Prospective Study

Effects of Movement and Postural Positions in Spinal Cord Stimulation in the New Rechargeable Systems

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Background: Despite recent developments in implantable neurostimulation devices, the adjustment of stimulation levels to the patient's postural changes has remained a problem so far.

Objective: This study was conducted with the newest rechargeable devices, in order to compare its results with the ones published from conventional systems.

Study Design: It is a prospective study.

Setting: In 46 patients implanted with rechargeable constant current stimulation systems we measured impedance, stimulation thresholds, therapeutic range, as well patients' satisfaction and sensation in 7 different body postures.

Results: Data analysis was performed in 46 patients, whose most frequent pathologies were failed back surgery syndrome (FBSS) and complex regional pain syndrome (CRPS).

The lowest amplitude needed to reach the different thresholds was always scored in the supine decubitus position, with no significant changes in the therapeutic range and impedance. For all stimulation thresholds, there is always a difference between the supine position and all other postures. No statistically significant differences with regard to patients' satisfaction and sensation were found for the different postures.

Limitations: Sample sample size.

Conclusion: The findings of the present work are similar to those described in previous publications that showed the relationship between postural changes and several stimulation thresholds and pulse energy. The posture which requires lower energy — and whose corresponding therapeutic range (TR) is narrower — is supine decubitus.

Key words: Spinal cord stimulation, change posture, rechargeable systems, sensor generation, threshold perception, threshold discomfort

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Since the beginning of this therapy almost 40 years ago (1), we have seen great advances in neurostimulation systems which allow for higher precision and greater efficacy, as well as rechargeable battery devices and sophisticated programming options (2). The development of these novel options has increased the number of patients considered candidates for these therapies (3-5). Despite these technological advances, the variation in the intensity of neurostimulation due to body position remains an issue. Different daily body postures are a practical problem, which may result in overstimulation or understimulation leading to frequent manual adjustments (6). In this study, involving 119 patients, we noted that 71% of patients experience an unpleasant stimulation sensation resulting from postural changes; of these, almost 60% identify this unpleasant stimulation when lying down and almost 20% while sleeping. To counteract this sensation, patients often switch off the stimulation system, with the subsequent loss of the treatment's beneficial effect. This fact, which has already been studied and clinically proven by other authors (7-10), forces the patient to use his patient-programmer at least once a day simply to overcome problems caused by changes in posture. Previous studies showed that thresholds to attain the desired level of stimulation are lower in supine decubitus and therefore energy requirements to reach this threshold are lower.

There are anatomical and electric explanations for this phenomenon. The electric current produced in the stimulator reaches the lead's electrodes and generates a voltage, i.e., a potential difference between positive and negative charges (anodes and cathodes); the circuit is then closed through the neural tissues, generating a charge flow and an electric field that stimulates the nerve roots and posterior spinal fibers, which in turn inhibits spinothalamic tract fibers and increases activity in the descending pathways (11). This current spreads in a tridimensional space whose shape and size depends on the electrode type, stimulation parameters, tissues' electric properties, permittivity and conductivity of anatomical structures, and Poisson's Law (12-14). As far as the anatomical structures are concerned, it is worth mentioning that cerebrospinal fluid (CSF) is highly conductive when compared to other neural structures participating in spinal cord stimulation (SCS); in fact, less than 10% of the generated current reaches the spinal cord (15) because it is quickly driven away by the CSF layer. Anatomically, the main factor explaining this issue seems to be the distance between the electrodes and the CSF (16). Other factors affecting the quality of stimulation are different levels of excitability of the various nerve structures, the orientation of the leads, and the stimulation pattern because the electric properties of the central nervous system are heterogeneous and anisotropic. The electrical properties of the tissues vary with postural changes, due to the changes in the dimensions and orientation of neural elements as the distribution of neural elements is not random: for example, the distribution of current in white matter is easier when it enters parallel to the axon than when it enters transverse or perpendicular to it (17). The aim of this study is to assess –stimulation – perception (Tp), therapeutic (Tt), and discomfort (Td) – thresholds, and therapeutic range [TR = (Td - Tp)/(Tp - 1)], as well as patients' satisfaction while changing posture with rechargeable SCS systems. We also checked how postural changes relate to the pulse charge (E) needed to reach a stimulation level (E = Tt x pulse width [Pw]).

Methods

The study was approved by the hospital's Ethics Committee and every patient enrolled signed a written consent prior to their inclusion in the study.

Fifty patients implanted with constant-current rechargeable neurostimulation systems between 2006 and 2010 were enrolled. Four patients were excluded from the final analysis due to different problems in data collection. The study was carried out during routine visits, and no treatment modification methods were performed on the patients. Forty-six systems were analyzed, each one connected to 2 percutaneous octopolar leads: 24 Eon mini (mod. 3788, Advanced Neuromodulation Systems-St. Jude Medical, Plano, TX) with Octrode leads (mods. 3183/3186, Advanced Neuromodulation Systems-St. Jude Medical, Plano, TX) and 23 Precision Plus (mod. SC-1110-02, Boston Scientific, Valencia, CA) with Linear ST leads (mod. SC-2218, Boston Scientific, Valencia, CA).

For each patient, we measured impedance (Z), stimulation thresholds (Tp, Tt, and Td), therapeutic range (TR), paresthesia quality on a subjective scale (very good, good, uncomfortable, fair, bad) and degree of satisfaction, also on a subjective scale (very satisfied, satisfied, neither satisfied nor unsatisfied, unsatisfied) in different body positions: walking (W), standing (S), sitting (St), right lateral decubitus (RLD), left lateral decubitus (LLD), prone decubitus (PD), and supine decubitus (SD). All of these measurements were obtained with the stimulation program (polarity, frequency [Fc], and PW), which was preferred and regularly used by the patients. Before each postural change, the patient was kept sitting with the stimulation off for 5 minutes. The authors involved in the study design agreed to adopt a 5 minute period since there is no previously standardized period to determine whether significant differences occur (9,10).

Statistical Study

For the statistical study we used SPSS v16.0 software. To analyze the data, loss of follow-up was managed as intention to treat. Continuous variables are indicated by N (valid and lost), standard deviation (SD), minimum (min), maximum (max), 25th percentile (p25), 50th percentile (p50), and 75th percentile (p75). Categorical variables are indicated using rates (valid and lost) and percentages (total, valid, and cumulative). For statistical analysis, we applied the Levene Test to assess the equality of variances, T Test for equality of averages, as well as Pearson's X2 Test. All data are expressed as mean ± standard deviation, with a confidence interval of 95%. Values of $P \leq 0.05$ are considered to be statistically significant.

Results

Data analysis was performed on 46 patients (30 women, 16 men) with a mean age of 51.89 ± 14.24 years. Average time from implantation was 1.8 ± 1.02 years.

The most frequent pathologies: failed back surgery syndrome (FBSS) and complex regional pain syndrome (CRPS), represent 78.3% of the patients. The rest of the pathologies are shown in Table 1.

Average stimulation parameters at the time of the study are shown in Table 2.

The most commonly used polarity combination was single bipole (cathode-anode) in 89.1% of the cases; the rest (10.9%) were guarded cathode (anode-cathode-anode). Stimulation was programmed in continuous mode for 86.7% of patients and in cycle mode for the rest. Coverage was higher than 50% in 45 cases (97.6%) and higher than 80% in 39 cases (82.9%). Ninety-five point three percent of patients considered the stimulation quality as good or very good, and satisfaction level was satisfied or very satisfied in 93% of the cases.

Thresholds and therapeutic range variations according to the different postures are shown in Table 3.

Table 1. *Pathologies treated in patients with neurostimulation systems.*

Pathology	N
FBSS	28
CRPS	8
Headache	7
Visceral pain	1
Painful inguinal herniorrhaphy	1
Visceral neuropathy	1

FBSS: Failed Back Spinal Syndrome, CRPS: Complex Regional Pain Syndrome.

Table 2. *Parameters used in the study. Mean/standard deviation.*

Parameter	Mean	Standard Deviation
Tp (mA)	4.4	2.8
Td (mA)	7.2	3.9
Tt (mA)	5.5	3.2
TR	0.6	0.9
Fq (Hz)	56.5	13.3
PW (μs)	376.4	125.7
Z (Ω)	505.8	292.0

Tp: Perception Threshold; Td: Discomfort Threshold; Tt: Therapeutic Threshold; TR: Therapeutic Range; Fq: Frequency; PW: Pulse Width; Z: Impedance.

Table 3. *Stimulation thresholds and therapeutic range variations related to postural changes.*

	Mean (mA)	Standard Deviation (mA)
Tp		
Walking	5.1	3.1
RLD	4.7	2.8
LLD	4.6	3.0
Prone	4.3	3.0
Supine	3.8	2.3
Standing	4.9	3.0
Sitting	4.7	2.8
Td		
Walking	8.1	5.2
RLD	7.6	5.7
LLD	7.2	5.2
Prone	7.3	5.9
Supine	6.4	5.4
Standing	7.9	5.1
Sitting	7.8	5.2
Tt		
Walking	6.7	4.5
RLD	6.4	5.3
LLD	6.0	4.5
Prone	6.0	5.4
Supine	5.5	5.1
Standing	6.6	4.6
Sitting	6.3	4.6
TR		
Walking	0.66	0.62
RLD	0.68	0.86
LLD	0.61	0.81
Prone	0.79	1.10
Supine	0.72	1.10
Standing	0.72	0.67
Sitting	0.73	0.65

mA: Milliamperes

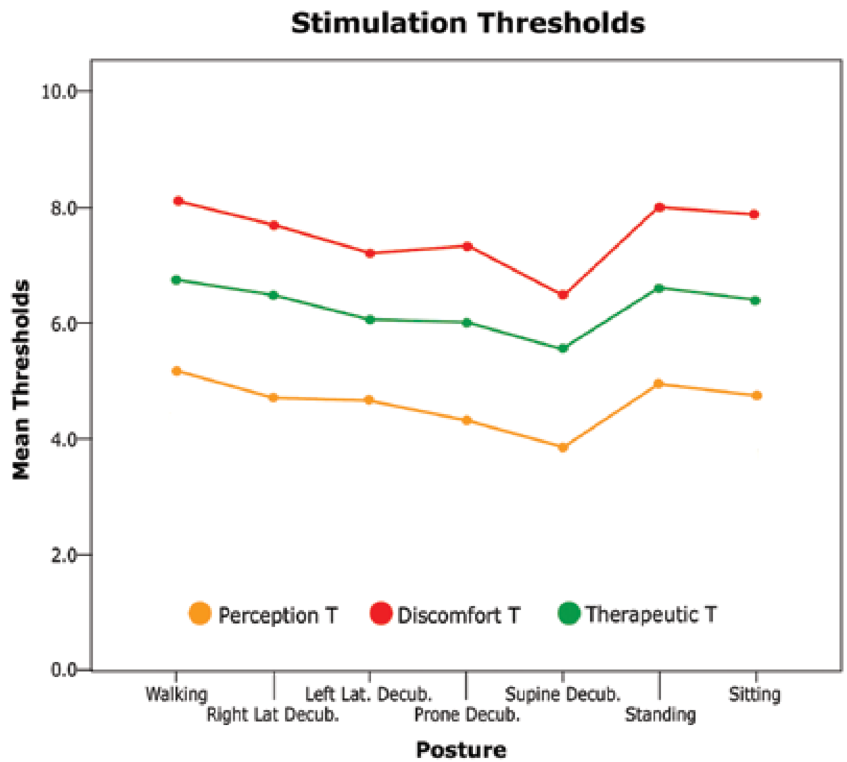

Fig. 1. Relationship between stimulation thresholds and postural changes.

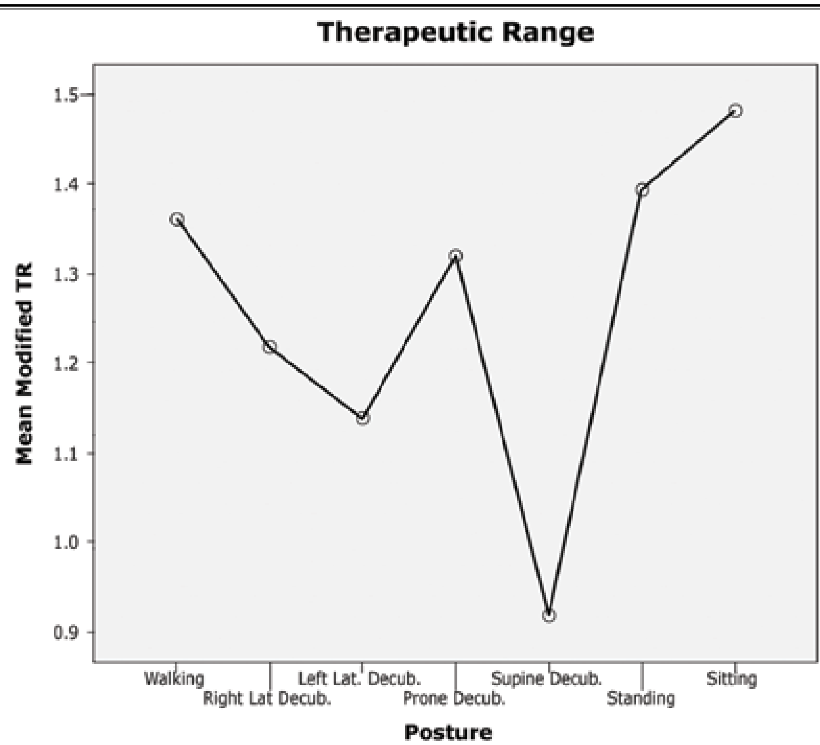

Fig. 2. Relationship between therapeutic range and postural changes.

The lowest amplitude needed to reach the different thresholds (Tp, Tt, Td) was always scored in the DS position, as can be seen in Fig. 1. As expected therapeutic range behavior is similar in all postures (Fig. 2).

Despite the clinically observed differences, these is statistically significance ($P \leq 0.05$), only when comparing S, W, and SD positions. However, data analysis shows that for all stimulation thresholds there are always differences between the supine position and all other postures, from 1.3 – 0.7 mA in Tp, 1.7 – 0.7 in Td, and 1.2 – 0.5 mA in Tt. The same applies to TR.

Subjective sensations (paresthesia quality) recorded in the different postures were good or very good in 97% of cases. The posture with the lowest percentage of patients with good or very good quality was SD (95.3%). These differences are not statistically significant.

As far as the satisfaction score is concerned, 92% of patients say they are satisfied or very satisfied. The lowest satisfaction was also observed in SD position as well as in LLD, with 90.7% of patients being satisfied or very satisfied. Again these differences were not statistically significant.

No statistically significant differences were found in Z changes related to posture, although the lowest Z value, both in cervical and thoracic leads, was found in SD. Impedance was lower also in leads implanted less than 6 months before the measurements.

Pulse charge (E) is lower for SD posture (Fig. 3), although these differences were not statistically significant.

Discussion

To our knowledge, this is the first study that links multiple postural changes with stimulation thresholds in patients with the new rechargeable systems. In all cases the results highlight the fact that DS is the posture that needs lower amplitudes and energy requirements. The outcomes of our study do not differ from those published in other articles that analyze the relationship between postural changes and stimulation thresholds and energy requirements (7-10). The difference is that our study takes into account left and left lateral and prone decubitus positions not analyzed previously. In a detailed analysis of our data no statistically significant differences were found. Nevertheless lower thresholds

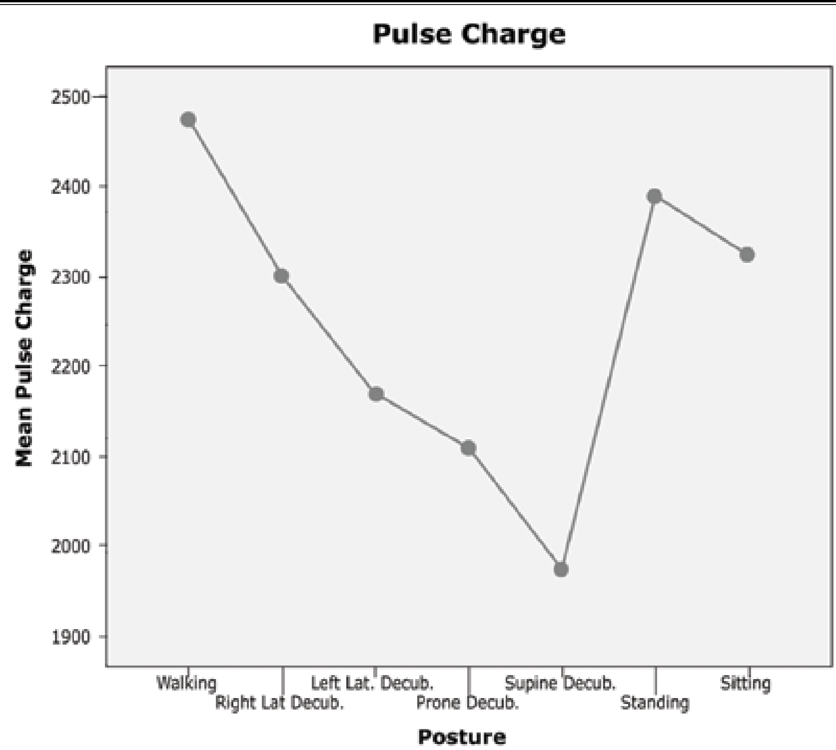

Fig. 3. *Pulse charge necessary to obtain therapeutic stimulation at the different postures.*

were found for DS compared to other postures. No clinical or statistical differences were observed in the different decubitus postures.

Technological advances and rechargeable systems allow greater possibilities for programming than those used in the 1990s. Also the management of patients with more complex pain syndromes has improved since studies of the relationship between postural changes were first originated. Despite these improvements, the issue of patient postural changes has not yet been addressed, since our results are similar to those published 2 decades ago (7,8).

Only patients with constant current systems were involved in this study. This was done to eliminate bias concerning voltage-regulated patients and the possible influence that impedance could have in postural changes, even though our previous study in non-rechargeable systems demonstrates that impedance doesn't influence those changes.

If our results with current constant systems are compared to previously published articles related to dependent voltage (8,11) or current constant systems (7), as well as to our previous ones (9,10), all results are similar. All of them show reduced energy requirements and lower stimulation thresholds when the patient is at DS. In view of these results, it seems clear that the type of implanted system or technological advances does not affect this finding in stimulation systems.

It seems that the most important factor involved in this issue is anatomical, involving the distance between the electrodes and the spinal cord (13,20), and other factors such as the relationship between CSF and the width of spinal space. The electric field is inversely proportional to the square of the distance to the origin of the electric field and is defined by the following formula .

This fact is corroborated in nuclear magnetic resonance image studies that show the spinal cord gets closer to the posterior zone of the spinal canal when the patient is in DS compared to other postures, with a 2.2 mm of average displacement between the SD and PD posture in T11 and more than 3.4 mm in T12, with corresponding variation of stimulation thresholds (21,22). This may explain why new technological advances do improved this issue.

Thus, during postural changes and movement, the spinal cord moves into the subarachnoid space in anterior-posterior and transverse directions, more significantly in the anterior-posterior direction. The stimulation thresholds are proportional to CSF thickness and depend on the distance between the electrodes and the spinal cord (Table 4). In SD the spinal cord is closer to the posterior zone of the spinal canal and consequently electrodes approach the nerve structures. This could explain why the amplitude must be adjusted to accommodate patients' postural changes in order to maintain a constant electric field and to avoid or prevent overstimulation or understimulation.

In view of the clinical and experimental studies published over the last 2 decades, it doesn't seem that technological improvements in hardware and software have addressed these complications. Thus another type of tool is needed to adjust stimulation to patients' postural changes. Accelerometers and other activity sensors have been widely employed in cardiac pacemakers for over 25 years. In these systems accelerometers move on a single axis allowing the pacemaker to adapt the patient's physical activity, thus improving his physical abilities and quality of life (23,24). In 1997, Dijkstra et al (25) already proposed a prosthesis design that could detect the distance between the electrode and the spinal cord during postural changes to adjust stimulation as is the case with pacemakers.

Conclusions

The outcome of our study confirms previous publications both on voltage and current controlled neurostimulation systems showing that the amplitude needed to reach the different thresholds (Tp, Tt, Td) is statistically significantly lower for the DS posture. We observed a trend in which patients in DS sense lower quality of paraesthesia and satisfaction (although the last t2wo findings are not statistically significant).

Potentially, larger sample populations would be necessary to confirm statistical significance.

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Table 4. *Coverage and satisfaction scores with Adaptive Stimulation turned off.*

Patient	Posture	Ut(V)	Standing		Supine		Stim. Pattern
			Cov	Sat	Cov	Sat	
1	Standing	0.9	5	4	5	4	+ -
	Supine	0.9	5	4	5	4	
2	Standing	1.9	5	5	5	1	+ -
	Supine	1.3	1	1	5	5	
3	Standing	3.8	3	5	3	1	- -++
	Supine	3.1	1	1	3	5	
4	Standing	3.1	3	5	3	2	+-+
	Supine	2.1	1	1	3	5	
5	Standing	2.9	5	5	5	1	+-+
	Supine	1.8	1	1	5	5	
6	Standing	4.8	5	5	5	2	+-+
	Supine	3.7	4	3	5	5	
7	Standing	0.7	5	5	5	3	+-+
	Supine	0.5	4	3	5	5	
8	Standing	5.2	5	5	5	1	+-+
	Supine	4.3	1	1	5	5	
9	Standing	4.5	5	5	5	2	+- +-
	Supine	2.8	1	1	5	5	
10	Standing	4.3	5	5	5	2	+-+
	Supine	3.1	1	1	5	5	

References

1. Shealy CN, Mortimer JT, Reswick JB. Electrical inhibition of pain by stimulation of dorsal columns: Preliminary clinical report. *Anesth Analg* 1967; 46:489-491.
2. Oakley J, Varga C, Krames E, Bradley K. Real-time parestesia steering using continuous electrical field adjustment. Part I: Intraoperative performance. *Neuromodulation* 2004; 7:157-167.
3. Krames E. The right place at the right time. *Neuromodulation* 2005; 8:149-152.
4. Slavin KV. Peripheral nerve stimulation for neuropathic pain. *Neurotherapeutic* 2008; 5:100-106.
5. Verrills P, Mitchell B,Vivian D, Sinclair C. Peripheral nerve stimulation: A treatment for chronic low back pain and failed back surgery syndrome? *Neuromodulation* 2009; 12: 68-75.
6. Kuechmann C, Valine T, Wolfe D. Could automatic position-adaptive stimulation be useful in spinal cord stimulation? Proceedings of the 6th Congress of European Federation of IASP Chapter (EFIC) Lisboa, Portugal, 2009.
7. Cameron T, Aló KM. Effects of posture on stimulation parameters in spinal cord stimulation. *Neuromodulation* 1998; 1:177-183.
8. Olin JC, Kidd DH, North RB. Postural changes in spinal cord stimulation perceptual thresholds. *Neuromodulation* 1998; 4:171-175.
9. Abejon D, Feler C. Is impedance a parameter to be taken into account in spinal cord stimulation? *Pain Physician* 2007; 10:533-540.
10. Abejón D, Camacho M, Pérez-Cajaraville J, Del Pozo C, Del Saz J. Effect of posture on spinal cord stimulation in patients with chronic pain syndromes: Analysis of energy requirements in different patient postures. *Rev Esp Anestesiol Reanim* 2008; 56:292-298.
11. Bradley K. The technology: The anatomy of a spinal cord and nerve root stimulator: The lead and the power source. *Pain Medicine* 2006; 7:27-34.
12. Holsheirmer J. Electrical stimulation and the relief of pain. Pain research and clinical management. In: Simpson BA (ed). *Principles of Neurostimulation*. Vol 15. Elsevier Science, UK, 2003, pp 17-36.
13. He J, Barolat G, Holsheimer J, Struijk JJ. Perception threshold and electrode position for spinal cord stimulation. *Pain* 1994; 59:55-63.
14. Grill WM. Principles of electric field generation for stimulation of central nervous system. In: Krames E, Peckham

PH, Rezai AR (eds). *Neuromodulation*. Elsevier, UK, 2009, , pp 145-156.

15. Holsheimer J. Which neuronal elements are activated directly by spinal cord stimulation? *Neuromodulation* 2002; 5:25-31.
16. Barolat G. Epidural spinal cord stimulation: Anatomical and electrical properties of the intraspinal structures relevant to spinal cord stimulation and clinical correlations. *Neuromodulation* 1998; 2:63-71.
17. Grill WM. Modeling the effects of electrical fields on nerve fibers: Influence of tissue electrical properties. *IEE Trans Biomed Eng* 1999; 46:918-928.
18. Simpson BA. Selection of patients and assessment of outcome. In: Simpson BA (ed). *Electrical Stimulation and the Relief of Pain. Pain Research and Clinical Management.* X ed. Vol. 15. Elsevier Science BV, Amsterdam, The Netherlands, 2003, pp 237-249.
19. Oakley JC, Prager J, Krames ES, Weiner RL, Stamatos L, Bradley K. Variability of contact impedance over time in spinal cord stimulation. Proceedings of the Meeting of the American Society of Stereotactic and Functional Neurosurgery Cleveland, Ohio, 2004.

    www.controlyurpain.com/printables/clinical/evidence/2.pdf. Accesed 02/18/10.
20. Barolat G. Spinal cord stimulation for persistent pain management. In: Gildenberg P, Tasker RR (eds). *Textbook of Stereotactic and Funcional Neurosurgery.* McGraw-Hill, New York, 1998, pp 1518-1537.
21. Holsheimer J, den Boer JA, Struijk JJ, Rozeboom AR. MR assesment of the normal position of spinal cord in spinal canal. *Am J Neuroradiol* 1994; 5:951-959.
22. Holsheimer J, Barolat G, Struijer JJ, He J. Significance of the spinal cord position in spinal cord stimulation. *Acta Neurochirc* 1995; 64:119-124.
23. Ross E, Abejón D. Improving patient experience with spinal cord stimulation of position-related change in neurostimulation. *Neuromodulation* 2012 (to publish).
24. Lau CP, Tse HF, Camm AJ, Barold S. Evolution of pacing for bradicardias: Sensors. *Eur Heart J* 2007; 9:I11-I22.
25. Dijkstra EA, Holsheiner J, Olthuis W, Bergveld P. Ultrasonic distance detection for a Closed-loop spinal cord stimulation systems. Proceeding of 19th International Conference – IEEE/EMBS, Oct. 30 – Nov. 2, 1997, Chicago, IL, USA.

    http://doc.utwente.nl/17395/1/00758723.pdf