TO: Professor K. LaGrandeur
FROM:
SUBJECT: Audience Analysis for project 4
DATE: 12/17/06

PURPOSE:
The purpose of this memorandum is to present an analysis of the individuals who would read this report. This report was created as a project for a Writing for Technical Professions class. The goal of the project was to analyze the effectiveness of a technical innovation. My chosen technology was Occipital Nerve Stimulation for the treatment of migraine headaches.

AUDIENCE DESCRIPTION:

When writing this technical report, I imagined 3 various types of readers. One type of reader would be a sufferer of Migraine headaches who holds personal interest in such a technology. The next type of reader is a physician who treats patients with migraine headaches, and is interested in current research on the topic. The last type of reader is an employee of a pharmaceutical company interested in capitalizing on the new technology, or evaluating the competitive threat to the current medications they produce. The First type of reader would me most interested in the introduction and patient response, while the second and third types of readers would most likely read the entire report.

HOW THE AUDIENCE DESCRIPTIONAffected the Research Report:

This report was targeted towards all 3 types of readers. In the introductory section of the report, I summarize the technology involved, the population that would most benefit from ONS therapy, and the current research. All three readers would be interested to read this section.

In the results section, the scientific principle was aimed mostly at the physician reader, as it is slightly more technical. However, all terms and principles are defined and explained, both in the section and the glossary. Therefore, patients would also benefit from reading this section.

The following current research section was aimed mostly at the physicians and pharmaceutical companies, with specific reference to research centers and technical language.

The comparison of ONS with other drug therapies section was aimed at the pharmaceutical employee and the physician. The reader can learn what percentage of patients do not respond to other medications.

The final section gives accounts of individual patients who were treated with ONS, and is therefore aimed at all three types of readers, since the reaction to this invasive but life altering therapy is very important for all audiences.
RESEARCH ON THE EFFECTIVENESS OF OCCIPITAL NERVE STIMULATION IN THE TREATMENT AND PREVENTION OF MIGRAINE HEADACHES

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Executive Summary:

A large percentage of Americans suffers from Migraine Headaches, and many of these individuals do not respond to drug therapies. **Occipital Nerve Stimulation (ONS)** is a growing trend in modern Migraine research, proving a safe and effective alternative for many sufferers. This report examines the scientific principle of ONS, the current research being conducted on ONS, a comparison with other drug alternatives, and a consumer interest in this neurostimulator technology.

Introduction:

This report details the results of my research on the clinical effectiveness of Occipital Nerve Stimulation in the treatment and prevention of Migraine Headaches. This research was conducted by consulting scientific journals, newspaper articles, Clinical Trial descriptions, and Internet articles.

Nearly 30 million Americans suffer from a condition known as Migraine Headaches. Migraines are a neurological disorder characterized by painful throbbing headaches. ONS involves implanting a 2-inch, paddle-shaped neurostimulator under the skin at occipital lobe of the brain. The device delivers electrical impulses near the occipital nerves via insulated lead wires tunneled under the skin that run to an implanted pacemaker. Patients use a remote control to set the frequency and amplitude of the electrical impulses, leaving it on all day or using it on an as-needed basis.

While there are many drugs available for the management of migraines, many patients can not tolerate the side effects of such drugs, or are simply unresponsive to therapies. It is estimated that approximately 40,000 people in the U.S. do not respond to existing treatments, and many may be candidates for alternative therapies. (Mayo clinic,
2006) Due to the growing knowledge in the field of neurology and the limited current treatment options, many researchers believe Occipital Nerve Stimulation will play a greater role in the treatment of Migraines in the future.

The Mayo Clinic in Arizona has conducted successful clinical trials that have proven ONS to be a safe, effective treatment for chronic headaches. Further research is being conducted by 3 international groups to learn more about ONS. Currently, the short term risks include infection during surgery and migration of the wires post surgery, which will require subsequent surgery to correct.

This report will evaluate the effectiveness of ONS therapy in terms of scientific principle, results of clinical trials and current research, effectiveness of current Migraine medications, and Patient Interest in ONS.

Research Methods

In order to understand the effectiveness of Occipital Nerve Stimulation in the treatment of Migraine headaches, the following research methods were completed.

1. To learn about the scientific principle behind ONS therapy, I consulted a New York Times News Paper article from an online database, Wikipedia, and several other scientific and general articles.

2. To discover the current research taking place on ONS, I gathered information from various articles derived from Proquest, an online database.

3. To draw a comparison between ONS and other drug therapies, I consulted the Maryland Medical Center website for Migraine Headache Information.
4. To gauge patient interest in ONS, I consulted a New York Times article which detailed individual responses to therapies, and I gathered information from various online articles.

Results

This section contains information of the research I conducted. First, I describe the scientific theory behind the Occipital Nerve Stimulation technology in the treatment of Migraine headaches. Then I give an outline of the current research taking place. Next, I show the drawbacks of drug therapies to treat Migraine Headaches, and compare then to ONS. Finally, I conclude with a section on predicted patient interest in ONS.

1. Scientific Principle

Modern Scientific developments in neuroimaging have found that Migraine headaches do not, contrary to past belief, result from vascular defects. It is currently known that the phenomenon responsible for the disorder is known as “cortical spreading depression”, or the depolarization of an area of the brain cortex. The result is inflammation and irritation of cranial nerves, specifically, the trigeminal nerve. (Wikipedia, n.d.). Due to the convergence of the trigeminal nerve with the great occipital nerve at the cervical spinal cord (Caputi, Vincenzo, 1997), stimulation of the great occipital nerve can reduce prevalence or symptoms of Migraine headaches. The great occipital nerve is depicted in the image below:
In occipital nerve stimulation, a pacemaker-like device is connected to 2 in electrodes placed at the back of the head just under the skin where the greater occipital nerve is located. (NY times, 2006) Electrical current is delivered through these electrodes, stimulating the occipital nerve with the goal of reducing the inflammation of the cranial nerve. Boston Scientific Corp. has developed an implantable neurostimulator that could be used in Occipital Nerve Stimulation. The Precision device is the smallest rechargeable neurostimulator and is already approved by the FDA for spinal cord stimulation to treat chronic pain (Medical Devices & Surgical Technology Week, 2005). Patients use a remote control to set the frequency and amplitude of the electrical

*Figure 1*

Location of the Greater Occipital Nerve on the Posterior of the head.

(Image adapted from the online edition of the 20th U.S. edition of Gray's Anatomy of the Human Body, 1918.)
impulses, leaving it on all day or using it on an as-needed basis. Figure 2 below depicts a schematic image of an Implanted Occipital Nerve Stimulator.

![Figure 2](image)

**Figure 2**

Schematic depiction of the placement of the Electrode near the greater occipital nerve.

(Image of human head and facial nerves adapted from the online edition of the 20th U.S. edition of Gray's Anatomy of the Human Body, 1918)

2. **Current Research**

Clinical Trials on Occipital Nerve Stimulation in the treatment of Migraine Headaches have been undertaken by three different large scale companies: (1) Advanced Neuromodulation Systems, a division of St. Jude Medical; (2) Advanced Bionics, a Boston Scientific company; and (3) Medtronic.)
Influential research has been done by Mayo clinic in Arizona. The Mayo Clinic study involved 16 patients, nine of whom underwent Occipital Nerve Stimulation Therapy. Patients experienced an average decrease in pain of 54%.

In another study entitled PRISM (PRrecision Implantable Stimulator for Migraine), researchers will use Boston Scientific’s Precision neurostimulator to gauge its effectiveness in Migraine Relief. (Medical Devices & Surgical Technology Week, 2005) This study will involve 150 patients. The first person to receive an implant in the trial was a 52 year-old woman who currently experiences more than 20 headache days per month, and has suffered from headaches for the last 32 years. Results on this trial are still pending (Medical Devices & Surgical Technology Week, 2005).

3. Comparison of ONS with Other Drug Therapies

There are many drug therapies available for Migraine Headache relief. This section will draw a comparison between such drugs and Occipital Nerve Stimulation therapy. **Nonsteroidal anti-inflammatory (NSAIDs)** over the counter drugs, such as low-dose aspirin or naproxen may reduce the occurrence of Migraines by about 20% of patients. Prescription-strength NSAIDs are documented to reduce headache frequency in about 50% of patients. However, long term use of NSAIDs can cause gastrointestinal bleeding and stomach ulcers, and 50% of patients do not respond to this treatment.

**Beta-blockers**, such as Propranolol and timolol are also useful in the reduction of Migraine frequency in some patients. While semi effective for those patients unresponsive to NSAIDs, Beta-blockers are dangerous for individuals with history of stroke, and side effects of the drugs range from asthma to sexual dysfunction. A percentage of the population will not respond to Beta-blockers, and others will not be able to tolerate the side effects.
A third category of drugs to treat Migraine headaches are anticonvulsants, such as Valproate and Divalproex Sodium. These drugs, while reducing headaches up to 50% over the course of a year, do not affect those who suffer from headaches with auras. A significant drawback to these therapies is the cause of birth defects when taken during pregnancy. Occipital Nerve Stimulation is effective against headaches with auras, and its effect during pregnancy has not yet been documented. (University of Maryland Medical Center, 2002)

Several other therapies exist as well, but the general trend is severe side effects and incomplete effectiveness in the population. The benefits of ONS lie in that percentage that can not respond to other therapies, or for whom the side effects are intolerable.

4. Patient Response

Some patients of clinical trials have reported great results. One patient of a clinical trial, Cheryl Myers, attested to the benefits of Occipital Nerve Stimulation Therapy. Myers suffered from chronic and disabling migraines that forced her to quit work, and would often confine her to her bed. Narcotics would help, but the frequency of Migraine Onsets made this option implausible. In 2004, Myers enrolled in a clinical trial at the Michigan Head-Pain and Neurological Institute, where she had an occipital nerve stimulator surgically implanted. Soon after the device was turned on, Ms. Myers reported having fewer migraines with decreased severity. Within a few months, she was also able to return to work. While still taking Percocet, a pain relieving narcotic, several times a week, Myers can not enjoy a normal life. (NY Times, 2006)

However, patients have reported dissatisfaction as well. In 2003, Kerrie Smyres from Seattle was implanted with an Occipital Nerve Stimulator independent of a clinical
trial. Two years later, the leads from the electrodes began slipping out of position. The movement of the implant caused sharp pinching pain and sometimes set off another migraine. The Implanted Occipital Nerve Stimulator also restricted Smyres from certain activity that had helped her maintain cope with her Migraine headaches, such as yoga and kayaking. "Over time, I realized that it caused more pain and was more limiting than it was helping," she said of the device. Smyres had her stimulator removed. (NY Times, 2006)

Occipital Nerve stimulation Therapy targets the population of Migraine sufferers who do not respond to or can not tolerate noninvasive drug therapies. Individuals who are afflicted with unmanageable Migraine headaches can not lead normal lives, nor can they function in a normal working environment. It is estimated that approximately $3,309 are lost annually per sufferer solely due to missed work days. Other patients much quit work all together. Due to this data, and the testimonials of patients, the Predicted patient interest is high. (Wikipedia, n.d.). Doctors are very optimistic about the hope advanced technology and continuing research could bring to the treatment of Migraine Headaches. "There is still a lot of unmet need," said Dr. Lipton, a professor of neurology at the Albert Einstein College of Medicine and director of the Montefiore Headache Center, "So the idea of having stimulatory devices that can be used to prevent headaches or to treat them acutely is very attractive to me, and I think very attractive to patients as well." (NY times, 2006)

Conclusions

Occipital Nerve Treatment has proved a safe and effective option for patients who are unresponsive to other noninvasive drug therapies. While the scientific principle is
outlined well in every scholarly source, the common consensus is that the reason for effectiveness if not yet wholly understood. Migraine Research is a large field that still contains many gaps to fill, especially on the causes of the disorder. This incomplete knowledge causes difficulties in ONS research. New research is underway, and doctors are optimistic of the expected outcomes. There is currently little available long term effects documented for ONS therapy, and more drawbacks may appear with time. One negative aspect of the implant has surfaced in patients in whom the implant has migrated. A follow up surgery would then be necessary to replace or remove the electrodes. As with any invasive therapy, ONS is reserved for those unresponsive to other medications. As this is 40,000 people in the US alone, Occipital Nerve Stimulation Therapy holds a bright future in Migraine Treatment and Prevention.
Glossary

Migraine: spasms of the blood vessels in the head. Symptoms include nausea, auras, or the loss of vision in one eye or a symptom known as tunnel vision, heightened sensitivity to light or sound, difficulty of speech and intense pain predominating on one side of the head. (University of Maryland Medical Center, 2002)

Occipital Nerve Stimulation (ONS): technology which involves the stimulation of the Occipital nerve by electrodes implanted at the back of the head

Neuroimaging: a term referring to the various methods of visualizing areas of the nervous system

cortical spreading depression: the transient depolarization of the brain cortex which is believed to cause aspects of the migraine headache

Trigeminal Nerve: Cranial nerve V. It is responsible for sensation in the face

Great Occipital Nerve: a spinal nerve. Disorder of this nerve may cause headaches

Nonsteroidal anti-inflammatory drugs (NSAIDs): drugs which reduce pain, fever and inflammation without the use of steroids

Beta-blockers: drugs which treat hypertension, cardiac arrhythmias and several other disorders

Anticonvulsants: a class of drugs used mostly in the prevention of seizures
Bibliography


RESPONSE SHEET: TECHNICAL REPORT

KEY: 3=PRETTY GOOD; 2=O.K.; 1=NEEDS WORK

I. AUDIENCE ANALYSIS is well thought out and presented____3____

II. CONTENT_____3-_____(you don’t give your conclusions in your executive summary)

II. ORGANIZATION of presentation is clear____3______

III. FORMATTING of document is proper_____3_____

III. GRAMMAR   A.) Word order is clear____3______
          B.) Word choices are clear and well-considered__3_____
          C.) Punctuation____3_____

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