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Monday, December 10
0700-0800, Poster #1

Feasibility Study of an Implantable Cortical Stimulation System for Patients with Major Depression

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Introduction

Functional neuroimaging studies demonstrate abnormal regional glucose metabolism in subjects with major depressive disorder (MDD). Compared with control subjects, areas of ventral prefrontal cortex, such as subgenual cingulate, are relatively hypermetabolic in MDD, whereas dorsal regions such as left dorsolateral prefrontal cortex (DLPFC) are relatively hypometabolic.[1] High-frequency (>10Hz) rTMS can temporarily increase cerebral metabolism of targeted areas and when applied to the left DLPFC, has short-lived antidepressant effects.[2] Therefore, we examined an investigational implantable cortical stimulation (CS) system as a long-term method for stimulating left DLPFC in MDD.

Materials and Methods

After an observation phase of ≥8 weeks with stable psychotropic medication, 12 patients with treatment resistant MDD were implanted with an epidural CS system (*Renova™ DT*, Northstar Neuroscience, Seattle, WA). Patients were randomized to active or sham stimulation for 8 weeks, then active stimulation thereafter. Psychotropic medications were not changed unless clinically indicated. Safety outcomes were assessed. Efficacy assessment included Hamilton Depression Rating Scale (HDRS) and Global Assessment of Function (GAF). Baseline FDG-PET scans were obtained at baseline and post-stimulation.

Results

At submission, 11 patients have completed the 8-week primary endpoint. A 12th patient is in baseline observation. At baseline, HDRS averaged 34.6±5.3, GAF averaged 41.4±6.0, failed antidepressant treatments averaged 9.6±1.5, and duration of current depressive episode averaged 7.3±8.9 years. At the 8-week primary endpoint, active stimulation patients decreased in HDRS by 24±21% whereas sham stimulation HDRS decreased by 3±17%. After 16 weeks of active stimulation for all patients, HDRS and GAF improvements doubled compared with 8 weeks, from 21% to 41% for HDRS and from 29% to 58% for GAF. There were no device related serious adverse events. PET data will be shown.

Conclusion

This feasibility study describes the first use of an epidural CS system targeting the left DLPFC in patients with MDD. Preliminary results indicate that CS may have a treatment effect that increases over time and exceeds that of sham stimulation.

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Acknowledgements

This study was funded by Northstar Neuroscience, Inc., the manufacturer of the implanted stimulation device system.

Figure and Table Legend

Figure 1. Graph depicting efficacy of active cortical stimulation system over time. Y-axis represents per cent change in rating scale. HDRS-Hamilton Depression Rating Scale. MADRS-Montgomery-Asberg Depression Rating Scale. GAF-Global Assessment of Function

Monday, December 10
0700-0800, Poster #2

Therapeutic effect of deep brain stimulation of the nucleus accumbens on refractory drug addiction: a case report

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Introduction

The mesolimbic dopaminergic (DAergic) pathway projecting from the ventral tegmental area (VTA) to the nucleus accumbens (NAC) may play a critical role in the initiation of psychological dependence on morphine. Bilateral ablating the nucleus accumbens has been demonstrated to be an effective treatment for drug addiction. But there are many concerns about the effects of producing irreversible lesions in neural centers_such as food intake, sexual behaviour and probably a myriad other more mundane daily pleasures. In order to avoid these complications, DBS may be the best choice to prevent permanent damage of nucleus accumbens.

Materials and Methods

We report the bilateral nucleus accumbens DBS in a a 24-year-old young man who has started intravenous heroin injections for five years. Treatment included UROD first, three days later, bilateral nucleus accumbens were implanted two electrodes for DBS. In UROD program The patient was treated with naloxone(0.2mg/kg) under anesthesia. In DBS program the nucleus accumbens target coordinates were as follows: 7.5mm in front of the anterior commissural, 6mm below the midcommissural point, and 6.5mm lateral to the midline. the final stimulator settings: amplitude 2.5 volts; pulse width 90μsec; rate 145 Hz; electrodes monopolar C +, 1-, 3-.

Results

The patient has been followed-up for over two years, irregular randomly selected examination of urine samples and naloxone tests show that he has completely abandoned his drug usage without any ancillary treatment . He has even returned to full –time work for more than one year. One month ago, the stimulator was turned-off and the patient's condition was satisfactory. The temporary postoperative complication were clouding of consciousness, somniloquy and Urine incontinence, they were recovered within 2-3 days. While the insomnia recovered after about 4-5 months latter. WMS, WEIS-RC and MMPI before and after the DBS assessed by psychologist revealed that the patient’s intelligence remembrance and personality were intact.

Conclusion

Our preliminary study demonstrate that deep brain stimulation of the nucleus accumbens has therapeutic effort on refractory drug addiction.

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Acknowledgements
The electrodes and the programmable pulse generators implanted in the patient are supported by Medtronic, Inc.

Monday, December 10
0700-0800, Poster #3

Accuracy of stereotactic electrode placement in deep brain stimulation
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Introduction
In this study, we report in vivo measurements of the accuracy of stereotactic electrode placement in patients undergoing DBS electrodes by using intra- and post-operative computed tomography (CT). The position of the implanted electrode and their contacts were measured and compared with the planned position.

Materials and Methods
24 patients with movement disorders (Parkinson disease (n = 7), tremor (n = 10), dystonia (n = 7)) treated with bilateral deep brain stimulation (DBS) (overall 48 target points) were investigated [1, 2, 3]. The target point of the electrode was planned stereotactically in combination with a pre-operative stereotactic helical computed tomography (CT). A post-operative CT was performed in order to control the position of the electrodes in relation to the previously planned target point. The position of the four electrode contacts (Medtronic 3387 or 3389, Inc.) was measured according to the Talairach space (AC-PC line) and compared with the coordinates of the planned target point.

Results
The mean minimal distance is 1.39 mm (SD = 0.86 mm) and ranges from 0 to 4.5 mm. The average absolute deviation from pole 0 is in x axis 1.71 mm, in y axis 1.43 mm and in z axis 1.88 mm.
The mean euclidian distance (distance target point to tip of the electrode) is 3.26 mm (SD = 1.77). You have to keep in mind that different electrode sizes were used. Therefore the electrode contacts can cover a range up to 10.5 mm.

Conclusion
This study demonstrates the accuracy of stereotactic electrode placement. The error in this patient related investigation is not much larger than in phantom studies [4, 5]. Nevertheless there should be caution regarding patients with a large atrophy and much loss of liquor.

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Learning Objectives:
1. Stereotactic electrode placement is an accurate procedure.

Monday, December 10
0700-0800, Poster #4

Where are activated electrode contacts located anatomically in parkinson disease: In the target structure or superior or inferior?

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Introduction
Deep brain stimulation is an accepted and safe surgical treatment for many movement disorders, especially for advanced parkinson disease (PD) [1]. The positions of the active electrode contacts for internal pallidal stimulation and thalamic stimulation are situated within the target nucleus. The stimulation of the subthalamic nucleus seems to be effective in and above the target [2].

Materials and Methods
Intraoperatively we define the best electrode placement by using 5-channel microrecording und semimacro stimulation and by clinical observation of the stimulation effects and side effects [3]. Decisive are the clinical effects on rigidity, bradykinesia, tremor the occurrence of diskinesias and the absence of side effects. The second lowest electrode contact of the quadripolar Medtronic electrode 3389 is placed there. The postoperative programming of the stimulator is done by neurologists, unaware of the spatial position of the electrode contacts in respect to anatomical structures, solely guided by clinical effects. Documentation was performed with the UPDRS motor score. Postoperatively we analyzed the spatial distribution of the selected active electrode contacts in a series of 72 implanted electrodes by using postoperative stereotactic helical computed tomography projected in the preoperative imaging and the Talairach space.

Results
The average measurements of the chosen electrode contacts in respect to the AC – PC line showed a laterality of 12.5 mm (Range 9.2 until 16.5), 2.2 mm under AC – PC line (Range +3.4 until -6.3) and 0.3 mm behind the midcommissural point (Range +3 until -5).

Conclusion
Our findings show clearly that the clinical most effective electrode contacts are projected in the superior third of the subthalamic nucleus but also in adjacent (superior located) anatomical structures, namely lenticular fascicle and zona incerta.

References
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Learning Objectives:
1. Our findings show clearly that the clinical most effective electrode contacts in PD are projected in the superior third of the subthalamic nucleus.

Monday, December 10
0700-0800, Poster #5

Automatical classifiaction of microelectrode recording signals (MER) in deep brain stimulation of the subthalamic nucleus (STN)

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Introduction
MER has become a useful tool in deep brain stimulation procedures. However it is time comsuming , sometimes difficult and depends very much upon the experience to interpret the signals in a correct way.

Materials and Methods
To support the surgical team in STN surgery, an automatical, computer based classifier was constructed. It consits of 3 levels. At the 1st level, the background activity is analyzed, at the 2nd, bursty or irregular signals are detected, based on single cell burst activity. At the 3rd level, the spike rate of duplicated intervals from levels 1 and 2 are analyzed.
The essential elements of this algorithm are different kinds of wavelet transformations to remove background noise, as well as to enhance certain signal properties.

Results
The classifier has been tested in 2134 MER traces from regular STN surgeries and compared in a blinded way with the results of an surgeon with high level experience in MER signal interpretation. The results of the automatical classifier were congruent in 95%.

Conclusion
Automatical online MER signal analysis of human STN signals is possible with high accuracy using a mainly wavelet transformation based algorithm. This may safe time and may increase accuracy and objectivity mainly in DBS teams with less experience.

Learning Objectives:
Automatical classification of microelectrode recording signals in STN suregry is possible and reliable with this newly developed algorithm. This may increase the objectivity and reduce the operation time in DBS procedures.

Monday, December 10
0700-0800, Poster #6

ELECTRICAL STIMULATION OF HIPPOCAMPUS (ESH) IN PATIENTS WITH INTRACTABLE TEMPORAL LOBE EPILEPSY: A LONG TERM FOLLOW UP STUDY.
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Introduction
Evaluation of ling efficacy of ESH in the treatment of complex partial seizures in nine patients with intractable mesial temporal lobe epilepsy was performed

Materials and Methods
All Patients had a 6 months basal period (for seizure diary collection and neurological testing) after which they underwent bilateral hippocampal electrode implantation to establish focus laterality and location. 3 patients had bilateral and 6 had unilateral foci. Diagnostic electrodes were explanted and definitive Medtronic electrodes were implanted directed to the hippocampal foci. Position was confirmed with MRI and afterwards the DBS system internalized. Patients signed the informed consent approved by the Hospital´s Ethics committee and started a double blind stimulation protocol. Patients attended every 3 months for seizure count and neuropsychological test.

Results
Follow up went from 18 months to 5 years. Patients were divided in two groups: 5 had normal MRIs and seizure reduction of >95%. 4 had hippocampal sclerosis and seizure reduction of >50%. None had neuropsychological deterioration. No patient showed adverse effects. 1 patient was explanted after 2 years due to skin erosion in the trajectory of the system.

Conclusion
ESH provides a non lesional method that improves seizure outcome without deterioration of memory in patients with hippocampal epileptic foci.

Learning Objectives:
1. Alternative reversible neurosurgical technique (neuromodulation) evaluation.
2. Conserving cognitive functions in epilepsy.

Monday, December 10
0700-0800, Poster #7

Vim plus posterior subthalamic area DBS concurrently with Voa-Vop thalamotomy for Essential Tremor

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Introduction
Essential tremor is mainly a postural or kinetic tremor of the hands and sometimes the head. Because of some limitation and rather high morbidity of lesioning, deep brain stimulation (DBS) on ventralis intermedius (Vim) has been widely accepted procedures now on days. But the need for large target and complexity of tremor made us to find new targets. In this report, we describe our surgical results of 15 patients of essential tremor treated with a new surgical technique, DBS on Vim plus posterior subthalamic area and thalamotomy on Voa-Vop in the unilateral thalamus for controlling essential tremor.

Materials and Methods
Between October, 2005 and February, 2007, we performed Vim plus posterior subthalamic area DBS concurrently with Voa-Vop thalamotomy for 15 patients who were diagnosed as severe proximal essential tremor and showed refractory to medications. Only one patient was female and the mean age was 56.4 (range 43 to 77). All procedures were performed unilaterally because all patients were right-handed, except for 3 patients, who were suffering from bilateral symptom. All procedures were performed under microelectrode recordings to select the target precisely, and author made two electrode contact (0,1) below the thalamus for subthalamic area stimulation. And additional small lesioning was made between Voa and Vop by moving 2mm anterior to Vim-Vop border.

Results
More than10 months were followed up (10 to 24 months), and mean improvement of tremor rating scale was 85.6%. All patients were right-handed, and the right side mean improvement was 87.7%. Voice tremor and head tremor of three patients was also improved.

Conclusion
DBS on Vim plus posterior subthalamic area concurrently with Voa-Vop thalamotomy showed good results for severe proximal form or axial type of essential tremor, and this combining procedures (targeting at two other site) are much more effective for controlling severe proximal tremor and subtle remnant tremor after single procedure.

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Learning Objectives:
1. To find more effective target for controlling the component of severe and complicated proximal tremor in essential tremor

Monday, December 10
0700-0800, Poster #8

NEUROMODULATION ON INFERIOR THALAMIC PEDUNCLE IN FIVE PATIENTS WITH OBSESSIVE COMPULSIVE DISORDER TREATED WITH NEUROMODULATION

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Introduction
Deep brain stimulation (DBS) has been used in the treatment of refractory obsessive compulsive disorder (OCD). Inferior thalamic peduncle is a bundle of fibers that link non-specific thalamic system with orbitofrontal cortex. Experimental, neurosurgical and PET scan image suggest that this system could be useful in treatment of OCD symptoms.

Patients and Methods
One study was performed in five patients with OCD refractory to conventional treatments. Our principal objective was to determinate safety and effectiveness of DBS of inferior thalamic peduncle (ITP). Bilateral stereotactic implantation of tetra-polar electrodes was aimed at ITP and corroborated by electrophysiological responses and magnetic resonance imaging (MRI). All patients were in OFF stimulation 1 month after implantation. In ON period, parameters were set at 5 volts, 450 microsecond of width pulse, 130 Hertz in bipolar and continuous mode. Clinical changes were evaluated every 3 months for 12 months by means of Yale-Brown Obsessive Compulsive Scale (YBOC-S) and Global Assessment Functioning Scale (GAF). Statistical significance was assessed by Friedman and Wilcoxon statistical test.

Results
By the end of the study Y-BOCS score decreased 20 points (p <0.001), and GAF score improved from 20 to 70% (p <0.0001). Neuropsychological battery showed no changes and there were no side effects in the chronic period.

Conclusions
We conclude that ITP stimulation is a safe and maybe effective alternative in treatment of those OCD cases refractory to conventional treatments.

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Learning Objectives

1. Patho-physiology in obsessive compulsive disorder
1. Advantages of neuromodulation in psychiatric disorders
1. Safety of neuromodulation procedures in new target

Monday, December 10
0700-0800, Poster #9

Subcutaneous stimulation in cluster headache

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Introduction

Subcutaneous neurostimulation (NSS) is a recent practice, which is based on the same scientific grounds as both electroacupunture and transcutaneous electrical stimulation. (1)

Materials and Methods

The following case report deals with a 36-years-old female patient affected by left cluster headache complicated by both a continuous high intake of analgesics and by the presence of a depressive/anxious syndrome. The pain was originally located around the left orbit and in the temporal area. It then spread throughout the occipital lobe area: the patient experienced side effects of lacrimation, nasal obstruction, rhinorrhea and homolateral ptosis, nauseous and vomiting symptoms, phonofobia, photofobia, frozen ends, tachicardy and increasing blood pressure levels (often followed by post critical asthenia). On 2nd September 2006 a subcutaneous peripheral stimulator was applied: a quadripolar subcutaneous lead was inserted through a retroauricular incision, reaching the upper left orbit region (2): after the trial phase of the stimulation had taken place, the main lead was tunnelized towards the retromastoid region. The perception area perfectly matched the pain origin area. After a month's trial with either no pain crisis or drugs assumption, the permanent IPG was implanted in the subclavian groove.
The stimulation parameters are as follow:
Electrodes + - + -,
Frequency 40 Hz
Pulse width 200 µsec
Amplitude 1.2 V

Results

By now the patient is both in pain-free and drug-free conditions. She has gone back to work: she had previously been forced to quit her job because of the headache attacks. She has also gained a lot of self-confidence: the relationship with her family has been improving and she has gradually been taking back on her social activities.

Conclusion

Some elements should be taken into consideration for a correct evaluation of the technique:
Reflex bow in the spinal cord induced by both cutaneous and muscular electrostimulation of A-delta fibers (3,4)
Activation of the interneurons of the grey commisure belonging to the posterior horns in the spinal cord: as a consequence there has been an inhibition of the ascending motion of pain impulses (5)
Induced release- in the central canal of the medulla- of endogenous opioids (i.e. endorphins and enkephalins) (6)
Strengthening of the inhibitory descending pathways
Sensorial/affective modulation of the pain sensation at hypothalamic/limbic level

References

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Learning Objectives:
1. The case positive outcomes are in line with the therapeutic evidence reported in the official literature.
2. The case reported underlines how subcutaneous neurostimulation (NSS) can be applied when the neuropathic pain component prevails- as either an alternative mean or before the adoption of any invasive or destructive surgical interventions.
3. The role played by electric stimulation still has to be deeply analysed in terms of technical data (e.g. low/high and alternating frequency parameters).

Monday, December 10
0700-0800, Poster #10

Deep brain stimulation for pain: a 50 case experience.
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Introduction
Worldwide, 1300 patients have received deep brain stimulation (DBS) for chronic neuropathic pain refractory to drug treatments over the last four decades. However, failures to demonstrate efficacy adequately in clinical trials led to the procedure being refused FDA approval. Few centres worldwide have published findings from patients treated for pain by DBS during the last decade using current technological standards. Here we present our contemporary experience of DBS of the thalamus and periaqueductal gray.(1) We also propose and apply novel evidence-based methodology for evaluating outcomes in DBS predicated upon increasing the signal to noise ratio of efficacy versus disease natural history and obviating requirements for multi-centre randomised controlled trials.(2)

Materials and Methods
Prospective evaluation was undertaken of 50 patients with chronic pain treated by DBS at a single British neurosurgical centre from 1998 to 2006. Subjective reports and quantitative assessments of pain (Visual Analog Score and McGill Pain Questionnaire) and quality of life (Short Form 36 and Euroqol) were undertaken before surgery, during the postoperative week, at 1,3,6 months and 6 monthly intervals thereafter. Stimulator settings were recorded when changed together with pain scores. Conventional and novel statistical techniques were used to interpret the evidence.

Results
DBS is efficacious for pain after amputation, stroke, cranial and facial pain including anesthesia dolorosa. Other groups with multiple sclerosis, malignancy, failed back syndrome and trauma pain may benefit from DBS.

Conclusion
DBS is effective treatment for certain chronic pain aetiologies in carefully selected patients. Ethical and practical challenges can limit the translation of case series to randomised trials, however both N-of-1 trials and signal to noise ratios provide compelling evidence of efficacy auguring for their adoption in the field of pain surgery.(3)

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Acknowledgements
The authors are supported by the Norman Collisson Foundation, Charles Wolfson Charitable Trust and UK Medical Research Council.

Learning Objectives:
1. Discuss deep brain stimulation (DBS) as a re-emerging treatment for chronic pain
2. Identify useful outcome measures in evaluating DBS for pain
3. Describe novel methods for evaluating evidence in DBS and pain surgery

Monday, December 10
0700-0800, Poster #11

Primary motor cortex stimulation for intractable neuropathic pain
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Introduction
Motor cortex stimulation (MCS) has proved to be an effective treatment for intractable neuropathic pain[1]. In this retrospective analysis, the pain relieving effects of modified MCS (electrode within the central sulcus) and the preoperative prediction of MCS effect were analyzed.

Materials and Methods
Thirty-five patients with intractable neuropathic pain underwent MCS; 19 patients with post-stroke pain, one pontine injury, two patients with spinal cord lesions and 13 patients with peripheral neuropathic pain (seven cervical root avulsions, four phantom-limb pains, one trigeminal neuropathic pain, and one peripheral nerve injury). Electrodes for MCS were implanted in the subdural space (33 cases), within the central sulcus (12 cases) and in the epidural space (three cases). The mean postoperative follow-up was 38.8 months (range: 1-105 months). Twelve cases received repetitive transcranial magnetic stimulation (rTMS) of primary motor cortex preoperatively[2].

Results
The MCS within the central sulcus was more effective than that on the precentral gyrus in the test stimuli of most cases (83%), however, after 6 months follow up, its results did not show any significance of pain reduction. In 6 of 20 (30%) with a cerebral lesion and seven of 13 (54%)) with a non-cerebral lesion (a spinal cord or peripheral lesion), pain reduction more than 50% was obtained throughout follow-up more than six months.

Conclusion
Neuropathic pain with a cerebral lesion tended to be more refractory to MCS than that with a non-cerebral lesion. The pain reduction rate of rTMS was well correlated with that of MCS. Therefore, rTMS may be a good predictor of MCS efficacy.
Dissection of central sulcus leads to pain reduction but the effect of MCS within the central sulcus does not continue for long term.

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Acknowledgements
This research is supported by Ministry of Health, Labor and Welfare, Japan.

Learning Objectives:
1. Brain stimulation
2. Intractable pain
3. Repetitive transcranial magnetic stimulation

Monday, December 10
0700-0800, Poster #12

UNILATERAL PALLIDOTOMY VS UNILATERAL ELECTRICAL STIMULATION OF GPI IN BILATERAL SYMPTOMS OF PARKINSON'S DISEASE AT ONE YEAR FOLLOW-UP

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Introduction

Although, deep brain stimulation (DBS) of subthalamic nucleus (STN) is gold standard in surgical treatment of Parkinson's disease (PD); alternative target are options in control of tremor, rigidity and bradikinesia. DBS of globus pallidus (Gpi) or pallidotomy could get around 35 to % improvement in Unified Parkinson's Disease Rating Scale (UPDRS) in patients with PD in Höehn and Yahr (H-Y) III to V with rigidity, bradicinesia, gait disturbance and imbalance. In addition to this, ablative surgery of STN is no usual procedure yet and the cost of bilateral DBS devices is not easy to get. The principal question of this study was: Does unilateral DBS of Gpi have more effective clinical outcome than unilateral pallidotomy in patients with PD in H-Y III to V?

Materials and Methods

We select 30 patients with PD in H-Y III to V for a clinical assay in a one year of follow-up. Inclusion criteria were: Bilateral symptoms of PD with rigidity, bradicinesia, gait disturbance and imbalance.
Improvement minor of 50% according UPDRS with pharmacotherapy and important side effects.
Age from 30 to 75 years. Each patient was randomized and assigned to pallidotomy or DBS of Gpi contralateral to predominant symptoms. Stereotactic surgery was performed for ablative procedure or lead implantation using Zamorano-Dujovni frame and Praezis image fusion software. Target coordinates were 9/10 of AC-PC length lateral to midline, 1.5/10 anterior to intercomissural point and 2/10 caudal to AC-PC level. Trans-operative macro-stimulation was made in all cases. The lesion in pallidotomy cases was made with N50 (Leibinger) radiofrequency system with 90ºc during 90 seconds. In DBS cases MRI was made one day after implantation in order to check right location of leads (Medtronic 3387) and generator pulse was implanted (Medtronic 7495-91). Neuromodulation started one week post-operative period. Parameters of monopolar stimulation were 1.5 to 3 V, 60 to 330 ms, 130 Hz in continuous program.

Results

No statistical differences are showed between groups in demographics conditions. Final scores between pallidotomy vs DBS of Gpi are not statistical different but they did not get 50% of improvement in UPDRS of base line score. Pallidotomy is more efficient than DBS of Gpi to improve final conditions of patients, particularly in Schwab and England scale (S-E) and UPDRS. There are not statistical differences between two procedures in control of contralateral or ipsilateral symptoms but pallidotomy is more efficient in bilateral control of rigidity and DBS of Gpi is more efficient in control of imbalance. There were not mortality and morbidity was transient

Conclusion

Either pallidotomy or DBS of Gpi have similar bilateral effects principally in rigidity and imbalance.
Final score improvement in UPDRS is minor than 50% but S-E score can get improve in general conditions with unilateral procedure without side effects. We can use unilateral ablative procedure in initial treatment of advanced PD.

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Learning Objectives:
1. Efficacy of pallidal stimulation in Parkinson´s disease.
2. Comparative methods ablative procedure and stimulation.
3. Clinimetric changes.

Monday, December 10
0700-0800, Poster #13

Efficacy of Extradural Motor Cortex Stimulation in Advanced Idiopatic Parkinson's Disease: The Experience of the Functional Neurosurgery Study Group of the Italian Neurosurgical Society

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Introduction
Extradural Motor Cortex Stimulation (EMCS) was recently attempted to treat different movement disorders: we report the results obtained by the Italian Functional Neurosurgery Study Group on Parkinson's disease (PD).

Materials and Methods
41 patients affected by advanced idiopathic PD were enrolled: they were either not eligible for or refused DBS. All patients had long history of disease (5–22 years, mean 13.95 +/-4.97 yrs).They scored III to V on Hoehn-Yahr scale. The score of the UPDRS off-medication was 49-120 (mean 91.173 + - 22.189). Quadripolar plate electrode (Model 3587A; Medtronic, Inc.) was introduced in extradural space over hand motor area of one hemisphere usually controlaterally to the worst clinical side. 8 cases were implanted bilaterally: only results of the unilateral stimulation will be reported. Clinical assessment was performed by UPDRS at 1, 3, 6, 12 months and then at least every 6 months in various conditions: a. before implantation: baseline evaluation off-medication/off-stimulation. b. during treatment: on-medication/on-stimulation and off-medication/on-stimulation. The follow-up varied from 6 months to 3 years.

Results
Stimulation induced significant improvement in total UPDRS score ($p<0.050$ Wilcoxon-test) and in UPDRS III score (up to 23.12%, $p<0.02$) in off-medication condition; improvement was mostly observed in activities of daily living (ADL), posture, gait, balance, bradykinesia, speech and facial expression (UPDRS III, items 27-28-29-30-31). Clinical benefits were more evident in most affected patients, whose quality of life improved, requiring less care-giving too. In addition, according to UPDRS IV data, there was marked attenuation of levodopa-induced dyskinesias persisting throughout one year follow-up. Antiparkinsonian drugs intake showed a trend to reduction although not statistically significant.

Conclusion
Unilateral EMCS relieves mostly above axial symptoms, ADL and L-dopa induced dyskinesias. Italian clinical experience adds favorable data to enlarge the series of parkinsonian patients treated by EMCS.

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Learning objectives
1. New target in Brain Stimulation for PD
1. Results of Extradural Motor Cortex Stimulation in advanced PD
1. Motor Cortex Stimulation vs DBS in PD

Monday, December 10
0700-0800, Poster #14

Mechanisms of deep brain stimulation in Parkinson's disease
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Introduction
Two major factors are responsible for effects of chronic stimulation of various basal ganglia structures in Parkinson's disease – functional block and stimulation of the neural elements surrounding electrode's tip. They are equivalent to a lesion and adding noise to the system, correspondingly. Classical conceptual brain understanding cannot provide adequate explanation of deep brain stimulation mechanisms.

Materials and Methods
This theoretical research based on new conceptual understanding of the brain explains how both factors, lesion and noise, alleviate motor symptoms.

Results
The following ideas are the foundation for the explanation (Baev et al, 2002). The basal ganglia play the role of predicting system in motor cortico - basal ganglia - thalamocortical loop. It models a behavior of the body and an environment during motor control, i.e., it generates feedforward model. Dopaminergic neurons are a part of an error distribution system that provides the model with information about the quality of predictions. The lack of adequate error signals caused by the death of dopaminergic neurons leads to erroneous predictions. Wrong predictions result in pathological behavior. A case of wrong prediction is treated by the controlling system as if the controlled object was perturbed by an external force and the controlling system tries to correct its state. A basal ganglia lesion or its equivalent decrease resolution power of the predictive system. As a result, the controlling system becomes less reactive to errors in its predictions. A noise added to the controlling system has a double effect on it. The first consists in decreasing the sensitivity of the system to afferent and model signals. The second, the noise helps the system to slide down to the global minimum on the error surface, and the model becomes better tuned on the controlled object.

Conclusion
Described mechanisms of chronic stimulation of various basal ganglia structures is applicable to other neuromodulation therapies.

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Learning Objectives:
1. Deep brain stimulation mechanisms are perfectly explained based on new conceptual understanding of the brain. The latter includes neural network computational principle and generic functional organization of hierarchical neural systems controlling automatic animal motor behaviors.

Monday, December 10
0700-0800, Poster #15

Parkinsonian movements in model and experiment
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Introduction
Parkinson's disease (PD) is known to originate from a degeneration of dopaminergic neurons in the substantia nigra. One of the most debilitating aspects of PD is the inability to initiate and execute voluntary movements (bradykinesia and akinesia). PD patients are particularly impaired in the performance of complex movements, e.g. simultaneous and sequential motor tasks. Despite a huge amount of anatomical and physiological data regarding the structure of the basal ganglia and their

connections, the computational processes performed by the basal ganglia in health and disease remain unclear [1-5]. The goal of the current research is to develop a mathematical model of the functional scheme of the 'motor' basal ganglia-thalamocortical circuit. In addition, an experimental study is set up to investigate movements performed by PD patients, and the effectiveness of DBS.

Materials and Methods
Model
The model of the 'motor' basal ganglia-thalamocortical circuit investigated the interaction between two competing motor channels, controlling two movement directions (flexion/extension). PD was simulated as a reduction in the level of dopamine, as well as a loss of functional segregation.
Experiments
The measurements consisted of a series of movements, ranging from a simple movement to sequential movements, and several UPDRS tests. The movements are registered using accelerometers.

Results
The primary deficits in movement resulted directly from dopamine loss. Loss of functional segregation contributed to the bradykinetic symptoms, due to a reduced ability to suppress unwanted movements. It also led to excessive neurotransmitter depletion, affecting the performance of sequential movements. Similar trends were observed in movement time and peak velocity in the simulated and experimental data.

Conclusion
The results of the present research should advance the understanding of the role played by the basal ganglia in motor control, as well as the causes of the deficits seen in Parkinson's disease and the effectiveness of DBS.

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Learning Objectives:
1. Role of Basal Ganglia in motor control and causes of bradykinesia and akinesia.
2. Comparison of movement (simple and complex) in healthy subjects and Parkinson's patients.
3. Effectiveness of DBS on motor control in Parkinson's patients.

Monday, December 10
0700-0800, Poster #16

Improvement of the upper limb movements of Parkinsonian patients after bilateral subthalamic DBS
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Introduction
Deep brain stimulation of the subthalamic nucleus (STN-DBS) reduces bradykinesia and rigidity in Parkinson's disease but its impact on fine motor functions of the upper extremity remains unclear. Some studies show an improvement on the grip force after DBS [1,2,3,4] but none studied finer movement allowing patients to be more autonomous at home. Our goal was to establish if there was an improvement in upper extremity motor skills as well.

Materials and Methods
To assess improvement of the upper extremity movement, the following tests were performed on five (5) patients: Tempa [5,6], Cotnab and Finger-nose. These tests were done pre-operatively then 6 months after programmation of their bilateral STN-DBS. Each of these tests was done for both hands and on-medication/on-stimulation.

Results
A better score was observed on finger-nose test for all patients due to improvement of the bradykinesia and alleviation of the rigidity. As suspected, the time taken to perform the Cotnab test was improved as well as the overall performance. Moreover, a significant improvement was seen for the Tempa test. Tempa test is divided into performing daily tasks and in lifting weights. The capability of lifting heavier weight during a longer time was improved as shown by other authors but more interestingly the capability of performing daily tasks was also improved.

Conclusion
Tempa and Cotnab tests are validated tests for elderly. These measure finer movement and general improvement of the upper limb allowing patients to be back to a more autonomous life. Our study shows that DBS treatment is not only good to alleviate bradykinesia and levodopa-induced dyskinesia but also allows patient to perform movements useful in their daily life increasing their autonomy. This study will be pursued with a larger population of STN-DBS patients and on a longer term follow-up to measure the consistency of these results.

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Learning Objectives:
1. To understand the impact of STN-DBS on fine motor skills
2. To measure the capability of DBS patients on performing daily activities.

Monday, December 10
0700-0800, Poster #17

Vim plus posterior subthalamic area DBS concurrently with Voa-Vop thalamotomy for Essential Tremor
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Introduction
Essential tremor is mainly a postural or kinetic tremor of the hands and sometimes the head. Because of some limitation and rather high morbidity of lesioning, deep brain stimulation (DBS) on ventralis intermedius (Vim) has been widely accepted procedures now on days. But the need for large target and complexity of tremor made us to find new targets.
In this report, we describe our surgical results of 15 patients of essential tremor treated with a new surgical technique, DBS on Vim plus posterior subthalamic area and thalamotomy on Voa-Vop in the unilateral thalamus for controlling essential tremor.

Materials and Methods
Between October, 2005 and February, 2007, we performed Vim plus posterior subthalamic area DBS concurrently with Voa-Vop thalamotomy for 15 patients who were diagnosed as severe proximal essential tremor and showed refractory to medications. Only one patient was female and the mean age was 56.4 (range 43 to 77). All procedures were performed unilaterally because all patients were right-handed, except for 3 patients, who were suffering from bilateral symptom. All procedures were performed under microelectrode recordings to select the target precisely, and author made two electrode

contact (0,1) below the thalamus for subthalamic area stimulation. And additional small lesioning was made between Voa and Vop by moving 2mm anterior to Vim-Vop border.

Results
More than10 months were followed up (10 to 24 months), and mean improvement of tremor rating scale was 85.6%. All patients were right-handed, and the right side mean improvement was 87.7%. Voice tremor and head tremor of three patients was also improved.

Conclusion
DBS on Vim plus posterior subthalamic area concurrently with Voa-Vop thalamotomy showed good results for severe proximal form or axial type of essential tremor, and this combining procedures (targeting at two other site) are much more effective for controlling severe proximal tremor and subtle remnant tremor after single procedure.

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Learning Objectives:
1. To find more effective target for controlling the component of severe and complicated proximal tremor in essential tremor

Monday, December 10
0700-0800, Poster #18

Neurophisyologycal Characterization of the subthalamic posterior area
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Introduction
The main targets described by literature to treatment Parkinson disease are Gpi, Vim, STN. Prelimniscal Radiations, have been used as an alternative target at the Hospital General de Mexico. These are the fibers located at the posterior subthalamus whose role in Parkinson's physiopathology is not yet been totally clear. Despite the published information on its efficacy, it is not frequently used as treatment by neurosurgeon's community that deals with abnormal movements.

Among the reasons for the short use of the treatment, is the lack of basic studies on the zone. Thus, it would be worthy an interesting to aboard this issue using the microelectrodes recording to define its neurophysiological characteristics and its spacial limits.

Materials and Methods
Microelectrodes recording was done in 10 patients subject to prelemniscal radiations intervention (injury or electrical stimulation). The recording was made with Ledpoint 4 (Medtronic inc.) electrodes, registering each millimeter from 1cm before the target up to 0.5 cm before it. After satisfactorily obtaining the recording, the planned surgery took place. Ben Gun (5 electrodes simultaneously) was used in some patient, obtaining simultaneous registries in the target's adjacent structures.

Conclusion
The recordings obtained so far reveal that the Prelemnical Radiations is an electrophysiological structure different from others as STN and ZI. Although there is not a characteristic record, this is the only zone whose fiber activity can be easily

distinguished from the neighboring nucleus. In conclusion, prelemniscal radiations are not electro-physiologicaly part of any other neighboring structures, although its relation and interaction is not yet totally defined.

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J.D. Carrillo-Ruiz, F. Velasco, F. Jimenez, AL Velasco, M Velasco, G. Castro
Acta Neurochir Suppl (2007); 97(2): 185-200

Monday, December 10
0700-0800, Poster #19

EEG ATR May Predict Clinical Response to Cortical Stimulation Therapy: Initial Findings from the PROSPECT Study

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Brad Fowler, M.A., Northstar Neuroscience, Inc., Seattle, WA, USA for the PROSPECT Study Investigators

Introduction

Prior investigations of frontal quantitative EEG (fqEEG) markers in antidepressant treatment of patients with Major Depressive Disorder (MDD) demonstrated that Aspect's Antidepressant Treatment Response ("ATR") algorithm predicts eventual clinical response as early as 1 week into treatment with SSRI antidepressants[1]. In this study, ATR (0 to 100, low to high probability of treatment response) was prospectively evaluated in MDD patients undergoing investigational Cortical Stimulation (CS) therapy.

Materials and Methods

Following IRB approval and patient consent, four-channel frontotemporal EEGs were recorded at pretreatment baseline and after 2 weeks of cortical stimulation therapy in a subset of the MDD patients enrolled in the PROSPECT[#] Study. Clinical Response was defined as the percentage improvement (decrease) in the Hamilton Depression Rating Scale (HDRS) after 8 weeks of stimulation relative to the HDRS assessment prior to start of CS therapy. Pearson Correlation Coefficients measured association between ATR and Clinical Response.

Results

In this interim dataset, 4 patients had EEG recordings at baseline and after 2 weeks of treatment from which to calculate an ATR prediction. ATR at 2 weeks significantly correlated with 8-week change in HDRS in the 3 subjects who reached the 8 week endpoint ($R=0.99$, $p = 0.037$.) The fourth subject, who had improved 30% after 4 weeks of treatment but has not yet reached the 8 week endpoint, is predicted by ATR to be a responder to CS therapy. Two week change in HDRS was not predictive of 8 week clinical response ($R=0.101$, p=n.s.)

Conclusion

Results from this pilot study were consistent with prior findings and suggest that monitoring fqEEGs before and early into treatment with cortical stimulation may predict clinical response and could provide opportunities for treatment optimization.

[#]*CAUTION-Investigational Device. Limited by Federal (or United States) Law to Investigational Use*

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Acknowledgements

This research was supported financially by Northstar Neuroscience, Inc. EEG collection and analyses were conducted by Aspect Medical Systems, Inc.

Learning Objectives:
1. To become familiar with recent work using a frontal quantitative EEG biomarker (ATR) to predict clinical response to antidepressant treatment in patients with Major Depressive Disorder (MDD)
2. To understand that the PROSPECT Clinical Trial was a feasibility study of Cortical Stimulation therapy in MDD patients
3. To appreciate interim results from the PROSPECT study which suggest that the ATR biomarker assessed at pretreatment baseline and 2 weeks after start of treatment may predict eventual clinical response to cortical stimulation therapy in MDD patients

Monday, December 10
0700-0800, Poster #20

Treatment of Tourette syndrome with self-injurious imminent blindness by bilateral chronic electrical stimulation of the globus pallidus internus: report of a case
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Introduction
Tourette syndrome (TS) is a neuropsychiatric disease characterized by motor and vocal tics and, occasionally, associated with self-injurious behavior. A limited number of patients suffering from treatment-refractory TS have been benefited from deep brain stimulation (DBS) of the globus pallidus internus (GPi).

Material-Methods
We report on a 34-year-old man who suffered, from the age of 7 onward, from serious TS. The disorder was characterized by hyperkinesias, mainly in the form of blepharospasm, abrupt jerks of upper and lower limbs, and vocal dystonia (echolalia and coprolalia), as well as symptoms of obsessive-compulsive disorder, anxiety and depression. Over the last two years, serious self-injurious behavior added in case history; the patient used to move violently his fingers towards his eyes more than 300 times per day causing thus permanent lesions to the cornea. The threat of blindness was clearly considered and the possibility of cornea transplantation seemed to be the last hope providing that his psychiatric disorder could be treated. Maximum doses and combinations of established treatments proved to be unsuccessful. The impact of the disorder in patient's quality of life was dramatic, restraining him physically and preventing him from participating in work and social activities. Based on reported experience, electrodes for chronic stimulation were implanted bilaterally in the posterolateroventral nucleus of the GPi.

Results
At 2 months following DBS, the patient stopped his self-injurious behavior. Follow-up at 12-months, proved significant better scores in YGTSS (Yale Global Tic Severity Scale), MRVBTS (Modified Scoring Method for the Rush Video-based Tic Rating Scale, Y-BOCS (Yale-Brown Obsessive-Compulsive Scale), and GAF (Global Assessment of Functioning Scale).

Conclusions
Chronic electric stimulation of the GPi may prove to be an effective alternative therapy in otherwise refractory cases of TS, even complicated with serious self-injurious behavior.

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Learning Objectives:
1. New applications of deep brain stimulation
2. New treatment options for medically-refractory Tourette syndrome

Monday, December 10
0700-0800, Poster #21

Double-blind, randomized and controlled study of motor cortex electrical stimulation in patients with neuropathic pain intractable to drugs.

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Introduction
The objective of this study was to establish the efficacy of motor cortex stimulation (MCS) in patients with intractable neuropathic pain.

Materials and Methods
Unilateral neuropathic pain evaluated by visual analog scale [VAS] from 8–10 of diverse topography and etiology were selected for MCS. Grid with 20 contacts was implanted using a craniotomy over MC contralateral to the area of pain. MC area was localized using differents studies including somatosensory evoked potentials, acute electrical stimulation, cortico-cortical evoked potentials and magnetic resonance. A temporal therapeutic stimulation trial allowed to determinate the most efficient pair of contacts to use for chronic MCS. The grid was replaced with a 4-contact electrode connected to an internalized stimulator. Parameters were fixed at 40 HZ, 90 µsec, 2.0–7.0 V, 1-h ON 4 h OFF was used. Pain was studied with VAS, Bourhis, and McGill pain scales applied each month for 1 year. Stimulators were turned OFF for 30 days in a randomized, double-blind fashion at 60 or 90 days. The statistical tool utilized was Wilcoxon test.

Results
Eleven patients were reported. Three patients did not report any improvement in the sub-acute trial and were excluded due to chronic MCS; eight patients underwent long-term stimulation. Significant improvement of pain was induced by MCS *(p* <0.01), that persisted during the follow-up period. Turning OFF stimulation increased pain significantly *(p* <0.05). Improvement at 1 year was >40% (40–86%) in all cases.

Conclusion
MCS is an efficient treatment for neuropathic pain evaluated by a double-blind maneuver. Temporal sub-acute stimulation trials are recommended to determine the optimal MC area to be stimulated and to identify non-responders.

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Acknowledgements
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Learning Objectives:
1. Efficacy of motor cortex stimulation in intractable pain.
2. Using methodological pathways to clarify the efficacy.
3. Clinimetric changes.

Monday, December 10
0700-0800, Poster #22

Correlation study between motor outcome and stimulation parameters of globus pallidus in patients with Parkinson's disease (Review study).

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Introduction
The aim of this study was to compare all the data that has been published about the globus pallidus stimulation in Parkinson's disease, determine its efficacy and correlation with different variables.

Materials and Methods
The search was made in PubMed, Acad Search and RefWorks, recovering all the bibliographical appointments that included the key words and their combinations. The inclusion criteria included full-text original articles, written between 1994 and august 2007, single or comparative with lesion or STN, unilateral or bilateral, and with indication of the localization of the effective contacts. The exclusion criteria included absence of UPDRS score, absence of stimulation parameters, with co-morbidity, in combination with lesion or with previous neurological surgery. Only 22 articles fulfilled the criteria and all were included. Statistical analysis was made by a Wilcoxon test.

Results
From the 327 patients that underwent GPi stimulation, 13.6% had unilateral procedure performed, 59.1% bilateral, and 27.3% unilateral or bilateral in different cases within the same study. A baseline UPDRS score in off medication was represented with a mean of 52.7 (range 26.5-77.2), a postoperative score mean of 33.7 (8-36.5) in off medication/on stimulation; mean delta 19.1 (8-36.5) ($p<0.001$). Mean postoperative follow-up of 14.6 months (3-49) with only one study that reported an increase of the UPDRS (Visser-Vandewalle V, 2003) at the maximum follow-up. The most common localization used was posteroventral (54.5%), with MRI & ventriculography combined, as the most frequent method of targeting (40.9%). Micro-recording assistance was presented in 68.1% of the cases. Parameters were established in 3.4 ± 1.8 Volts, 149.2 ± 31.0 Hz and 145 ± 95.6 µsec. The parameters related with delta, showed that voltage had a high correlation with the results, in which case determination coefficient (R2) was 1.0. The same could not be said in frequency and pulse-width, 0.6 and 0.4 respectively.

Conclusions
Pallidal stimulation is a highly effective target for neuromodulation in Parkinson's disease. Bilateral procedures are more effective than unilateral according to UPDRS score delta in motor outcome. Frequency and pulse-width have no direct relation with clinimetric changes; nevertheless voltage demonstrates to be highly correlated with motor improvement.

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Figure and Table Legend

Table 1. Demographic table with the 22 articles included that fulfilled the inclusion and exclusion criteria.

Figure 1. Localization and extension of electrode placement for stimulation, superimposed to an axial section of the anatomical atlas.

Figure 2. Correlation between neurostimulation parameters (pulse-width, frequency, voltage) and resultant delta, from baseline UPDRS score and post-surgery evaluation at maximum follow-up.

Figure 3. Statistical analysis from UPDRS score baseline, post-surgical at maximum follow-up, delta, and neurostimulation parameters reported.

Learning Objectives:
1. Efficacy of pallidal stimulation in Parkinson´s disease.
2. Revision of methods in pallidal neuromodulation.
3. Clinimetric changes related to neurostimulation parameters.

Monday, December 10
0700-0800, Poster #23

Computer modeling of Motor Cortex Stimulation: Effects of Anodal, Cathodal and Bipolar Stimulation
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Introduction
Motor cortex stimulation (MCS) is a promising clinical technique for treatment of chronic pain. However, optimization of the therapeutic efficacy is hampered since it is not known how electrically activated neural structures in the motor cortex can induce pain relief. Furthermore, multiple neural elements are present in the motor cortex such as cell bodies, dendrites and axons which are parallel or perpendicular to the cortical layers. Which of these neural elements are immediately excited by the electrical pulses in MCS depends on positioning of anodal and cathodal electrodes and stimulation parameters. A proper insight on these effects would be useful for peroperative decision making on electrode positioning and for the interpretation of stimulation results after implantation. Computational modeling studies can help to identify the effects of electrical stimulation on cortical neural tissue, elucidate mechanisms of action and ultimately to optimize the therapy.

Methods
The activation of neural elements in the precentral gyrus and in the anterior wall and lip of the central sulcus was studied by (1) calculating the stimulus-induced electrical field using a realistic 3D volume conductor model, and (2) simulation of the response of neural elements using compartmental neuron models including the axon, soma and dendritic trunk.

Results
While neural elements perpendicular to the electrode surface are preferentially excited by anodal stimulation, cathodal stimulation excites those with a direction component parallel to its surface. When stimulating bipolarly, the excitation of neural elements parallel to the bipole axis is additionally facilitated. The polarity of the contact over the precentral gyrus determines the predominant response. Inclusion of the soma-dendritic model generally reduces the excitation threshold as compared to simple axon model.

Conclusions
Electrode polarity and electrode position over the precentral gyrus and central sulcus have a large and distinct influence on the response of cortical neural elements to stimuli.

Learning Objectives
1. Which neural elements are activated by Motor Cortex Stimulation?
2. What is the effect of MCS electrode positioning on neural activation?
3. What is the role of Anodal, Cathodal and Bipolar stimulation?

Monday, December 10
0700-0800, Poster #24

A prospective, multi-centered, 1 year post-implantation clinical evaluation of the Genesis® Implantable Pulse Generator (IPG) in combination with paddle or percutaneous leads for the management of chronic pain of the trunk and limbs.
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Introduction
Spinal Cord Stimulation (SCS) is a proven treatment for chronic pain, but there is still a need of additional high-quality prospective clinical study data. The final results of a prospective, multi-centered, 1 year follow-up study of the Genesis IPG (ANS; Plano, TX) are presented.

Materials and Methods
This study was designed as a prospective, multi-centered, 1 year post implantation study. After informed consent was obtained, patients were screened according to the inclusion/exclusion criteria. Following system implantation, patients were seen at 1-month, 3-months, 6-months and 1-year. The primary endpoint was patient satisfaction at the 1 year visit. Data also collected included: device programming and stimulation coverage, pain evaluation, Short Form McGill Pain Questionnaire, Short Form-36, and adverse events.

Results
A total of 195 patients were enrolled from 17 investigational sites. Over 80% of patients reported being “Very Satisfied” or “Satisfied” with the SCS therapy at the 1 year visit. Additionally, 75% of patients reported quality of life as “Greatly Improved” or “Improved” since implant. On average, patients reported using 2 programs. The mean reduction of VAS from baseline to 1 year was 3.4 on a 10 cm scale. The mean percentage of patient reported pain relief as “Excellent” or “Good” was 58.5% and 68.8% respectively. The lead migration rate during the course of the study was 3%.

Conclusions
The Genesis® IPG in combination with the ANS® leads offers a safe and effective treatment option in the management of chronic intractable pain.

Acknowledgements
The support of Advanced Neuromodulation Systems, a division of St. Jude Medical, for this project is gratefully acknowledged.

Learning Objectives:
1. Describe results of spinal cord stimulation using percutaneous and paddle leads in treatment of chronic pain.
1. Discuss low rate of surgical and treatment-related complications of spinal cord stimulation.
1. Discuss ability to maintain patient satisfaction and quality of life with spinal cord stimulation over time.

Monday, December 10
0700-0800, Poster #25

Thalamic pain and spinal cord stimulation. Long term results of five cases
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Introduction
An special kind of pain can results after stroke, trauma, infections, surgery and other processes affecting the Central Nervous System (CNS). This neuropathic pain is called Thalamic Pain or Central Pain. Usually this pain affects a hemibody and/or is of so severe that profoundly interferes with daily living activities. Pain is clearly described with neuropathic features: pain on sensory affected skin areas, alodynia, burning sensation, etc. Partial lesion somewhere of the CNS somatosensory pathways seems to be relevant (1) despite initial description by Dejerine and Roussy (2). Surprisingly, CNS right structures are more affected than left ones (3). Disappearance of the sensory deficits with persistence of pain can occur. And the converse: Sometimes pain disappears after a new stroke (4). It is generally accepted that thalamic pain does not appear immediately after stroke (5) but weeks to years after. Pharmacological and surgical treatment strategies have been developed to treat this difficult process (6). Despite modest and transient good results, there is general agreement that Spinal Cord Stimulation (SCS) should not be considered in treating these patients (7). Almost ten years ago we speak about our good experience with five patients suffering from severe thalamic pain treated on with spinal cord stimulation (8). This communication shows our experience on this matter.

Materials and Methods
Between May 1992 and December 2006, 8 patients suffering from severe neuropathic pain of cerebral origin were considered for treatment through spinal cord stimulation. Table 1 shows the clinical features of our series. There were 5 males and 3 females aged from 28 to 67. In six cases pain was related to stroke (in one case this etiology was doubtful). Two cases were related with multiple sclerosis disease. In no one case pain extended to face nor hemibody. Usually one extremity was affected alone or with part of the trunk. Trunk was involved in six cases. Medtronic Quad or Quad Plus

electrodes were implanted percutaneously in the appropriate cervical or dorsal area. The follow-up extended to date or after pain cessation or death.

Results

Two patients (cases 5 and 8) not were implanted because of ineffective response despite good paresthesiae coverage. Another two patients (cases 3 and 6) have excellent results after 13 and 6 years of follow-up. Another three patients obtained good results (cases 1, 2 and 4). Case 1 re-stroke and died after three years, case 2 obtained good results for five years and pain resolved spontaneously. Case 4 re-stroke after good results for 4 years and pain disappeared. One case (case 7) obtained good results for 18 months. Actually obtains fair alleviation despite good paresthesiae coverage. There are no complications in this series. One electrode fractured and was replaced (case 3).

Conclusion

Certain cases of thalamic pain can be treated through SCS. Twenty five per cent of our cases have obtains sustained good results. Spontaneous good results have been obtained in similar figures.

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Figure and Table Legend

Cases	Age (years)	Sex	Painful area	Date of implant	Diagnosis	Follow-up	Results
1	53	Male	R-leg	Apr-1993	Stroke	3 years	Good. Died (re-stroke)
2	46	Male	L-trunk	Aug-1994	Stroke	To present	Good for 5 years
3	53	Female	L-arm & upper trunk	Dec-1995	Stroke	To present	Excellent (3 bat. changes)
4	67	Male	R-low trunk & leg	Apr-1996	Stroke	To present	Good for 4 years. Re-stroke
5	28	Male	R-arm & upper trunk	Jan-1998	Multiple sclerosis	Only trial phase	No pain relief enough
6	36	Male	L-distal arm	Sep-2001	Stroke	To present	Excellent (1 bat. change)
7	27	Female	L-arm & upper trunk	Oct-2003	Multiple sclerosis	To present	Good for 18 months
8	67	Female	L-trunk	Jan-2006	Stroke (suspected)	Only trial phase	No pain relief enough

Learning Objectives:

1. Spinal Cord Stimulation can effectively alleviate thalamic pain not involving the face.
2. Long-term good results are attained in 25 %.

Monday, December 10
0700-0800, Poster #26

Neurogenic Mediated Intense Response of Psoriasis with Spinal Cord Stimulation Therapy
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Introduction
Spinal cord stimulation (SCS) is an effective treatment for patients with pain but the mechanisms of its action are inconclusive. Within a functional network of neurohormones, neuropeptides and cytokines[1], its not surprising that SCS increases blood flow[2,3] or releases neuropeptides from sensory nerve endings[4]. We report a case where a patient treated with SCS for postlaminectomy syndrome with lumbar radiculopathy, experienced an intense flare-up of lower leg psoriasis.

Materials and Methods
A 44-year old female presented with postlaminectomy syndrome with lumbar radiculopathy. After months of conservative treatment (medication, nerve blocks, physical therapy and TENS), there was little reduction in pain. In for an SCS-trial, the patient was sterilely prepped and draped; the skin was anesthetized with 5cc of 2% lidocaine with epinephrine and 0.25% marcaine. A 14-gauge Tuohy needle was inserted and entered the epidural space at T12-L1. Separately, two 8-electrode leads (Advanced Bionics, Precision) were advanced up to T8, connected, programmed and stimulation covered the painful areas.

Results
With SCS-trial, pain score in the lower back and legs fell to 7 from highs of 10/10 but the underlying psoriasis was intensely aggravated. Skin on both lower legs became red and flakey with the patient feeling things crawling on her legs. The device was removed at day-7. Photographs at 2 days following lead removal show the skin was red and flakey but not as intense with the SCS turned on.

Conclusion
We showed that a preexisting condition of psoriasis was aggravated by SCS treatment. Others have shown that psoriasis resolves at sites of anesthesia, neuropeptides are up regulated and there is a proliferation of terminal cutaneous nerves[5,6].and that arterioles can dilate further[7]. Since the mechanism of cutaneous neurogenic inflammation is associated with the release of neuropeptides from sensory endings[5,8] and that SCS increases blood flow[2,3], its likely that SCS elicited the release of neuropeptides[4] aggravating the psoriasis.

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Figure and Table Legend
Although an effective treatment for pain, SCS treatment has effects on the functional network of neurohormones, neuropeptides and cytokines. As shown here in this example of an underlying condition of psoriasis, was aggravated by SCS treatment giving further insights into its mechanism of action. Use of pharmacological agents to counter the aggravation of psoriasis may be considered when SCS is indicated

Learning Objectives:
Although an effective treatment for pain, SCS treatment has effects on the functional network of neurohormones, neuropeptides and cytokines. As shown here in this example of an underlying condition of psoriasis, was aggravated by SCS treatment giving further insights into its mechanism of action. Use of pharmacological agents to counter the aggravation of psoriasis may be considered when SCS is indicated.

Monday, December 10
0700-0800, Poster #27

Reducing Mental Fatigue by Transcutaneous Electrical Acupoint Stimulation
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Introduction
Mental fatigue is a common symptom in neurology and psychology especially central nervous system, which can affect sense, memory, motion and emotion, resulting in reduced work efficiency, so the evaluation and countermeasure are becoming urgent problems to solve. Other then the usual countermeasures of drug, limited work load and proper rest, we have developed a method of transcutaneous electrical acupoint stimulation (TEAS) to release mental fatigue especially typical driving fatigue.

Materials and Methods
36 testees, 9 for daily fatigue and 26 for simulated driving fatigue, were measured and stimulated. The main tools to evaluate fatigue are time domain analysis and power spectrum analysis of EEG (Electroencephalogram). Assistant measures include subjective evaluation, driving performance evaluation and EOG (Electro-Oculogram) evaluation. TEAS is researched for therapy of fatigue, in which three acupoints of Fengchi, Hegu and Neiguan are used for electrical stimulation. The stimulation parameters are: amplitudes of 3-5mA, rates of 2Hz or 2Hz/100Hz, and pulse widths of 600_s for 2Hz and 200_s for 100Hz.

Results
For most testees, fatigue is lessened after TEAS in daily fatigue experiment and simulated driving fatigue experiments. The changes in EEG are the decreases of fascicled _ waves and large-amplitude _ waves. And the values of average power spectral density of _ band, _ band, _ band and _ band are reduced as well. The changes of assistant measures are consistent with EEG. Subjective feeling of fatigue is weaker, error of driving performance is less and the eye blinking tends to be normal. TEAS has positive effect on restraining fatigue for most testees, but the effects are negligible or even negative for some testees.

Conclusion
TEAS can reduce mental fatigue for most testees, and provides an effective approach to fatigue therapy. The mode and parameters of the electrical stimulation which are not suitable for all testees need to be studied and improved.

Acknowledgements
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Figure and Table Legend

Table 1. Ratios of G values (Average Power Spectral Densities) in _, _, _ EEG bands for Testee 1# (F: Fatigue, S: After Stimulation)

Brain Region	$\frac{G_S(\theta)}{G_F(\theta)}$	$\frac{G_S(\alpha)}{G_F(\alpha)}$	$\frac{G_S(\beta)}{G_F(\beta)}$	Brain Region	$\frac{G_S(\theta)}{G_F(\theta)}$	$\frac{G_S(\alpha)}{G_F(\alpha)}$	$\frac{G_S(\beta)}{G_F(\beta)}$
F3	0.556	0.540	0.584	P3	0.769	0.576	0.792
Fz	0.884	0.654	0.702	Pz	0.891	0.553	0.838
F4	0.707	0.543	0.584	P4	0.933	0.567	0.902
C3	0.691	0.615	0.811	O1	0.772	0.607	0.626
Cz	0.815	0.612	0.790	Oz	0.449	0.502	0.442
C4	0.671	0.537	0.758	O2	0.593	0.598	0.614

Learning Objectives:
1. TEAS is an effective method to reduce mental fatigue.
2. EEG is important evidence for fatigue evaluation and TEAS effectiveness.
3. EEG can be used for feedback for treatment such as TEAS.

Monday, December 10
0700-0800, Poster #28

Vagus Nerve Stimulation for the Treatment of Intractable Epilepsy

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Introduction

To explore the effectiveness and mechanism of VNS therapy in intractable epilepsy.

Materials and Methods

Vagus Nerve Stimulation were performed in eleven patients from April 2004 to December 2006, three patients with secondarily generalized partial seizures after cephalitis (multi-lesion), three patients with Lenonx-Gastaut Syndrome (LGS), others with generalized seizures. All patients have tried more than two antiepilepsy drugs without effect. The operations were conducted under general anaesthesia, 3cm long incision was made in the front of left sternocleidomastoid near thyroid cartilage. Left vagus nerve stem was exposed, gyrate electrode of VNS device was wrapped the cervical vagus nerve stem. The skin incision was made in left side of the chest wall and VNS generator was implanted, electrode was connected with generator and fixed. The generator was turned on 2 weeks after operation. Stimulation parameters were 30seconds ON and 5minutes OFF, the frequency was 30Hz, and the pulse width was from 500_s to 1000_s. The output currents adjusted from 0.25mA to 1.5mA–[1-3]–.

Results

After 0.5_2 years of intermittent stimulation of the left vagal nerve, the seizure frequency was reduced by 60% occurred in all patients. Tonic-clonic seizures were significantly controlled and the seizure severity was alleviated significantly. Neuropsychological test showed a moderate improvement in mental functioning, behavior, and mood.

Conclusion

VNS is a minimal invasive surgery with few side effects, Which can obviously reduce seizure frequency. And can greatly improve the quality of life in patients with epilepsy. It is also an alternative and better way for patients with refractory epilepsy[4-6].

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Learning Objectives:
1. The goal of this research is to improve the therapeutic effects and the making of VNS system by study the correlativity between the parameters of VNS and the frequency of epileptic discharge.

Monday, December 10
0700-0800, Poster #29

Neuromodulation of the epileptic focus for intractable seizures originating in non lesional eloquent areas
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Introduction
Neuromodulation for intractable seizures has been applied in different targets: centromedian (Velasco AL, et al (2006) *Epilepsia* 47:1203-1212) or anterior thalamic (Kerrigan JF, et al (2004) *Epilepsia* 45:346-354), cerebellar (Velasco F, et al(2005) *Epilepsia* 46:1-11), vagus nerve stimulation (Amar AP, et al (2004) *Neurosurgery* 55:1086-1093). Epilepsy surgery in non-lesional patients with intractable focal seizures originating in eloquent areas constitutes an important problem epileptologists have to deal with specially because there is a high risk of neurological sequelae. Neuromodulation could be an alternative non-lesional surgical method in these cases.

Materials and Methods
The study was approved by the Ethical and Research Committees of the General Hospital. A total of seven patients were included, five of them with mesial temporal lobe epilepsy, one with supplementary motor area seizures and one with motor seizures. They signed an informed consent. Patient and caregiver were trained to have a reliable seizure count. They underwent neuropsychological testing, EEG. All of them had normal magnetic resonance imaging. They underwent intracranial electrode or grid implantation to localize the precise site of focus. Once it was localized, diagnostic electrodes were used as guides to implant permanent electrodes for brain stimulation. High frequency stimulation was used. Follow-up was performed 3-6-12 months with seizure count, EEG and neuropsychological tests to evaluate performance.

Results
All patients showed seizure reduction between 90 to 100%. None of them showed neurological impairment and their neuropsychological tests either remained same as baseline or showed improvement.

Conclusion
Neuromodulation is a non-lesional reversible method which reduces seizures without impairing neurological function in patients with mesial temporal or motor area epilepsy.

Learning Objectives
1. Establish the criteria for patient selection
2. Precise the stimulation target for chronic neuromodulation
3. Support the conservation of verbal and non-verbal memory

Monday, December 10
0700-0800, Poster #30

Inhibition of Histamine-induced Bronchoconstriction in Guinea Pigs by Pulsed Electrical Vagus Nerve Stimulation
Peter Staats, M.D.MBA
Charles Emala, M.D.; Hecheng Hu, M.D.; Puyun Guo, Ph.D.; Steven Mendez, MS,BA

Background
Electrical stimulation of the vagus nerve has long been known to induce bronchoconstriction and increase pulmonary inflation pressure. Vagal nerve-induced bronchoconstriction is known to be mediated in part by histamine receptor activation of vagal nerve efferents. We believe that the component of histamine-mediated vagal nerve-induced bronchoconstriction can be significantly reduced by applying a specific pulsed electrical signal to the vagus nerve.

Methods
A well-established model of airway responses was used to measure pulmonary inflation, blood pressure and heart rate on anesthetized, paralyzed and ventilated male Hartley guinea pigs that were challenged with IV histamine to increase peak pulmonary inflation pressure (Ppi). In each animal, histamine challenges alone were alternated with histamine challenges while the specific pulsed electrical signal was applied to the left and right vagus nerves.

Results
Histamine challenges alone increased Ppi by an average of 3.04 +/-1.35 cmH_2O. Histamine challenges with the electrical signal applied to the vagus nerve increased Ppi by an average of 1.80 +/- 0.73 cmH_2O. The Ppi was reduced by an average of 1.24 cmH_2O (P=0.012; n=8). The specific electrical stimulation of the vagus nerve decreased the effect of IV histamine on Ppi by over 40%.

Conclusion
This study suggests that stimulation of the vagus nerve with the specific pulsed electrical signal can reduce bronchoconstriction caused by histamine, and may have clinical relevance in the treatment of pulmonary conditions like asthma and anaphylaxis.

Monday, December 10
1200-1300, Poster #1

Deep brain stimulation and external cardiac defibrillation in an animal model: Evidence for tissue damage?
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Introduction
Parkinson's disease patients with long term L-dopa syndrome benefit from deep brain stimulation. Other indications are movement disorders like essential tremor, dystonia and intractable pain syndromes. When the advanced life support algorithm demands cardio version or defibrillation in these patients, undesired effects of monophasic electroshocks might occur on brain tissue adjacent to the stimulation electrodes (e.g. thermal injury) but also on the stimulation device itself.(1,2)

Materials and Methods

The present animal study (n = 6 pigs) investigated the effects of repeated defibrillation (2x 200J (n = 1) and 2 x 360J (n = 5)

at the implantation site of cerebral stimulation electrodes (Medtronic 3387 and 3389) and on stimulation device functionality

(Medtronic Kinetra).

Results
Repeated defibrillation did not cause (thermal) injury at the implantation site of the cerebral stimulation electrodes in different stimulation combinations nor cause injury to the tissue adjacent to the impulse generator. Functionality of the stimulator device following defibrillation, however, ranged from normal to total loss of function.

Conclusion:
We show here that repeated external cardiac defibrillation is safe with regard to thermal injury of brain tissue adjacent to the cerebral stimulation electrodes and the impulse generator pocket. The electrode combination or bipolar versus monopolar stimulation shows no difference. When performing defibrillation, however, the greatest possible distance must be maintained to the stimulator device implantation site. Subsequent testing of the stimulator device's functionality after defibrillation is absolutely necessary.

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Learning Objectives:
1. Cardiac defibrillation is safe with regard to thermal injury of brain tissue adjacent to the cerebral stimulation electrodes and the impulse generator pocket.

Monday, December 10
1200-1300, Poster #2

Automatic AC/PC Detection and Target Determination in Deep Brain Stimulation
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Introduction
Image based target determination for current deep brain stimulation procedures (DBS) is difficult and requires a lot of experience from the neurosurgeon. Using techniques of digital image processing, a software prototype was developed, that supports the computer-based DBS operation. The system detects the anatomical targets for the stimulating electrodes automatically in a sequence of T1-weighted magnet resonance images (MRI). Based on a determination of the anatomical landmarks AC and PC (anterior and posterior commissure), the coordinates of the target points are indirectly determined due to well known topographical relations.

Materials and Methods
AC and PC have to be localized in the midsagital plane (MSP) of the brain. An algorithm is described for an extraction of the MSP based on a segmentation of the third ventricle. Possible rotations or inclinations of the head in the MRI are examined and corrected by 3D image rotation. Localization of AC and PC is achieved by a procedure, which combines structural and morphological feature extraction.

Results
The prototype was tested with 39 MRI data sets taken from different patients at various hospitals in Europe. As a result the developed software system detected AC/PC in more than 90% of the cases correctly. These cases are characterized by a maximum difference between the automatically detected coordinates of AC and PC in contrast to coordinates which were manually determined of less than 1 mm in x and y direction and less than 1.5 mm in z direction (slice thickness). The remaining data sets could were not correctly classified due to major anatomical variations or because of poor image quality yielding to higher differences of the ACPC-coordinates.

Conclusion
Automatic ACPC determination is possible in a very short time and high accuracy with this algorithm using commonly available MRI´s. This will shorten the planning time and may increase the accuracy and objectivity in DBS procedures.

Monday, December 10
1200-1300, Poster #3

Feasibility Study of an Implantable Cortical Stimulation System for Tinnitus

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Introduction

About 12 million US adults suffer from tinnitus severe enough to require medical treatment. Pharmacological approaches may improve emotional and psychological reaction to tinnitus but are less effective in improving tinnitus percept. Masking and retraining therapies provide mixed benefits. Recent evidence suggests aberrant cortical plasticity as an underlying mechanism.[1] Transcranial magnetic stimulation, epidural, and direct current stimulation of the auditory cortex can suppress tinnitus perception.[2,3,4] This study explored the feasibility of an investigational epidural auditory cortex stimulation system for tinnitus suppression.

Materials and Methods

Patients with predominantly unilateral tinnitus for >1 year and scoring >33 on Tinnitus Reaction Questionnaire (TRQ) were implanted with an extradural electrode over the auditory cortex using fMRI targeting, connected to a subclavicular pulse generator (Northstar Neuroscience, Seattle, WA). Two-week periods of active and sham stimulation were alternated in blinded random sequence, followed by active stimulation with stimulation parameter adjustments to maximize tinnitus suppression. Safety outcomes were assessed.

Results

At baseline, 8 patients had tinnitus for 15.8±3.7 years, scored 83±22 for loudness and 58±23 for TRQ. No acute changes in tinnitus were noted within the 4-week crossover period but significant improvements were observed after several weeks of continuous stimulation. For responders, onset of relief was 2 to 27 weeks after stimulation initiation and took several more weeks (7 to over 24) for maximum effect. Thus far, 4 patients have lasting tinnitus suppression, and two others have experienced periods of total tinnitus suppression lasting 24-48 hours. At 6 months, 6 patients had significant improvements (53±23%) in TRQ. There were no device related serious adverse events.

Conclusion

Electrical stimulation of the auditory cortex for the suppression of tinnitus is feasible and appears safe. After several week of CS, substantial and lasting suppression of tinnitus symptoms was observed in half of the patients. Additional studies will further characterize efficacy and best patient population.

References

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Acknowledgements

This study was funded by Northstar Neuroscience, Inc., the manufacturer of the implanted stimulation device system.

Figure and Table Legend

Figure 1. Picture montage depicting implantation procedure. At left, fMRI data is seen in stereotactic database. The yellow line indicated the central position of the implanted electrode array. At right, scalp incision used and the electrode array in-situ are seen.

Learning Objectives

1. Understanding the role of posterior peri-sylvian regions in the pathophysiology of tinnitus
2. Understanding the mechanisms of cortical electrical stimulation as a means of neuromodulation

Monday, December 10
1200-1300, Poster #4

Efficacy of Ziconotide in Combination With Intrathecal Opioids
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Co-presenter(s):
Kathy F. Clagg, RN, ONC

Introduction
Ziconotide, the synthetic version of a naturally occurring _-conotoxin, blocks N-type voltage-sensitive calcium channels, whereas opioids act as agonists at mu opioid receptors. These differing mechanisms of action may provide additive analgesia when ziconotide and opioids are used in combination. This case series examines the safety and efficacy of ziconotide as an adjuvant to intrathecal opioid therapy in chronic pain patients failing intrathecal opioid monotherapy.

Materials and Methods
This prospective, open-label case series evaluates patients with implanted intrathecal pumps that had inadequate pain relief (Visual Analog Scale of Pain Intensity score >5 cm) despite dose titration or exhibited intolerable side effects with existing intrathecal opioid treatment. Ziconotide is initiated at 0.5 mcg/d and increased monthly by 0.5 mcg/d (maximum 5.0 mcg/d); daily intrathecal and oral opioid doses are held constant throughout the observation period. Efficacy is evaluated at baseline and at 3 and 6 months using the Visual Analog Scale of Pain Intensity and the Oswestry Disability Index; safety is evaluated via adverse event reports.

Results
To date, 11 patients (eight males) aged 48 to 73 years have been enrolled (one patient for <3 months, three patients for 3-6 months, seven patients for >6 months). Concomitant intrathecal opioids are fentanyl (n=1) and hydromorphone (n=10). Mean baseline Visual Analog Scale of Pain Intensity score is 7.27 cm; mean improvements are 23% at 3 months (n=10; mean ziconotide dose, 1.34 mcg/d) and 23% at 6 months (n=7; mean ziconotide dose, 2.36 mcg/d). Mean improvements on the Oswestry Disability Index are evident on nine of the 10 measures at 3 months and eight of the 10 measures at 6 months. Three patients have had at least one adverse event (memory loss, auditory hallucinations, confusion, weakness, difficulty urinating, and balance difficulties). All adverse events have been classified as mild or moderate, and all have resolved after ziconotide dose reduction (n=1) or discontinuation (n=2).

Conclusion
Addition of relatively low-dose ziconotide to a stable dose of intrathecal opioid may be an effective, well-tolerated treatment option for patients with intractable pain failing intrathecal opioid alone. Further research is warranted.

Acknowledgments
The support of Elan Pharmaceuticals, Inc., for this project is gratefully acknowledged.

Learning Objectives
1. Describe the benefits of combining ziconotide with an opioid in intrathecal therapy
2. Recognize that adverse events commonly associated with ziconotide treatment generally resolve with ziconotide dose reduction or discontinuation
3. Recognize the importance of further research on ziconotide combination therapy

Monday, December 10
1200-1300, Poster #5

A Retrospective Study of Microgram Intrathecal Morphine Sulfate for Control of Pain in Failed Back Surgical Syndrome with a Prior Failed Spinal Cord Stimulator Trial or Spinal Cord Stimulator Implant
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Introduction
Chronic back and leg pain from Failed Back Surgical Syndrome (FBSS) is a difficult problem in pain management. In the worst cases, spinal cord stimulation (SCS) and intrathecal catheter medication management are used with varying degrees of success. In six patients with FBSS, opioid detoxification for six weeks followed microgram dosing was used to control pain.

Methods
Six patients who had failed a SCS trial or had a SCS implanted but were not under pain control were put through detoxification. Six weeks later an inpatient intrathecal catheter trial was. All patients started at a dose of morphine sulfate (MS) 2.4mcg/day. They were increased over three days to dosages decreasing their pain to an acceptable level. Each patient went on to have a Medtronic Synchromed II Pump implanted. Follow up has been from four to eighteen months.

Results
Pre-detoxification to post-detoxification pain scores remained about the same. The highest level to control pain was MS 30mcg/day. The average was MS 12.8mcg/day. All pumps are still under MS 40mcg/day. Patients stopped from one to four drugs with microgram-ICMM (mcg-ICMM). One patient was converted to hydromorphone. There was one post dura puncture headache. One patient has a new herniated disc and is pending surgery. This is the only pain score to significantly increase.

Conclusion
Three patients were either disabled or not working when presenting to the practice. All three have returned to forty hour per week jobs. One of these is the new disc herniation. Mcg-ICMM is allowing the patient to remain working during the workup. The two longest running patients had additional injuries. The oldest had a broken leg in which the dosage has gone up. The other had a cervical fusion. All patients said this is the best treatment they had for their pain.

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Acknowledgements
Rob Ashby, M.D., addictionologist
Kathy Vendt-Howe, R.N., pump coordinator

Figure and Table Legend
Figure 1: Morphine Sulfate Trial Dosing
Table 1: Visual Analog Scores During Patient Care
Table 2: Medication Type and Dosage per Time Period

Monday, December 10
1200-1300, Poster #6

Benefit of Intrathecal Drug Administration for Patients with Severe Chronic Pain
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Introduction
Conservative treatment of severe chronic pain often is very difficult, unsatisfactory and very expensive (1).
Intrathecal administration of drugs offer an efficient, minimally invasive alternative/supplement to conservative therapy(3,6).
Compared to conservative drug therapy alone, Intrathecal therapy can improve pain treatment results and reduce treatment-related cost (2,4,5).

Materials and Methods
101 patients who had been implanted with infusion systems for intrathecal drug therapy were studied. Over a period of 8 years a total of 126 drug pumps were implanted in 101 patients - including pump replacements. On average the longevity of the pumps was 4.5 years. All patients suffered from severe chronic pain syndrome. Etiology of the underlying chronic pain syndromes were mainly failed back surgery syndrome (FBSS) followed by chronic lumbalgia without prior surgery. On average, the age of the patients was 49.2 years, the period of anamnesis was 66 months. First choice of intrathecally administered drug was morphine, followed by hydromorphone. The analysis compares both the pain relief of conservative pain therapy and intrathecal drug administration and the costs of the conservative and intrathecal therapy.

Results
Evaluation of the standardized patient questionnaires showed the following results: Intensity of pain on the Visual Analog Scale (VAS) before intrathecal drug therapy - 8.1. VAS after intrathecal morphine therapy – 4.6. This corresponds to an alleviation of pain by 57 %. This alleviation is statistically significant ($p > 0,01$). On average, the interviewed patients assessed their satisfaction with the therapy with 4.6 on a scale ranging from 1 to 10, their activity improved by 4.6, the quality of their sleep by 4.4. Moreover, an alleviation of the nausea which was before triggered by oral opioids, was manifested by a reduction from 3.8 to 2.9, constipation problems were reduced on average from 4.3 to 3.6. A conspicuous aspect was an increase in drug-induced hyperhidrosis from 3.0 to 3.8 and of sleepiness from 3.1 to 3.6. The reduction of costs that is accomplished is of considerable importance. The annual costs for the required analgesics were reduced from € 5,621 to € 1,207, and the number of patients that were hospitalized for drug therapies went down from 3.6 to 0.5. With an average therapy period of 44.7 months, € 11.461 had to be spent for the required pumps - 76 % Medtronic SynchroMed® and 24 % Medtronic IsoMed™.

Conclusion
Intrathecal drug delivery offers an efficient, minimally invasive treatment option for patients refractory to conservative medical therapy and moreover reduces costs on a long-term basis.

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Acknowledgements
I would like to express my gratitude to Medtronic Inc. Germany

Learning Objectives:
1. Benefit of intrathecal drug administration
2. Efficient, minimally invasive treatment
3. Reduces costs on a long-term basis

Monday, December 10
1200-1300, Poster #7

Novel Approach to Intrathecal Opioid Therapy for Chronic Nonmalignant Pain
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Introduction
The use of intrathecal opioids for acute and cancer pain is widely accepted. Their use in chronic nonmalignant pain is less clearly defined. Concerns with intrathecal opioid therapy include efficacy, tolerance, opioid-induced hyperalgesia (OIH) and side effects. Significant differences exist among pain practitioners regarding patient criteria, trial parameters, and the continued use of oral opioids. In a case study we describe an approach which has been successful in providing pain relief to patients while utilizing relatively low intrathecal doses of morphine without concurrent use of oral opioids.

Materials and Methods
The patient in this case study is an 84yo male with lumbar spinal stenosis who was not a surgical candidate. Patients were considered to be appropriate candidates for intrathecal therapy based on established practice criteria. PO opioids were discontinued over 6-8 weeks while adjuvant analgesics were continued. A three day trial in the university hospital with intrathecal morphine was performed. Patients were followed by the Chronic Pain and Physical Therapy services. Intrathecal morphine infusion was begun at 0.024mg/day and was increased to a maximum of 0.384mg/day at 12-14hr intervals.

Results
Initial pain rating of 10/10 with minimal activity was reduced to 6/10 after 12 hours. Incremental increases in dose resulted in resolution of pain (0/10) and improved functional activity (0.096mg/day) with no opioid-related side effects. At twelve months the intrathecal morphine dose has stabilized at 0.161mg/day with average pain rating of 4/10 with activity without PO opioids.

Conclusion
A low-dose intrathecal morphine protocol without requirement for concurrent PO opioid therapy to manage severe chronic pain in a patient with lumbar spinal stenosis is presented. CNS neural plasticity, opioid tolerance, OIH and opioid side effects are all likely to be of consequence with long-term intrathecal opioid therapy and may be lessened through use of protocols aimed at managing chronic nonmalignant pain with lower doses of opioids.

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Learning Objectives:
A low-dose intrathecal morphine protocol without requirement of concomitant administration of oral opioids has been described.

Monday, December 10
1200-1300, Poster #8

Intrathecal Pain Management with Patient-Controlled Analgesia: 12-Month Study with the Personal Therapy Manager
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Introduction
Patient-controlled analgesia (PCA) is used extensively to treat acute pain. Recently, a PCA device to treat episodes of breakthrough pain in patients with implanted programmable drug delivery systems has become available. The oPTiMa registry has evaluated the use of the Personal Therapy Manager (PTM, Medtronic,Inc.) in combination with the infusion pump (SynchroMed®, Medtronic,Inc)

Materials and Methods
This prospective registry was conducted in 17 European centers. Patients with (group A) or without (group B) a pre-existing implanted pump experiencing breakthrough or unstable pain were included and followed up to 12 months.
Data collected include pain scores, quality of life (QOL), patient and physician satisfaction, infused drug doses/concentrations, oral medication and complications.

Results
A total of 168 patients were enrolled (A=79, B=89). Compared to baseline, the average pain scores (VAS) decreased significantly at 12 months in both groups, although statistical significance was reached only in group B (A: 6.4 to 5.5, B: 8.0 to 4.1). Oral opioid consumption tended to decrease in both groups. 79% of the patients reported they were satisfied with the PTM system. They particularly liked the personal control of pain relief made possible. The QOL as assessed by EQ-5D improved.
No serious adverse events related to the PTM device occurred.

Conclusion
The data indicate the PTM system is a valuable addition to chronic pain management. The average pain score decreased in both groups of patients and the quality of life improved. Patients used the device regularly without major problems and were satisfied with the results.

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The oPTiMa study group: W. Ilias (Krankenhaus der Barmherzigen Brueder, Wien, Austria), B. le Polain (UCL St Luc, Brussels, Belgium), E. Buchser (EHC - Hôpital de Morges, Morges, Switzerland), J. Neuhold (Krankenhaus der Elisabethinen, Graz, Austria), W. Schleinzer (Swiss Paraplegic Center, Nottwil, Switzerland), S. Eldabe (James Cook University Hospital, Middlesborough, UK), J. Maeyaert (Heilig Hart Kliniek, Eeklo, Belgium), E. Reig (Clinical Puerta de Hierro, Madrid, Spain), G. Fortini (Ospedale di Circolo e Fondazione Macchi, Varese, Italy), A. Ver Donck (AZ St Jan, Brugge, Belgium), H. Glawe (Neurochirurgische Praxis Oranienburg, Oranineburg, Germany), JR Gonzaléz-Escalada (Hospital Ramon y Cajal, Madrid, Spain), V. Heidecke (Klinikum der Med. Fakultät der MLU Halle Wittenberg, Halle, Germany), A. Costantini (Ospedale Clinicizzato SS. Annunziata, Chieti, Italy), T. Riegel (Klinikum der Philipps-Universität Marburg, Marburg, Germany), R. Becker (Asklepios Kliniken Schildautal, Seesen, Germany), A. Seeliger (Gemeinschaftspraxis für Neurochirurgie, Köln, Germany)
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Learning Objectives:
1. PTM has an added value for treating fluctuating pain in chronic pain patients with a programmable, implantable pump.
2. Patients are satisfied with the PTM
3. Patients can use the PTM easy and safely

Monday, December 10
1200-1300, Poster #9

Intrathecal Ziconotide for Complex Regional Pain Syndrome: Six Case Reports
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Introduction
Ziconotide is a nonopioid indicated for the management of severe chronic pain in patients for whom intrathecal therapy is warranted and who are intolerant of or refractory to other treatments such as systemic analgesics, adjunctive therapies, or intrathecal morphine. There is a paucity of information regarding ziconotide use in patients with complex regional pain syndrome.

Materials and Methods
Six cases in which intrathecal ziconotide was used to treat patients with complex regional pain syndrome were summarized.

Results
Patients (two males, four females; age, 17-49 years) had achieved inadequate pain relief with various conventional/interventional treatments. Three patients received ziconotide monotherapy (initial dose, 0.48-10.0 mcg/d; treatment duration, 1-8 years). Mean pain score was 93 (range, 80-100) at ziconotide therapy initiation and decreased by a mean of 79% (range, 38%-100%) at the last available assessment. Two of these patients have discontinued ziconotide and are pain-free. Adverse events in monotherapy patients included urinary retention, depression, anxiety, and hallucinations, which generally resolved spontaneously, with treatment, or with ziconotide dose reduction. Two patients initially received ziconotide monotherapy (initial dose, 0.5-2.4 mcg/d; duration, 4-12 months), followed by combination therapy (ziconotide/sufentanil/bupivacaine or ziconotide/morphine; duration, 0.25-1.8 years). Both patients had a pain score of ~80 at combination therapy initiation. At the last available assessment on combination therapy, pain score had not improved in one patient but had improved by ~69% in the second patient. Resolution of edema, color changes, and hypersensitivity in the leg of the second patient was attributed to ziconotide. This patient has discontinued all intrathecal medications and manages pain with intermittent oxycodone (most recent pain score, 15). Hallucinations occurred in both patients and resolved with ziconotide dose reduction/interruption. One patient was treated with ziconotide/sufentanil/bupivacaine combination therapy only (initial ziconotide dose, 0.5 mcg/d). Her pain score was 70 before initiation of ziconotide therapy and improved by 57% after 28 months on ziconotide. She reported no adverse events.

Conclusion
Ziconotide appears to be useful for treating patients with complex regional pain syndrome. Further investigation is warranted.

Acknowledgments
The support of Elan Pharmaceuticals, Inc., for this project is gratefully acknowledged.

Learning Objectives
1. Identify the potential benefits of ziconotide therapy in patients with complex regional pain syndrome
2. Identify adverse events that are commonly associated with ziconotide therapy and how these events may be managed
3. Recognize the need for additional investigation of ziconotide therapy in patients with complex regional pain syndrome

Monday, December 10
1200-1300, Poster #10

Safety and efficacy of non commercially preparations of bupivacaine 4% and clonidine 0,4 % intrathecally used for refractory pain.

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Introduction
Many patients suffering from severe chronic pain are treated via intrathecal drug delivery devices. Morphine is the first line (the “gold standard”) medication used. Bupivacaine and Clonidine can be safely used in a second step (1, 2).
Reservoir volume of totally implantable devices is typically of 20 ml. When pain control is attained, refill procedures should be separated as much as possible to minimize costs and troubles to patient. Lapsus between refills varies with daily dosage and concentration of the medication. In Spain, Morphine 4 % is commercially available for intrathecal use, which is useful enough to manage most patients. Instead, Bupivacaine and Clonidine are available in lower concentrations (0,75 % and 0,05 % respectively), which implies more often refills. The experience of our Pain Unit in using Bupivacaine 4 % and Clonidine 0.4 % since 2003 is reported.

Materials and Methods

23 patients receiving Bupivacaine 4 % and 17 patients receiving Clonidine 0,4 % have been retrospectively analyzed. Both Bupivacaine 4 % and Clonidine 0,4 % are manufactured by Farmacia del Dr. E. Carreras Ginjaume (3). Sterile 5 ml conservative-free ampoules, are supplied after specific authorization for each patient has been obtained, according to Spanish law.

Results
Any complications, incidents or side-effects have been observed during the study period. During all refill procedures, old medication withdraw of reservoir was send to bacteriological culture. In three instances growth of Staphylocccus aureus or epidermidis was reported. Patients were advised for narrow observation of symptoms related to eventual infection which never occurred. Posterior refill procedures did not result in bacteriological events. External skin contamination was assumed.

Conclusion
Bupivacaine 4 % and Clonidine 0,4 %, free-conservative, sterile ampoules of galenic pharmacy preparations are both safe and effective in long-term treatment through intrathecal drug delivery pumps.

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Learning Objectives:
1. Non-commercially available galenic formulations can be used for treatment of chronic pain patients through intrathecal drug delivery pumps.
2. According to Spanish Law, special authorizations are required for each patient.
3. Long-term results indicate that sterile, free-conservative ampoules of Bupivacaine 4 % and Clonidine 0,4 % are safe and effective.

Monday, December 10
1200-1300, Poster #11

Biological consequences of long-term intrathecal administration of opioids: Comparison of Nociceptin and immune hormones Levels in the Cerebrospinal Fluid of Chronic Pain Patients With or Without Intrathecal Administration of Morphine
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Introduction
The intrathecal administration of opioids produces a powerful analgesia through the activation of the spinal opioid receptors, and is successfully used for the treatment of chronic cancer and non-cancer pain (1,2,3). Exogenous opioids can interact with their receptors outside the classical nociceptive system, and can modulate the activity of various biological systems such as immune and endocrine systems (4,5). The knowledge of the effects of opioids and the influence of their administration route on these systems is of primary importance.
Little is known about the effects of opioids administered by spinal route on various body systems. Here we focussed on the neuropeptide nociceptin/orphanin FQ (N/OFQ), which is thought to be involved in pain transmission and modulation (6,7). Human studies have not yet defined its role in pain patients (6). We investigated the presence of N/OFQ in the cerebrospinal fluid (CSF) of human controls and patients with chronic noncancer pain, including those treated with intrathecal morphine, and studied if pain or treatment with long-term intrathecal morphine influences its levels.

Materials and Methods
The CSF of 40 patients (10 controls and 18 with chronic noncancer pain: 12 treated chronically with intrathecal, morphine and six opioid naıve) was analyzed, blindly, with radioimmunoassay methods.

Results
N/OFQ was detected in all patients. Mean CSF concentrations were lowest in the morphine-treated group and highest in the untreated chronic pain patients (12.06 1.19 and 57.41 10.06 fmol/ml, respectively), and the difference between the morphine-treated group and controls was statistically significant (44.72 13.56 fmol/ml, P <0.05).

Conclusion
The presence of N/OFQ peptide in human CSF may correlate with biological activities that are influenced by different pain states and long-term intrathecal-morphine treatment. Further studies should verify whether the determination of this peptide CSF level may provide information on opioid treatment efficacy and on the presence of opioid tolerance.

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Figure and Table Legend
Table 1: CSF N/OFQ-LI Concentrations in Group C, Group CP, and Group ITM
Fig. 1. CSF nociception levels in human controls (Group C), in patients with chronic noncancer pain (Group CP), and in patients with chronic non-cancer pain under treatment with intrathecally administered morphine (Group ITM). Data are shown as mean SE. *P <0.05, Dunnett's test.

Learning Objectives
To verify the presence of N/OFQ in the cerebrospinal fluid (CSF) of human controls and patients with chronic noncancer pain, including those treated with intrathecally administered morphine, and to determine whether pain or treatment with long-term intrathecal morphine influences its levels.

Monday, December 10
1200-1300, Poster #12

A Randomized, Multidose, Double-blind Study to Evaluate the Analgesic Response and Safety of Ziconotide Intrathecal Bolus Injection in Patients With Severe Chronic Pain
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Introduction
Ziconotide is a nonopioid analgesic approved by the US Food and Drug Administration for the treatment of severe chronic pain in patients for whom intrathecal therapy is warranted and who are intolerant of or refractory to other treatments such as systemic analgesics, adjunctive therapies, or intrathecal morphine. The efficacy and safety of ziconotide have been established using continuous intrathecal infusions, but no published studies have investigated ziconotide bolus administration.

Materials and Methods
In this double-blind, placebo-controlled study, each patient received four direct lumbar spinal injections that contained 0, 2, 4, or 8 mcg of ziconotide in a randomized sequence over a 1-month period. Data were obtained immediately before the injection (baseline) and hourly postinjection for 6 hours. The number of responders (ie, patients with a >30% or >50% reduction from baseline in Visual Analog Scale of Pain Intensity score) was calculated for each dose group. Safety evaluations included measurement of hemodynamic, respiratory, and neurologic parameters, as well as recording of adverse events.

Results
Six patients participated, yielding data for 24 injections. Responder results are summarized in Table 1. Patients who had a >50% reduction in pain score are also included in the >30% reduction group. Hemodynamic, respiratory, and neurologic measurements showed no significant changes from baseline with placebo or ziconotide. With the 8-mcg ziconotide bolus, two patients (33%) reported ataxia at 6 hours postinjection as well as nausea and vomiting with onset approximately 4 hours postinjection. Mild nausea and/or dizziness were reported after 33% of ziconotide boluses and 16% of placebo injections.

Reduction in Pain Score	Treatment			
	Placebo	2 mcg Ziconotide	4 mcg Ziconotide	8 mcg Ziconotide
>50%	0	1	1	3
>30%	1	1	2	4
<30%	5	5	4	2

Conclusion
Ziconotide bolus administration may allow for rapid assessment of intractable pain that is responsive to ziconotide, and bolus administration of ziconotide was well tolerated. Further research with larger sample sizes is warranted.

Acknowledgments
The support of Elan Pharmaceuticals, Inc., for this project is gratefully acknowledged.

Figure and Table Legend
Table 1. Pain Relief After Bolus Injection

Learning Objectives
1. Describe the analgesic response to bolus administration of ziconotide
2. Recognize the adverse events associated with bolus administration of ziconotide
3. Understand the implications for future research regarding bolus administration of ziconotide and long-term intrathecal infusion of ziconotide

Monday, December 10
1200-1300, Poster #13

Intrathecal Combination Therapy of Ziconotide and Baclofen: Case Series
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Introduction
Intrathecal ziconotide is indicated for the management of severe chronic pain in patients for whom intrathecal therapy is warranted and who are intolerant of or refractory to other treatments such as systemic analgesics, adjunctive therapies, or intrathecal morphine. Intrathecal baclofen is indicated for use in the management of severe spasticity. Currently, there is limited information regarding intrathecal ziconotide-baclofen combination therapy in patients with refractory neuropathic pain and spasticity.

Materials and Methods
Six case studies of intrathecal ziconotide with baclofen therapy were reviewed. Patient characteristics, medical history, ziconotide and baclofen doses, concomitant medications, Visual Analog Scale of Pain Intensity scores, and clinical observations (including adverse events) were identified.

Results
Six adult patients (four male, two female; age range, 44-73 years) with long-standing neuropathic pain and spasticity had failed to achieve satisfactory pain relief. Diagnoses included traumatic spinal cord injury (n=4), quadriparesis (n=4), cerebral palsy (n=1), bilateral lower extremity neuritis (n=1), and transverse myelitis (n=1). Agents previously used for intrathecal therapy that failed to provide adequate pain relief included morphine and bupivacaine. All patients but one were initially stabilized on baclofen monotherapy; the remaining patient had baclofen added to ziconotide therapy. Ziconotide was initiated at doses between 1.2 mcg/d and 2.4 mcg/d, and dose adjustments occurred as needed. The average time to onset of pain relief was 9 weeks (range, 1-26 weeks) with a mean ziconotide dose of 4.5 mcg/d (range1.3-14.4 mcg/d). At the last available assessment, mean percentage reduction in pain intensity scores from baseline was 48.7% (range, 30.0-75.0%). Patients continued to use concomitant medications such as systemic opioids and antiepileptic drugs. Adverse events were recorded and included one patient reporting nausea and vomiting with dehydration and another patient reporting loss of bladder control; it was uncertain if the adverse events were directly related to the intrathecal agents. In all six cases, patients achieved considerable pain relief with minimal adverse events.

Conclusion
The case studies suggest that intrathecal ziconotide with baclofen therapy is a viable and safe treatment option for patients with refractory neuropathic pain and spasticity.

Acknowledgments
These case studies were sponsored by Elan Pharmaceuticals, Inc.

Learning Objectives
1. Describe the therapeutic effect of intrathecal administration of ziconotide in combination with baclofen
1. Identify adverse events that may be associated with intrathecal ziconotide-baclofen combination therapy
1. Recognize the need for additional investigation of the intrathecal combination therapy of ziconotide and baclofen in pain management and rehabilitation

Monday, December 10
1200-1300, Poster #14

Our experience with complications of intrathecal baclofen drug delivery systems
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Introduction
Intrathecal baclofen (ITB) delivered by programmable pump device can solve severe spasticity of various origins (1) where systemic administration of antispastic drug or local injection of botulinum toxin has an insufficient effect. However, adverse events are unavoidable part of such treatment. The main problems are pharmacological side effects of ITB, surgical complications, and device-related complications. In this study, we show our experience with such complications. One catheter-related complication is described in detail.

Materials and Methods
Based on positive test trials with ITB we have implanted thirteen pump systems (5x Synchromed EL, 8x Synchromed II, Medtronic) for severe spasticity in multiple sclerosis (9 cases) and in spinal cord injury (4 cases). Implantation technique was routine except one when partial hemilaminectomy was used for catheter re-implantation in patient suffered from ankylosing spondylitis.

Results
Catheter dislodgement developed in two patient and both they were re-operated. Plain x-ray, CT scan and/or perimyelography documented catheter replacement. One patient suffered from local catheter infection and was successfully

treated with antibiotics. Twice we observed cerebrospinal fluid leaks, once with the fluid subcutaneous fistula with necessity of surgical resolve.

Conclusion
Most of adverse events and complications were connected with catheters and they were minor and treatable ones. Identification of catheter malfunction requires careful investigation. Surgical approach is requested when there are difficulties with percutaneous catheter implantation. Although intrathecal drug delivery systems are associated with various side effects and complications, their benefits outweigh their risk. Prevention, early recognition, and prompt management optimize the patient outcomes.

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Acknowledgements

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Learning Objectives:
1. Intrathecal baclofen delivered by programmable pump device represents an important treatment modality in severe spasticity of various origins.
2. Adverse events and complications are usually minor and treatable ones.
3. Catheter malfunction requires careful investigation followed by surgical repair.

Monday, December 10
1200-1300, Poster #15

Clinical Experience Using Intrathecal Bupivacaine in Refractory Neuropathic Pain
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Introduction
Patients suffering from refractory chronic benign pain continue to be a treatment challenge. Patients were initially treated with conventional medical management (CMM) consisting of pharmacotherapy and physiotherapy. The non-responders go on to be treated with spinal cord stimulation (SCS). Some patient's who prove refractory to SCS, either initially or as late failure, receive intrathecal drug therapy primarily consisting of opioids, baclofen and clonidine. We found that 17 of our patients proved refractory to the above pain management methods and form the basis of this presentation. The treatment of this select group of patients remains controversial, yielding poor results.

Materials and Methods
We present a retrospective study of the 17 patients who proved refractory to CMM, SCS and intrathecal opioid therapy, who went on to be treated with the introduction of primarily intrathecal bupivacaine, administered through their previously implanted programmable pump. This group consisted of 2 cases of CRPS I, 2 cases small fibre neuropathy, 8 cases of neuropathic pain secondary to failed back surgery syndrome, and 5 cases of mixed pain syndromes. These patients have been followed for a mean period of 42 months (6 – 86 months). Patients were evaluated using Visual Analog Scale (VAS), Oswestry Disability Index (ODI), Beck Depression Index (BDI), EuroQol 5D (EQ-5D), and SF-36 Questionnaires

Results
The mean daily dose of bupivacaine was 4.83 mg/day (0.68–8.80 mg/day). The mean VAS score decreased by 32.19 mm, the mean ODI score decreased by 19.1%, the mean BDI score increased by 11.3 (18.0%), and the mean EQ-5D score increased by 0.56. SF-36 showed the most statistical improvement in body pain and vitality.

Conclusion
In a select group of cases of chronic benign pain who prove refractory to other treatment modalities, the addition of bupivacaine to their already existing intrathecal drug therapy improves pain and quality of life.

Learning Objectives:
1. The introduction of intrathecal bupivacaine is a salvage procedure in a select group of patients with chronic refractory benign pain.

Monday, December 10
1200-1300, Poster #16

Safety and Tolerability of Ziconotide (Prialt®) in Polyanalgesic Intrathecal (IT) Therapy.
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Introduction
Ziconotide intrathecal infusion became available for commercial use January 31st 2005. The Polyanalgesic Consensus on Intraspinal Drug Delivery provides best evidence for utilizing IT medications in combination; however experience of ziconotide in combination is limited. A retrospective chart review of our experience with ziconotide in combination with various IT medications was conducted

Methods
A retrospective chart review was conducted on all patients receiving ziconotide in combination with other IT medications from February 1st through August 12, 2007.

Results
Fifty patients in our clinic that have been exposed or are currently on ziconotide during 31 month period evaluated with 42% of patients remaining on ziconotide in combination with other IT medications. The average duration of treatment with ziconotide is 12 mos. The mean ziconotide dose is 3.58 mcg/day with range of (0.6mcg/day-12mcg/day). Combination IT opioid doses: (14) hydromorphone, 4.4mg/day (0.75mg-12.4mg/day); (3) fentanyl, 104.75 mcg/day (14- 175 mcg/day); and (1) morphine at 8.4 mg/day. Reasons for discontinuation were (14%) nausea and vomiting, skin (2- lesion, 2-rash), (10%) anorexia, (7%) mood change, increase pain, dizziness, peripheral edema, (< 5%) hair loss, urinary retention, loss of taste, memory difficulties, worsening of myoclonus, and weakness, mucositis. Four severe adverse events were reported (3) unrelated (pulmonary embolism, death due to terminal illness, death deemed natural cause). One patient hospitalized for severe urinary retention (related).

Conclusion
Ziconotide is a novel non-opioid IT therapy to combat severe chronic pain. This retrospective chart review demonstrates preliminary safety and tolerability information when utilizing ziconotide in combination with other IT medications. In our experience, when ziconotide is initiated at low infusion rates and titrated slow, alone or in combination, intolerable side effects have been avoided

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Acknowledgments
The support of Elan Pharmaceuticals Inc. is gratefully acknowledged.

Figure and Table Ledged
1. Patient demographics

1. IT drug combinations and doses

1. Adverse Events

Learning Objectives

1. To evaluate discontinuation rate due to adverse events or tolerability issues associated with the use of ziconotide in combination with other IT therapies

1. To identify the average ziconotide and opioid doses used in combination therapy

Monday, December 10
1200-1300, Poster #17

Variability of spasticity in patients on intrathecal baclofen (ITB) and the use of the Personal Therapy Manager (PTM) to treat this variability of spasticity

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Introduction

Intrathecal baclofen infusion using implantable pumps is widely acknowledged to be clinically effective in the relief of intractable spasticity of either spinal or cerebral origin by reduction in muscle tone and spasms, and is generally well tolerated. With respect to the previous situation in our experience the majority of the patients was satisfied. However careful inquiring showed that in a part of the patient population an optimal twenty-four hours' period could not be reached. We quantified in a limited amount of patients variations in spasticity and secondly tried to manage fluctuations by giving an additional bolus above the continuous intrathecal baclofen infusion (topping up bolus) using the recently developed PTM (patient therapy manager, Medtronic Minneapolis, USA).

Materials and Methods

Fourteen patients were asked to assess the occurrence of spasticity four daily periods using a VAS score for at least one month. In 8 patients a pilot study with the use of the PTM has be performed. For evaluation the Ashworth-, spasm- and clonus scale, the VAS score spasticity and the unset of the effect was measured with a stopwatch, the number of successful or unsuccessful activations as well as the side effects were monitored. The implantable pump was programmed without changing the baseline dose, the bolus was programmed as 5 %, and increased to 10% of the daily dose if the patient noticed no effect. For safety reasons the patient could only apply 4 boluses in 24 hours.

Results

The VAS scores for spasticity demonstrated a tremendous daily and intradaily variation. The preliminary results of the application of the PTM device were promising. The latency of the topping up effects was 30 minutes. There were neither complications or side-effects. The majority of the patients need a 10% bolus for a clinical effect.

Conclusion

The clinical impression of frequent deviations in spasticity could be confirmed with the VAS-scores of spasticity. This indicates the need for a more optimal dose regimen. In larger controlled studies the preliminary benefits of PTM should be confirmed.

Acknowledgements
The study was performed with support of Medtronic Europe Sàrl, Tolochenaz, Switzerland

Learning Objectives:

1.Variations in spasticity
2.Usefullness of PTM
3.Safety of PTM

Monday, December 10
1200-1300, Poster #18

The Chemical Stabilities of Admixtures Containing Ziconotide and Fentanyl or Ziconotide and Sufentanil During Simulated Intrathecal Administration

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Introduction
The chemical stability of a combination of intrathecal analgesics may affect the dose actually delivered and the frequency of pump refills. This investigation characterized the chemical stabilities of admixtures containing ziconotide and either fentanyl or sufentanil under simulated clinical conditions.

Materials and Methods
Admixtures containing 25 mcg/mL ziconotide and 1000 mcg/mL fentanyl citrate or sufentanil citrate were prepared from commercially available ziconotide (25 mcg/mL) and powders of the opioid drugs, then sparged with nitrogen to remove residual oxygen. Implantable intrathecal pumps that had been previously exposed to ziconotide were rinsed twice with 5 mL of admixture, then filled with 20 mL of admixture and stored at 37°C. Drug concentrations were determined with reverse-phase high-performance liquid chromatography from samples collected within minutes of pump fill (Day 0) and at varying intervals over the next 40 days. The percentages of the Day 0 drug concentrations at each sampling point were plotted versus time, and 95% confidence intervals (CI) were determined for the linear regression of percent initial concentration versus time.

Results
At study end (Day 40), ziconotide concentrations averaged 87.5% of initial in the ziconotide-fentanyl admixture and 89.3% of initial in the ziconotide-sufentanil admixture; opioid concentrations remained at 100% of initial. In the ziconotide-fentanyl admixture, the lower 95% CI for the percentage of the initial ziconotide concentration intersected the 90% specification at 26 days and the 80% specification at 58 days. In the ziconotide-sufentanil admixture, the lower 95% CI intersected the 90% and 80% specifications at 33 days and 68 days, respectively.

Conclusion
When combined with fentanyl (1000 mcg/mL), ziconotide (25 mcg/mL) was 90% stable for 26 days and 80% stable for 58 days. When combined with sufentanil (1000 mcg/mL), ziconotide (25 mcg/mL) was 90% stable for 33 days and 80% stable for 68 days. The opioids remained 100% stable throughout the study.

Acknowledgements
These experiments were sponsored by Elan Pharmaceuticals, Inc.

Learning Objectives:
1. Recognize the importance of chemical stability when selecting combinations of intrathecal medications
1. Estimate the stability of ziconotide when combined with fentanyl or sufentanil
1. Estimate the stability of fentanyl or sufentanil when combined with ziconotide

Monday, December 10
1200-1300, Poster #19

Evaluation of the Safety and Efficacy of PRIALT (ziconotide) Combination Intrathecal Therapies: Retrospective Case Studies

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Introduction
Intrathecal ziconotide administration is a nonopioid analgesic treatment indicated for the management of severe chronic pain in patients for whom intrathecal therapy is warranted and who are intolerant of or refractory to other treatment such as systemic analgesics, adjunctive therapies, or intrathecal morphine. Although ziconotide is approved for use only as monotherapy, combination intrathecal therapy is commonly used in patients with intractable pain; using analgesics with varying mechanisms of action may provide additive or synergistic effects.

Materials and Methods
This retrospective study evaluated 30 patients who had ziconotide added to their existing intrathecal treatment regimens and who received pump refills every 30 to 45 days. Visual Analog Scale of Pain Intensity scores were collected before ziconotide exposure (baseline) and at refills. Patient function was assessed using the Oswestry questionnaire at baseline and at final refill. Intrathecal and oral drug use were assessed. Safety was evaluated via adverse event reports. Safety assessments included all patients, whereas efficacy analyses included only those patients who completed 6 refills.

Results
Mean patient age was 57.8 years, 63.3% were female, and 100% had neuropathic pain. Intrathecal drugs used concomitantly with ziconotide included morphine, hydromorphone, fentanyl, meperidine, clonidine, baclofen, bupivacaine, ketamine, and droperidol. Mean ziconotide doses ranged from 0.74 mcg/d (first refill) to 2.02 mcg/d (final refill). Mean Visual Analog Scale of Pain Intensity scores improved by 43% from baseline to final refill ($p<0.0001$). Mean functional improvements of >60% were seen in 9 out of 10 sections of the Oswestry questionnaire. Oral opioid consumption declined overall. Base intrathecal opioid doses were lowered in 56.5% of patients. Ten percent of patients reported adverse events (emotional disturbance, n=2; somnolence, n=1). All adverse events were classified as mild.

Conclusion
In a small retrospective study, significant improvements in analgesia and functionality were attained by the addition of ziconotide to established intrathecal treatment regimens in this chronic pain population. Adverse events were mild and infrequent.

Acknowledgments
The support of Elan Pharmaceuticals, Inc., for this project is gratefully acknowledged.

Learning Objectives:
1. Describe the intrathecal therapies used with ziconotide
1. Describe the clinical results of adding ziconotide to existing intrathecal treatment regimens
1. Recognize the need for continued research into treatment options for patients with intractable pain

Monday, December 10
1200-1300, Poster #20

Motor Cortex Stimulation for Intractable Chronic Pain
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Introduction
Motor Cortex Stimulation (MCS) is currently considered an acceptable safe, and effective treatment for patients with intractable chronic neuropathic pain conditions. We report our initial results with 31 MCS patients.

Materials and Methods
All patients who underwent MCS from 1998 - 2006 were reviewed. All patients suffered from intractable chronic pain that was refractory to medical therapy. All patients were evaluated by a pain psychologist and were deemed acceptable candidates for implantable pain therapy. MCS was performed in two stages: 1) for a minimum of one week an epidural electrode was implanted over the motor region corresponding to the pain topography; 2) patients who were judged to derive significant reduction in pain were implanted with an internal pulse generator for long-term stimulation in a second stage procedure. Pre- and post operative visual analog pain scores (VAPS) were recorded in all patients. Patients were also asked to estimate the percent pain reduction derived from the procedure.

Results
Individual pain diagnoses as follows: trigeminal neuropathic/deafferentation pain (n=22); post-stroke pain (n= 7); post-herpetic neuralgia (n=1), and phantom limb pain (n=1). The average duration of symptoms was 5 years; mean follow-up after surgery was 1 year. For all 31 patients, the mean pre- and post-VAPS were 8.3 and 4.3 respectively. The average subjective pain reduction was 41%. For the 22 patients with facial pain, mean pre and post-operative VAPS were 9.0 and 3.8, respectively ($p=0.01$). For patients with post-stroke pain, VAPS scores were reduced from 9.0 to 6.0 ($p > 0.05$). Of the 22 patients who had a successful trial and received a permanent implant, the average VAPS at the most recent follow-up

was 4.3, providing those patients with an estimated pain reduction of 50%. Three patients had an isolated seizure during IPG programming. Otherwise there were no significant complications.

Conclusion
MCS provides significant pain relief for patients with intractable trigeminal neuropathic/deafferentation pain and to a lesser for those with post-stroke pain.

Learning Objectives:
1) Understand the pain conditions that respond to motor cortex stimulation

Monday, December 10
1200-1300, Poster #21

Peripheral Nerve Field Stimulation (PNFS) for Treatment of Failed Back Syndrome (FBS)
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Introduction
Patients with failed back syndrome continue to experience low back pain despite conventional treatments and minimally invasive procedures like spinal cord stimulation which is more successful for radicular type of pain. Control for axial low back pain is difficult to achieve during the trial or maintain after placement of spinal cord stimulation.[1] Peripheral nerve field stimulation has been used to treat patients with injuries to a specific nerve,[2] including application to occipital,[3-6] ilioinguinal,[7] supraorbital,[8,9] and trigeminal neuralgia.[10] Peripheral nerve field stimulation utilizes percutaneous placement of leads in the area of pain and direct stimulation of the region of affected nerves.[11]

Materials and Methods
Fifty-two patients with failed back syndrome who had undergone placement of peripheral nerve field stimulation were included in the analysis. In this group 18 patients already had spinal cord stimulation and 11 patients had implanted intrathecal pumps. Patients were evaluated at 1, 3, 6 and 12 months postoperatively and assessed with regards to their pain relief (>50% improvement on the visual analog scale), functional status and pain medication use. Data were compared between baseline and at 1, 3, 6 and 12 months post-treatment.

Results
Pain level and medication use were significantly decreased and functional status was improved at 1, 3, 6, and 12 months following this neuromodulation technique. A total of 84.6% of patients reported 50% or more pain relief at 1 month, 88.4% at 3 months, 90.3% at 6 and 12 months. Percentages of patients reporting improvement of functional status at 1 month were 53.8%, 61.5% at 3 months, 67.3% at 6 months, and 78.8 at 12 months. Overall 40.3%, 63.4%, 76.9%, and 82.6% of patients indicated a reduction in pain medication intake. Five patients with intrathecal pumps who had good pain control by using peripheral nerve field stimulation underwent removal of intrathecal devices.

Conclusion
Peripheral nerve field stimulation appears to be effective, safe and less invasive treatment for patients who exhausted traditional and even advanced treatments like spinal cord stimulation or intrathecal pumps.

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Learning Objectives:
1. Learn about novel neuromodulation techniques to treat failed back syndrome.
2. Identify patients who may benefit from peripheral nerve field stimulation.
3. Recognize the need for prospective, randomized, controlled studies to assess its efficacy and determine the patient characteristics for whom this procedure is more appropriate.

Monday, December 10
1200-1300, Poster #22

Ultrasound-guided placement of a permanent percutaneous femoral nerve stimulator leads for the treatment of intractable femoral neuropathy

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Introduction
Femoral nerve injury is a rare complication of cardiac catheterization with a reported incidence of 0.21%. It is usually caused by direct trauma during femoral artery access, compression from a hematoma or because of prolonged digital pressure for post-procedural hemostasis [1]. We are reporting a novel approach for femoral nerve electric stimulations for the treatment of intractable femoral neuropathy using a percutaneous approach with real-time ultrasound imaging to non-invasively identify the nerve and avoid vascular injury which was the initial cause of the femoral neuropathy.

Case Report
We report on a 61-year- old male who developed a right groin hematoma after cardiac catheterization for chest pain evaluation 18 months before presentation. Subsequently, he developed sharp stabbing pains in the right groin and the anterior aspect of the thigh radiating down the medial aspect of the leg to the big toe. Electromyography (EMG) and nerve conduction studies confirmed the diagnosis of right femoral nerve neuropathy. Patient neurological examination showed weakness of the right quadriceps muscle, decreased patellar reflex, and decreased touch sensation and paresthesias along the distribution of the saphenous nerve. He failed multiple treatment modalities (tricyclic antidepressants, different membrane stabilizers, NSAIDs, narcotics, topical agents, PT, TENS, acupuncture) and continued to complain of severe neuropathic pains that markedly interfere with his daily activities. After appropriate psychological evaluation, we elected to proceed with a trial of peripheral nerve stimulation. A curved array ultrasound probe 2-5 MHz (HD11- XL, Philips) was used to identify the femoral nerve and vessels. Two percutaneous octad leads (Medtronics, Minneapolis, MN) were placed under real-time sonography and the placement was double checked with fluoroscopy (Fig 1-3). One lead was placed along the longitudinal axis of the nerve and the patient had good coverage over the anterior thigh areas but not below the knee. So another lead was placed horizontally across the femoral nerve to be able to stimulate all the branches and the patient reported good coverage along the saphenous distribution down to the foot. The patient then underwent a permanent implant after a successful trial for 7 days with the subcutaneous implant of a rechargeable generator (Restore®, Medtronics, Minneapolis, MN) in the right lower quadrant of the abdomen. The patient continues to be pain free 6 months after the implant and he managed to off all his pain medications.

Discussion
Peripheral nerve stimulation has been used to treat different pain syndromes in the upper and lower extremities with variable success and it usually requires an open surgical approach [2-3]. Here we described a percutaneous approach for femoral

nerve stimulation with ultrasound guidance which allowed precise placement of the stimulating lead very close to the femoral nerve without the need for surgical exploration.

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Acknowledgements

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Figure and Table Legend

Figure (1): Short axis image with the needle (arrows) out-of-plane in order to pass the lead longitudinally. V, femoral vein. A, femoral artery. N, femoral nerve.
Figure (2): Short axis image with the needle (arrows) in-plane in order to pass the lead across the nerve. V, femoral vein. A, femoral artery. N, femoral nerve.
Figure (3): AP view showing both leads. A: regular octad lead (longitudinal). B: compact octad lead (horizontal).

Learning Objectives:

1. To emphasize the role of peripheral nerve stimulation in the management of neuropathic pain syndromes.
2. To discuss percutaneous versus surgical approaches to neuromodulation.
3. To identify ultrasound imaging as a new tool in the arena of neuromodulation.

Monday, December 10
1200-1300, Poster #23

Peripheral Nerve Field Stimulation: Is age an indicator of outcome?

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Dr. Bruce Mitchell M.D., Dr. David Vivian M.D. and Dr. Chantelle Sinclair PhD

Introduction

The aim of this study was to assess peripheral nerve field stimulation as a treatment for chronic pain and to test for indicators of successful outcome.

Materials and Methods

We reviewed all patients who were permanently implanted with peripheral nerve field stimulators over the past 24 months. A questionnaire was used to assess outcomes including: pain indices, post-operative changes in analgesic use and patient satisfaction. Twenty-three patients responded (85%).
Patients were implanted with octrode, percutaneous leads placed subcutaneously in maximum pain regions including: low back (n=13), occipital (n=5), thorax (n=2), abdominal (n=2) and elbow (n=1).

Results

Using Pain Index 1 (absolute difference in pre and post treatment visual analogue scores) a significant average decrease of 4.02 was observed. An age effect was detected: younger patients (<60 years) reported an average pain relief of 4.79 points, older patients (>61 years) 2.83 points. Younger and older patient subsets did not differ in mean pre-treatment pain scores. Region of implant demonstrated significant decreases: low back 3.77 and occipital 5.9 points.
Using Pain Index 2 (pain relief as a percentage of original pain) an overall improvement of 53.7% was observed. Fifteen (65%) patients reported pain relief of more than 50%. No age effect was detected using this index.
Most patients reported a decrease in analgesic use. Almost all patients were satisfied with their treatment. Pain relief was significantly and highly correlated with reduced analgesic intake and patient satisfaction.

Conclusion

The approach of measuring success using pain index 2 has limitations: it skews data relative to original pain levels. An alternative, more sensitive index may be absolute change in visual analogue points.

This study demonstrates a potential treatment option that is safe, reversible and effective, particularly for patients less than 60 years old.

Learning Objectives
1. Peripheral nerve field stimulation is a potential treatment option for chronic pain that is safe, reversible and effective, particularly for patients less than 60 years old. Patients 60 years and younger reported a mean pain relief of 4.79 VAS points while older patients reported a mean of 2.83 VAS points.
2. Region of implant demonstrated significant differences in VAS: low back 3.77 and occipital 5.9 points.
3. Measuring treatment outcome as a proportion of original pain skews data relative to original pain levels. An alternative, more sensitive index may be to use the absolute change in VAS pain scores.

Monday, December 10
1200-1300, Poster # 24

Electrode placement and relationships of periurethral nerves of an implantable electrostimulator, Accessa™, in female human cadavers.
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Introduction
Accessa Neuromuscular Stimulation Therapy (NMS™) is a technology for the treatment of urinary urge incontinence and other bladder dysfunction. NMS consists of an implanted periurethral electrode and a pulse generator. Although the exact mechanism is not known, the therapeutic effect is believed to be achieved by activating inhibitory reflexes to reduce undesired bladder contractions via the stimulation of afferent nerves.

Materials and Methods
In this study, we examined the periurethral electrode placement and its relation to nerve distribution in eight female human cadavers. Electrodes were inserted according to a standardized surgical protocol. Periurethral tissue including the vagina, bladder and supporting structures were next excised, fixed in formalin and processed for paraffin sectioning. Serial sections were stained with antibodies against S100/-PGP 9.5, -Substance P, -vesicular monoamine transporter and -nNOS to identify general, afferent, sympathetic and NOS efferent nerve fibers, respectively.

Results
Electrode contact sites were found located adjacent to the upper or middle thirds of the urethra. Transversely the electrodes were found within/lateral (n=4), within/posterolateral (n=9), and anterolateral (n=1) to the external urethral sphincter (EUS). The distance from the electrode in those locations to the EUS was 0.25 ± 0.5, 2.9 ± 3.3, and 1.0 ± 0.0 mm, respectively. The distance from the electrode to the urethra and vagina averaged 7.6 ± 3.4 mm and 8.8 ± 4.3 mm, respectively. Positive staining with all
antibodies was found around the electrode with varying nerve densities depending on the electrode's location. Nerve densities were generally higher near the lumen of urethra and vagina wall than in the periurethral tissue parenchyma.

Conclusion
Placement of a permanent periurethral electrode in a female cadaver does interface the external urethral sphincter. The distribution of nerve fibers near the electrode is supportive of proposed neuromuscular therapeutic mechanisms.

References
Kenneth P. Roberts, Kathy M. Ensrud-Bowlin, Guangjian Wang, James L. Whiteside.

Acknowledgements
The protocol, study and manuscript have been developed with input from the authors and supported by American Medical Systems, Inc. USA.

Learning Objectives:
1. Electrode location in periurethral region
2. Identify nerve fiber distribution around electrode

Monday, December 10
1200-1300, Poster #25

Peripheral subcutaneous nerve stimulation
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Introduction
After the introduction of stimulation techniques for the treatment of chronic pain by means of SCS and PNS in the 70s, PNS-stimulation for treating Mononeuropathy, as well as sympathetic pain, underwent a renaissance. PNS techniques were introduced for treatment of CRPS I, occipital neuralgia, migraine, as well as neuropathies.

Materials and Methods
Following the convincing results, introduced by Barolat 2004, we performed a so-called “Field Nerve Stimulation” pilot study from May 2005 to February 2006 in 30 patients with different indications, mainly after FBSS. The indication was a well described exactly localized area of pain, partly connected to Allodynia. Leads were placed, allowing accessing the outer border of the area of pain.
Eleven out of thirty-one Patients, who received an implantation of one to four leads (quadrode/octrode) and then underwent a one-week trial-phase, received an implantation of a complete system.

Results
Approximately 30% of the patients displayed a pain relief of more than 50% for a period of up to one year. 16 patients, who did not profit from peripheral nerve stimulation, were treated by SCS, according to our therapy scale. Since an adequate pain relief could not be achieved by SCS either, it can be assumed that simple subcutaneous stimulation can serve as a predictor for the success of spinal stimulation. In addition, patients who subsequently received an intrathecal opiate therapy showed significantly weaker results than other patients.

Conclusion
Peripheral nerve stimulation is a simple, promising method, with the best indication being a well localizable pain, and can be considered as the first step of invasive pain therapy for treating well-described pain emission. The operation technique is very simple and of low risk, however, long-term results have to be awaited.

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Learning Objectives:
1. New Target in the therapy scale of chronic pain
2. Change of invasive pain algorithm

Monday, December 10
1200-1300, Poster #26

Cranial Peripheral Nerve Stimulation for Intractable Headache: Prospective Two Year Followup Results
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Introduction
Chronic stimulation of the occipital nerve(s) is reportedly effective in the treatment of medically intractable headache and pain involving the posterior head and neck. Many patients present with head pain outside this distribution involving the frontal and/or temporoparietal regions. We have prospectively evaluated the effect of chronic stimulation of those nerves whose sensory distribution parallels that of patient’s head pain with a minimum followup of 2 years.

Materials and Methods
35 patients have been treated in this protocol; 30 have complete 2 year followup data. Stimulation was performed of one or all of the following nerves depending upon the semiology of the patient's head pain: greater and lesser occipital, supraorbital, infratrochlear and auriculotemporal nerves. Trial stimulation was performed for 3 to 4 days and if successful, a permanent stimulation system consisting of one and four leads and pulse generator were implanted. Followup data was obtained for a minimum of two years on all patients.

Results
One of the 35 patients failed to obtain sufficient relief during trial stimulation to warrant permanent implantation (3%). 26 of 30 implanted patients obtained good to excellent pain relief (87%). Three patients failed to obtain lasting relief and ultimately had the device removed (10%). Seven of 30 patients underwent one or more reoperations due to hardware failure or electrode migration (23%); this failure rate has fallen significantly with new fixation techniques and with the use of stronger lead constructs. Complications include two episodes of electrode erosion through the skin (7%) and one infection (3%) related to this erosion.

Conclusion
Chronic stimulation of the cranial peripheral nerves whose sensory distribution parallels the semiology of patient's head pain appears to be a low risk and highly effective treatment for medically intractable headache and head pain.

Learning Objectives:
1. Participant will become aware of the potential treatment of chronic headaches with neuromodulation
2. Participant will understand the potential efficacy of treatment of chronic headaches with neuromodulation
3. Participant will become aware of the risks and complications of treatment of chronic headaches with neuromodulation

Monday December 10
1200-1300, Poster #27

A Spiral Electrode for Peripheral Nerve Stimulation
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Introduction
Peripheral nerve stimulation has both theoretical and practical advantages over spinal cord stimulation. Although Medtronic once made cuff electrodes for peripheral nerve stimulation, their manufacture was discontinued for both economic and biologic reasons. Cuff electrodes applied too tightly to the nerve created new nerve damage and it was impossible to direct the stimulation to those fibers innervating the painful area within the territory of a nerve. Furthermore, inappropriate positioning of the electrode and lead wire could lead to angulation of the cuff and nerve compression. When the cuff electrode was abandoned, surgeons tried to adapt spinal cord electrodes to stimulate peripheral nerves. Some have used PISCES electrodes, others used paddle electrodes sewn together at one edge to create a V trough for the nerve, others tried to lie the nerve on a paddle electrode, etc. None of these improvisations has been satisfactory. Medtronic does not manufacture an electrode for peripheral nerve stimulation.

Materials and Methods
The spiral electrode we have designed solves some of the electrode-nerve interface problems and does not appear to damage the nerve in any way. It is easy to apply and to remove, if necessary. However, the diameter of the helix is a critical feature. Our electrode was designed for the sciatic nerve and is too large for the nerves of the arm. It will be necessary to have several sizes of helix to properly utilize this design concept for peripheral nerve stimulation. It is not known if more than four contacts will improve outcomes.

Results
The results in our series of 18 patients will be presented. Fourteen of 18 patients implanted had partial or complete relief of pain.

Conclusion
Peripheral nerve stimulation requires the development of electrodes designed for this purpose and appropriately sized for the nerve to be stimulated.

Learning Objectives:
1. Understand peripheral nerve stimulation for pain relief.
2. Understand electrode design issues for peripheral nerve stimulation.

Monday, December 10
1200-1300, Poster #28

Therapeutic trial of peripheral neuromodulation using inexpensive monoelectrode temporary stimulating catheters
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Introduction
Within the peripheral nervous system neuromodulation may be directed from an implanted device to peripheral nerves, plexuses or to the centre of non-dermatomal areas of pain. Associated risks and costs (approximately $1500) however are a barrier to use for indications with which experience is limited. We report use of cheap (approximately $100) regional anaesthesia-use stimulating catheters to predict response to implanted devices.

Materials and Methods
We undertook a retrospective case note review of temporary monoelectrode catheters sited in our tertiary-referral pain management clinic. Procedures were offered on a compassionate basis to patients reporting an unsatisfactory response to drug-based therapies, in the context of an institutional algorithm for neuropathic pain. Catheters were introduced through a stimulating needle to determine the optimal site for placement. Patients kept a pain diary to record twice daily the intensity of their pain on a numerical rating scale.

Results
91 temporary catheters for peripheral neuromodulation have been inserted to date in our institution. The most common approach (25 patients) targeted the centre of a non-dermatomal area, including to the chest wall in 3 for post-mastectomy pain and 6 for angina. Nerve- or plexus-directed catheters were introduced to the psoas compartment/lumbar plexus (10), lumbar sympathetic chain (9), brachial plexus (8), sciatic nerve (6), sacroiliac joint (6), ulnar nerve (5), coccyx (5), femoral and genitofemoral nerves (4 each), paravertebral space (4), coeliac axis (4), and scalp (1). Catheters were usually left in situ for one week but in a few up to 3 months with weekly review for infection. 62 patients (68%) judged their therapeutic trial to be successful, and following psychological assessment 36 proceeded to permanent implants (13 more awaiting), generally providing good pain relief.

Conclusion
A therapeutic trial of peripheral neuromodulation using a temporary monoelectrode catheter accurately predicts success of a subsequent permanent implant.

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Goroszeniuk T, Hamann W, Kothari S. Percutanous implantation of the brachial plexus electrode for management of pain syndrome caused by a traction injury. Neuromodulation 2007; 10:148-55.
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Learning Objective:
To understand the role of temporary catheters in assessment for implantation of peripheral neuromodulation devices for neuropathic pain.

Monday, December 10
1200-1300, Poster #29

Pulsed Radiofrequency As a Type of Neuromodulation Treatment
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Pulsed radiofrequency (PRF), in which the target structure is exposed to the RF electric field without raising the mean tip temperature to neurodestructive levels. It is unclear how PRF works, but several recent research works have demonstrated totally different action mechanisms that attribute to its effect on pain reduction and neuromodulating action. Here, experience on PRF in patients with refractory pain in last 5 years is presented with literature review.

Retrospective review on PRF gasserian ganglion rhizotomy for refractory trigeminal neuralgia (6 on V2 division, 4 in V3, 2 in V1, 1 in all 3 divisions, and 3 neuropathic pain) demonstrated that pain relief of excellent or good quality was observed in 75% of patients at 12 months. However, this effect was observed only in 56.3% at 24 month. There were 3 cases of recurrent pain (18.8%) during 2-year follow up period (average 14.3 mos). Review on 50 patients with chronic low back and radicular pain who underwent PRF treatment and followed for at least 12 months revealed satisfactory results (> 50% reduction of pain) in 76% at 1 month, 64%at 6 months, and 60% at 1 year period. Other study to verify the effect of PRF on dorsal root ganglion in management of refractory postherpetic neuralgia in 50 patients indicate that it provides successful pain relief in 70.0% of patients for more than 6 months. There were no complications from these studies.

The initial clinical data on PRF demonstrate response rates similar to conventional RF lesions for various chronic pain disorders However, delayed maximal response, less satisfactory long term response and higher recurrence rate are considered as disadvantages and should be weighted with other potential merits and advantages of this type of treatment, namely less discomforts, side effects and complications with additional indications for patients with neuropathic pain.

Monday, December 10
1200-1300, Poster #30

Mechanical properties of electrode tips for spinal cord stimulation of two different companies
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Introduction
Occasionally, patients in whom electrodes were implanted for spinal cord stimulation, experience unpleasant sensations at sudden movements. The impression arose that this only occurred with electrodes manufactured by company A (CA). We tested the mechanical properties of these electrodes in comparison with electrodes from another company (CB), which did not result in similar morbidity.

Materials and Methods
The Young's modulus of eight electrodes was established. Tested were 2 eight-points electrodes from CA, 2 eight-points from CB, 2 four-points from CA and 2 four-points from CB. The testing device was a low-load compression tester, equipped with a microbalance. All electrodes were tested four times.

Results
The Young's moduli of the four-points electrodes of CA were 0,0063 and of the CB electrodes 0,0014. The Young's moduli of the eight-points electrodes of CA were 0,0032 and of the CB 0,0060.

Conclusion
The results indicate that the 4-points electrodes from CA were 4-5 times stiffer than similar electrodes from CB. On the other hand, the 8-points electrodes from CA were less stiff than those from CB. Since the Young's moduli of the 4-points electrodes from CA and the 8-points electrodes from CB were in the same order of magnitude, it appears unlikely that the described morbidity was caused by differences in mechanical properties of the electrodes.

Learning Objectives:
1. Mechanical properties of spinal cord electrodes from different companies can differ to some extent which may result in unwanted side-effects
2. Companies sometimes modify electrodes without notifying their customers

Monday, December 10
1200-1300, Poster #31

Effects of sacral surface electrical stimulation to the uterine dysfunctions

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Kazunori Seki, MD, PhD
Yasunobu Handa, MD, PhD

Introduction

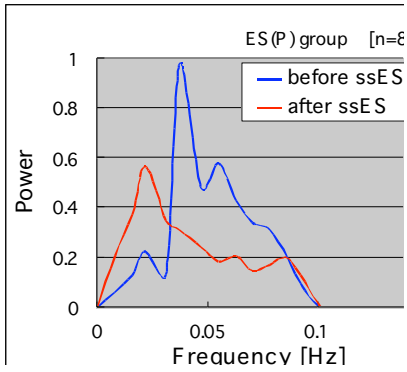
Previous studies have indicated that the electrical stimulation is effective for severe pain due to primary dysmenorrheal[1]. However, no one has described the effect of electrical stimulation for dysmenorrhea on morphological and/or functional changes of the uterus. The purpose of this study is to clarify the uterine function changes during menstruation induced by sacral surface electrical stimulation (ssES) using static and cine mode MR imaging. Furthermore, we investigated the clinical effects of ssES to relieve symptoms of dysmenorrhea using by self-assessed visual analogue scale.

Materials and Methods

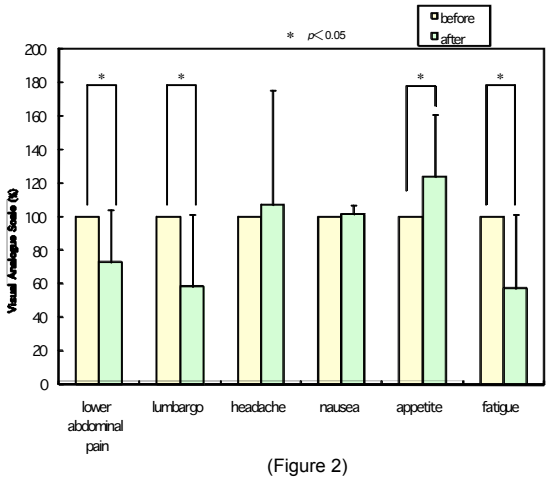
Subjects were healthy females and all of them were reproductive age. They had severe menstrual pain in every menstruation. We put the electrodes on the skin just above the posterior sacral foramens of the S2-4 and applied the cyclic electrical stimulation (3Hz or 30Hz) for 15 min to all subjects just in menstruation period (Day 1 or 2). Static T2-weighted FSE imaging (T2WI), cine mode T1-weighted SPGR imaging (T1cine) and cine mode T2-weighted HASTE imaging (T2cine) were performed by using 0.2T permanent and 1.5T super conducting magnet system before and after ssES. The morphological and functional changes were measured from these MR imaging. Furthermore, the self-assessed visual analogue scale (VAS) was performed to evaluate lower abdominal pain, lumbago, headache, nausea, appetite loss and fatigue before and after ssES.

Results

The muscle tension of the uterine smooth muscle was significantly decreased after ssES. Also, the peristaltic movement of the uterus in the subjects accompanied by severe menstrual pain became slow and weak significantly after ssES (Figure 1).
The VAS score of lower abdominal pain, lumbago and fatigue were significantly decreased after ssES (Figure 2). Furthermore, the score of appetite loss was significantly improved after ssES, although most of the subjects had no symptoms on headache and nausea.



(Figure 1)



(Figure 2)

Conclusion

One of the possible explanations of clinical dysmenorrheal symptoms were improved by ssES, ssES might have the effects to decrease uterus contraction and to modulate the uterine dysfunction. SsES causes an inhibition of the parasympathetic pelvic neurons and/or a facilitation of the sympathetic hypogastric neurons in the spinal cord[2] via electrically induced afferent volleys of the pudendal nerve.

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Figure and Table Legend
Figure 1 : Averaged power spectrum of uterine peristalsis before and after ssES.
Figure 2 : The mean normalized score of self-assessed visual analogue scale before and after ssES.

Learning Objectives
1. To clarify the morphological and functional changes of the uterus during menstruation induced by sacral surface electrical stimulation in the healthy subjects with severe menstrual pain using MRI and MR cine technique.
2. To clarify the clinical effects of sacral surface electrical stimulation to relieve symptoms of dysmenorrheal using by self-assessed visual analogue scale.

Monday, December 10
1200-1300, Poster #32

Neurotechnological Developments
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Introduction
Neuro-implant is a device that electronically stimulates the nerves system under the skin after surgery. Neurostimulation is a process, by which nerves partially loosing their function as a result of disease or travma, are stimulated using artificial electrical pulses for regeneration. Electrical signals used for this purpose must be consistent with the nature of human neurophysiology [1]. The application, started in 1967, nowadays has clinically been established, e.g. spinal cord stimulation to control chronic pain, vagus nerve stimulation for the management of epilepsy, depression and Alzheimer disease, phrenic nerve stimulation for diaphramme pacing in respiratory disorders, deep brain stimulation for the management of Parkinson's disease [2-7]. The existing implants generally operate utilizing either radio-frequency (RF) transmission or fully implantation technics [8]. In both case, some electronic components are implanted in the body. Totally implantable systems have also an implanted battery. To overcome the problems encountered with present implants such as component failure, limited battery life, programming difficulties and high cost, a new system, namely tulgar neuro-implant, that is based on trans-dermal coupling principles, has been developed [9].

Materials and Methods
A general object of the present invention is to provide an improved system and method for the transmission of stimulating signals to an electrode implanted in the body. The system mainly consists of two parts: implantable passive part and external active part (Figures 1a and b). Therapeutic signals produced by an external stimulator are linked to external active element that is placed on the skin overlying the implanted passive element, and are transmitted across the skin of patient by inductive coupling. The implanted passive element is connected to the electrode located near by target neural tissue.

Results
Animal tests showed that the new system could reliably be implanted in the living tissue [10]. Also a pilot clinical study has recently (on May 29, 2007) been undertaken employing TULGAR TI1 Model Vagal Stimulator Implant System for the Management of Drug-Resistent Epilepsy after the approval of Ethical Committe of the Ministry of Health of Republic of Turkey. The history of patient who participated in the pilot clinical study is as follows: a 37 year old guy, refractory epilepsy for 24 years with heavy seizures. 15 days post-implantation (during recovery - no stimulation) no seizures, 4 days post-stimulation (during set up procedure) only two slight seizures of less than 1 minute with 10 hours interval; 9th day post-stimulation (still set up period) 4 slight seizures of less than 1 minute with 2 hours interval, since then no seizures (Figure 2).

Conclusion
Tulgar implants, which are patented with full quality assurance certificates (CE, ISO 9001:2000 and EN ISO 13485:2003), appears to be competitive to the presently known neuroimplants in terms of quality, safety, reliability, reduction in size and cost.

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Figure and Table Legend
Figure 1 – Tulgar TI1 model vagal stimulator implant system for the management of refractory epilepsy, chronic depression and Alzheimer disease. **(a)** implantable passive part **(b)** external active part.
Figure 2 – Patient to whom Tulgar TI1 model vagal stimulator was first implanted.

Learning Objectives:
1. After successful animal testing, the tulgar implant, the latest patented technology, has recently been employed in a human pilot study that is first reported here to be effective in reducing frequency and intensity of epileptic seizures.
2. The main goal of the present invention is that there are neither any electronic components nor a battery in the internal part of the system; therefore, no breakdown due to component failure is likely, and patients can use this externally powered and controlled system along life-time.
3. Tulgar implants, on the other hand, provides 80 % reduction in size which enhances implantation surgery especially in children.

Monday, December 10
1200-1300, Poster #33

SENS in the Management of Chronic / Neuropathic Pain
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Dr Paul Murphy, MD, MRCPI, FCARCSI, FFPMANZCA
Dr Oleg Ilyinski MB, FCARCSI, Dr Abdul AlMajadi MB, FCARCSI, Dr Aamir Zuberi MB, FCARCSI

Introduction
Subcutaneous Electrical Nerve Stimulation (SENS) utilising Stimulation Cord Stimulator electrodes may be utilised to treat a variety of peripheral neuropathic conditions.

Materials and Methods
A retrospective review of 85 SENS cases performed over a four-year period in St. Vincent's University Hospital, Ireland. A wide range of pain conditions were treated including post surgical pain syndrome, hemicranias continua, chronic back pain, and intractable migraine.

Results
The main age of patient was 50.5 years with male / female ratio of 2:1. Effective pain control (> 50% pain reduction) was achieved in 71% of pt. Successful treatment was associated with significant reduction in medication utilisation. Successful outcomes were achieved with ANS, Advance Bionics and Medtronic systems. Complications included infection and lead migration.

Conclusion
The utilisation of Spinal Cord Stimulation electrodes to proved SENS is effective in the management of a wide range of peripheral neuropathic pain conditions.

References
Gorosezeniuk T, Kothari S, Hamann W. Subcutaneous neuromodulating implant targeted at the site of pain. Reg Anesth Pain Med 2006 31: 168 – 71.

Learning Objectives:
1. Subcutaneous Electrical Nerve Stimulation is effective modality in a wide range of neuropathic pain states

Monday, December 10
1200-1300, Poster #34

SCS in three different pathologies. 20 years experience
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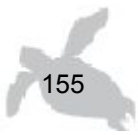
Introduction
The goals of the study are to value the effectiveness and security of the spinal cord stimulation (SCS) during 20 years of experience. The effectiveness is valued according to the type of pathology that suffers the patients, divided in 3 groups, failed back surgery syndrome (FBSS), peripheral vascular disease (PVD) and complex regional pain syndrome (CRPS)(1,2,3).

Materials and Methods
A retrospective observational study is made from 1983 to the 2002 analyzing the patients submissive SCS. The patients with 3 different diagnoses compare themselves. The degree of pain the patient according to one climbs verbal of 4 degrees (slight, moderate, intense and unbearable pain), and according to a visual analogical scale from 0 to 100 (where 0 is non pain and 100 are an unbearable pain). On the other hand the effectiveness of the stimulation is analyzed according to an own scale of 4 variables, nothing (0%), fair (30%-49%), much (50%-79%) and total (80%-100%). The statistical analysis in the three groups' diagnoses is made by means of the test of square Chi to verify if significant difference in the degree of improvement among pathologies.

Results
The sample is compound of 260 patients, divided by group's diagnoses: in 98 patients with PVD, 65 with FBSS, 40 with CRPS and the rest with several diagnoses. The specialty that derived most frequently derived patients to the Unit during this period was Cardiovascular Surgery Service. The most frequent pain was the neuropathic pain and the final location of the electrodes most frequent was the thoracic. The improvement in global terms was of 64%. The use of the SCS in the patients with CRPS was made in 50% of the cases in the cervical zone and the rest in the thoracic. The improvement superior to 50% was obtained, in this group, 55% of the sample. The rate of complications was of 32%. The group with PVD diagnosis is made up of 98 patients with an improvement of 88% and one rate of complications of 17%. Finally the group with FBSS diagnosis is made up of 65 patients with an improvement near 51% with a rate of complications of 29%.



Conclusion
The study shows the experience during 20 years in SCS. All the results in our patients are similar to other authors, and the best of that are in PVD.

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Learning Objectives:
1. The scs is very success in PVD, in which we can reduce the numbers of amputations.
2. The scs is one of the best treatments in FBSS and the rate of success in CRPS are close to 80%.
3. We didn't have major complications with this kind of treatment.

Monday, December 10
1200-1300, Poster #35

Can we identify microcirculatory parameters predictive of the outcome of spinal cord stimulation (SCS) in patients affected with non-reconstructable chronic critical leg ischaemia (CLI)?
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Dott. GD. Babbolin

Introduction
Aim of the study was to identify microcirculatory parameters predictive of the outcome of spinal cord stimulation (SCS) in patients affected with non-reconstructable chronic critical leg ischaemia (CLI). 1,2,3,4,5,6,7,8,9,10.

Materials and Methods
50 patients affected with non-reconstructable CLI were investigated by means of transcutaneous oxymetry and dynamic capillaroscopy before implantation of SCS (Octrode System®,Advanced Neuromodulation Systems [ANS],Plano,TX,USA)and after 1-month trial stimulation.

Results
Two groups of patients were identified, A and B, according to baseline TcPO2-TcPCO2 postural response. Group A showed: _TcPO2 (depending-supine; mmHg) 18, _TcPCO2 -14; group B: _TcPO2 8 and _TcPCO2 -7. Dynamic capillaroscopy provided information about the nutritional flow, revealing the following before stimulation: in group A blood cell velocity (rCBV) 0,07 mm/sec, capillary density (CD) 14/mm2, % open capillaries (%OC) 14,2%; in group B: rCBV 0,05 mm/sec, CD 9/mm2, %OC 11%. After 1-month stimulation, a different improvement of transcutaneous oxymetry between the two groups was observed: in group A supine TcPO2 32,3 ± 6,8 (+70%) (mean _TcPO2 13); in group B supine TcPO2 17,3 ± 3 (+44%) (mean _TcPO2 5). Evidence of capillary recruitment after stimulation was provided by capillaroscopy: group A achieved a rCBV 0,18, CD 20, %OC 72%; group B showed a rCBV 0,09, CD 11, %OC 40%. Pain relief after stimulation was >50% in all patients, and after 12 months it turned out significant ($p<0,005$).

Conclusion
On the basis of our results and considering the complex microcirculatory reactivity, selection of patients should be based on more than one microcirculatory parameters. In our study a good outcome was associated with a postural _TcPO2 >15 mmHg and also with an absolute value upon dependency ≥ 20 mmHg; thus, patients with a baseline supine TcPO2 <10 mmHg, could also benefit from SCS, when showing an acceptable microcirculatory reserve capacity. So far, the above mentioned microcirculatory parameters allow for a good selection of patients which may enhance treatment effectiveness

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Learning Objectives
1. Could we identify clinical parameters different from the answer of the patient to prove efficacy of SCS?
2. Could the microcirculatory parameters be considered critical factors in the selection of SCS candidate among patients affected with non-reconstructable chronic critical leg ischaemia (CLI)?
3. Could we avoid unnecessary and expensive SCS trials basing patients selection on these parameters?

Monday, December 10
1200-1300, Poster #36

The historic origins of neuromodulation in antiquity
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Introduction
Although a workable electric apparatus was not truly developed until after the Renaissance, “natural electricity” was in use therapeutically in antiquity[1,3].

Material
As early as 2750 BC, Egyptian hieroglyphic depictions in tombs witness the presence of the “electric fish” (i.e. torpedo fish) in fishing scenes. Hippocrates and Aristotle provide the first written records of the torpedo ray, known to them as “narke” because of its ability to cause numbness. The Roman physician Scribonius Largus (46 AD) first introduced the electric powers of the fish into clinical medicine and applied neurostimulation for the alleviation of pain[1,2,3]. This was based on a report that Antheros, a freed slave, relieved from severe gout suffering when he stepped on an “electric fish”. Galen (131-201 AD), the most influential figure in medicine until Renaissance, clearly suggested as analgesic the direct application of torpedo fish on the body part which is in pain because of various illnesses, headache being the most common indication. For the next 1,500 years, technological advances were scarce and the application of electrical torpedo fish remained the very first means of achieving transcutaneous electrical nerve stimulation for therapeutic purposes.

Conclusions
The extended anatomical dissections of torpedo fish and animal experiments greatly contributed to better understanding of nerve conductivity and pathophysiological function of nervous system[2]. Apparently, the dramatic effects of stimulation of the body or nervous system have been recognized since antiquity and the use of neuromodulation has its origin in those early observations.

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2. Debru A. The power of torpedo fish as a pathological model to the understanding of nervous transmission in Antiquity. C.R. Biologies 2006; 329: 298-302
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Learning Objectives:
1. The early use of “neuromodulation” procedures in ancient times

Monday, December 10
1200-1300, Poster #37

Chronic low back and leg pain treatment using modern SCS technology: a Spanish case series.
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Introduction
Chronic, neuropathic pain associated with failed back surgery syndrome, intractable to other treatment modalities, has traditionally been difficult to treat with SCS [1]. Particularly its lower back component remains elusive due to an apparent anatomical inconvenience of this body part representation in the central nervous system [1, 2]. Our initial results utilizing recent SCS technology to address aforementioned pain are reported here.

Materials and Methods
The case series comprises 8 patients who all received two 8-contact leads inserted in parallel in the dorsal epidural space and a rechargeable SCS stimulator featuring 16 independent current-controlled sources (Precision™, Boston Scientific). To date, patient follow-up ranges 2 to 14 months (average of 6.5). The overall therapy satisfaction and pain relief (VAS score at each visit and % pain relief rating) were gathered as well as % pain area coverage by paresthesia (legs and back individually). In addition, stimulation parameters and usage were retrieved from the stimulator memory capturing the month preceding visits.

Results
Lead placements at Th8 (4 patients), Th9 (3) gave a satisfactory coverage of the painful back area (≥50% and in three cases 100%). A complete coverage of the targeted leg(s) was always achieved. Paresthesias were stable throughout follow-up. In one patient, with Th11 lead placement, back coverage was not achieved and leads repositioning is due.
Among the remaining 7 patients, satisfaction with the therapy, VAS score reduction and rating of pain relief were respectively 75-89%, 39% and 60% (median values) and appeared stable over the follow-up. Five patients used 1, while two patients used 3 programs. Seven (of total 11) programs consisted of multiple channels. Channels often comprised more than one cathode and anode with fractionalized current. The range of pulse width across channels was 280-790 μsec with median value of 530 μsec. Six patients used stimulation ≥28 days in the last month, but the usage per day varied in the range 1-22 hours among patients.

Conclusions
Although this case series is limited in volume and duration of the follow-up, it indicates that leg and back pain can be treated and treatment maintained over time by means of SCS utilizing novel technology with extended stimulation parameter ranges. Further follow-up and expansion of the patient group is planned.

References:
[1] Oakley J. Spinal cord stimulation in axial low back pain: solving the dilemma. Pain Medicine 7:58-63, 2006.
[2] Holsheimer J. Does dual lead stimulation favor stimulation of the axial lower back? (Editorial) Neuromodulation 3:55-57, 2000

Learning Objectives
1) chronic neuropathic leg and back pain can be treated with SCS
2) appropriate placement of the lead(s) is needed in order to achieve a good paresthesia coverage
3) achieving and maintaining a good paresthesia coverage often requires enhanced technical capabilities of the SCS system

Monday, December 10
1200-1300, Poster #38

Retrospective analysis of SCS and Failed back surgery patients
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Introduction
A retrospective analysis of 50 patients with failed-back surgery syndrome (FBSS) treated with spinal cord stimulation (SCS). Chronic Neuropathic pain after spine surgery is a difficult task and Neuromodulation through SCS is a good treatment option.

Material and Methods
50 patients between 28 and 82 years old had a SCS implanted (Medtronic, Memphis, TE, USA). All cases are FBBS-patients. 38 patients had multiple lumbar surgeries and 12 had multiple cervical surgeries. All patients failed to improve pain-related symptom after multiple surgeries. No sign of any instability (nociceptive pain) was detected on clinical and radiological examinations. Patients have chronic Neuropathic pain with sympathetically maintained pain (SMP) or sympathetically independent pain (SIMP). Patients had chronic refractory pain with worst score on VAS. In our implantation protocol patients stayed 48 hours in the Hospital. The implantation trial was done only in the first cases (4 cases). The remained 46 patients did the implantation without trial. Patients stayed one more day to evaluate complete response to implantation. Electrodes implanted were Resume II in all cases except eight cervical, four with a quadripolar PISCES and four with a RESUME TL. Patients were evaluated with Visual Analogic Scale (VAS), Oswestry Disability Index Score (ODIS) and Prolo Functional Outcome Scale (PFOS) at 6, 12 and 18 months follow-up.

Results
Spinal Neuromodulation was statically significant and improved scores of VAS, OSDI and PFOS. There was no infection and 1 patient needed a revision surgery due to electrode dislodgement (Resume II, cervical). All patients were without narcotic analgesic medications. At 18 months there was a statistically economic advantage with spinal cord stimulation with least medications and other pain treatment modalities.

Conclusions
Spinal Neuromodulation is effective in long-term follow-up of FBBS Patient selection is of outmost importance. Complications can be avoided with a one-day procedure implantation.

Monday, December 10
1200-1300, Poster #39

The Failed Neck Syndrome: A Case Series
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Introduction
The spinal cord stimulation is an useful treatment for failed back syndrome; this treatment appear to be useful also in patients suffering from results by cervical spinal surgery (1). We present a series of 5 patients previously operated for cervical disc didease or spondylosis treated by cervical spinal cord stimulation.

Materials and Methods
In the last 4 years at Neurosurgical Clinic of Insubria University 5 patients (2 men and 3 woman) have been implanted with cervical spinal cord stimulator; all patients suffering from intractable neck and/or upper extremity pain after cervical spinal surgery for cervical disc herniation or spondylosis.
Two patients underwent anterior cervical discectomy with fusion, two without fusion, one underwent open door laminotomy.
In all patient the visual analogic scale (VAS) was reported before and at follow up (mean 20 months).
The problems of surgical procedure and the complications due to this technique were recorded.

Results
The mean preoperative VAS was 7 while at last follow up was 3. One patient was implanted by 2 surgical electrode with 8 poles, one patient required after lead migration and infection 2 percutaneous electrode with 16 poles, one patient was implanted by 2 percutaneous electrode with 8 poles, two patients had 1 percutaneous electrode with 4 poles. One patient 13 months after implant showed lack of IPG benefit due to worsening of the spondylosis.

Conclusion
The spinal cord stimulation in failed neck syndrome seems to be a successful treatment, yet the percutaneous lead migration can be rather frequent. Moreover the evolution of the spondylosis or the discal degeneration in the segment under or above fixation should be kept in mind. In case of posterior cervical surgical approach the implant of surgical electrode is mandatory.

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Learning Objectives:
1. To document the treatment of “failed neck syndrome” by neurostimulation
2. To present benefits and disadvantages of devices

Monday, December 10
1200-1300, Poster #40

Alternative revision spinal cord stimulation (SCS) implants: Comparisons of pain relief, paresthesia coverage, and patient preferences.
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Introduction:
Recent reports described case studies of patients with sequential SCS experiences, in which an initial SCS system is explanted for various reasons besides clinical ineffectiveness and replaced with that of a different manufacturer. These patients are in the unique position to compare/contrast the clinical efficacy of different SCS technologies, and anecdotal reports indicate that improvements in therapy may be attained by implanting another SCS system. Here, using a robust design that includes all revision SCS patients at a single pain management practice, retrospective chart review was followed by prospective outcomes assessment.

Materials and Methods:
An independent researcher, who was not involved in patient care, reviewed medical charts and then placed telephone calls to all subjects using a scripted questionnaire to gather outcomes and preference data.

Results:
Ten subjects (6M/4F, average age: 53 years) suffering from chronic back/leg pain, most commonly due to lumbar radiculopathy (n=8), reported pain at 9.1 out of 10 (range: 7-10). Subjects used a voltage-controlled SCS system for an average of 52 months, during which time the average pain score was 5.7. All subjects underwent device explant following device failure (n=4), lead migration (n=3), or battery depletion (n=3). Subjects were then re-implanted with a multiple independent current-controlled SCS system, and over 10 months reported average pain scores of 4.2, a 1.5-point improvement relative to the first system ($p<0.05$). Subjects also reported that paresthesia coverage was more complete with the second system (4.2 vs. 3.5 where 1=very poor coverage, 5=very good). Seven subjects preferred the second system (four strongly preferred) and six subjects expressed that their quality of life improved after receiving their second implant.

Conclusions:
Subjects reported superior pain relief, better paresthesia coverage, and preference for the second of two sequentially-implanted SCS devices. Although recency effects cannot be discounted, these findings support consideration of alternative SCS technology after device failures.

Acknowledgements:
AF is an employee of Boston Scientific Neuromodulation. Funding was provided by the same.

Learning objectives:
1. Assess SCS clinical efficacy for pain
2. Compare outcomes with sequential implantations of SCS systems

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Monday, December 10
1200-1300, Poster #41

A controlled comparative cadaveric investigation of percutaneous spinal cord lead anchoring
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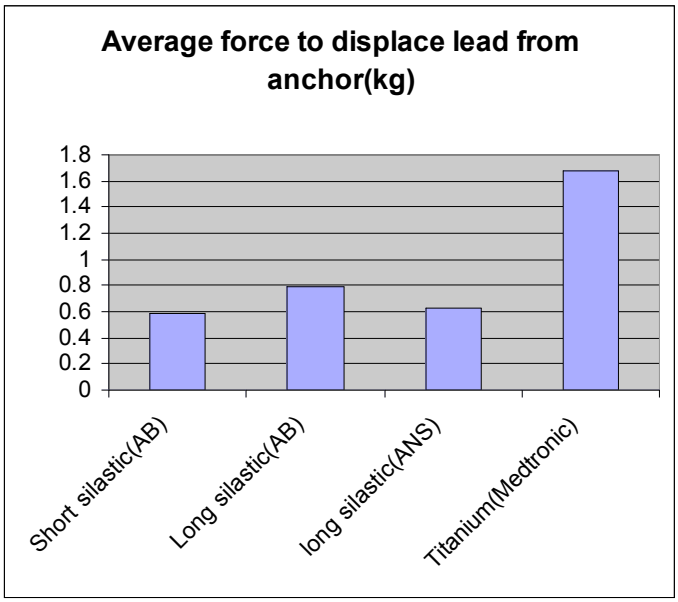
Introduction
Maintenance of paraesthesia with spinal cord stimulation remains a problem due to lead migration. We have undertaken a controlled comparative *in vitro* investigation of the commoner anchor designs.

Materials and Methods
Four operators of varying experience undertook lead placement and anchoring of percutaneous spinal cord stimulator leads in cadaveric specimens using instrument tied square knots. 34 lead anchorings were undertaken in total. Short silastic tapered suture sleeve (SC-4305) (Advanced Bionics) (n= 8) ; long silastic anchor (SC-4310) (Advanced Bionics) (n= 7), (1106) (Advanced Neuromodulation Systems) (n=9) ; titanium anchor (3550-39) (Medtronic) (n=10). An increasing weight was applied to the lead and its movement observed by an investigator blinded to the force applied.

Results
There was a significant difference in applied force to produce lead movement between anchor types (2 –way ANOVA, $F = 11.04$, $p < 0.001$). There was a significant difference between the Titanium anchor and the silastic anchors ($p < 0.003$). There was a significant difference between long and short silastic anchors ($p < 0.01$). There was no significant difference in force to cause lead movement between the operators (unpaired t test for samples of unequal variance, $t = 0.15$, $p = 0.88$)

Conclusion
In this cadaveric investigation we have found a difference in the force required to cause lead movement within its anchor as a function of the anchor type. A greater force could be applied to leads anchored with long compared with short silastic anchors and a greater force still could be applied to leads anchored with Titanium anchor compared with the silastic anchors.



Learning Objectives:
1. In an *in vitro* investigation, the force required to displace a lead in its anchor varies with anchor type.
2. The force required to cause lead displacement is greater with longer silastic anchors compared with shorter.
3. The force required to cause lead displacement is greater with a titanium anchor than with silastic anchors.

Monday, December 10
1200-1300, #42

24 Years Spinal Cord Stimulation Experience in the Treatment of Failed Back Surgery Syndrome from 1984 to 2007. Data Analysis in 1984-1997 versus 1998-2007 Periods

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Introduction
We present our data related to patients affected by Failed Back Surgery Syndrome (FBSS) treated with Spinal Cord Stimulation (SCS) in 1984-1997 versus 1998-2007 periods.

Materials and Methods
A)1984-1997(1)
26 patients:follow-up in 17(65.3%).
Age:32-80;mean :55.8.
Pain: lumbar in 13.9% of patients,lumbar with lower limb/s irradiaton in 83.3%,lower limb/s only in 2.8%.
Mean epidural stimulation trial:16.5 days.Mean stimulation =4.2 h/day.
Poor final result in one IPG placed with unsatisfactory trial.
Medtronic-USA percutaneous epidural leads were used (monopolar till 1985,single quadripolar later).
IPG were 12(NS/EI 70.5%).

B)1998-2007
126 patients:follow-up in 97(76.9%);
Age:54-84;mean:66.8.
Pain: lumbar with lower limb/s irradiaton in 48.4%,lower limb/s only in 51.6%.
Epidural stimulation trial:21 days standard.Mean stimulation =19.4 h/day.

Medtronic-USA single and dual percutaneous quadripolar and laminectomy-style leads were used.

IPG were 62(NS/EI 63.9%).

Pain Evaluation:
- Pain level(1-10)
- Pain daily duration(1-5)
- Disability level(1-5)
- Drug daily demand(1-4)

Outcome :
- EXCELLENT = pain suppression>75%,activity/work resumption,subtotal drugs eradication
- GOOD = pain improvement 50-75%,disability and drug levels reduction
- POOR = other

Results
Follow up lasted for 10 years, or till patient death or SCS interruption.

A)1983-1997
Mean follow-up:4.1 years
SCS interruption in 2 dead patients and in 2 patients for poor results.
Outcome:
- Excellent = 2(16.6%)
- Good = 5(41.6%)
- Poor = 5(41.6%)

Positive outcome (Excellent+Good) in 7 patients(58.2%).
No major complications:1 abdominal infection.

B)1998-2007
Mean follow-up:4.4 years
SCS interruption in 8 dead patients and in 6 patients for poor results.
Outcome:
- Excellent = 14(22.5%)
- Good = 32(51.6%)
- Poor = 16(25.8%)

Positive outcome (Excellent+Good) in 46 patients(74.1%).
No major complications:3 abdominal infection.

Conclusion
Improvement in our positive outcomes in last 10 years should be due to:
- Patients increase but strict selection:NS/EI reduction
- Lumbar pain only exclusion
- Better technology and surgical versatility.

References
Mearini M et al. : 15 years' experience of different etiology low back pain and failed back surgery syndrome treated with spinal cord stimulation. Presented at Pain Management '98–Rotterdam: 67-68, 1998.

Learning Objectives
1. SCS for FBSS positive results in a long time experience
2. SCS better outcome in last decade
3. Technological advances and surgical versatility in these last 10 years

Monday, December 10
1200-1300, Poster #43

Spinal Cord Stimulation with Interleaved Pulses: A Randomized, Controlled Trial
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Objective
The development of multi-contact spinal cord stimulation electrodes and programmable, implanted pulse generators has increased the likelihood of achieving and maintaining pain/paresthesia overlap. This study sought to determine if delivering interleaved stimulation pulses (rapidly interleaved pulse trains using two different contact combinations) and/or doubling frequency would improve overlap in patients with failed back surgery syndrome.

Methods
Using a patient-interactive computer system that quantifies pain/paresthesia overlap and presents various stimulation settings in randomized, double-blind fashion, we compared the effect on overlap of interleaved stimulation versus standard treatment with a single contact combination, controlling for frequency doubling. The interleaved pulses were generated by using the computer system to gate the pulses of a single-channel generator, emulating multichannel stimulation by adjusting the interpulse interval to the smallest possible value of 0.66 milliseconds. Amplitude (charge per phase, determined by varying pulse voltage or width) was maintained at a subjectively comfortable intensity for all trials. Additional variables were the number of percutaneous electrodes used (one or two) and the phase angle between interleaved pulses. At our default 60 pulses per second ("low frequency"), each 360° interpulse interval occurs in 16.7 milliseconds; therefore, 0.66 milliseconds approximates a phase angle of 14°. We studied the effect of stimulation with phase angles from 14 to 346°.

Results
Multivariate analysis of 266 test results from 15 patients revealed a statistically significant ($p \leq 0.05$) association between increased computer-calculated pain/paresthesia overlap and 1) high and low frequency interleaved stimulation using two contact combinations and 2) frequency doubling using one combination. We found no significant effect for electrode configuration (single or dual), pulse width matching, or phase angle.

Conclusions
The statistically significant advantages we observed for interleaved stimulation are explained, in part, by the effects of frequency doubling and have important implications for the design and adjustment of pulse generators.

References
Author 1 , Author 2, Author 3, Author 4, Author 5, Author 6, et al. Title. Journal Year. Volume: start page-end page.

Acknowledgements
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Figure Legends
Figure 1. For each test, the patient adjusted amplitude, drew the area of paresthesia, and rated pain/paresthesia overlap. The computer then calculated overlap, and the patient let stimulation subside before the next test.
Figure 2. Waveforms produced by interleaved stimulation of contact combinations "A" and "B" on a 4-contact electrode (scale exaggerated) with no contact used twice. In this example, the pulses in A lead and lag those in B by the same interval (a 180° phase angle).
Figure 3. Avoiding use of the same contacts for combinations A and B allowed us to deliver standard stimulation simultaneously to all contacts used in either combination. With the single channel output connected to cathodal and anodal poles on the pulse generator common to both, voltage and pulse width are necessarily the same. (Right) Simultaneous delivery of different pulse amplitudes and/or widths to different contact combinations would require a true multichannel stimulator and is beyond the scope of this study.
Figure 4. (Top) Stimulation with contact combination "A," results in an area of paresthesia (A) and an area of sub-threshold stimulation (a). (Bottom) Rapid, interleaved stimulation, A+A, which is comparable to frequency doubling, expands the area of paresthesia A+A to include area a+a and, thus, also expands the area of sub-threshold stimulation to *a+a*.
Figure 5. The effects of interleaving two pulse trains are non-linear and significantly more than the sum of the parts. Is the expansion confined to the intersection A+B, which is exposed to frequency doubling, or does A itself expand with the addition of B, and vice versa? Each area of paresthesia is surrounded by an area of sub-threshold stimulation "a" and "b." If the perception threshold is exceeded at the intersection of a+b, the area of paresthesia will increase.

Learning Objectives
Understand the impact on SCS-generated pain/paresthesia overlap of 1) low frequency, rapidly interleaved stimulation of two different contact combinations on one or two electrodes, 2) doubling the stimulation frequency using one contact combination, 3) electrode configuration (one or two electrodes), 4) pulse width matching of amplitudes, and 5) phase angle.

Monday, December 10
1200-1300, Poster #44

Quality of life evaluation of pain patient with neurostimulator

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Introduction
Neurostimulator is now a well-accepted treatment for refractory pain[1]. However, if patients seem to be satisfied with the outcome, there are only a few surveys that evaluate their quality of life (QoL)[2, 3, 4]. Thus, we examined the effect of neurostimulator on QoL of patients.

Materials and Methods
A series of 70 patients who underwent spinal cord stimulator implantation between 1996 and 2006 was interviewed by a third party (52,0 ± 27,6 months post-implantation). Among questionnaires, patients answered the Whoqol-Bref [5] and the Brief Pain Inventory –Interference Scale (BPI) [6]. They were also asked the Global Impression of Change questionnaire (GIC) and had to quantify the percentage of improvement since their surgery.

Results
The Whoqol-Bref showed that patients got a sustained improvement of their physical and psychological health while their social relationship and environment changed little following their implantation. If patients mostly answered "little better" at the GIC, the vast majority of them also answered that their neurostimulator had helped them and they would undergo surgery again. Finally, the BPI shows main improvement on mood, social interactions, and sleep while employment was the least improved.

Conclusion
Neurostimulator improves certain aspects of quality of life more than others. Walking and return to work seems to be the more difficult aspect to regain after the treatment by neurostimulator.

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Acknowledgements
We gratefully thank Lynda Nolet, Lise Dubé and Danielle Fortin for their wonderful work with patients.

Learning Objectives:
1. To understand how neurostimulator can affect the quality of life over years.
2. To evaluate the degree of satisfaction of patients and its sustainability post-implantation.

Monday, December 10
1200-1300, Poster #45

Our experience with neurostimulation analgetic systems

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Ivana Stetkarova, Doc., M.D.,CSc., Jiri Kozak, M.D.

Introduction
Neuromodulation procedures divided in two different methods: long-term intraspinal drug administration and neurostimulation of nerves, spinal cord or structures of brain. Neurostimulations seem very suitable analgetic methods, mainly for treatment of neuropathic pain, especially failed back surgery syndrome (FBSS). We introduced these methods in our clinical practice in 2000. Since we have implanted 51 neurostimulation systems in 40 patients in our neuromodulation center.

Materials and Methods
There are now 36 working neurostimulator systems from firm Medtronic. We have used these systems: 2x Mattrix, 3x Itrel 3, 3x Synergy and 1x Restore. We describe our experience with the choice of patients, our implantation technique, complex care about our patients and especially results: achievements and complications.

Results
Eleven neurostimulation systems have been implanted for treatment of angina pectoris, three ones for complex regional pain syndrome and twenty-six ones for FBSS. Average pain reduction in our patients was up 65% according to VAS scale /0-10/ (from 8,4 to 3,6) and we have recorded additional positive changes in patient´s life. During neurostimulation treatment we had to also resolve some of complications. There were mainly electrode complications (12 dislocation); the serious ones were 3 infections. We had to take out 2 systems (infection with necrosis and intractable pain around the system).

Conclusion
Implantable neuromodulation methods, mainly neurostimulation, are an effective treatment of good selected patients with intractable chronic pain in highly qualified neuromodulator centers. It is necessary to use these methods very carefully, correctly and safely for their next development in Czech Republic.

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Acknowledgements
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Learning Objectives:
1. Neurostimulation systems
2. Results of our patients
3. Complications

Monday, December 10
1200-1300, Poster #46

Expectation and Treatment of Psychiatric Comorbidity in Chronic Pain Patients With and Without Spinal Cord Stimulation
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Introduction
Despite an increase in the number of study in the last years, the level of evidence of the efficacy of Spinal Cord Stimulation (SCS) in chronic pain is “mediocre” (3; 5). Psychosocial dimension was considered as a risk factor for a good outcome of SCS devices but little consistency have reported in several studies (6; 2).

Materials and Methods
Before implant SCS device, chronic pain patients have screened by a multidisciplinary team. Intensity and dimensions of pain were assessed using the Italian Pain Questionnaire (1). A DSM-IV structured diagnostic interview (MINI) (4) was used to assess psychiatric disorders.

Results
Thirty-four patients have been implanted SCS devices (42.5%) of eighty consecutive chronic pain patients enrolled. Current psychiatric disorders was diagnosed in 25 patients with SCS (52.94%) and 24 without SCS (52.16%). Four patients with SCS (11.76%) and 11 without SCS (23.91%) assumed the psychiatric treatment at the follow up. The improvement of pain after six months was found in both groups, but pain relief ≥ 50% resulted in 4 patients with SCS implant (11.76%) and in 7 without SCS implant (15.21%). Treatment of psychiatric comorbidity in pain relief ≥ 50% patients was 1 for SCS implanted group versus six in the control group. Treatment of psychiatric disorders have a statistical relevance in the improvement of pain ≥ 50% only in the group without SCS implant (ANOVA RM).

Conclusion
Poor compliance for psychiatric treatment is showed in this study, more in the SCS implanted than control group. Treatment of psychiatric comorbidity affects the relief of pain ≥50% at 6 months. The expectation of analgesia only by SCS implant an not for treatment of psychiatric comorbidity also affects on the outcome of SCS implant devices.

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Learning Objectives:
1. expectation of SCS analgesia
2. the weight of psychiatric comorbidity in the management of patients with SCS device for pain
3. the influence of treatment of psychiatric comorbidity in the outcome of SCS therapy for pain

Monday, December 10
1200-1300, Poster #47

Dual Device Therapy (Spinal Stimulation and Intrathecal Drug Delivery) for Treatment of Multi-Focal Pain
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Introduction
A subset of patients require treatment with both spinal cord stimulators and intrathecal drug pumps. An FDA approved clinical study of a novel drug pump (Prometra™, InSet Technologies, Mt. Olive, NJ, USA) allows the prospective evaluation of this dual-therapy population. Patients with both spinal stimulators and intrathecal pumps may have better control of both their neuropathic and nociceptive pain than those with only one system.

Materials and Methods
The PUMP Study is a prospective, open-label study evaluating the accuracy, efficacy and safety of the Prometra pump system in treating pain. As of August 1, 2007, 69 patients have been enrolled in the PUMP Study. Of those, 10 (age: 49 ± 9.4*, gender: 5F) have a concurrent stimulator at 4 clinical sites. Baseline data is collected pre-implant and follow-up is monthly for the first 6-months post-implant. Data collected includes adverse events, accuracy measure (returned morphine volume), pain scores (VAS, NRS, and ODI) as well as longitudinal intraspinal and systemic morphine dosing. Data is being tabulated by an independent third party (inVentiv clinical solutions, The Woodlands, TX).

Results
There have been no deaths or major morbidity. There has been one early catheter dislodgment requiring re-operation to correct. After a total of 605 device-days of follow-up, accuracy of drug delivery is 99.4% ± 2.4%. Programmed daily doses were 1.76 ± 1.9 mg* (range: 0.28- 6.79 mg). VAS values show a 22.3% (NS) improvement, NRS values a 2.1 (NS) point improvement and ODI values a 24.6% (p=.04) improvement. *mean ± standard deviation

Conclusion
Preliminary data indicate that dual-device therapy can be safely performed and improves patient outcomes. The Prometra pump has been shown to be accurate in this population. Future analyses will include a longitudinal analysis of opioid dosing correlated with catheter-tip location, pain-type as well as lead position.

References
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Acknowledgements
The PUMP Study is funded by InSet Technologies Incorporated, Mt. Olive, NJ, USA.

Learning Objectives:
1. Spinal Morphine infusions in patients with previously implanted Spinal Stimulators
2. Introduction of a new programmable Spinal Infusion Pump

Monday, December 10
1200-1300, Poster #48

Outcome of vagus nerve stimulation for intractable epilepsy: Comparison of children and adult
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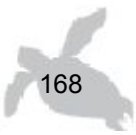
Introduction
The purpose of our study is to compare with outcome of vagus nerve stimulation for children and adult with intractable epilepsy.

Materials and Methods
We evaluated a retrospective review of 31patients who underwent vagus nerve stimulation implantation for intractable epilepsy at single center from 1998 to 2006. Eleven patients were older than 18 years, 20 patients were 18 or younger. We assessed seizure frequency, number of antiepileptic drug, and quality of life.

Results
Eleven (55%) patients had a seizure frequency reduction of more than 50%, five (25%) patients failed to respond to the vagus nerve stimulation treatment in children and three patients (28%) had a seizure frequency reduction more than 50%, fifteen (45%) patients failed in adult . Seven patients had a Improvement of quality of life in patients without significant reduction of seizure. Transient hoarseness and cough were found in seven patients and wound infection in one patient.

Conclusion
Our results suggest that vagus nerve stimulation is a safe and effective treatment for children with intractable epilepsy more than adult with intractable epilepsy.

Learning Objectives
1.The effectiveness and safety of vagus nerve stimulation in intractable epilepsy
2.Usefulness of vagus nerve stimulation in children with intractable epilepsy



Monday, December 10
1200-1300, Poster #49

Experimental Study on Therapeutic Effects of Vagus Nerve Stimulation (VNS) for Epilepsy
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Introduction
Neural stimulation is a promising new technology for the treatment of medically-intractable seizures [1,2]. Vagus-nerve stimulation (VNS) is as effective as antiepileptic drug therapy, and serious complications are rare[1,3,8]. Stimulation of the vagus nerve has reduced partial seizures by 50% or more in approximately one third of patients[4,7].However, several fundamental questions remain to be resolved: (1) What are the criteria for selection for VNS? (2) Which seizure types or syndromes will benefit most from the treatment? (3) What are the most effective and safe stimulation parameters, and do these vary depending on the seizure type? [5,6,9] The goal of this research is to improve the therapeutic effects and the improving of VNS system by study the correlativity between the parameters of VNS and the frequency of epileptic discharge.

Materials and Methods
Improved epilepsy model by injected 0.1% KA 5~10_l into the brain cortex of rabbit. Implanted the VNS system, which made in China, into the rabbit. Analyzed and evaluated the VEEG of the epilepsy rabbit which treated with different parameter VNS.

Results
The EEG frequency of normal rabbit was 14~18Hz, and the amplitude voltage is 20~50 mv. The epileptic discharge could be recorded after KA injection 30 minutes later. The frequency was 2~30 Hz. Different VNS parameters of treatment had vary different results in different frequency epileptic discharge. Lower frequency VNS had a better result to lower frequency discharge, and the same as higher frequency VNS to higher frequency discharge.

Conclusion
There were some pertinency between the parameters of VNS and the frequency of epileptic discharge. These results had directed significance to the choice of VNS parameters in clinical and the developing of new VNS device.

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Learning Objectives:
1. To improve the therapeutic effects of vagus nerve stimulation (VNS) for epilepsy.
2. To improve the making of VNS system.

Monday, December 10
1200-1300, Poster #50

Role of Neuromodulation for seizure control in infancy catastrophic epilepsy (Lennox-Gastaut Syndrome)
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Introduction
Children with Lennox-Gastaut Syndrome have multiple generalized seizures (tonic clonic generalized, tonic, atonic and atypical absences) which are refractory to medical treatment, they also have psychomotor impairment and a characteristic electroencephalogram (slow spike wave complexes). The surgical alternatives can produce severe neurological impairment, no psychomotor improvement and, above all, poor seizure control. Neuromodulation of different targets as vagus nerve stimulation have limited results. Our aim was to evaluate the efficacy of electrical stimulation of the centromedian thalamic nucleus in treatment of generalized seizures of the Lennox-Gastaut syndrome and improvement of patient disability.

Materials and Methods
The study was approved by the Ethical and Research Committees of the General Hospital. Thirteen patients with LGS were studied. They had severe generalized tonic-clonic seizures and atypical absences. All patients had at least a 6-month baseline before bilateral electrode implantation to the centromedian nuclei of the thalamus to undergo therapeutic electrical stimulation of the centromedian nuclei. Once implanted, electrodes were temporally externalized through a retro mastoid point for electrophysiological (cortical responses) and anatomic (magnetic resonance imaging confirmation of their placement. After target confirmation, stimulation parameters were set. Patients came for follow-up assessment of seizures and neurophysiologic tests every 3 months during an 18-month period of time; antiepileptic drug therapy was not modified.

Results
The surgical procedure as well as electrical stimulation was well tolerated by all patients. No side effects occurred with the therapeutic stimulation parameters used, and patients were not aware of device activation. Two patients were explanted because of repeated and multiple skin erosions that could not be controlled by plastic surgery procedures. Overall seizure reduction was 80%. The three patients with poorest outcomes for seizure control did not improve their ability scale score. In contrast, the two patients rendered seizure free are living a normal life at present. The remaining eight patients experienced progressive improvement, from being totally disabled to becoming independent in five cases and partially dependent in two. Patients with adequate electrode placement had a seizure reduction >87%. To consider that an electrode is correctly placed, both stereo tactic placement and neurophysiologic responses are taken into account.

Conclusion
ESCM provides a nonlesional, neuromodulatory method with improvement in seizure outcome and in the abilities of patients with severe LGS.

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Learning Objectives:
1. Present Neuromodulation as a noninvasive surgical alternative
2. Support clear indications for Neuromodulation in generalized epileptic seizures
3. Present methods anatomic and neurophysiologic methods for target localization

Monday, December 10
1200-1300, Poster #51

A Comparison of Lead Configurations used to Provide Effective Low Back and Lower Extremity Coverage
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Timothy R. Deer, MD

Introduction
Coverage of axial and lower extremity pain is the most common indication for spinal cord stimulation (SCS), although attaining this goal is not a simple task. A comparison of techniques to produce this coverage was tested using different SCS leads.

Materials and Methods
Fifteen patients with bilateral low back and lower extremity pain, divided into three groups of five patients in each group, underwent the insertion of SCS electrodes. One group with a single, across the midline, percutaneous Octrode (ANS) lead (1), one group underwent the insertion of dual, percutaneous, Octrode leads, on either side of the midline, and the third group underwent implantation of a Lamitrode paddle lead (ANS). Different programming modes were used to achieve bilateral or unilateral back and leg coverage.

Results
In all patients, with all types of leads, fair coverage of bilateral low back and lower extremity pain was achieved. In the group with a single, across midline lead, coverage was always achieved by using a "guarded cathode" array, with the electrode at the midline crossing point used as the cathode. In the other two groups, this coverage required different combinations of cathodes and anodes, with up to five active electrodes in the paddle group, and up to 6 active electrodes in the dual percutaneous leads. Reasonable separation of stimulation to just the left or right side was also achieved in all patients.

Conclusion
Any of the tested lead configurations will produce adequate coverage for axial and lower extremity pain. However, it seems that this coverage can be achieved with simpler and more structured programming, using a single, across midline, percutaneous lead.

References

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Spinal Cord Stimulation Dramatically Reduces Lead Migration. Neuromodulation 2004; 7:32-37

Learning Objectives:
1. Learn about axial back coverage with spinal cord stimulation
2. Learn functionality of different types pf spinal cord stimulation leads
3. Discussing programming of spinal cord stimulator

Monday, December 10
1200-1300, Poster #52

Management of Interstitial Cystitis Related Pain Using Antegrade SCS Lead
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Introduction
Neuromodulation will continue to be a useful therapeutic modality in interstitial cystitis. Application of antegrade spinal cord stimulator lead at the level of T7 is a novel alternative treatment for pelvic pain secondary to interstitial cystitis.

Materials and Methods
We present a case report of a male with pelvic pain secondary to interstitial cystitis that was successfully treated with a spinal cord stimulator lead placed at the level of the vertebral body of T7. The trial was conducted for one week using an Advanced Bionics Linear eight contact lead (Advanced Bionics Valencia, California). The patient had significant pain improvement (> 70% reduction in his VAS of pain). After the trial he underwent surgical implantation of the lead. Excellent coverage of the painful pelvic area achieved in the immediate postoperative period and in one week after the implantation and after 12 months of follow-up.

Conclusion
This case demonestrates adequate coverage of pelvic pain by antegrade dorsal colum stimulation. The implantation of sacral nerve stimulator leads in the treatment of pelvic pain using retrograde approach had been associated with, in addition to technical difficulty during placement, increased likelihood of lead lateral migration. Also, due to the relative mobility of the conus and the large fiber afferents from the pelvis, stimulation at the upper lumbar and lower thoracic levels in attempt to cover pelvic pain, frequently produces inconsistent and undesirable paresthesia in adjacent regions. One of the possible mechanisms for the pain relief may involve modulation and interruption of the midline relatively deep dorsal column pathways that mediate the perception of pelvic pain secondary to interstitial cystitis. Patients may have responded well to electrical stimulation by tightly spaced electrode as in the compact lead used in this case report. These leads are known to

drive stimulation deeper into the dorsal spinal column where these pathways may be located. That might explain adequate coverage that can be achived by modulating these pathways that are deep into the dorsal column at the midthoracic level.

References

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Learning Objectives:

1. Neuroanatomy of the Pelvis
2. Pathophysiology of Interstitial Cystitis
3. Neuromodulation of the Dorsal Column *Stimulation and the Relief of Pain*. Boston, Mass.: Elsevier; 2003. Pain Research and Management, Vol. 15.

Acknowledgements

This research was funded by Advanced Neuromodulation Systems.

Learning Objectives

1. Understand the difference between constant current and constant voltage pulses
2. Review the patient's responses to constant current and constant voltage stimulation
3. Consider how pulse shape and charge may influence stimulation sensation