The Effects of Treatment of an Interactive Cutaneous Neurostimulator on Recurrent Sinusitis

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Introduction:

Acute exacerbation of recurrent sinusitis is thought to be a biofilm mediated infection. The clinical presentation is thought to be one of headache and signs of sepsis. Currently, nasal decongestants and antibiotics are used but associated with recurrence in a large number of patients. The effects of an INS device in the treatment of people with this condition is described.

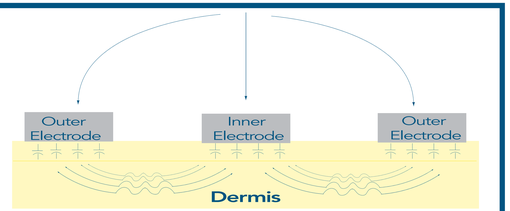
Method and Devices:

The INS device, a non-invasive, hand held devices that produces electrical current with normal skin as conduit by two stainless steel, concentric electrodes. The device produces a damped biphasic waveform with a frequency of 59.3 cycles per second, a pulse delivery between 15 and 360 pulses per second. Power, frequency, pulse grouping and waveform damping were varied with the patients treated.

The InterX 5002 is a hand-held battery operated, interactive neurostimulation device.

The Small Circular Electrode is attached to the main InterX 5002 device and provides easier treatment applications for smaller areas.

This INS can be used to identify optimal treatment points. This allows the INS to be scanned over the skin to identify localized galvanic response related to sympathetic nerve activity. Stimulation can then be targeted very specifically to these nerve endings.



Impulse coupling between the electrodes and conductive dermis allows current to flow to the upper layers of tissue and stimulate nerve fibers.

Static waveforms are widely believed to allow nerve accommodation, reducing the effectiveness of treatment. The parameters of the dynamic INS waveform constantly adjust to changes within the tissue as treatment is applied. Due to the unique design of INS and the sensitivity of the interactive waveform, conductive gel is not required.

Pulsed, damped, bi-phasic, sinusoidal waveform

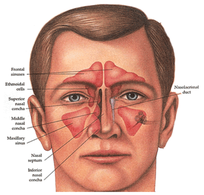
No Skin Contact | **High Impedance** | **Low Impedance**

Treatment Protocols:

The treatment approach is driven by the area of complaint and associated symptoms of pain, discomfort and limitations of function. Therapists will determine the type or category of sinusitus based upon observation and clinical judgement. Treatment zones include frontal, maxillary and infra-orbital as well as other targeted nerve points for a period of 15 - 30 minutes. The patients selected had acute exacerbations of recurrent sinusitus.

Acute Exacerbation:

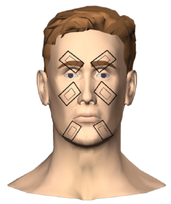
Frequency: 2X/Daily for 4-6 days
Duration: 15 minutes



Sinus Cavities

Slide the electrode along the sinus cavity outward (ie draining sinus cavities)

Stimulate the primary exit points of the Trigeminal nerve as illustrated



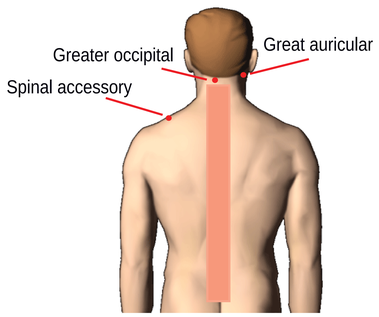
Trigeminal points

Recurrent Sinusitus:

Frequency: 2X/Daily for 4-6 days
Duration: 15 minutes

Provide stimulation to the Greater auricular and greater occipital supraorbital and infraorbital nerves.

Additional stimulation is applied to the spine for a centrally mediated response.



Results:

Ten patients were treated. The patients got immediate relief of headaches associated most commonly with a hissing sensation from decompression of the sinuses occurring during treatment. The patients also had purulent discharge shortly after the decompression of the sinuses

Conclusion:

Chronic sinusitus has been used as a study model for biofilm growth on keritonized epithelial membranes. Chronic recurrent sinusitus is extremely disabling and not well treated with antibiotics. This pilot study demonstrates efficacy in the treatment of this disorder. The effects are thought secondary to prostaglandin mediated anti-inflammatory effects and possible disruptions of biofilms. Further studies are indicated.

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