Prolonged percutaneous SNM testing does not cause infection-related explanation

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What's known on the subject? and What does the study add?

- Sacral neuromodulation (SNM) is an effective treatment option of different pelvic-related dysfunctions. SNM evaluation by either temporary or permanent electrodes is generally accepted. Extended testing with temporary electrodes has been reported on before but less is known about infection-related risks during prolonged evaluation with definitive electrodes.
- The present findings show that prolonged testing (mean = 52.3 days) with permanent electrodes does not increase infection-associated explantation rates, although bacterial colonization was found in more than one-third of the patients. Prolonged SNM evaluation under everyday conditions might improve long-term success.

Objective

- To evaluate the impact of prolonged stage 1 testing on bacterial electrode colonization, infection and treatment success.

Materials and Methods

- In all, 21 patients who underwent sacral neuromodulation (SNM) for periods ≥1 month were prospectively evaluated; nine patients had overactive bladder syndrome (OAB), 10 had urinary retention, two had faecal incontinence (FI), and 13 had diabetes and overweight/obesity.
- After stage 1 testing electrode extension leads were microbiologically analysed to assess bacterial colonization.
- The primary measurements were pre- and post-SNM treatment comparisons based on patient-agreed criteria using an increased 70% minimum improvement rate; secondary measurements were bacterial colonization and impact of infection.

Results

- The mean stage 1 evaluation period was 52.3 days; 16 patients (76%) progressed to stage 2, and five patients were explanted due to inadequate improvement (<70%).
- There was bacterial colonization in 42.9% of patients and 38.2% of extension leads.
- Stage 2 patients showed no infection or wound-healing disorders at a mean follow-up of 33.9 months.
- The success rate for stage 2 implantation treatment was 94%.

Conclusions

- There are few studies in the literature evaluating SNM testing periods vs the risk of clinically relevant implant infection rates. The present study shows that prolonged testing could potentially enhance treatment efficacy without infection-related explantations of the chronic implant, despite the identification of bacteria.
- SNM-implanted patients with diabetes mellitus or obesity should be followed closely.
- Clinicians might consider using prolonged testing under everyday conditions.
- Prolonged SNM stage 1 testing is a very effective minimally invasive treatment option to evaluate pelvic-related dysfunction.

Keywords

sacral neuromodulation, tined-lead electrode, infection, prolonged testing, overactive bladder, faecal incontinence

Introduction

Since Tanagho and Schmidt [1] introduced the bladder pacemaker for urological application in 1979, further improvements have led to what is now known as sacral neuromodulation (SNM), resulting in an interdisciplinary approach to treating overactive bladder syndrome (OAB) with and without urinary incontinence [2,3],

non-obstructive chronic urinary retention [4], chronic pelvic pain syndromes [5] and, especially due to efforts in recent years, faecal incontinence (FI) and bowel dysfunction [6]. Currently SNM effectiveness is assessed by either peripheral nerve evaluation (PNE) with testing electrodes or by implantation of the definitive quadripolar electrodes (two-stage implant), both connected to an external impulse generator [7].

The optimal assessment time period remains unclear, but prolonged test periods up to 4 weeks in urological applications resulted in improvement rates of 50–80% in evaluated patients when a symptom improvement of ≥50% was considered to indicate successful treatment [8,9]. Despite its potential success, these prolonged evaluation periods, using PNE or skin-penetrating electrode extension leads (stage 1 SNM), can cause bacterial colonization with subsequent wound infection. This risk causes further concern, not only in patients who have benefited from an immediate neuromodulation implant, but where the impulse generator pocket could adversely harm overall treatment success, resulting in surgical revision or even explantation. With regard to the permanent quadripolar electrode, Kessler et al. [10] previously reported on the feasibility of prolonged testing over a median of 28 days with respect to clinical complications, but without microbiological testing. In another 30-day study, Huwyler et al. [11] identified a bacterial colonization rate of ≈20% using explanted tined-lead electrodes with a 5% infection rate ($n = 20$ patients). Due to unsuccessful tined-lead testing, a clinical follow-up of the neuromodulator device and rates of wound infection was not possible.

Advances in SNM have resulted in the treatment being widely used in urology and proctology, especially in patients in whom other approaches have proved insufficient. SNM has also been successfully used in spinal cord injury patients for the management of lower urinary tract dysfunction [12]. The optimal testing periods for SNM are unproven, but prolonged stage 1 testing has shown enhanced treatment outcomes [11]. The current prospective SNM study analysed prolonged testing periods while prospectively evaluating the impact of both bacterial colonization of the electrode extension lead (growth at the connection location of the extension and the chronic electrode) and wound infections during the ongoing SNM process. An institutional requirement of ≥70% symptom improvement rate for stage 2 progression was adopted to ensure long-term success.

Material and Methods

From September 2008 to January 2011, 21 patients (Table 1) were prospectively enrolled in the study (approval: 337/2010A). Bladder dysfunction was diagnosed in nine patients due to idiopathic detrusor overactivity, in 10 patients due to detrusor hypocontractility with non-obstructive chronic urinary retention, and in two patients due to FI. Potential infection-abetting conditions, especially diabetes mellitus and overweight/obesity (defined as body mass index [BMI] ≥ 25 kg/m^2), were recorded.

Table 1 Patients' characteristics.

	n (%) or mean (range)
Total number of patients	21
Gender (female : male)	20 (95): 1 (5)
Diseases	
OAB	9 (43)
Chronic urinary retention	10 (48)
Bowel dysfunction/FI	2 (9)
Age, years	64 (29–87)
Interval between tined-lead(s) implantation and SNM, days	52.3 (27–116)
Follow-up after SNM stage 2, days	1017 (553–1349)
Number of electrodes	
One	8 (38)
Two	13 (62)
Indications for bilateral electrodes (no. of patients)	
OAB	2
Chronic urinary retention	10
Bowel dysfunction/FI	1
Implantation site	
S3	20 (95)
S4	1 (5)
Co-morbidities with risk for infection	
Diabetes mellitus	4 (19) (two insulin dependent)
Overweight/obesity (BMI > 25 kg/m^2)	13 (62)
No co-morbidities	7 (33)

Patients were placed in a prone position under general anaesthesia. After skin disinfection (povidone-iodine 1%), a sterile plastic film was placed over the surgical field, including the exposed anus. Standard 9 cm foramen needles were used to identify the nerve root causing optimal anal contraction [9]. The tined-lead electrode was implanted into the S3 foramina in 20 patients, and into the S4 foramen in one patient. Bilateral tined-lead electrode implantation during stage 1 was performed in patients with detrusor hypocontractility with chronic urinary retention. The electrodes were connected to the extension leads at the planned implantation side of the impulse generator device. The extension leads were subcutaneously tunnelled to the contralateral buttock penetrating the skin. Before wound closure, all incisions were flushed with a solution of 5% gentamicin (as per the institution's standard procedure) in sodium chloride 0.9% after each step. Patients received perioperative antibiotic prophylaxis with i.v. gentamicin (160 mg once daily) continuously for 3 days and oral flucloxacillin (1000 mg three times daily) for another 7 days. As instructed, the bandage was changed with additional povidone-iodine gel every second day.

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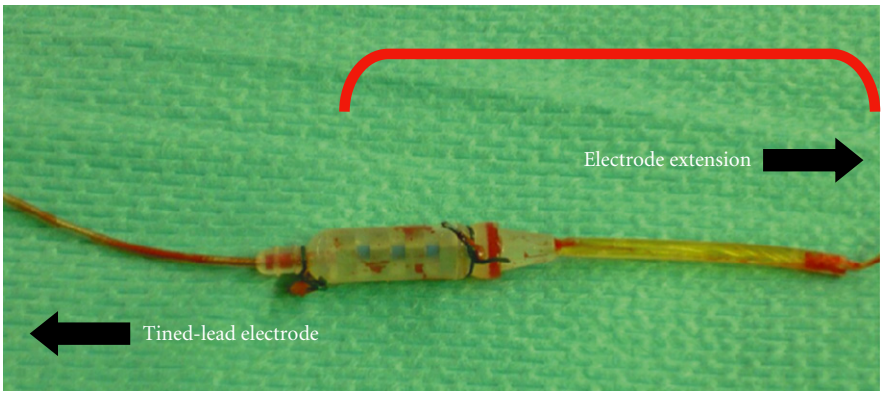

Fig. 1. Tined-lead electrode and electrode extension. The red bracket indicates the part of the implant that underwent microbiological testing after SNM stage 1.

The primary measures were the symptom-based patient-specific protocol variables at baseline and after the stage 1 prolonged evaluation period. Treatment success was defined as a symptom reduction of ≥70% (e.g. daily quantities of pads, leakages, voids, catheterizations or pain experienced based on the 0–10 scale) in relevant protocol variables as agreed upon with the patient. If the agreed-upon criteria were achieved, the patient received the subcutaneously placed impulse generators at least 4 weeks after electrode positioning [11]. In an identical surgical setting, after removal of the electrode extension lead (this was gently withdrawn as far as possible from the skin, then cut off; a very small skin incision was then made to remove the remaining portion), the impulse generator was implanted followed by multi-layer wound closure, flushing the skin pocket with gentamicin after each closure step. The removed extension lead (Fig. 1) that was formerly connected to the chronic electrode was sent for microbiological testing in separate sterile containers. Routine culture tests of the lead extension connection, which contains the end of the chronic electrode (Fig. 1), were also performed to detect bacteria and fungi. Patients were followed for wound infection and clinical treatment success during their hospitalization and regularly every 3–6 months within 4–6 weeks after discharge. Patients with ineffective SNM evaluation (<70% improvement) were offered alternative treatment options according to the guidelines [13].

Both stage 1 and stage 2 procedures were carried out as in-patient treatments, which is the generally accepted reimbursement practice in Germany. During this time, wound hygiene and SNM optimization procedures were also practised.

Results

The mean (range) stage 1 SNM evaluation period was 52.3 (27–116) days (Table 1). Although patients were experiencing symptom improvement in stage 1, there were various reasons to lengthen the evaluation time-frame: the symptom improvement did not reach the given 70% threshold and therefore the patients, noticing an improvement, requested the prolonged test phase rather than concluding a failed stage 1; and they had already fulfilled the success criteria but private issues caused them to postpone their return to the clinic. The patient with the longest (116 days) testing period was among those who progressed to stage 2 SNM and received successful a chronic implant; 14/21 (67%) patients were evaluated for at least 40 days.

Table 2 Study results.

	n/*N* patients (%) (unless noted otherwise)
Bacterial detection on electrodes	13/34 electrodes (38) in 9/21 patients (43)
Diabetes mellitus	3 patients
BMI > 25 kg/m^2	7 patients
Wound infections	0/21 (0)
SNM or electrode explantations due to infection	0/21 (0)
Electrode explantations due to negative patient evaluation (baseline not met)	5/21 (24)
Therapeutic success of permanent SNM	15/16 (94)

Microbiological laboratory analysis identified bacterial colonization on 13/34 electrode extension leads, in nine of 21 patients (five with bilateral and three with unilateral implantation) (Table 2). The most frequent colonization was with *Staphylococcus epidermidis* (six electrodes), followed by *Staphylococcus capitis* (four electrodes), *Peptostreptococcus* spp., *Enterococcus faecalis* and *Micrococcus luteus* (one electrode) (Fig. 2).

No surgical revisions were required and no postoperative complications were noted. None of the 21 patients had a wound infection or prolonged wound healing, either at the site of the impulse generator device or at the former skin penetration site of the electrode extension lead after surgery or during the postoperative long-term follow-up. In

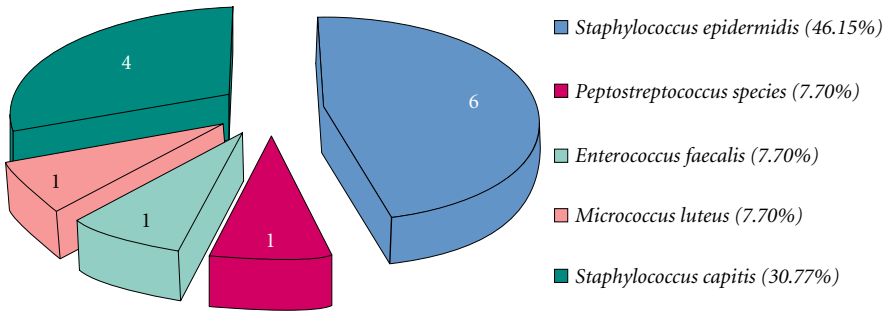

Fig. 2. Bacterial colonization of electrode extension leads.

all, 16 patients with a successful stage 1 evaluation progressed to stage 2, where they received the impulse generator. Five patients with <70% improvement as recorded in their protocol underwent complete electrode explantation due to negative evaluation, again without clinical signs of wound infection, including the skin incisions of the tined-lead electrode.

Three of the nine patients with bacterial colonization of the electrode extension lead had type 2 diabetes mellitus. Overweight/obesity was recorded in seven of the nine patients with bacterial colonization (mean [SD] study group BMI = 29.90 [7.61] kg/m^2).

In patients with complete two-stage implantation, the SNM success rate was 94% (15/16 completely implanted patients) with an uneventful mean follow-up of 1017 days (33.9 months), all of whom fulfilled the implantation criteria of a ≥70% improvement of the initial symptoms. One stage 2 SNM patient was explanted due to a lack of efficacy after 243 days. All patients with successful stage 2 implantation used continuous neuromodulation with impulse generator programming while managing their daily hygienic routines.

Discussion

Sacral neuromodulation is known to be an effective treatment option for detrusor overactivity, chronic urinary retention, chronic pelvic pain syndrome and FI [3,4,6]. Different studies have investigated the safety and long-term efficacy of SNM [2,5]. The reported treatment success rates were achieved using a distinct patient evaluation with either a PNE or a two-stage implantation of the permanent quadripolar electrode [9,14]. Kessler et al. [8] reported an increased stage 2 eligibility from 50% to 80% with a prolonged stage 1 evaluation period (up to 28 days) in a urological application with the permanent quadripolar electrode. Some studies have reported varied outcomes with infections in chronic SNM. In 2009 White et al. [15] reported an infection rate of 3.5% (seven of 221 patients) during two-stage SNM. Hijaz et al. [16] identified the need for implant explantation due to infection in 5% of the stage 1 SNM patients after less than 3 weeks. El-Gazzaz et al. [17] reported an 8.3% explantation rate in a 2-week PNE evaluation followed by implantation of an electrode and impulse generator. Pannek et al. [18] identified bacterial colonization on temporary electrodes during PNE in 45% of the patients within 3 days of evaluation, while Sievert et al. [19] did not observe local infections until up to 22 days.

In 2008, Kessler et al. [10] explicitly investigated the feasibility and safety of prolonged two-stage SNM. While 71% of the patients received a generator, there were no clinically apparent infections. However, they did not specifically investigate the bacterial or fungi growth at the junction between the extension lead and the chronic electrode [10]. In a subsequent study, the research team reported that 20% of the patients tested positive for microbial testing, but they analysed only those patients in whom the electrode was removed due to ineffectiveness of SNM [11].

The present study is new in that it combines what is currently the longest reported evaluation period of SNM (stage 1), 116 days (mean = 52.3 days), with microbiological analysis results. The present study had an improvement rate of 70%, above the standard (manufacturer) 50% rate, and a success rate of 94% for the completed implant over a mean (range) time period of 1017 (553–1349) days. In addition, a microbiological examination was carried out on the connection between the extension lead and the chronic electrode after stage 1 in an ongoing study in which patients successfully progressed to stage 2. Neither explantations were required due to post-surgical complications nor were revisions required.

Investigator-driven experience has led us to set the implantation success threshold at >70% reduction in symptoms, as compared with the manufacturer's suggested rate of 50%, which helped to further reduce the chronic stage 2 implant failure rate. Establishing the ≥70% symptom improvement rate within the prolonged stage 1 testing period led to a long-term SNM success rate of 94%, despite the possible infection and explantation concerns that are typically noted with prolonged stage 1 evaluations. One could argue that even more patients would have benefited with the commonly used 50% symptom

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improvement rate, but in the investigators' experience, a higher stage 1 failure rate was recorded with a 50–70% symptom improvement rate. Safe prolongation of stage 1 SNM not only enhances the patients' eligibility to receive a chronic implant, but also provides the important ability to test the treatment efficacy in the patient's daily life. The ability to safely prolong stage 1 evaluations is important for three reasons: because in-patient evaluation is completely different with regard to the physical and psychological stress of the patient and might lead to better outcomes; because positive outcomes are essential in the context of the current cost pressures in the health care system that make it crucial to attain highly successful SNM stage 1 rates to ensure 'long-term' SNM treatment success [20]; and because SNM reimbursement costs vary by country, and it could be important to maintain the required testing time-frames so that reimbursements are not negatively impacted. Further, patient health or travel inconvenience can delay return to the clinic, resulting in prolonged stage 1 evaluations.

Previous studies have focused on patient predictors of SNM complications. In 2010 Daniels et al. [21] reported equivalent long-term results between diabetic and non-diabetic patients but identified a significantly higher device explantation rate due to infection in the presence of diabetes (16.7% vs 4.3%). Although bacterial colonization (biofilm-positive) was verified in the present study, especially in patients with diabetes, none of these patients presented any signs of clinical infection or required explantation in the long-term follow-up.

As reported by White et al. [15] in 2009, preoperative BMI $\geq$ 25 kg/m^2 does not seem to increase the risks for complications, especially infections, which is consistent with reported outcomes, where colonization is present but does not lead to infection or even device explantation. However, it should be noted that changes in the patient's BMI with chronic SNM might result in adverse events such as local pain [15].

Bacterial colonization of electrode extension leads mirrors the typical microbial skin flora. *Staphylococcus epidermidis*/*capitis*, *Corynebacterium* spp. and *Micrococcus luteus* are all part of normal skin flora and comprise 75% of the bacteria contaminating the electrode extension leads. *Peptostreptococcus* spp. and *Enterococcus faecalis* have been found predominantly in the gastrointestinal tract; apocrine skin glands can also harbour these species [22]. The combination of flucloxacillin and gentamicin, which has been known to mitigate characteristic bacterial skin environment, facilitates optimal therapeutic efficacy against pathogenic gram-positive and gram-negative bacteria. Despite bacterial colonization, which in some cases is normal within the body, there were no signs of infection.

To address most of the potential bacteria (Gram-positive), patients received flucloxacillin, because of its excellent bactericidal effect on *Staphylococcus*. The disadvantage of flucloxacillin is its lack of effect on Gram-negative bacteria. Gentamicin was chosen for its good intraoperative flushing of the transplant and wound. This therapeutic gap was effectively used in only 8% of the patients. This series shows the enhanced effectiveness of this combined antibiotic application at the critical time when the primary bacteria can potentially contaminate the implant, especially during the implantation of the impulse.

Different factors can have an impact on the treatment success of chronic SNM with regard to infection and explantation risk during prolonged SNM. Subcutaneous tunnelling of the extension lead is used effectively in other procedures such as the placement of peritoneal catheters or central nervous catheters [23,24], where the technique appears to form a 'bacterial barrier'. A possible explanation for the efficacy of subcutaneous tunnelling is the prolonged length of the tunnelling and the response of the immune system to 'foreign material' [25]. Another factor that might positively influence the reduction in clinically relevant infection rates is that the current study used a standard operating procedure of preoperative hygiene, shaving in the operating room and perioperative antibiotic prophylaxis using a sterile plastic bioskin film. The multi-layered skin closure and disinfection procedure might also have had a positive impact on infection rates. On the other hand, the patients' infrequent practice of wound re-dressing could have negatively influenced bacterial colonization through the exit site of the electrode extension lead. In the current study's prolonged stage 1 evaluation, we recommended that our patients changed their bandages with additional povidone-iodine every other day, if not daily.

While a limitation of this prospective study could be the relatively small number of patients investigated, we believe that the positive results attained prove the method and contribute to enhancing the SNM testing process, thus making it clinically pertinent. Although the criteria for inclusion in the study led to a heterogeneous patient group, the surgical procedure was identical for all. Therefore, this did not influence the investigated procedure of the prolonged stage 1 implantation.

Generally a stage 1 evaluation requires patient compliance with regard to the handling of the protruding electrode extension leads during the activities of daily living, especially during personal hygiene. Although none of the patients in the present study reported any major dissatisfaction in this regard, it could potentially reduce the number of patients considered for prolonged evaluation.

In conclusion, previous studies have shown that tined-lead outcomes are far superior to PNE. Studies have also shown

that SNM is an effective and minimally invasive treatment for a variety of neurologically related diseases. There are few studies in the literature evaluating SNM testing periods vs the risk of clinically relevant implant infection rates. The present study shows that SNM is an effective way to evaluate and treat patients with pelvic-related dysfunction. Prolonged testing has the potential to enhance treatment efficacy without explantation as a result of clinically relevant infection, despite the identification of biofilm-positive bacteria.

Although an exact time-frame for the evaluation period cannot be recommended based on our data, clinicians might consider prolonged testing under everyday conditions in certain circumstances. Patients with an increased infection risk from co-morbidities such as overweight/obesity and diabetes should be followed closely.

Conflict of Interest

Karl-Dietrich Sievert is a Consultant to Sponsor.

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Abbreviations: FI, faecal incontinence; OAB, overactive bladder syndrome; PNE, peripheral nerve evaluation; SNM, sacral neuromodulation.