping in an acute pediatric rehabilitation setting was investigated in a pilot study by Yasukawa et al.¹⁵ The purpose of this pilot study was to describe the use of the "Kinesio-Taping" method for the upper extremity in enhancing functional motor skills in children admitted into an acute rehabilitation program. Fifteen children (4 to 16 years of age), who were receiving rehabilitation services participated in this study. The improvement from pre- to post-taping was statistically significant. These results suggest that "Kinesio-Tape" may be associated with improvements in upper-extremity motor control and function in the acute paediatric rehabilitation setting. The authors concluded that the use of "Kinesio-Tape" as an adjunct to treatment may assist with the goal-focused occupational therapy treatment during the child's inpatient stay.

In their pilot study, Tsai et al. evaluated the effects of a bandage replacement by "Kinesio-Tape" in decongestive lymphatic therapy (DLT) for breast-cancer-related lymphoedema.¹⁶ Forty-one patients with unilateral breast-cancer-related lymphoedema for at least 3 months were included in this study. The study results suggested that Kinesiology tape could replace the bandage in DLT, and it could be an alternative choice for the breast-cancer-related lymphoedema patient with poor short-stretch bandage compliance after 1-month intervention.

Lie et al. studied the application of "Kinesio-Tape" in patients with lateral epicondylitis.¹⁷ The experimental results indicated that wearing "Kinesiology Tape" causes the motions of muscle on the ultrasonic images to be enhanced which the authors believe to indicate that the performance of muscle motion was improved.

Yoshida et al. studied the effect of "kinesio-taping" on lower trunk range of motions. ¹⁸ Thirty healthy subjects with no history of lower trunk or back issues participated in the study. Based on their findings, the authors determined that the application Kinesiology tape applied over the lower trunk may increase active lower trunk flexion range of motion.

In their publication, Jaraczewska et al. indicated that the "Kinesio-taping" method could improve the upper extremity function in the adult with hemiplegia. ¹⁹ The article discusses various therapeutic methods used in the treatment of stroke patients to achieve a functional upper extremity. The only taping technique for various upper extremity conditions that has been described in the literature is the athletic taping technique. According to the authors' conclusions, the "Kinesio-taping" method in conjunction with other therapeutic interventions can facilitate or inhibit muscle function, support joint structure, reduce pain, and provide proprioceptive feedback to achieve and maintain preferred body alignment. Restoring trunk and scapula alignment after the stroke is critical in developing an effective treatment program for the upper extremity in hemiplegia.

The clinical efficacy of Kinesiology taping in reducing oedema of the lower limbs in patients treated with the Ilizarov Method was investigated by Bialoszewski et al. ²⁰ The study involved 24 patients of both sexes subjected to lower limb lengthening using the Ilizarov method who had developed oedema of the thigh or leg of the lengthened extremity. The mean age of the patients was 21 years. The patients were randomized into two groups of twelve, which were then subjected to 10 days of standard physiotherapy. The study group was additionally treated with Kinesiology taping (lymphatic application), while the control group received standard lymphatic drainage. The application of Kinesiology taping in the study group produced a decrease in the circumference of the thigh and leg statistically more significant than that following lymphatic drainage. It was concluded that Kinesiology taping significantly reduced lower limb oedema in patients treated by the Ilizarov method and that the application of Kinesiology taping produced a significantly faster re-education of the oedema compared to standard lymphatic massage.

Fraizer et al. examined in a case series the clinical outcomes for patients with shoulder disorders who were treated with a comprehensive physical therapy program that included Kinesiology taping techniques. ²¹ 5 Patients were treated among other interventions with this taping method. All patients demonstrated clinically important improvements in function. The authors conclude that "Kinesio-taping" should be considered as an optional clinical adjunct in the treatment of shoulder pain as part of a comprehensive physical therapy regimen.

Hsu et al. investigated the effect of elastic taping on kinematics, muscle activity and strength of the scapular region in baseball players with shoulder impingement.²² Seventeen baseball players with shoulder impingement were recruited from three amateur baseball teams. All subjects received both the elastic taping (Kinesio Tex[™]) and the placebo taping (3M Micropore tape) over the lower trapezius muscle. The elastic taping resulted in positive changes in scapular motion and muscle performance. The results supported its use as a treatment aid in managing shoulder impingement problems.

In a prospective, randomized, double-blinded, clinical trial using a repeated-measures design Thelen et al. investigated the clinical efficacy of "Kinesiology tape" for shoulder pain. ⁶ Forty-two subjects clinically diagnosed with rotator cuff tendonitis/ impingement were randomly assigned to 1 of 2 groups: Therapeutic kinesio-tape group or sham kinesio-tape group. The therapeutic kinesio-tape group showed immediate improvement in pain-free should abduction after tape application. It was concluded that kinesio-tape may be of some assistance to clinicians in improving pain-free active ROM immediately after tape application for patients with shoulder pain.

Risk Benefit Assessment

SpiderTech[™] Pre-cut applications represent "kinesiology tape products" and are intended to provide support and stability, without adversely affecting the general range of motion. SpiderTech[™] Pre-Cut Applications and SpiderTech is distributed to professional therapists only and are frequently used for applications such as strains and sprains, and injury prevention and protection.

The raw material supplier Nitto Denko markets a product with the identical material available in rolls since 1984 in Japan and since 2000 in Europe. Thus, a long-term experience with the tape material is available and Nitto Denko confirms the good tolerance by stating that there has been no case of bio-incompatibility since product launch. Moreover, biocompatibility tests performed with the tape material clearly show that the material has no skin irritation potentials.

Furthermore, the SpiderTech[™] Pre-cut products are latex free. Thus, the risk of skin irritation and possible allergies is minimized. Incorrect application techniques may also lead to negative reactions of the skin. The tape should therefore only be applied by a trained health care professional, or for long-term therapy the patient may be shown how to apply. NUCAP Medical Inc. therefore created special training videos (available at www.SpiderTech.com) in order to reinforce safe and correct application protocols.

Due to special 'wave' characteristics of the SpiderTech[™] material, activities of daily life such as sports or leisure are unrestricted but supported by the application of the tape. The waterproofed material allows the user to shower or bath without having to change the bandage.

The main benefits of the SpiderTech[™] tape can be evident within the first hour following application of the product. For some special injuries, a longer application may be necessary to demonstrate the positive effect.

In summary, the clinical evaluation has demonstrated the safety and efficacy of SpiderTech[™] Pre-Cut Applications and that the benefits outweigh the possible risks for the patient. A positive benefit – risk ratio has been justified for the product line.

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PROFESSIONAL PRODUCT DESCRIPTION