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The Role of the Neuromodulation in Management of Chronic Pain

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What is Neuromodulation?

Neuromodulation is a field of science, medicine, and bioengineering that encompasses implantable and non-implantable technologies, electrical, chemical, and optical that improves life for humanity. Neuromodulation is technology that impacts upon the neural interface.

Neuromodulation

Electrical

Spinal Cord Stimulation

Chemical

Intrathecal Drug Delivery

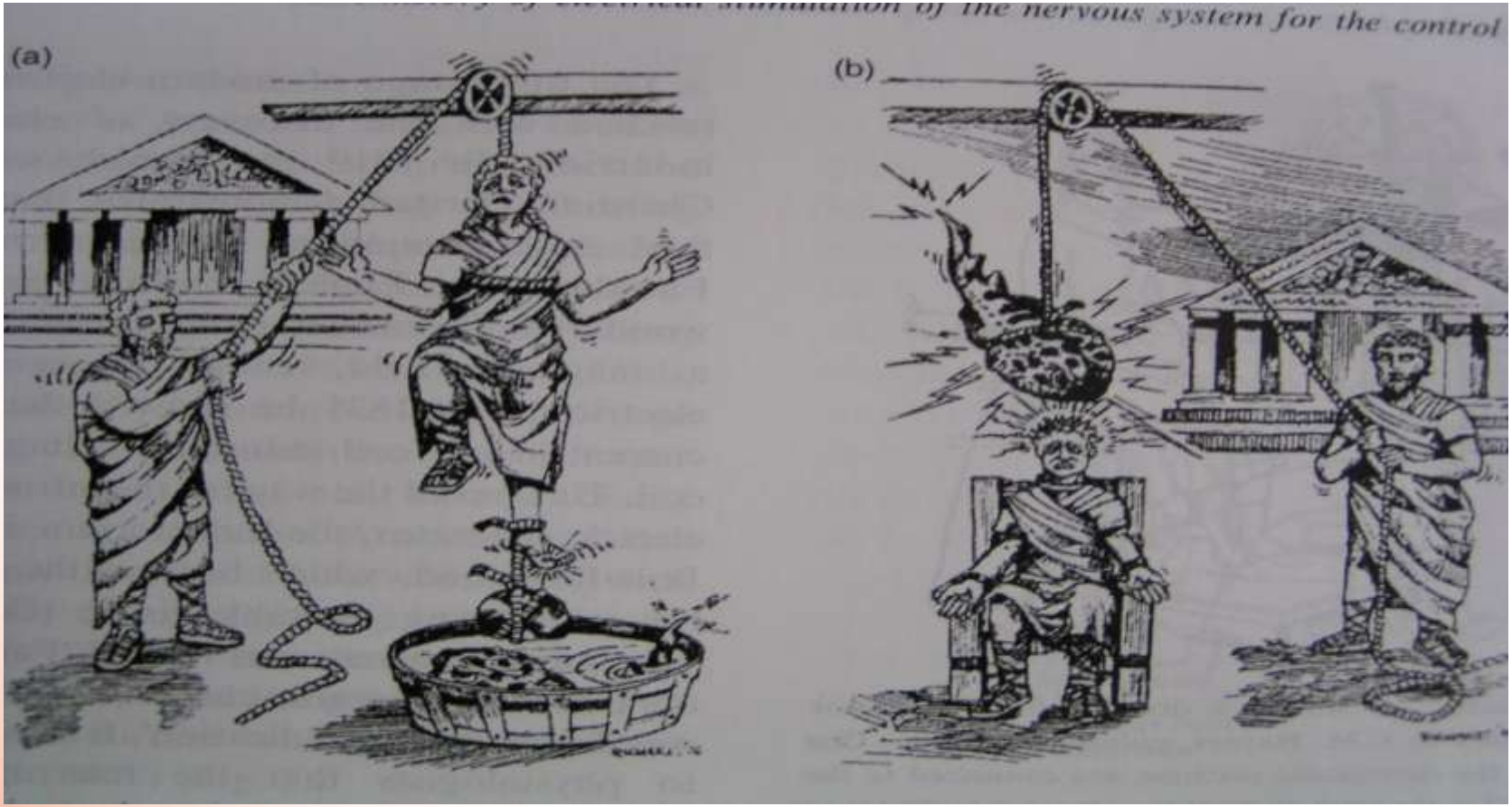
Early Applications of Electrical Stimulation for Pain

46 AD

Scribonius Largus describes the use of torpedos (aquatic animals capable of electric discharge) for medical applications.

"The live black torpedo when applied to the painful area relieves and permanently cures some chronic and intolerable headaches…carries off pain of arthrites…and eases other chronic pains of the body"

Early Applications of Electrical Stimulation for Pain



Gate Control Theory

Mezack,R., and Wall,P.,:Pain Mechanism: New theory.

Science, 150:971.1965

Neuromodulation was Born

1965

Sweet W

Peripheral Nerve Stimulation

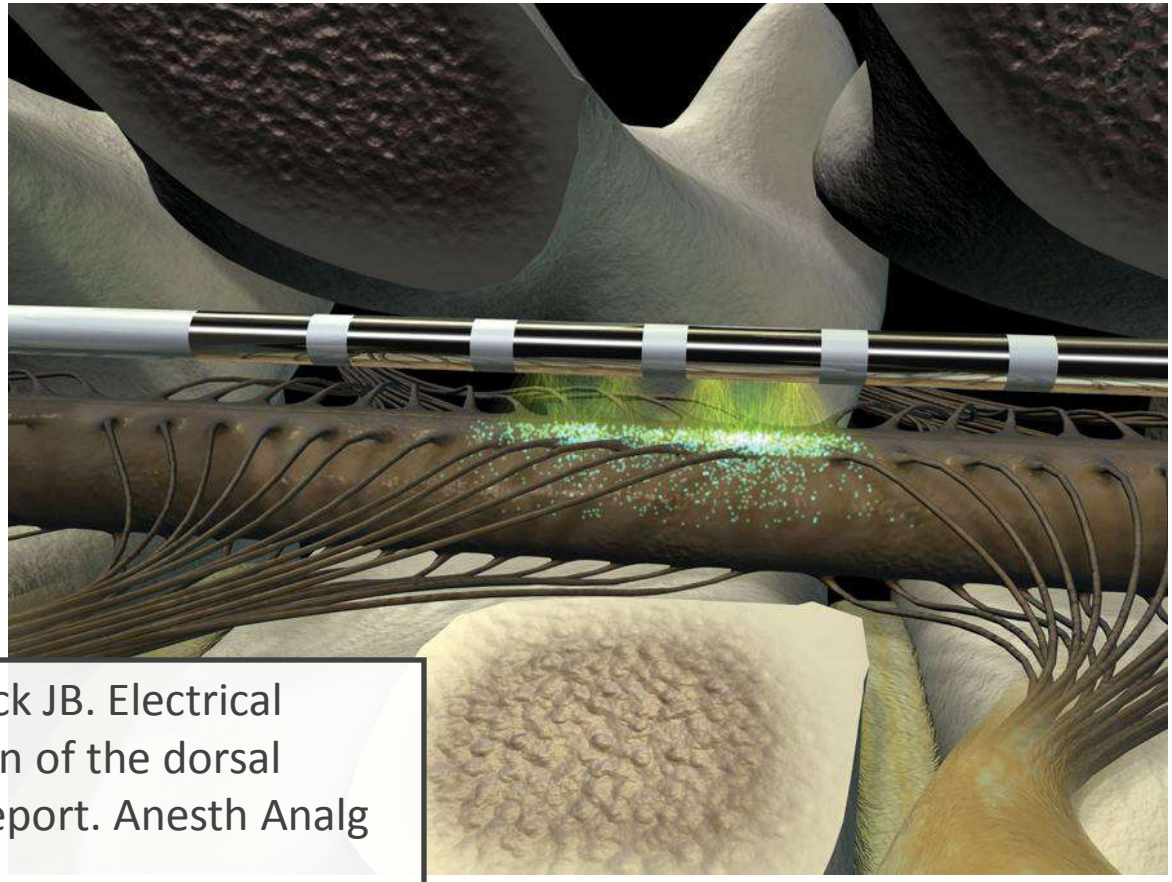
1967

Shealy C at al.

Spinal Cord Stimulation

First SCS Implant

C. Norman Shealy, MD, 1967
University Hospitals of Cleveland



Shealy CN, Mortimer JT, Reswick JB. Electrical inhibition of pain by stimulation of the dorsal columns. Preliminary clinical report. Anesth Analg (Cleve) 1967;46:489–91

Fastest Growing Medical Field

Neuromodulation is the fastest growing medical field today, both in numbers of procedures performed and the increase in indications for these procedures.

NEUROMODULATION INDICATIONS

APPROVED

DBS / CORTICAL
Essential Tremor
Parkinson's • Dystonia

COCHLEAR
Profound Deafness

VNS
Epilepsy • Depression

PNS / PNfS
Chronic Pain

SCS
Chronic Pain

SPINAL
Chronic Pain
Malignant Pain • Spasticity

SNS
Incontinence

FUTURE

OTHER THERAPIES
Hypertension • Renal Failure
Diabetes II • CHF • Paralysis
Fibromyalgia • RA • RLS
Eating Disorders

FUTURE

DBS / CORTICAL
OCD • Depression • Tinnitus • Epilepsy
Stroke • TBI • Pain • Coma • Paralysis
Tourette's

BRAIN
Epilepsy • Parkinson's • Alzheimer's

ARTIFICAL RETINA
Retinitis Pigmentosa

ONS
Headache

VNS
CHF • Obesity

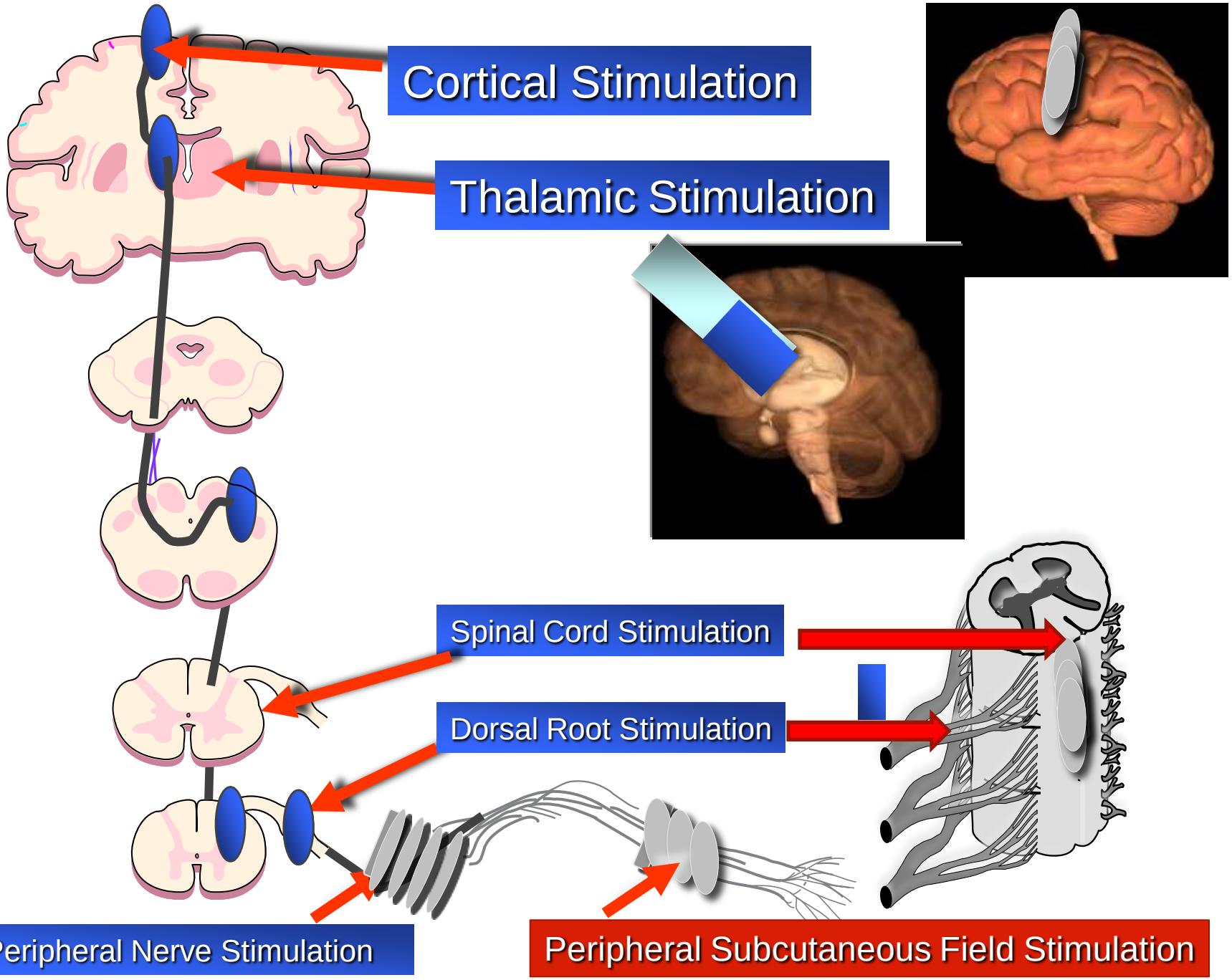
PULMONARY
Respiratory Support

SCS
Angina Pain • PVD Pain

SPINAL
ALS • Huntington's

GASTRIC
Obesity • Gastroparesis
Irritable Bowel Syndrome

SNS
Pelvic Pain • Sexual Disfunction


Cortical Stimulation
Thalamic Stimulation
Spinal Cord Stimulation
Dorsal Root Stimulation
Peripheral Nerve Stimulation
Peripheral Subcutaneous Field Stimulation

Good Evidence

Neuropathic pain in the limb eg following lumbar or cervical spine surgery (FBSS) and secondary to peripheral nerve damage

Complex regional pain syndrome

Refractory angina

Pain associated with peripheral vascular disease

Bladder disorders

Bowel disorders

Expanded Indications of SCS

Greater and lesser occipital neuralgia

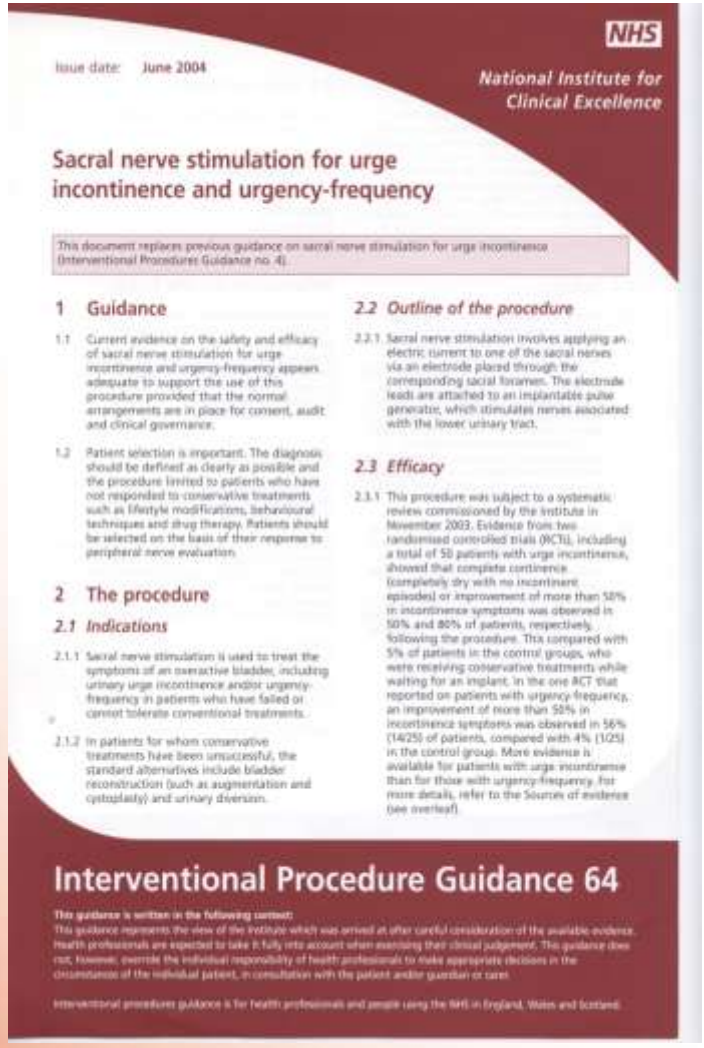
Headache

Abdominal disorders

- Pancreatitis
- Irritable bowel disorder

Pelvic pain

Nice Approval for Sacral Nerve Stimulation for Bowel and Bladder Dysfunction



NHS

Issue date: June 2004

National Institute for Clinical Excellence

Sacral nerve stimulation for urge incontinence and urgency-frequency

This document replaces previous guidance on sacral nerve stimulation for urge incontinence (Interventional Procedures Guidance no. 4).

1 Guidance

1.1 Current evidence on the safety and efficacy of sacral nerve stimulation for urge incontinence and urgency-frequency appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance.

1.2 Patient selection is important. The diagnosis should be defined as clearly as possible and the procedure limited to patients who have not responded to conservative treatments such as lifestyle modifications, behavioural techniques and drug therapy. Patients should be selected on the basis of their response to peripheral nerve evaluation.

2 The procedure

2.1 Indications

2.1.1 Sacral nerve stimulation is used to treat the symptoms of an overactive bladder, including urinary urge incontinence and/or urgency-frequency in patients who have failed or cannot tolerate conventional treatments.

2.1.2 In patients for whom conservative treatments have been unsuccessful, the standard alternatives include bladder reconstruction (such as augmentation and cystoplasty) and urinary diversion.

2.2 Outline of the procedure

2.2.1 Sacral nerve stimulation involves applying an electric current to one of the sacral nerves via an electrode placed through the corresponding sacral foramen. The electrode leads are attached to an implantable pulse generator, which stimulates nerves associated with the lower urinary tract.

2.3 Efficacy

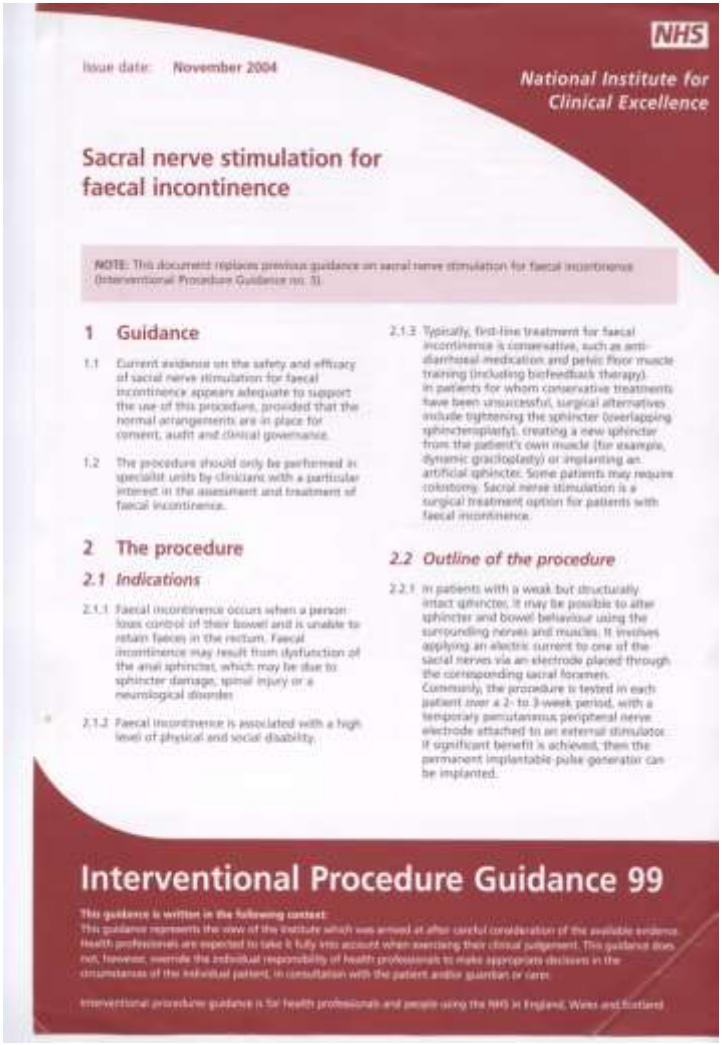
2.3.1 This procedure was subject to a systematic review commissioned by the Institute in November 2003. Evidence from two randomised controlled trials (RCTs), including a total of 50 patients with urge incontinence, showed that complete continence (completely dry with no incontinent episodes) or improvement of more than 50% in incontinence symptoms was observed in 50% and 80% of patients, respectively, following the procedure. This compared with 5% of patients in the control groups, who were receiving conservative treatments while waiting for an implant. In the one RCT that reported on patients with urgency-frequency, an improvement of more than 50% in incontinence symptoms was observed in 56% (14/25) of patients, compared with 4% (1/25) in the control group. More evidence is available for patients with urge incontinence than for those with urgency-frequency. For more details, refer to the Sources of evidence (see overleaf).

Interventional Procedure Guidance 64

This guidance is written in the following context:

This guidance represents the view of the Institute which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Interventional procedures guidance is for health professionals and people using the NHS in England, Wales and Scotland.



NHS

Issue date: November 2004

National Institute for Clinical Excellence

Sacral nerve stimulation for faecal incontinence

NOTE: This document replaces previous guidance on sacral nerve stimulation for faecal incontinence (Interventional Procedure Guidance no. 5).

1 Guidance

1.1 Current evidence on the safety and efficacy of sacral nerve stimulation for faecal incontinence appears adequate to support the use of this procedure, provided that the normal arrangements are in place for consent, audit and clinical governance.

1.2 The procedure should only be performed in specialist units by clinicians with a particular interest in the assessment and treatment of faecal incontinence.

2 The procedure

2.1 Indications

2.1.1 Faecal incontinence occurs when a person loses control of their bowel and is unable to retain faeces in the rectum. Faecal incontinence may result from dysfunction of the anal sphincter, which may be due to sphincter damage, spinal injury or a neurological disorder.

2.1.2 Faecal incontinence is associated with a high level of physical and social disability.

2.1.3 Typically, first-line treatment for faecal incontinence is conservative, such as anti-diarrhoeal medication and pelvic floor muscle training (including biofeedback therapy). In patients for whom conservative treatments have been unsuccessful, surgical alternatives include tightening the sphincter (overlapping sphincteroplasty), creating a new sphincter from the patient's own muscle (for example, dynamic graciloplasty) or implanting an artificial sphincter. Some patients may require colostomy. Sacral nerve stimulation is a surgical treatment option for patients with faecal incontinence.

2.2 Outline of the procedure

2.2.1 In patients with a weak but structurally intact sphincter, it may be possible to alter sphincter and bowel behaviour using the surrounding nerves and muscles. It involves applying an electric current to one of the sacral nerves via an electrode placed through the corresponding sacral foramen. Commonly, the procedure is tested in each patient over a 2- to 3-week period, with a temporary percutaneous peripheral nerve electrode attached to an external stimulator. If significant benefit is achieved, then the permanent implantable pulse generator can be implanted.

Interventional Procedure Guidance 99

This guidance is written in the following context:

This guidance represents the view of the Institute which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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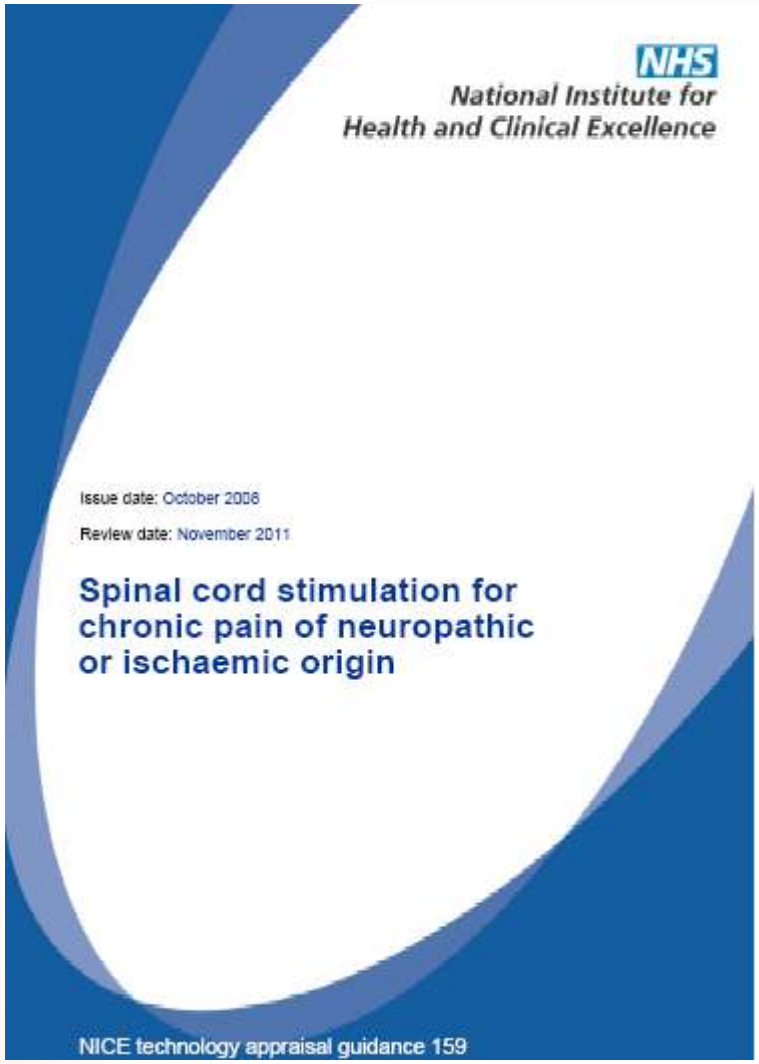
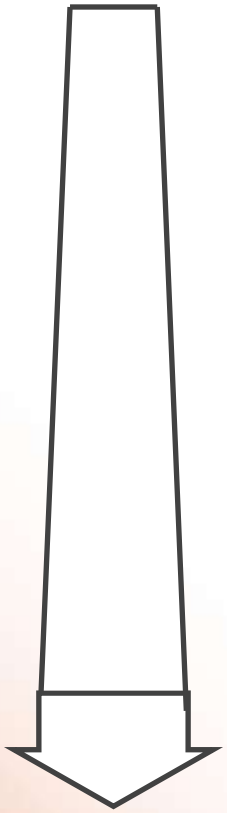
Nice Approval for Spinal Cord Stimulation for Neuropathic Pain



Nonmalignant Pain Treatment Algorithm



Over the counter drugs

Adjuvant analgesics

Physical Medicine and Rehabilitation Therapy

Cognitive-Behavioral Therapy

Therapeutic Nerve Blocks

Surgery Directed at Presumed Cause

Weak and Strong Opioids

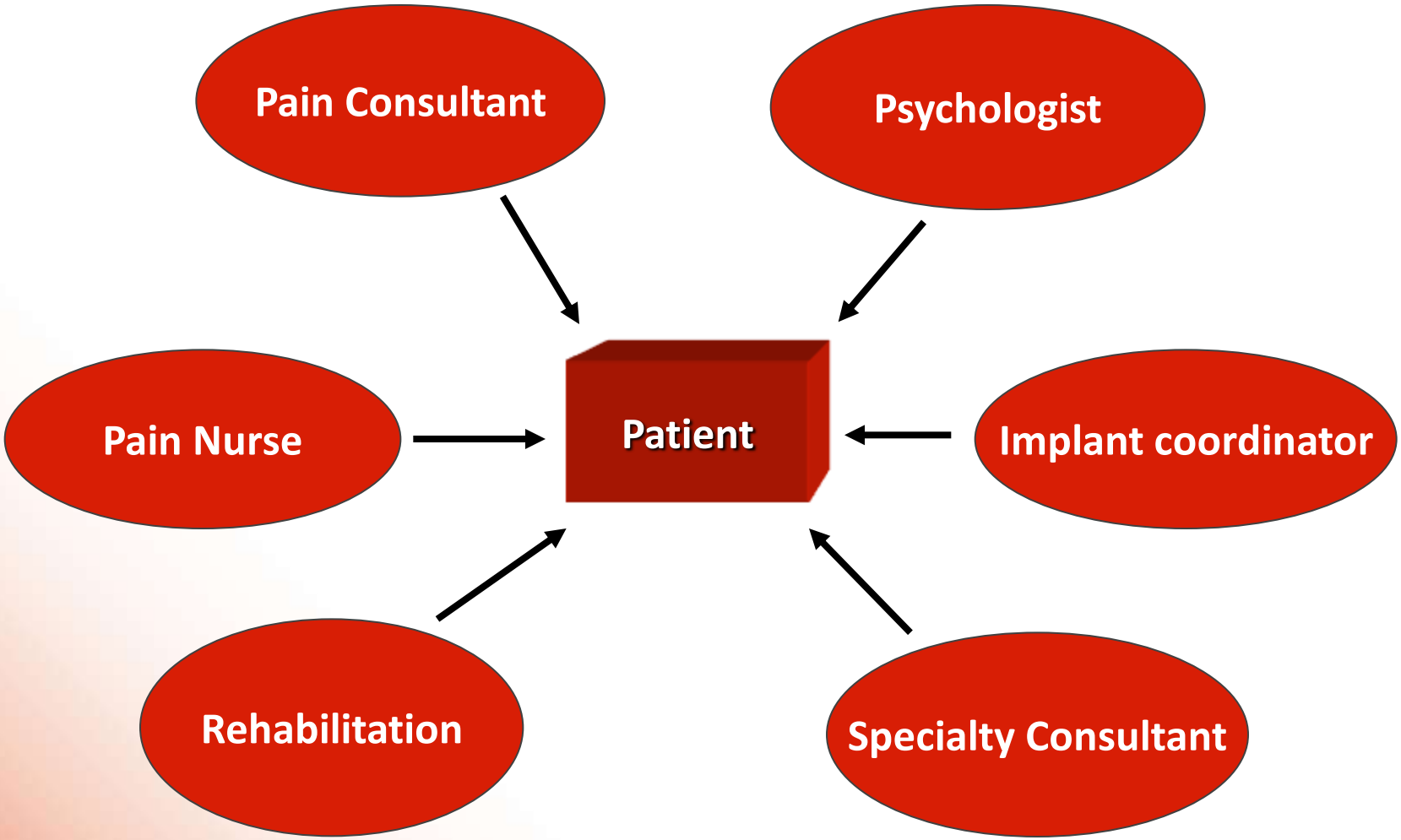
Spinal Cord Stimulation

Implantable Infusion Systems

Neurolytic Blocks

Neuroablative Therapies

Patient Selection Criteria/Team Approach



Implantation

Stages

– Trial

- Can use a trial/permanent lead which is left in for 7-14 days (sometimes longer) and then removed

- Can use a permanent lead which is surgically anchored and left in for a short trial after which the generator is implanted if the trial is successful or the lead is removed if the trial fails

Implantation

- **2 Stages**
  - Permanent
- If the trail is successful, the patient returns after a few weeks for implantation of the permanent lead/s and pulse generator

Lead Placement

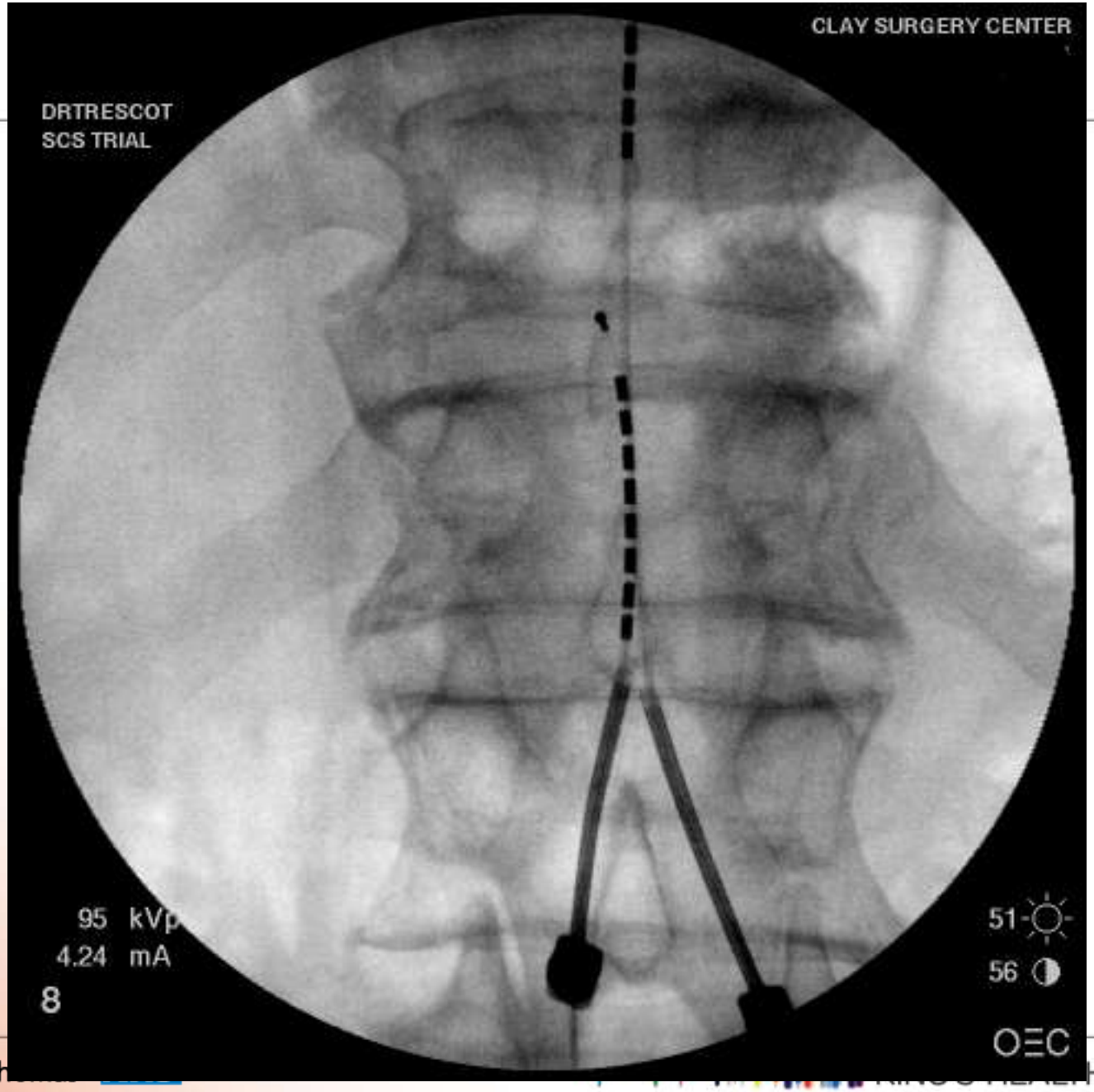
- Lateral decubitus or prone position
- Can use an ipsilateral or contralateral paramedian approach
- Enter the epidural space several levels below the intended level of lead placement to insure that all contacts of the lead will be in the epidural space

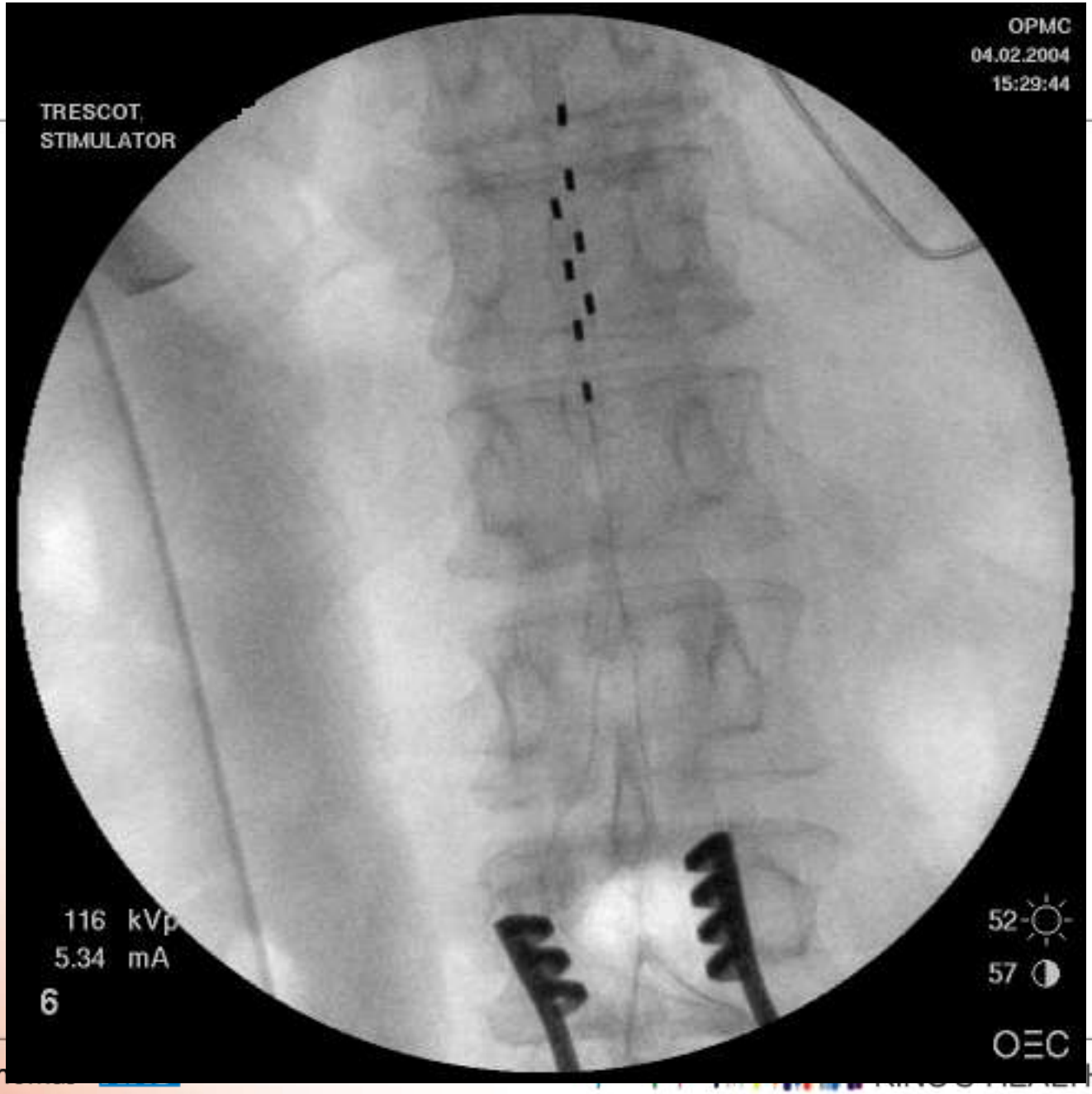
Lead Placement

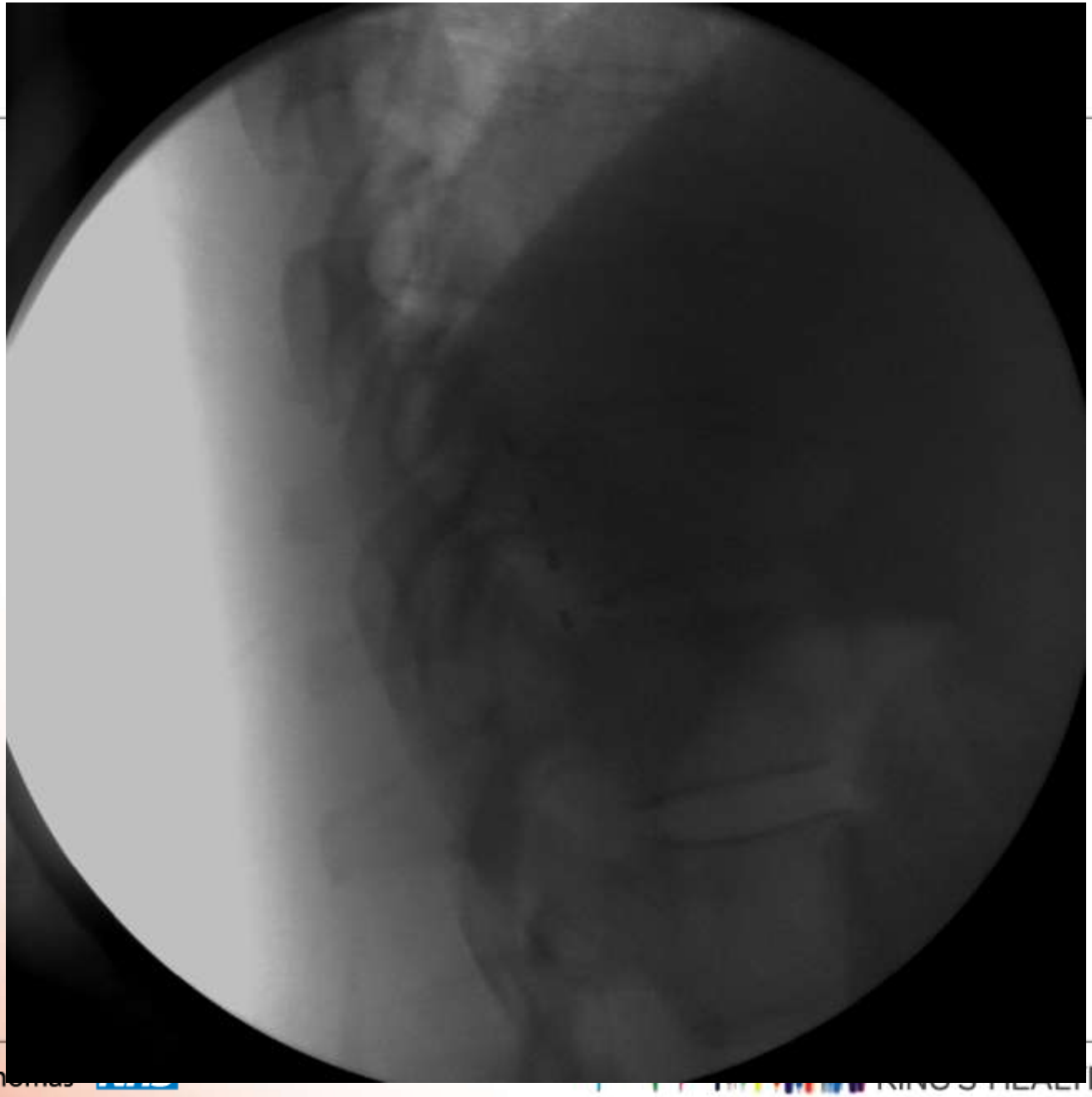
- **Once the epidural space is entered, insert the lead and slowly advance under continuous fluoroscopic guidance to the target level**
- **The lead can be guided to the target site by:**
  - Rotating the tip of the lead
  - Rotating the opening of the epidural needle
  - Manipulating the needle by pushing it laterally, medially, anteriorly or posteriorly

Target levels

- Cervical region: C_{2-5}
- Upper extremity: C_5-T_1
- Angina: C_{2-6}, T_{1-4}
- Thorax: T_{2-8}
- Abdomen: T_{5-9}
- Back: T_{8-9}
- Lower extremity: T_{10}-L_1


CLAY SURGERY CENTER
DRTRESCOT
SCS TRIAL
95 kVp
4.24 mA
8
51
56
OEC


OPMC
04.02.2004
15:29:44
TRESCOT
STIMULATOR
116 kVp
5.34 mA
6
52
57
OEC



Trial of Spinal Cord Stimulation

7 to 14 days

Percutaneous vs Tunnelled Trials

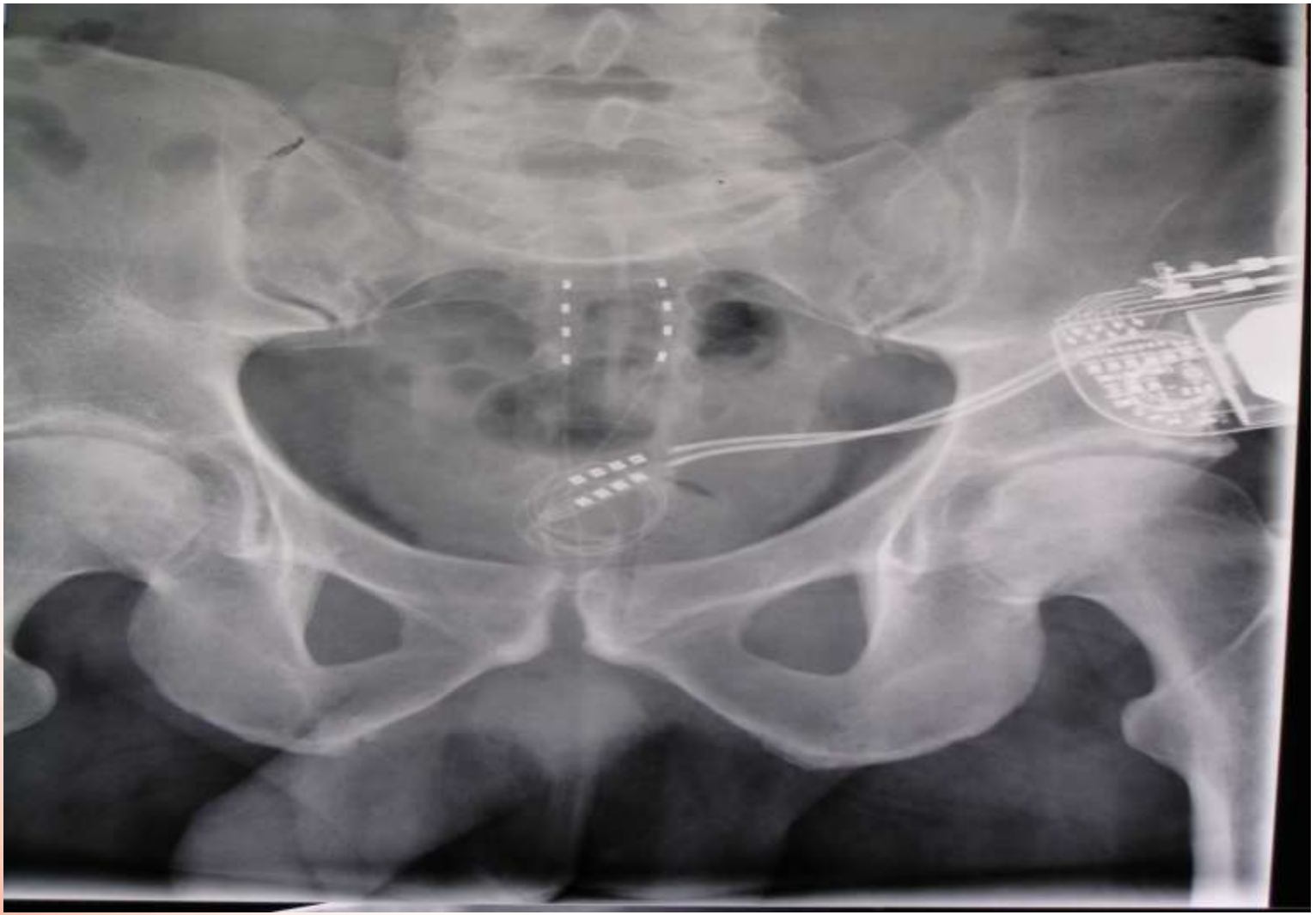
Outcome:

- **VAS**
- **Improvement in Function**
- **Reduce Medication**
- **Patient Satisfaction**

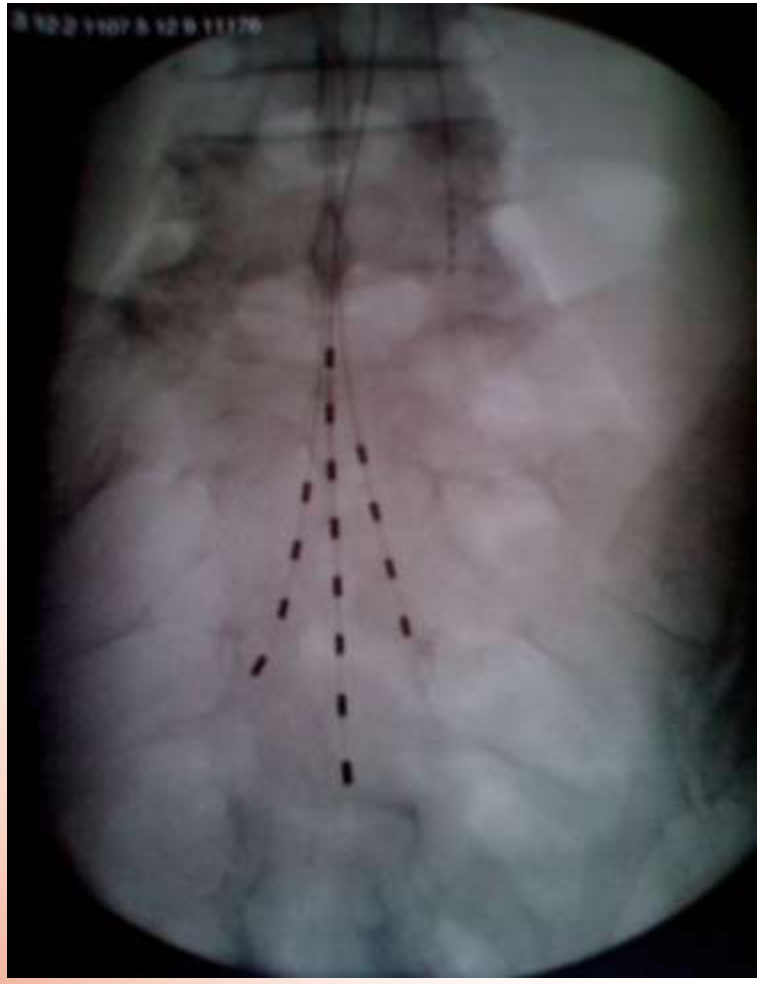
If there is significant improvement of the above the patient will be fully implanted

Failed Back Surgery Syndrome with Double Incontinence

Caudo-cephalad ‘Sacral Hiatus’



Trans-sacral Field Stimulation



Complications

- **Specific to SCS**
  - Hardware failure (11-45%)
- Generator failure
- Electrode fatigue fracture
  - Electrode migration/malposition
  - Extraneous influences
- Electromagnetic fields

Complications

- **General spinal surgical/interventional**
  - Spinal cord or nerve injury
  - CSF leak
  - Infection (3-5%)
  - Bleeding

Significant Progress in SCS Over the last few Years

Factors driving the progress:

- **Improving understanding of indications and treatment guidelines**
- **Evolving technology & techniques**
  - Dual lead systems
  - 8-contact leads
  - Wider parameter ranges
  - More complex programming
  - New lead configurations
  - High Frequency Stimulation

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THE ROLE OF HIGH FREQUENCY SCS IN THE TREATMENT OF CRPS.

PRELIMINARY DATA FROM A PROSPECTIVE, OPEN-LABEL STUDY

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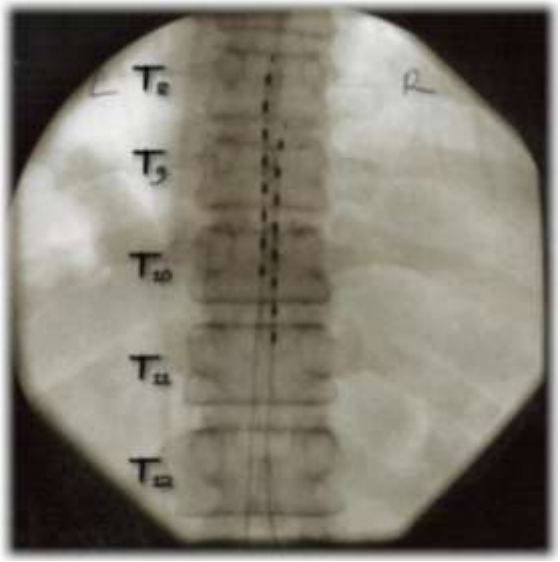
Technology and procedure

- Rechargeable IPG
- Dual octad lead placed between T8-T11
- Pulse width up to 40μs and rate of up to 10KHz

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Thank You