



Joint National Audit Project



Review of the literature and basis underlying the development of ANS/BSCN standards

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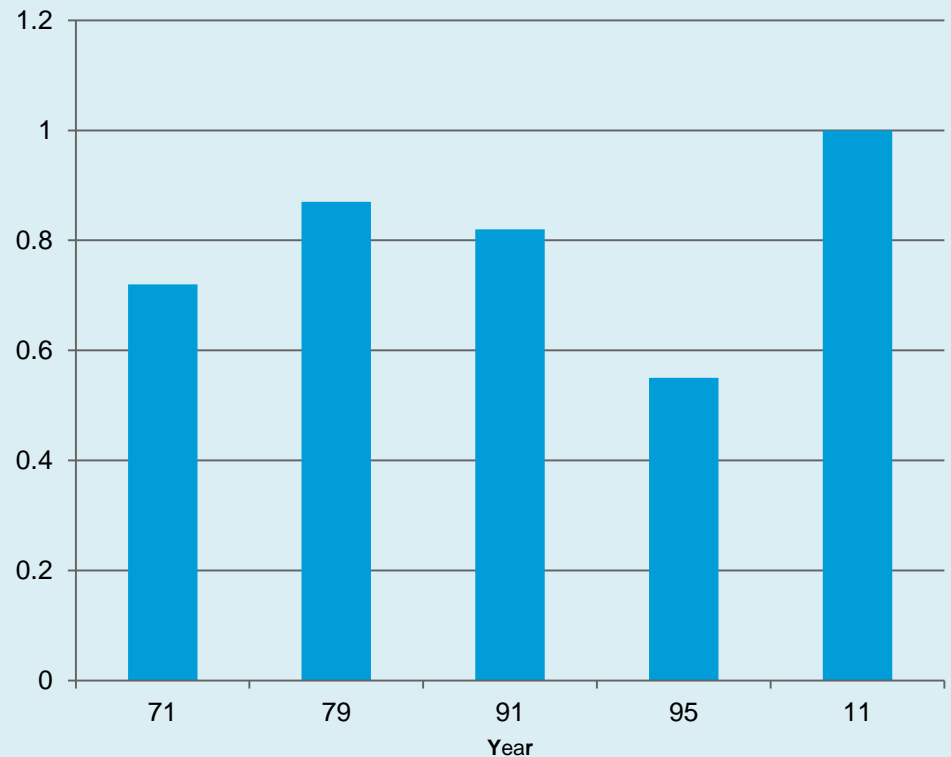
Southmead Hospital

Bristol

The role of IOM

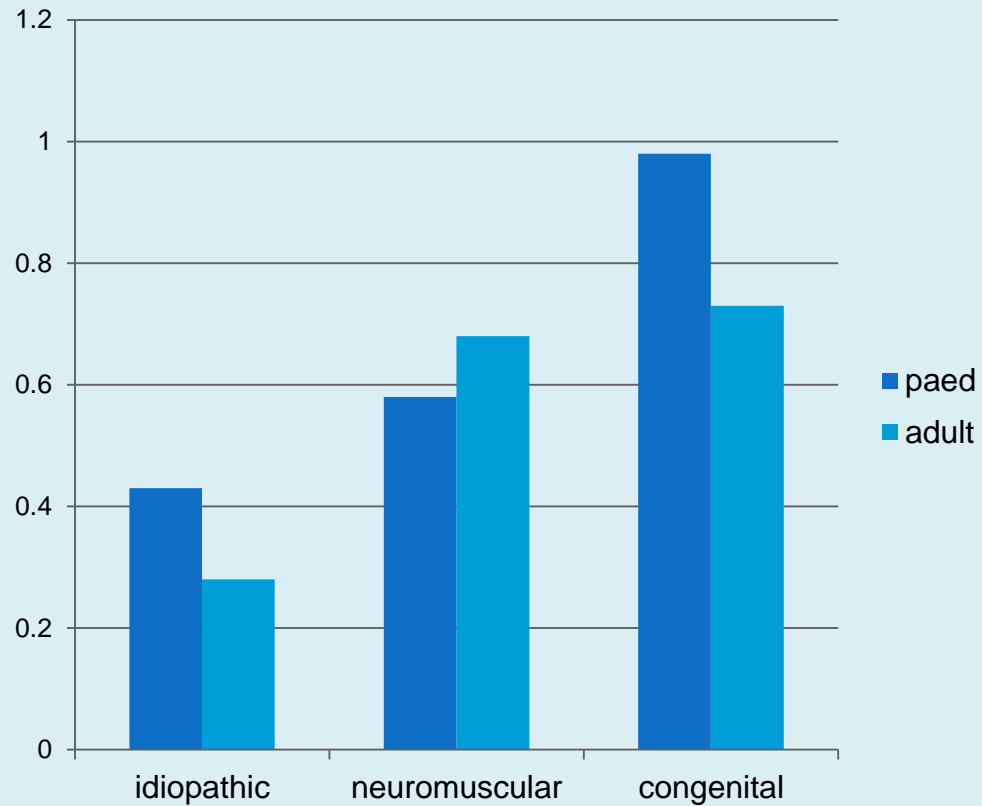
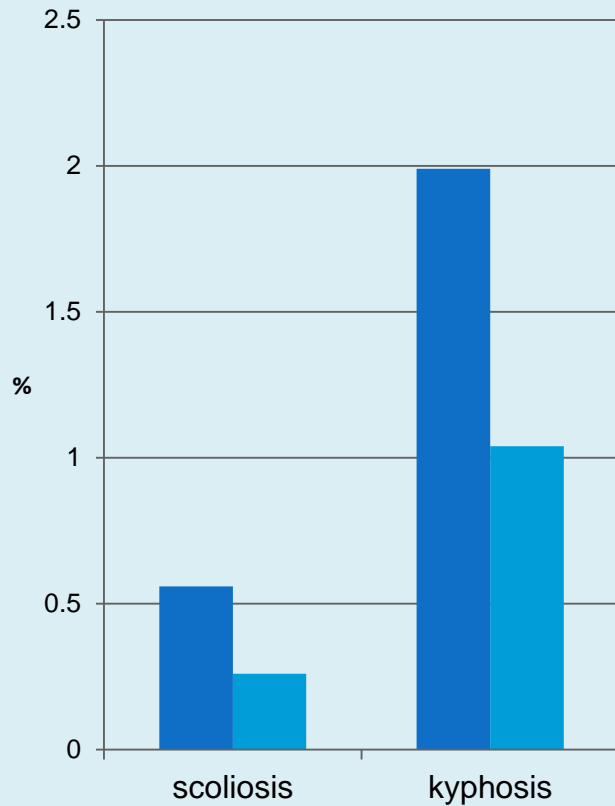
The practice of spinal deformity surgery has the risk of serious irreversible neurological damage.

- **MacEwan 1975**
 - 1965-1971
 - 7885 scoliosis
 - 0.72% neurological complication rate
- **SRS (unpublished) 1979**
 - 0.87%
- **SRS (unpublished) 1989-1991**
 - 0.82%
- **Coe 2006**
 - 2001-2003
 - 6,334 scoliosis out of 58,197 surgical cases
 - 0.49% neurological complication rate
- **Hamilton 2011**
 - 2004-2007
 - 26,625 scoliosis out of 108,419
 - 1.0% new neurological deficit



DEFORMITY

Rates of New Neurological Deficit Associated With Spine Surgery Based on 108,419 Procedures



The role of IOM

The intention of neurophysiological monitoring intraoperatively is to identify any change in function of vulnerable neurological structures, as soon as possible, to prevent permanent damage of the neurological structure.

What can the EPs actually do?

Surrogate endpoints and biomarkers are used when it is not ethical, possible or practical to use the clinical outcomes.

SEPs and TcMEPs monitor distinctly different pathways in the spinal cord.

SEPs reflect ascending sensory conduction in dorsal columns and posteriolateral tracts.

TcMEPs reflect descending anterior corticospinal motor conduction.

The 'wake-up' test

Functional monitoring of spinal cord activity during spinal surgery.

Vauzelle C, Stagnara P, Jouvinroux P.

Clin Orthop Relat Res 1973;**93**:173–8.

- Reversal of anaesthesia
- Requires patient cooperation
- Risk to patient
 - Moving on/falling off operating table
 - Tracheal extubation
- Only measures neurological (motor) function at time of testing

Early EP studies

A model for electrical monitoring of spinal cord function in scoliosis patients undergoing correction.

Nash CL, Brodkey JS, Croft TJ.

J Bone Joint Surg (Am) 1972;**54**:197–198.

Early EP studies

Spinal cord action potentials evoked by epidural stimulation of the spinal cord.

Kurokawa T.

Jpn J Electroenceph Electromyogr 1972;1:64-66.

Clinical utilization of the evoked spinal cord action potential in spine and spinal cord surgery.

Tamaki T, Yamane T.

Electroencephalogr Clin Neurophysiol 1975;39:196.

Early EP studies

Spinal cord monitoring during operative treatment of the spine.

Nash CL, Lorig RA, Schatzinger LA, Brown RH.

Clin Orthop Rel Res. 1977;**12**:100–105

Abstract

Twenty-six orthopaedic and 8 neurosurgical patients undergoing spine surgery had spinal cord monitoring before, during, and after operation using somatosensory, averaged cortical evoked responses.

Although no inherent risks were apparent in the technical application of this form of spinal cord monitoring, there are limitations that have yet to be evaluated.

Classically, somatosensory evoked responses have been considered a function of the posterior columns; however, the results of these studies indicate that more than the function of the dorsal columns alone can be evaluated with this technique.

In addition, much remains to be learned regarding the changes in signals noted and the corresponding clinical conditions. Techniques more sophisticated than visual evaluation of response patterns must be established and more sophisticated methods of analysis must be developed.

Despite the need for more knowledge of the nature of this system and the correlation between evoked responses and clinical conditions, the system has proved to be effective and to have great potential for improving spine and spinal cord surgery

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Early EP studies

Cortical evoked potential monitoring.

A system for intraoperative spinal cord monitoring.

Brown RH, Nash CL, Berilla JA, Amaddio MD

Spine 1984;**9**:256-61

300 orthopaedic surgical procedure

- 293 showed no changes and awoke with no deficit
- 4 cases showed changes of cortical evoked potentials that led to change in operative procedure
- 3 neurological deficits that were documented intraoperatively and confirmed postoperatively

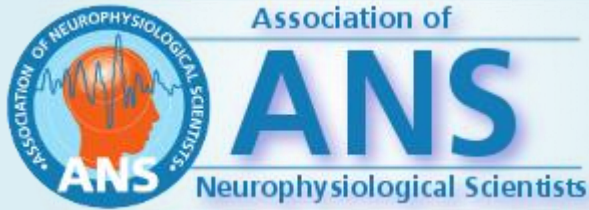


Somatosensory evoked potential spinal cord monitoring reduces neurologic deficits after scoliosis surgery: results of a large multicenter survey

Marc R. Nuwer ^{a,b,*}, Edgar G. Dawson ^c, Linda G. Carlson ^b, Linda E.A. Kanim ^c
and John E. Sherman ^{c,d}

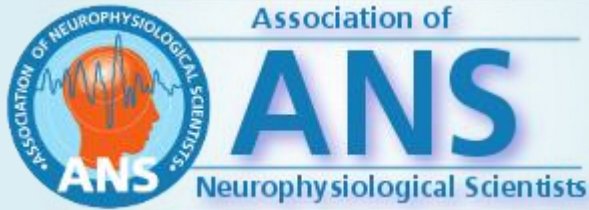
		SEP	
		Stable	Changes
Postoperative Neurology	No new deficit	True-negative 97.94%	False-positive 1.51%
	Changes	False-negative 0.13%	True-positive 0.42%

The Code of Practice for Spinal Cord Monitoring during
Scoliosis Surgery recommended by joint ABCN/BSS
Working Party ('90s)



Rationale:

- There are currently no up-to-date quality standards in the UK with respect to Intraoperative Monitoring (IOM) during scoliosis surgery.
- An advisory board was set up consisting of leading centres in the UK who perform IOM to help develop the following guidelines.
- This document seeks to recommend guidelines which are evidence based, relevant to current and future practice, auditable and in a comprehensive form that is achievable.



Rationale:

- This document is aimed to support people in their clinical practice and is not intended to exclude existing protocols and procedures in departments depending on local practice and resources.
- These guidelines are subject to change and will be regularly reviewed.
- IOM should be carried out by competent medical and physiological staff trained in this speciality.

ANS/BSCN Guidelines for Neurophysiological Recordings of the Spinal Cord during Corrective Spinal Deformity Surgery

Contributors:

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Institutions:

1. The Grey Walter Department of Clinical Neurophysiology, Frenchay Hospital, Bristol.
2. Royal National Orthopaedic Hospital, Stanmore, Middlesex.
3. Aberdeen Royal Infirmary, Aberdeen.
4. University Hospital of North Staffordshire (NHS) Trust, Stoke on Trent.

- General Principles
- Intraoperative SEPs
- Intraoperative MEPs

IOM using SEPs

Strength

- Broadly available and relatively affordable
- Allows continuous monitoring throughout the case
- Warning criteria firmly established
 - decreased amplitude >50% or increased latency >10% considered significant
- Excellent specificity (approaching 100%)
- May be used with NMB

Weakness

- Averaging of evoked responses leads to significant delays in signal change (may lag up to 16 mins behind TcMEP)
- Does not monitor corticospinal tract
 - Low sensitivity for motor deficit
 - May remain unchanged with anterior spinal artery injury

IOM using TcMEP

Strength

- Excellent sensitivity for motor deficit
(approaching 100%)
- Directly elevates *entire* motor axis
(cortex, corticospinal tract, nerve root, peripheral nerve, muscle)
- Allows immediate assessment of corticospinal integrity following high-risk manoeuvres.

Weakness

- Does not allow for continuous monitoring
- Precluded use of neuromuscular blockade and causes patient movement
- Highly sensitive to anaesthetic effects
- 'Relative' contraindications/risks
 - Epilepsy
 - Tongue/lip lacerations
 - Implanted medical devices
 - Skull defects

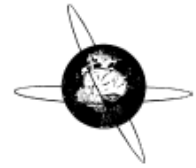


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Contents lists available at ScienceDirect

Clinical Neurophysiology

journal homepage: www.elsevier.com/locate/clinph



Guidelines

Intraoperative motor evoked potential monitoring – A position statement by the American Society of Neurophysiological Monitoring



D.B. MacDonald^{a,*}, S. Skinner^b, J. Shils^c, C. Yingling^d

“Relative TES contraindications include epilepsy; cortical lesions; skull defects; intracranial vascular clips, shunts, or electrodes; and pacemakers or other implanted bioelectric devices.

There is no proof that any of them increase TES complications and many patients with one or more of these conditions have undergone uneventful MEP monitoring.

One applies risk-benefit analysis; if the risk of motor deficit without MEP monitoring outweighs the uncertain additional risk of a relative contraindication, then it is justifiable to proceed with informed consent.”

Incidence of intraoperative seizures during motor evoked potential monitoring in a large cohort of patients undergoing different surgical procedures

Sedat Ulkatan, MD,¹ Ana Maria Jaramillo, MD,¹ Maria J. Téllez, MD,¹ Jinu Kim, MD,²
Vedran Deletis, MD, PhD,¹ and Kathleen Seidel, MD¹

J Neurosurg June 24, 2016

32/4179 monitored patient (0.8%) had seizure

– 3/1664 orthopaedic spine patients (0.18%) had seizure

“The low incidence of seizures induced by electrical brain stimulation, particularly short-train TES, demonstrates that MEP monitoring is a safe technique that should not be avoided due to the risk of inducing seizures.”

SPECIAL ARTICLE



Evidence-based guideline update: Intraoperative spinal monitoring with somatosensory and transcranial electrical motor evoked potentials

Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the American Clinical Neurophysiology Society *Neurology*® 2012;78:585-589

Published 2012

- Peer reviewed articles ~30yrs
- >600 identified
 - 40 / 608 articles met the criteria:
“being able to provide evidence to assess the role of IONM in the prediction of adverse outcomes.”

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- Only 12 showed class I (4) and class II (8) evidence
 - Cervical/spinal tumours (7/12)
 - Thoracic aortic aneurysm (3/12)
 - Spinal deformity (2/12)
- Minimum study size of >100 for orthopaedic procedures
 - SEP ankle-wrist stimulation with neck-scalp recording
 - TcMEP with muscle recording



Combined monitoring of motor and somatosensory evoked potentials in orthopaedic spinal surgery

Luciana Pelosi^{a,*}, J. Lamb^b, M. Grevitt^c, S.M.H. Mehdian^c, J.K. Webb^c, L.D. Blumhardt^d

^a*Department of Clinical Neurophysiology, University Hospital, Queens Medical Centre, Nottingham NG7 2UH, UK*

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^c*The Centre for Spinal Studies and Surgery, University Hospital, Queens Medical Centre, Nottingham NG7 2UH, UK*

^d*Division of Neurology, University Hospital, Queens Medical Centre, Nottingham NG7 2UH, UK*

Accepted 30 January 2002

126 operations in 97 patients

- 104 SEP/TcMEP
 - 18 SEP only
 - 2 TcMEP only
 - 2 no EP

108/124 (87%) monitored operations showed no significant EP changes and none developed new post-operative deficits.



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10 surgical events

- 4 SEP/TcMEP
 - 2/4 resolved with no deficit
 - 2/4 resolved with a new deficit
- 6 TcMEP
 - 4/6 MEPs resolved with no deficit
 - 1/6 MEPs resolved with a new deficit
 - 1/6 MEPs did not resolve (a sensory deficit)

6 systemic events

- 2 SEP/TcMEP
 - 2/2 resolved with no deficit
- 1 SEP
 - SEP resolved but patient had motor deficit
- 3 TcMEP
 - 2/3 did not resolve but no new deficit
 - 1/3 did not resolve with a deficit



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Accepted 30 January 2002

16 out of 126 monitored operations showed significant changes in one or both modalities

9/16 (56%) TcMEP only

- 16 patients (12.7%) *could have* had a deficit
- 6 patients (4.7%) awoke with a new deficit

Neurophysiological Detection of Impending Spinal Cord Injury During Scoliosis Surgery

By Daniel M. Schwartz, PhD, Joshua D. Auerbach, MD, John P. Dormans, MD, John Flynn, MD, J. Andrew Bowe, MD, Samuel Laufer, MD, Suken A. Shah, J. Richard Bowen, MD, Peter D. Pizzutillo, MD, Kristofer J. Jones, BA, and Denis S. Drummond, MD

Investigation performed at Children's Hospital of Philadelphia, Philadelphia, Pennsylvania; Alfred I. duPont Hospital for Children, Wilmington, Delaware; Robert Wood Johnson University Hospital, New Brunswick, New Jersey; and St. Christopher's Hospital for Children, Philadelphia, Pennsylvania

1121 patients from 4 paediatric centres

- All had SEP and TcMEP

1082 (96.5%) showed no signal change and awoke neurologically intact

38 (3.4%) had a signal change.

- 9/38 related to MAP (<65mmHg) and reversed with intervention
- 29/38 related to surgical events

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- 29/38 related to surgical events
 - 3/29 related to segmental vessel clamping (T12) and reversed
 - 26/29 related to surgical manoeuvre
 - 17/26 EPs reversed after surgical intervention
 - 9/26 had new neurological deficit
 - 7 purely motor (7/7 TcMEP changes v 3/7 SEP changes)
 - 3.3% (38/1121) *could have* had deficit
 - 0.8% (9/1121) had new (*transient*) neurological deficit

The prevention of neural complications in the surgical treatment of scoliosis: the role of the neurophysiological intraoperative monitoring

F. Pastorelli · M. Di Silvestre · R. Plasmati · R. Michelucci ·
T. Greggi · A. Morigi · M. R. Bacchin · S. Bonarelli ·
A. Cioni · F. Vommaro · N. Fini · F. Lolli · P. Parisini

172 patients (2005-2007)

- 106 SEP only
- 66 SEP/TcMEP

Historical control study

The prevention of neural complications in the surgical treatment of scoliosis: the role of the neurophysiological intraoperative monitoring

F. Pastorelli · M. Di Silvestre · R. Plasmati · R. Michelucci ·
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A. Cioni · F. Vommaro · N. Fini · F. Lolli · P. Parisini

- 106 SEP only
- 12 patient alerts
 - 10 reversed after intervention
 - 2 anaesthetic related
 - 8 surgical interventions
 - 2 awoke with neurological deficit
 - 1 permanent (vascular)
 - 1 transient (motor)
- 11.3% (12/106) *could have* had deficit
- 1.88% (2/106) had new deficit
- 66 SEP/TcMEP
- 7 patient alerts
 - 7 reversed after intervention
 - 3 SEP/TcMEP systemic/positional and reversed
 - 3 TcMEP only and reversed after surgical intervention
 - 1 SEP/TcMEP surgical intervention resolved
- 10.6% (7/66) *could have* had deficit
- 3% (2/66) had new (*transient*) deficit

Collecting the evidence

The randomised trial:

“...by universal consensus the ‘gold standard’, providing the strongest possible evidence of proof in medicine of the value of an intervention for changing outcome in a particular condition.”

JAMA users guide to the medical literature: essentials of evidence based clinical practice.

Guyat G. McGraw-Hill Medical 2008

Increased Risk of Postoperative Neurologic Deficit for Spinal Surgery Patients With Unobtainable Intraoperative Evoked Potential Data

Earl D. Thuet, BS, Anne M. Padberg, MS, Barry L. Raynor, BA, Keith H. Bridwell, MD, K. Daniel Riew, MD, Brett A. Taylor, MD, and Lawrence G. Lenke, MD

4,310 patients

- 59 patients (1.37%) had unobtainable EP data
 - although all had functional neural integrity
- In total 0.77% had post operative neurologic deficits
 - 3/59 (5.08%) in those with **no** data
 - 33/4310 (0.76%) in those with SEP/NMEP monitoring
 - **P=0.012**

“There was a far greater chance of surgically inducing neurologic injury in a patient without intraoperative monitoring data”

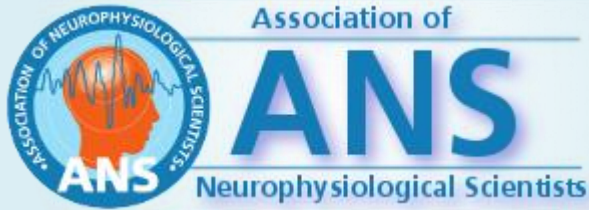
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“All studies were consistent in that all paraparesis, paraplegia, and quadriplegia events occurred in the IOM patients with EP changes, and non occurred in the IOM patients without EP changes.”



Summary

Combined IOM using SEP and Tc-MEP

- monitor distinctly different pathways in the spinal cord
- reduces the probability of observing false-negative events
- provides a continuous flow of independent, but also complementary, information

In combination, SEPs and TcMEPs have become a *standard of care* for spinal deformity surgery and are superior to single modality techniques.

Cost effectiveness of IOM

IOM machine

- £40K (1 case per wk for 10 years) *£80/case*

Staff

- Band 7 at £20/hr for 7 hours *£140/case*

Consumables

- 6 corkscrews/6twisted pairs/14 stick-on/2grounds *£50/case*

Total

£270/case

Cost effectiveness of IOM

40,000 people in UK living with SCI

- 1,200 per year (1 person every 8 hours)
 - 21% discharged to a nursing homes

Current cost of caring is £500m/yr

= £12,500 per person per year

Life time expectancy is 40 years

- **Cost £500,000 per person**

Cost effectiveness of IOM

Considering an incidence of new neurological deficit in spinal deformity surgery of 1%, the use of IOM is cost effective if £500K covers the cost of monitoring 100 cases

£0.5m covers >1,850 multimodal IOM cases!!