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Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 1: introduction and methodology

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Introduction to the Lumbar Fusion Guidelines

As scientific understanding of the pathophysiology of degenerative disease of the lumbar spine has increased, the possibilities for correcting the underlying problem and the resulting improvement in clinical function have expanded exponentially. Fueled by advances in material technology and surgical technique, treatment of greater numbers of individuals suffering from lumbar spinal disease has proliferated. Using data from the National Hospital Discharge Survey, Deyo and colleagues[4] described a 200% increase in the frequency of lumbar fusion procedures in the 1980s. Davis[3] observed that the age-adjusted rate of hospitalization for lumbar surgery and lumbar fusion increased greater than 33% and greater than 60%, respectively, from 1979 to 1990. Lumbar fusion has been described as a treatment of symptomatic degenerative disc disease, spinal stenosis, spondylolisthesis, and degenerative scoliosis. Lumbar fusion has been performed to treat acute and chronic low-back pain, radiculopathy, and spinal instability.

As practitioners have become caught up in the excitement of what can be accomplished, there are increasing questions regarding what should be done and how. These questions are being addressed in this current document, *Guidelines for the Performance of Fusion Procedures for Degenerative Disease of the Lumbar Spine.*

In January 2003, a group was formed at the request of the leadership of the CNS by the executive committee of the American Association of Neurological Surgeons/CNS Joint Section on Disorders of the Spine and Peripheral Nerves to perform an evidence-based review of the literature on lumbar fusion procedures for degenerative disease of the lumbar spine and to formulate treatment recommendations based on this review. In March 2003, this group was convened. Invitations were extended to approximately 12 orthopedic and neurosurgical spine surgeons active in the Joint Section or in the North American Spine Society to ensure participation of nonneurosurgical spine surgeons. The 50 recommendations that follow this introduction represent the product of the work of the group, with input from the Guidelines Committee of the American Association of Neurological Surgeons/CNS and the Clinical Guidelines Committee of North American Spine Society.

The first few papers in this series deal with the methodology of guideline formation and the assessment of outcomes following lumbar fusion. The next series of recommendations involve the diagnostic modalities helpful for the pre- and postoperative evaluation of patients considered candidates for or treated with lumbar fusion, followed by recommendations dealing with specific patient populations. Finally, several surgical adjuncts, including pedicle screws, intraoperative monitoring, and bone graft substitutes are discussed, and recommendations are made for their use.

Methodology

The development of practice parameters, guidelines, or recommendations is an onerous and time-consuming process. It consists of literature gathering (primarily through

Abbreviation used in this paper: CNS = Congress of Neurological Surgeons.

computerized literature searches), evaluation and classification of the quality of evidence provided by the literature, interpretation of this evidence to draw meaningful conclusions, and formulation of recommendations based on this process. The process is meant to be clear, and the reader is encouraged to read the entire document as opposed to the recommendations alone.

Guideline development within the specialty of neurosurgery has followed a rigorous process delineated early on in the advent of specialty-specific guidelines.[5] Following recommendations proposed by other specialty societies, the process used in neurosurgical guideline development divides the types of literature into classes depending on the scientific strength of the study design.[6] Because the publication of the ground-breaking and exemplary *Guidelines for the Management of Severe Head Injury*,[1,2] an effort has been made to adhere to these strict criteria for practice recommendations. The definitions of classes of evidence for therapeutic effectiveness are as follows: Class I, evidence from one or more well-designed, randomized controlled clinical trials, including overviews of such trials; Class II, evidence from one or more well-designed comparative clinical studies, such as nonrandomized cohort studies, case-control studies, and other comparable studies, including less well-designed randomized controlled trials; and Class III, evidence from case series, comparative studies with historical controls, case reports, and expert opinion as well as significantly flawed randomized controlled trials. For diagnostic tests, and clinical assessment, other study designs are used, and therefore the classification systems are slightly different, but still result in Classes I, II, and III evidence. This is reviewed in detail elsewhere.[6]

Class I evidence is used to support treatment recommendations of the strongest type, called practice standards, reflecting a high degree of clinical certainty. Class II evidence is used to support recommendations called guidelines, reflecting a moderate degree of clinical certainty. Other sources of information, including observational studies such as case series and expert opinion, as well as fatally flawed randomized controlled trials (Class III evidence), support practice options reflecting unclear clinical certainty.

On the surface, this appears to be a fairly straightforward task, but within the process the most difficult aspect is evaluating the quality of the evidence in each type. Disappointingly, studies in which evidence should be considered Class I or II because of study type have to be downgraded to a lower class of evidence due to methodological flaws that could cause false conclusions to be drawn from the evidence. This is discussed extensively within each topic, and all cited evidence is listed in outline form in the evidentiary tables, so as to ensure transparency of the development process.

The group culled through literally thousands of references to identify the most scientifically robust citations available concerning each individual topic. Not every reference identified is cited. In general, if high-quality (Class I or II) medical evidence was available on a particular topic, poorer-quality evidence was only briefly summarized and rarely included in the evidentiary tables. If no high-quality evidence existed, or if there was significant disagreement between similarly classified evidence sources, then the Class III and supporting medical evidence were discussed in greater detail. If multiple reports were available that provided similar information, a few were chosen as illustrative examples.

A consistent finding during the exploration of many of these topics was that many investigators reported studies in which the designs were unsophisticated. The use of invalid outcome measures, the lack of an appropriate power analysis, and the failure to identify distinct patient populations for study inhibited our ability to draw meaningful conclusions from many reports. Specific examples are provided in the text of each topic. Suggestions for future research are made at the conclusion of each paper. We, as spine surgeons, must improve the quality of our research practices to provide convincing evidence that the therapies we strongly believe in are safe, effective, and make economic sense.

During the development of these guidelines, the authors often found that their preconceived ideas regarding the proper treatment of patients with chronic low-back pain were founded on poor-quality or controversial medical evidence. Some recommendations have resulted in changes in the authors' practice patterns after every effort was made to classify the evidence and to interpret the results of the various studies in a scientifically rigorous fashion. Many recommendations are made at the lowest level, meaning that definitive evidence is lacking to support the recommendation but that evidence exists at some level. Some readers will undoubtedly disagree with one or more of our recommendations or with the level of a given recommendation. The justification for all of the recommendations is included in the scientific foundation portion and the summary section of each guideline. If the job has been done correctly, the reasoning behind the recommendation should be clear.

It is our hope, as well as that of the participating organizations, that these guidelines will help to elucidate the current knowledge on the topic of lumbar fusion and will stimulate the development of more rigorous scientific evidence justifying or refining—or, if appropriate, eliminating—aspects of this form of treatment.

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