Table 9. Intrathecal Baclofen Pump and other Neuromodulation

Author Year; Country Score Research Design Total Sample Size	**Methods**	**Results**
Lombardi et al. 2008 (males) Italy Prospective controlled trial Level 2 N=54	**Population:** 54 males with SCI (mean age 42.8) suffering from Lower Urinary Tract Symptoms (LUTS) and concomitant erectile impairment. Group A - 30 neurogenic patients, (mean age 41.3; range 27–69), all showing at least partial peripheral or central preservation of the upper motor neuron. 6 had incomplete SCI, 3 had myelitis, 1 had MS, 2 had disk herniation, and 2 had peripheral polyneuropathy. Group B consisted of 24 idiopathic patients (mean age 44.6; range 27–62). **Treatment:** To evaluate if sacral neuromodulation (SNM) using the InterStim system improves erectile function. Stimulation consisted of continuous pulses with a frequency of 20 Hz. **Outcome Measures:** the five-item version of the International Index of Erectile Function (IIEF-5) A score of IIEF-5 equal to or higher than 25% compared to baseline indicated remarkable clinical enhancement. Three months after permanent implantation, the IIEF-5 was completed again. Those who benefited significantly in erectile function completed the IIEF-5 semi-annually. A final checkup was performed in July 2007.	1. In the first post-SNM visit, there was a significant improvement in the median IIEF-5 score of group A (Neurogenics) (from 14.6 (range 11–18) to 18 (range 12–23) using the Wilcoxon test ($p<0.02$). 2. The patients' history revealed that erectile impairment was concomitant to LUTS (Fisher test P=0.008) in 12 neurogenic subjects compared to two idiopathic subjects. 3. Overall, 22 out of 52 males (42.3%) showed erectile impairment according to the IIEF-5. More precisely, 14 out of the 29 neurogenic patients (48.2%) and 8 out of the 23 idiopathic patients (34.7%) showed erectile impairment.

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Sievert et al. 2010 Germany Case control Level 3 N=16	**Population:** N: 16 Level: all thoracic; all complete; all AIS Score A Etiology: traumatic Experimental Group N: 10 Age: Mean 30.5 years, Range 19-38 years Control Group – N: 6 Age: Mean 36.5 years, Range 27-47 years **Treatment:** Sacroneuromodulation Stimulation (SNS) (Interstim- I & II) bilaterally implanted at the third sacral foramen. The control group was people with SCI given an antimuscarinic medication prescription with no stimulation. Follow-up schedule: 3 and 6 months, then every 6 months thereafter. **Outcome Measures:** bowel movement details (participant diaries), laxative use, and QOL questionnaire	1. The group with Sacral Neuromodulators (experimental group) reported sufficient colon movement without oral laxatives 2. People in the Stimulation group reported higher QoL than the controls: more independent and "normal social participation". 3. With additional Interstim- II programming, two patients experienced improved erectile function that permitted satisfying sexual intercourse.
Calabrò et al. 2014 Italy Pre-post Level 4 N=20	**Population**: 20 men (mean age 34.85±10.27 years) affected by severe spasticity due to SCI (10), vascular (3), degenerative (6) and congenital (1)d origins; level of lesion C4 - T10 with a mean disease duration of 6.1±4.45 years **Treatment**: Implantation of a Synchromed pump with port and a drug administration device (DAD) with a 20mL reservoir. Intrathecal	1. Decrease in the IIEF median scores before and after implantation. 2. Spasticity, spasms, and patient's perception of their own quality of life (QoL) improved after ITB administration but with a worsening of sexual functions. 3. Found a correlation between ITB dosage and IIEF scores (ρ=-0.60; $P < 0.05$). 4. Before implantation, 55% of participants declared difficulties

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	baclofen was administered through the pump and port system (mean dose of 75±25 mg/day). **Outcome Measures:** All patients underwent neurological and sexological tests using the International Index of Erectile Function (IIEF) and the Diagnostic Impotence Questionnaire (DIQ) before pump implantation and approximately 2 months after implantation. All participants underwent specific clinical scales to evaluate force, muscle tone, cognition and mood, and specific sexual questionnaires, including a semi-structured interview.	to achieve or maintain an erection, whereas after the pump implant 80% of the sample suffered from erectile dysfunction.
Lombardi et al. 2011 Italy Pre-post Level 4 N=75	**Population:** N: 75 men (8 completed NBS outcomes) Level: incomplete Duration: > 6 months **Treatment:** using sacral neuromodulation (SNM) implanted at third sacral foramen. and comparing: before (14-day baseline) vs. after implantation Follow-ups after: 1, 3, and 6 months then every 6 months after that. **Outcomes:** SF-36 QoL questionnaire, frequency of incontinence, frequency of evacuations, duration of evacuations, Wexner fecal incontinence and constipation questionnaires, pad usage, anorectal manometry and International Index of Erectile	1. Individuals (6) with neurogenic erectile dysfunction had a 37.4% improvement in IIEFS score and engaged in sexual intercourse without needing oral phosphodiesterase 5 inhibitors.

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	Function (IIEFS; male sexual function questionnaire)	
Jones et al. 2008 USA Pre-post Level 4 N=7	**Population:** 7 men with SCI (mean age 36.7 yrs) with positive bulbocavernous reflex and reported history of sexual activity since injury. **Treatment:** Implantation of intrathecal baclofen pump. **Outcome Measures:** Brief Sexual Function Inventory (BFSI) questionnaire; perception of spasticity questionnaire, developed by Schwartz et al.; SF-36 Health Survey.	1. Generally unchanged rating of perceived sexual functioning, sexual relationships, and ejaculation post-implant. 2. Modest to drastic improvements in the participants' perception of problems with sexual functioning. 3. In 3 participants, there was a relationship between baclofen dosage and perceived sexual function; as baclofen dosage increased, BFSI scores related to erections deteriorated. 4. Significant improvement in the spasticity scores from pre- to post-implant. 5. Improved health status score in all but 1 participant.
Denys et al. 1998 France Pre-Post Level 4 N=14	**Population:** 14 male participants. The time between injury and operation ranged from 1 to 15 years. All had a complete lesion of the spinal cord: in 16 cases situated between T1 and T10; in one patient at C5. **Treatment:** Implantation of intrathecal baclofen pump (average dose of 290(68.3) µg/day). **Outcome Measures:** yes or no questions (ability to sustain reflexive & psychogenic erections, obtain ejaculation without electrical, vibratory, pharmacologic stimulation); visual analog scale for penile rigidity; recall of maximal duration of stable erection (minutes); modification of libido.	1. Ability to sustain erections was not affected by treatment. 2. 3/5 participants reported decreased rigidity after treatment. 3. 4/5 participants reported decreased erection duration after treatment while 1 subject reported increased duration after treatment. 4. One participant who had the ability to obtain ejaculation without electrical, vibratory or pharmacological stim before treatment was no longer able after treatment. This ability returned after baclofen withdrawal.

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Van der Aa et al. 1995 Netherlands Post-test Level 4 N=17	**Population:** 5 men with SCI (mean age 35.8 yrs); all participants with sacral reflexes and reflexive bladder. **Treatment:** Implantation of the Finetech-Brindley bladder controller (Sacral anterior neuromodulator) **Outcome Measures:** Four days after surgery, bladder capacity, continence, and sexual function were measured.	1. A sustained full erection can be achieved in all our male patients using continuous stimulation; in 12 patients by stimulation of the S2 anterior roots; in 2 patients by stimulating the S3 anterior roots. There is no interference with bladder emptying.