Washington State Department of Labor and Industries
Technology Assessment
Pronex and HomeTrac Cervical Traction

1. Background

Cervical traction has been utilized to treat many causes of neck pain. Traction forces used in the clinic setting commonly reach between 20 and 50 pounds. Traction devices are also available to use at home. However, the traditional over-the-door traction units are generally limited to providing less than 20 pounds of traction. The Pronex and Saunders HomeTrac devices were developed to deliver cervical traction in the home comparable to forces applied by physical therapists in the outpatient setting. In addition, these devices are used in the supine position and do not cause pressure to the temporomandibular joint.

Glacier Cross' Pronex

The Pronex cervical traction device is reported to be user friendly, portable, comfortable, and convenient. Technically it provides an even distraction in the anterior and posterior cervical discs, and does not aggravate the temporomandibular joint.

Pronex cradles the reclining patient's head and neck on two soft foam cushions. One cushion supports the occiput and the other rests against the upper trapezius. An air-inflated bellows between them provides up to 20 lbs of continuously adjustable tractions. As the bellows expands, it lifts the head upward supporting the cervical curve and maintaining an even distraction in the anterior and posterior cervical discs. Patients have control over the amount of traction applied. Squeezing an inflator bulb increases the pressure, a release knob gently reduces it. No assembly is needed and there's no strain on the temporomandibular joint.

Saunders' HomeTrac

The Saunders Cervical HomeTrac provides up to 50 pounds of traction at a 15-degree angle. Traction forces are directed toward the occiput thereby preventing compression of the TMJ through the chin. Friction-free track and specially designed air cylinder allows smooth application of traction and stretching to the upper back and neck. Adjustable extension foot allows for additional traction angles of 20 and 25 degrees.

Most users can position themselves in the device without help due to an "easy-on" forehead strap and self-adjusting neck wedges. The gauge is calibrated in pounds and kilograms to provide feedback to the user and to promote consistency in treatment. Safety features include a pressure valve that limits the amount of the force to 50 pounds, and the traction force can be released easily and immediately by the patient if necessary.

2. Regulatory Status

The Pronex Cervical Traction Device was listed with the FDA in 1999 as a class 1 device. The manufacturer is Glacier Cross, Inc. The HomeTrac cervical traction device was listed with the FDA in 1996 as a Class 1 device. The manufacturer is The Saunders Group.

As class 1 devices, neither went through the 510K process. Each is listed as a non-powered traction apparatus.

3. Indications for Use (as listed on marketing brochures)

As class 1 devices, neither has approved indications by the FDA. However, they do list indications on their marketing literature.

Glacier Cross' Pronex lists its indications for use as the following:

- Hypomobility
- Joint changes
- Degenerative changes
- Joint pain/symptomatic facet joint
- Spasm/guarding
- Discogenic pain
- Postcompression fracture
- Herniated Disc
- Ligament Encroachment
- Osteophyte encroachment
- Spinal nerve root swelling
- Narrowing foramen
- Spondylolysis
- Spondylolisthesis

Saunder' HomeTrac lists its indications as:

- Osteoarthritis
- Headaches
- Herniated Discs
- Muscle Tightness
- Joint Stiffness
- Cervical Nerve Root Compression

4. Contraindications

Contraindications for the two devices include:

- Acute or traumatic injury
- Spinal instability
- Fracture
- Rheumatoid arthritis
- Spinal cord compression
- Infections and Inflammatory diseases
- Malignancy
- Extruded disc fragmentations

5. Literature Review

There is very little evidence documenting the efficacy of any type of cervical traction. For traditional cervical traction, there is some evidence in a retrospective study to suggest safety and efficacy, but there is no documentation of efficacy beyond short-term pain reduction.[1, 2] Reviews of controlled clinical trials[3] and review articles[4] show inconclusive evidence for the effectiveness of traditional traction. In addition, there are no clinical studies directly comparing the Pronex and Saunders cervical traction devices to conventional cervical traction modalities.

However, there is at least one study comparing the Pronex device to similar supine at-home devices.[5] (The Saunders HomeTrac device was not included in this study.) In Venditti (1995) the study did not attempt to determine the clinical efficacy of the devices, but focused on the following questions: Do the devices provide separation of the vertebral segments? Do the devices allow for relaxation of muscles around the temporomandibular joint and the posterior cervical region? How are the devices perceived by the users in terms of convenience, ease of instruction, setup, and comfort?

All five devices were found capable of distracting the cervical spine. The Pronex device, with a relatively low traction force, produced the lowest change in disc height. This study next looked at relaxation in the masseter and the posterior cervical musculature. The pettibone, a variant of the over-the-door water bag and harness traction system, caused marked muscle contraction as measured by the surface EMG. Subjects complained that it was uncomfortable and put extreme pressure on the jaw and forehead. For the other devices, there was no SEMG activity. However, SEMG does not receive signals from the deeper muscle groups and is not well suited to adequately determine muscle relaxation. Finally, in the ease of use and comfort section, Pronex scored best in all 11 statements on the survey.

Another concern is iatrogenic injury to the temporomandibular joints. In Franks (1967), a case report describes a 35-year-old woman with home cervical traction derived temporomandibular joint dysfunction.[6] In this case, additional pressure was placed on the joint due to several missing posterior teeth. In addition, it is noted that advancing age can cause the tissues to be more liable to disruption causing irreversible joint trauma.[7]

6. Economic Issues

Medicare currently pays $500 for the Pronex and Saunders devices ($50 per month for a rental) and $38 (or $5.50 per month for rental) for the over-the-door unit. Prices for the Pronex and Saunders devices as listed on Distributor sites on the Internet range from $300 to $600. Department costs for the year 2000 for over-the-door units totaled $5,384.86. Department costs for the same year for other units totaled $19,274.51.

7. Other Health Insurer's Positions

Medicare pays for thePronex and HomeTrac devices but does not have a national coverage policy regarding their use. Blue Cross Blue Shield of Massachusetts does not have a policy on these devices.

Group Health – Spokane uses the Pronex and HomeTrac devices preferentially over the over-the-door unit. They have found that these units are easier to set-up, and easier and more comfortable to use. Their feeling is that cervical traction is going to work only if the patient uses it and patients are much more likely to use the Pronex and HomeTrac devices than they are to use the over-the-door unit.

Aetna just recently changed its policy from one of non-coverage to a more encompassing coverage policy. Their current policy includes several criteria for approval. See Attachment 1.

Conclusion

The Pronex and Saunders cervical traction devices are approved for marketing as a form of traction. The scientific evidence for the use of these devices is no better or worse as compared to the over-the-door unit. Although the cost for Pronex or HomeTrac is more than the over-the-door unit, they are easier to use and less likely to cause aggravation to the TMJ. Therefore, the department will cover these devices similarly.

The recommendation is that all such cervical traction devices be covered with no prior authorization required.

1 Aetna's coverage policy bulletin, # 0453, Cervical Traction Devices, www.aetna.com/cpb/data/CPB0453.html

2 Swezey, RL, et.al., Efficacy of Home Cervical Traction Therapy. *Am. J Phys Med Rehabil* 1999; 78(1):30-32.

3 Gross AR, et.al., Physical Medicine Modalities for Mechanical Neck Disorders (Cochrane Review). In: *The Cochrane Library*, Issue 2, 2002.

4 Hoving JL, et.al., A Critical Appraisal of Review Articles on the effectiveness of conservative treatment for neck pain. *Spine* 2001; 26(2):196-205.

5 Venditti, D.C., et.al., Cervical Traction Device Study: A Basic Evaluation of Home-Use Supine Cervical Traction Devices. *JNMS* 1995; 3(2): 82-91.

6 Franks A, Temporomandibular Dysfunction Associated with Cervical Traction. *Annals of Phys Med* 1967; 8: 38-40.

7 Blackwood, H.J., *Brit.dent. J.* 1963; 115:317.

8 Informal Hayes summary of relevant literature

Aetna's Coverage Policy
Number: 0453
Subject: Cervical Traction Devices (Hometrac and Pronex)

Aetna covers the Hometrac and Pronex home cervical traction devices to alleviate pain caused by paravertebral muscle spasm when ALL of the following criteria are met:

- The patient has completed a 6 week course of physical therapy in the outpatient setting and still has pain; and
- The patient has failed medical therapy (e.g., oral anti-inflammatory medications, muscle relaxants); and
- The patient has failed a trial of over-the-door cervical traction; and
- The physician prescribes 20 pounds or more of home cervical traction; and
- The patient has had a series of trials of this device in the outpatient setting before sending a patient home with one; and
- Home therapy is being supervised by a physical therapist

OR

Patient fulfills the criteria above and has either:

- Temporomandibular joint disease which may become worse with over-the- door traction; OR
- Distortion of the neck and/or chin (e.g., radical neck dissection) making use of a chinstrap impractical.

Note: If both the therapist and patient feel that this is an appropriate choice for the patient, then a one-month rental is usually begun. Following a full month of home usage, the patient can more clearly determine whether the device warrants purchase.