

NORTH AMERICAN SPINE SOCIETY 2011 RESEARCH FUNDING APPLICATION

Research Grants

Young Investigator
Grants

Nontraditional
Nonsurgical
Treatment Grants

Clinical Traveling
Fellowships

Research Traveling
Fellowships

Important Dates:

Letter of Proposal
Deadline:
February 7, 2011

Grants Deadline:
(By Invitation Only)
May 2, 2011

Traveling Fellowships
Deadline:
May 2, 2011

 **NASS**
NORTH AMERICAN SPINE SOCIETY

The North American Spine Society (NASS) is a multidisciplinary medical organization with over 5,700 physician and affiliated healthcare members dedicated to fostering the highest quality, evidence-based, ethical spine care by promoting education, research and advocacy. NASS members include over 20 spine-related specialties including orthopedics, neurosurgery, physiatry, pain management, research and other disciplines, including allied health professionals. NASS strives to be a leading force in promoting and supporting spine research. Since 1989, NASS has funded more than \$2.2 million in multidisciplinary spine-related research. NASS relies on the generosity of its membership, nonmember donors and the spine industry* to provide funding for its research funds in support of the highest quality, peer-reviewed research.

NASS supports basic, clinical and translational science performed with integrity. The goal is to improve quality spine care for patients and understanding of underlying disorders. One way NASS achieves these goals is by funding grants and fellowships.

**NOTE: NASS retains full control of research award selection. Specific individuals or corporations do not have influence over the selection of recipients.*

TYPES OF FUNDING AVAILABLE

- **Research Grants.** General NASS research grants provide funding for promising research projects by qualified investigators in the field of spine. Funding amount and number of grants are at the discretion of the NASS Research Project Management Committee based upon merit of applications and amount of funding available each year. It is recommended that approved grant budgets not exceed \$50,000 per year.
- **Young Investigator Grants.** One to two Young Investigator Grants may be awarded each year. Principal investigators may be any age. MD applicants must be within five years of completion of training at the time of application; PhD applicants must be within five years of their post-doc training. Applicants may not have received previous grant funding from the NASS Research Project Management Committee. It is recommended that approved grant budgets not exceed \$50,000 per year.
- **Nontraditional, Nonsurgical Treatment Grants.** The Nontraditional, Nonsurgical Treatment Grant is the result of a donation to research as part of the settlement of a class action lawsuit unrelated to NASS. This grant supports research of disc-related and/or neuropathic back pain by nonsurgical techniques. These funds must be used for new, nontraditional methods of nonsurgical treatment of such back and neck pain and radiculopathy. If TNF-inhibitors other than etanercept are used in research and/or treatment funded, comparison studies using perispinal etanercept in at least as many research subjects or patients should be done. Funding amount and number of grants are at the discretion of the NASS Research Project Management Committee based upon merit of applications and amount of funding available each year. It is recommended that approved grant budgets not exceed \$50,000 per year.
- **Clinical Traveling Fellowship.** The Clinical Traveling Fellowship spans at least one month to be spent in three to five different medical centers studying spine techniques. The centers selected by the applicant should agree in writing to accept the applicant if he/she receives the Fellowship. The Fellowship primarily covers the costs of travel and housing, typically ranging from \$3,000-\$5,000.
- **Research Traveling Fellowship.** The Research Traveling Fellowship spans at least five months at one medical center (other than the facility at which the applicant currently practices). The center selected by the applicant should have appropriate research facilities and agree in writing to accept the applicant if he/she receives the Fellowship. The Fellowship primarily covers the costs of travel and housing and typically ranges from \$3,000-\$5,000. If funding for the actual research project is needed, please apply for one of the research grants.

GENERAL GUIDELINES

- Applicants do not need to be NASS members. Any qualified applicant in any specialty will be considered. International applicants are welcome to apply.
- Any spine-related proposal will be considered.
- NASS strongly encourages new investigators to apply.
- Any principal investigator or co-investigator that receives a research grant from NASS will not be eligible to apply for grant funding again until three years after the date of the previous award.
- Multiple grants will not be funded simultaneously to any principal investigator or co-investigator. The Letter of Proposal may be submitted in only one category; not multiple categories.
- There is no limit to the amount that may be requested for funding. See **Types of Funding Available** for recommendations.
- Funds are for work to be performed or works in progress, not works already completed.
- NASS does not support research for independent manufacturers, industry development or personal business financial gain. NASS will be sensitive to this issue.
- All correspondence will be sent to the principal investigator. It is the responsibility of the principal investigator to provide information to co-investigators.
- Grants are awarded for one to two years at the discretion of the Research Project Management Committee.
- Applicants are strongly encouraged to have mentors or other senior researchers review Letters of Proposal and any Invited Grant Application before submission to NASS.
- All projects are required to be completed within three years.
- All fellowship applicants and **invited** grant applicants are required to submit a conflict of interest disclosure through the NASS online disclosure website in accordance with NASS disclosure policy. See **Policies and Agreements**.
- Cost-sharing of projects is encouraged. Please list other funding institutions/organizations and amount requested and/or awarded. If cost-sharing does not apply, please state so.

SELECTION PROCESS

Letters of proposal for grants will be reviewed by the entire NASS Research Project Management Committee and scored in the same manner as that of invited grants (see below). Those proposal holders with a strong merit in significance, approach and feasibility will be invited to submit a full grant application within eight weeks of notification.

All invited grant applications and traveling fellowships are reviewed by the NASS Research Project Management Committee. Applications are rated on the basis of their scientific merit and include the following criteria:

- **Significance.** The extent, to which the project, if successfully carried out, will make an original and important contribution to biomedical and/or behavioral science in the spine community. Does this study address an important problem or scientific question? Does it address the significance of the topic, either health burden or biological importance?
- **Approach.** The extent to which the conceptual framework, design, methods and analyses are properly developed, well-integrated and appropriate to the aims of the project. Are the theories underlying the approach supported by valid science? Are the aims of the project clear and reasonable in the context of the project?
- **Feasibility.** The likelihood that the proposed work can be accomplished by the investigators, given their documented experience, expertise, etc. These criteria would consider the curriculum vitae of the investigators. Are the investigators appropriately trained and well-suited to carry out this work? Can the investigators deliver a result?

Scientific merit should always be the primary criterion for selection, but potential conflicts of interest will also be considered. The Research Project Management Committee will provide a brief, written critique of each invited application not approved for funding to the principal investigator. Applicants will not receive any feedback beyond the written critique; all scoring is confidential.

All applicants submitting a letter of proposal and/or invited application do so with the understanding that they will abide by the conditions, deadline policies and decisions of NASS. NASS reserves the right to change the format and/or amount of any awards at its sole discretion at any time, with or without notice. The number and amount of awards granted each year are at the discretion of the Research Project Management Committee, Research Council and the Board of Directors. NASS makes no guarantee that applicants will be awarded the grant requested or that applicants will receive the total amount of funds requested if approved.

INSTRUCTIONS FOR APPLICATION

Research Grants, Young Investigator Grants, Nontraditional Nonsurgical Treatment Grants: To apply for a grant, please submit a Letter of Proposal. Letters of Proposal should include the elements described in the **Letter of Proposal Guidelines** and be submitted to the NASS office by close of business **February 7, 2011**. **Letters of Proposal will be accepted by e-mail only.** Please e-mail to: Karen James, kjames@spine.org.

Research or Clinical Traveling Fellowship: To apply for a fellowship, please complete the appropriate application form and submit with a CD-ROM (CD-R or CD-RW, PC Format) containing any additional materials. All application materials (Word or PDF), any figures, tables, etc. must be part of the single Word or PDF document submitted. If a single file is not possible, please be sure to clearly identify all parts of the submission. *Applications submitted by fax or e-mail will NOT be accepted.* **Application and CD-ROM are to be submitted to the NASS office (not postmarked) by close of business May 2, 2011.** Please mail to:

Research Project Management Committee Chair
North American Spine Society
8320 St. Moritz Drive
Spring Grove, IL 60081

Questions?

Karen James, Assistant Manager of Research
Telephone: (630) 230-3691
E-mail: kjames@spine.org

DEADLINES

Deadline for letters of proposal: February 7, 2011

Invitations to submit full grant applications: March 14, 2011

All applications (invited grants and fellowships) must be received in the NASS Office: May 2, 2011

Letters to applicants confirming receipt of application: May 9, 2011

Notification to applicants of awards: August 22, 2011

Award payee information due: September 5, 2011

Award ceremony at Annual Meeting: Week of Nov. 1-5, 2010

Research commencement: January 1, 2012

AWARDS PRESENTATION

All awards will be officially presented at the NASS 26th Annual Meeting, November 1-5, 2011 in Chicago, Illinois. Each award recipient or a designated representative is expected to attend the Annual Meeting to accept the award (date TBD).

LETTER OF PROPOSAL GUIDELINES

A two to three page letter of proposal (Word or PDF) should be submitted by all grant applicants in 12 point font via e-mail to Karen James, kjames@spine.org. The Letters of Proposal should consist of potentially 9 parts with each section titled as the following:

- Proposal Title.**
- Type of Grant Being Applied for—Indicate Two Items.** Please indicate which type of grant is being applied for (select one): Research Grant, Young Investigator Grant or Nontraditional Nonsurgical Treatment Grant. Please also indicate if research is basic, clinical or translational (select one).
- Summary.** One to two sentence proposal overview.
- Rationale for Approaching the Sponsor.** Please indicate why NASS would be an appropriate funder for this proposal and how this research applies and benefits the spine field.
- Description of Problem/Background** (not more than 100 words) as it relates to the spine.
- Purpose, Hypothesis and Method of Research** (not more than 500 words) for the project. If applying for a second year of funding, please include a one page summary of all work completed in the first year of the project, including all preliminary work. The committee will not review applications for a second year of funding if this information is not included.
- Capabilities.** Indicate the identities, capabilities and credentials of authors as well as any participating institution. **Include contact information for applicant principal investigator.**
- Budget.** Budgets should include a specific request for funds and include permanent hard equipment, statistical analyses, consumable equipment, salaries to staff and other direct expenses. There is no limit to the amount applicants can request; however, most grants that are approved have budgets of no more than \$50,000/year. **The overhead or institutional costs should not exceed 10%-15% of the budget (Note: This is included in the budget amount).** Hard equipment purchases should not exceed \$5,000. The budget should not include salaries for the principal investigator or other investigators, although salaries for statisticians, lab technicians and other support personnel may be included. Budgets should not include costs for attendance and presentation at the NASS Annual Meeting. Grants may be awarded for one to two years at the discretion of the Research Project Management Committee. If budgets are for more than one year, please detail each year's budget separately and in total. Include listing of all other funding related to the project along with the amount and source.
- Closing Statement.** The closing statement should include any long-term research plans related to the study (ie, plans to apply for NIH grants, etc.)

POLICIES AND AGREEMENTS

Fellowship Applicants and Invited Grant Applicants

Only: In accordance with the NASS Disclosure Policy, it is required that all fellowship applicants and invited grant applicants (all investigators) complete the conflict of interest disclosure through the NASS online disclosure website. The online disclosure module is located at <http://disclosure.spine.org>. This online module adheres to the NASS disclosure policy which requires, among other things, specific dollar amounts for all relationships within the last 12 months. For more information about the NASS Disclosure Policy, please visit: <http://www.spine.org/Pages/PracticePolicy/EthicsProfConduct/Default.aspx>. If you are a NASS member, please use your NASS username and password. If you are not a NASS member, you will need to sign up as a new contact. At the end of the module, please e-mail a copy to the "Research Department" from the drop down menu or kjames@spine.org. Don't forget to e-mail yourself a copy.

All applicants selected to receive a grant or fellowship are required to submit an annual status report to the NASS Research Council. All research projects are required to be completed within three years; regardless if the project is a one year or two year project. All status reports are due July 31 of each year and should be submitted to: North American Spine Society via e-mail to Karen James, kjames@spine.org.

Upon completion of research, the applicant agrees to submit a final report as mandated by NASS format, which includes an abstract in hard and electronic copy to the NASS Research Department with a permissions authorization to publish in any NASS Research publications, website, etc. Formatting instructions can be obtained from the NASS Research Department. A podium presentation at a future NASS Annual Meeting will be required once the project is complete.

Citation

NASS must be cited as the source of funding in any publication, presentation or in any publicity resulting from the project or its results. NASS should be sent reprints of all papers and publications resulting from research supported by the grant.

Delinquent Research Reports

Investigators failing to submit an annual status report or final research findings will be noted as "nonresponsive" in any publication of NASS grants/funding, denied future funding and requested to return all funds distributed to them. This policy goes into effect one year past the due date of any delinquent report. Once submitted, eligibility is reinstated.

All Awards: Return of Funds

If the funded project does not take place, all monies awarded will be refunded to NASS. If it is terminated early, a partial refund with an accounting of the funds expended up to the termination date will be provided. At the conclusion of the completed project, any unused funds over \$50 will be refunded to NASS.

CLINICAL TRAVELING FELLOWSHIP

The Clinical Traveling Fellowship spans at least one month to be spent in three to five different medical centers studying spine techniques. The centers selected by the applicant should agree in writing to accept the applicant if he/she receives the Fellowship. The Fellowship primarily covers the costs of travel and housing.

To apply for a fellowship, please complete the application form and submit with a CD-ROM (CD-R or CD-RW, PC Format) containing any additional materials. **All application materials (Word or PDF), any figures, tables, etc. must be part of the single document submitted.** If a single file is not possible, please be sure to clearly identify all parts of the submission. **Applications submitted by fax or e-mail will NOT be accepted.** Application and CD-ROM are to be submitted to the NASS office (not postmarked) by close of business May 2, 2011. Please mail to:

Research Project Management Committee Chair
North American Spine Society
8320 St. Moritz Drive
Spring Grove, IL 60081

Questions?

Karen James, Assistant Manager of Research
Phone: (630) 230-3691
E-mail: kjames@spine.org

Applications should be page numbered at the bottom center of each page that is not a pre-printed NASS form, with the applicant's name on each page as a header in 12 pt. font. The application should be submitted in the following order:

- Completed Application Form. Please submit full name, academic degree(s), address, telephone, fax and e-mail.
- Narrative Description of Goals for the Fellowship
- Amount Requested With Expense Breakdown
- Curriculum Vitae
- Letters of Acceptance From Each Medical Center
- Three Letters of Recommendation
- NASS Online Disclosure Form (See Policies and Agreements)

Office Use Only—Clinical Traveling Fellowship Number: _____

Name _____

Address _____

City _____ State _____ Zip _____

Phone _____ Fax _____ E-mail _____

State your area of spinal interest: _____

(Continued on reverse side)

Please provide a narrative description of your goals for this Fellowship: (Attach additional pages as necessary).

Candidate's Agreement

If selected for an award, I shall present a report of my experience (including an accounting of funds) to the Research Council upon completion of my Fellowship for review at the Annual Meeting of the North American Spine Society (NASS).

If the funded Fellowship does not take place, all monies awarded will be refunded to NASS. If it is terminated early, a partial refund with an accounting of the funds expended up to the termination date will be provided. At the conclusion of the completed Fellowship, any unused funds over \$50 will be refunded to NASS. I have read and agree to all policies related to the NASS Traveling Fellowships.

Signature _____ Date _____

Printed Name _____

Office Use Only—Submission Date: _____

Action: Approved Not Approved

RESEARCH TRAVELING FELLOWSHIP

The Research Traveling Fellowship spans at least five months at one medical center (other than the facility at which the applicant currently practices). The center selected by the applicant should have appropriate research facilities and agree in writing to accept the applicant if he/she receives the Fellowship. The Fellowship primarily covers the costs of travel and housing; if funding is needed for the actual research, please apply for a research grant.

To apply for a fellowship, please complete the application form and submit with a CD-ROM (CD-R or CD-RW, PC Format) containing any additional materials. **All application materials (Word or PDF), any figures, tables, etc. must be part of the single document submitted.** If a single file is not possible, please be sure to clearly identify all parts of the submission. **Applications submitted by fax or e-mail will NOT be accepted.** Application and CD-ROM are to be submitted to the NASS office (not postmarked) by close of business May 2, 2011. Please mail to:

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- Completed Application Form. Please submit full name, academic degree(s), address, telephone, fax and e-mail.
- Narrative Description of the Research Project
- Amount Requested With Expense Breakdown
- Curriculum Vitae
- Letter of Acceptance From the Medical Center
- Three Letters of Recommendation
- NASS Online Disclosure Form (See Policies and Agreements)

Office Use Only—Research Traveling Fellowship Number: _____

Name _____

Address _____

City _____ State _____ Zip _____

Phone _____ Fax _____ E-mail _____

State your area of spinal interest: _____

(Continued on reverse side)

Please provide a narrative description of your research project and what you hope to accomplish during the Fellowship. (Attach additional pages as necessary).

Candidate's Agreement

If selected for an award, I shall present a report of my experience (including an accounting of funds) to the Research Council upon completion of my Fellowship for review at the Annual Meeting of the North American Spine Society (NASS).

If the funded Fellowship does not take place, all monies awarded will be refunded to NASS. If it is terminated early, a partial refund with an accounting of the funds expended up to the termination date will be provided. At the conclusion of the completed Fellowship, any unused funds over \$50 will be refunded to NASS. I have read and agree to all policies related to the NASS Traveling Fellowships.

Signature _____ Date _____

Printed Name _____

Office Use Only—Submission Date: _____

Action: Approved Not Approved

FUTURE DIRECTIONS FOR RESEARCH

The following list recommends future directions for spine research. It is derived from gaps identified in the spine literature during clinical guideline development.

Special Note to Researchers: Studies incorporating the concept and evaluation of value are encouraged to help further develop evidence in the spine field related to the relationship between cost and quality.

Studies evaluating treatment outcomes should utilize validated outcome measures and include results specific to each of the treatment methods implemented in the study for all subgroups studied.

Antibiotic Prophylaxis in Spine Surgery

Efficacy

Use of Antibiotic Prophylaxis vs. Patients Who Do Not Receive Prophylaxis

- Further study is needed on the use of collagen or other carriers for local antibiotic treatments.
- A case controlled study utilizing available national databases to determine the relative efficacy of antibiotic prophylaxis in single-level, instrumented cases.
- A series of randomized, controlled studies each dealing with a specific subpopulation defined by diagnosis and procedure.

Protocol

- Prospective, randomized, clinical trials to compare the efficacy of cephalosporins to aminoglycosides and other antibiotics.
- Prospective, randomized, clinical trials to compare different timing and dosage protocols, for example, single perioperative dose versus multiple dose protocols.
- Prospective, comparative drug studies to determine optimal antibiotic prophylaxis regimen.
- Prospective, comparative studies to determine optimal dosing regimens for antibiotic prophylaxis.
- A case controlled study utilizing available national databases to determine the relative efficacy of different antibiotic prophylactic protocols in single-level, uninstrumented cases.
- A case controlled study utilizing available national databases to determine the relative efficacy of different antibiotic prophylactic protocols in single-level, instrumented cases.
- Case controlled studies to evaluate rates of polymicrobial infection stratified by comorbidities to identify other high risk populations.
- Prospective, randomized studies to evaluate the effect of broad spectrum antibiotic coverage in reducing infection rates in various high risk populations treated with instrumented fusion.
- Prospective, randomized studies to evaluate the effect of broad spectrum antibiotic coverage in reducing infection rates in various high risk populations treated with instrumented fusion.

Redosing

- A case controlled study utilizing available national databases to determine the relative efficacy of redosing antibiotic prophylaxis in specific patient populations undergoing spine surgery.
- A series of randomized controlled studies evaluating dosing regimens. Each study could address a specific subpopulation defined by diagnosis, procedure and comorbidity.

Discontinuation

- Controlled studies comparing infection rates in spinal surgical patients who received antibiotics which were discontinued at 24 hours as compared with groups who received antibiotics for a longer period of time.

Wound Drains

- Controlled studies comparing infection rates in nonfusion and nonimplanted spinal surgical patients with drains and discontinuation at 24 hours as compared with longer duration prophylaxis.
- Controlled studies comparing infection rates in spinal surgical patients receiving spinal implants with drains and discontinuation at 24 hours as compared with longer duration prophylaxis.

Body Habitus

- Prospective, randomized clinical trials to evaluate the effect of antibiotic choice and altered dosing on infection rates in obese patients.

Comorbidities

- Prospective, randomized clinical trials to evaluate the effect of antibiotic choice and altered dosing on infection rates in potentially high risk patients.
- A case controlled study to help identify other potential comorbidities leading to higher infection rates in patients undergoing spine surgery.

Antithrombotic Therapies in Spine Surgery

Efficacy

- A randomized, controlled trial comparing mechanical prophylaxis alone (i.e. pneumatic compression boots or compression stockings) with combined LMWH and mechanical prophylaxis in high-risk patients to assess the respective incidence of DVT, PE, neurological deterioration secondary to epidural hematoma, postoperative bleeding and wound complications.
- A randomized, controlled trial comparing mechanical prophylaxis alone (i.e. pneumatic compression boots or compression stockings) with combined low-dose warfarin and mechanical prophylaxis in high-risk patients to assess the respective incidence of DVT, PE, neurological deterioration secondary to epidural hematoma, postoperative bleeding and wound complications.
- A prospective, uncontrolled, prognostic, multicenter study of a high number of patients undergoing a wide variety of spine surgeries to quantify the relative risk of a number of suspected predisposing factors for VTE that include, but

not be limited to, length of surgery, number of levels fused, underlying diagnosis, traumatic injury, paralysis and SCI. In addition, the relative risks of postoperative neurological deterioration from epidural hematoma, bleeding, wound complications, and transfusion requirements should be scrupulously defined for each subgroup.

Chemoprophylaxis

- A randomized, controlled trial of LMWH vs. heparin as a bridge therapy for patients on long term warfarin prophylaxis for cardiac or other vascular conditions.
- A comparative study identifying the risks of perioperative bleeding complications in spinal surgery patients with clopidogrel-coated stents compared with those taking ASA and controls.
- A comparative study investigating the rate of bleeding complications in patients discontinuing clopidogrel ten days, seven days and one day prior to elective spinal surgery.
- A prospective study investigating optimum duration of postoperative prophylaxis comparing three groups of spine surgery patients treated with LMWH, ASA or clopidogrel for one week and another three groups of patients treated with LMWH, ASA or clopidogrel for four weeks.
- A comparative study investigating the incidence of bleeding complications in spinal patients receiving LMWH immediately postoperatively with another group of patients receiving LMWH three days postoperatively.

Wound Complications

- Controlled studies documenting rates of wound complications in spinal surgical patients who received specific chemoprophylaxis protocols. Data recorded for each patient should include type of procedure as well as specific chemoprophylaxis protocol (chemoprophylaxis agent, dosage, timing and duration).

Degenerative Lumbar Spondylolisthesis

Natural History

- Prospective study of untreated patients, all with degenerative lumbar spondylolisthesis without neurologic compromise to provide Level I evidence regarding the natural history of the disease. This study could include stratification as to the type of spondylolisthesis and evaluate progression of radiographic severity and clinical severity over time.
- Any systematic study of patients with untreated spondylolisthesis who presented with varying degrees of neurologic deficit to provide evidence regarding the natural history of the disease in this patient population. For example, defining and following a group of patients with lumbar spondylolisthesis and sensory deficits as compared with those who present with motor deficits that have not been treated would yield Level I evidence.

History and Physical Exam

- A high quality, prospective study identifying specific aspects of the history and physical examination

and characterizing the subgroups of patients with degenerative spondylolisthesis. Ideally the study would enroll a large number of patients, screen for symptomatic and asymptomatic degenerative lumbar spondylolisthesis, and have greater than 80% follow-up. Subgroups for evaluation could include patients with or without instability, radiculopathy, neurogenic intermittent claudication and back pain.

Diagnostic Tests

- A prospective, appropriately powered study assessing the utility of supine (gold standard), standing and dynamic flexion-extension lateral radiographs in the evaluation of patients with degenerative spondylolisthesis. NOTE: These studies should assess a set of diagnostic criteria established a priori.
- A prospective, appropriately powered study assessing the utility of supine recumbent (gold standard), axial loaded and positional MRI in the detection and evaluation of stenosis via analysis of the dural sac area in patients with degenerative spondylolisthesis. NOTE: These studies should assess a set of diagnostic criteria established a priori.

Outcome Measures

- Further studies are needed to validate additional outcome measures (Stenosis Bothersome Index, LBP Bothersome Index, Oxford Claudication Score, Shuttle Walking Test, JOA and calculated Recovery Rate) for the treatment of degenerative lumbar spondylolisthesis. Currently, the best outcome measure for degenerative spondylolisthesis with symptoms of spinal stenosis is the ZCQ/SSS as a disease-specific outcome tool. General health outcome tools that are appropriate for degenerative lumbar spondylolisthesis are the SF-36 and ODI.
- Degenerative lumbar spondylolisthesis with back pain alone needs to be defined as a stand-alone clinical entity by outcomes research. The use of these outcome measures in this subgroup of patients needs to be studied.

Medical/Interventional Treatment

- The SPORT study demonstrated the intrinsic difficulties in conducting RCTs comparing surgical to medical/interventional treatment in the North American patient population. It is unlikely that higher quality data are achievable for the comparison of surgical and medical/interventional treatment. Future studies are needed to assess the effects of medical, noninvasive interventions for degenerative lumbar spondylolisthesis. These studies should include an untreated control group when ethically possible and should include results specific to each of the medical/interventional treatment methods implemented, presenting results stratified by patient symptomatology (e.g., axial back pain only, combination of axial back pain and radiculopathy).
- A randomized controlled study comparing the benefits of physical therapy with directional preference versus nonpreferential therapy for the treatment of degenerative lumbar spondylolisthesis.

Surgical Treatment

- Independent randomized controlled trials to validate what appears to be an effective and minimally invasive means (interspinous spacers) of decompressing the spinal canal in patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis.
- A high quality randomized controlled trial to provide meaningful information about the clinical benefits of achieving a solid fusion in patients treated with instrumented and noninstrumented fusion for symptomatic spinal stenosis and degenerative lumbar spondylolisthesis. This study should utilize validated, functional, disease-specific outcome measures with long-term follow-up of four years or more.
- A high quality RCT comparing decompression with instrumented posterolateral fusion to decompression with 360° (circumferential) instrumented fusion.
- Future long-term studies of the effects of surgical interventions for patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis are needed and should include an untreated control group, when ethically feasible. Continued follow-up of patients already enrolled in ongoing randomized controlled trials or prospective comparative studies will yield higher quality data regarding the relative efficacy of surgery compared to medical/interventional treatments.
- Future long-term outcome studies are necessary to compare different surgical techniques for the treatment of patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis.

Degenerative Lumbar Spinal Stenosis

Natural History

- A prospective study of untreated patients, all with lumbar stenosis of a moderate degree, would provide Level I evidence regarding the natural history of the disease. This study could include stratification as to type of stenosis (i.e., central vs. subarticular vs. foraminal), and evaluate progression of radiographic severity and clinical severity over time.
- Any systematic study of patients with untreated severe stenosis would provide evidence regarding the natural history of the disease in this patient population. For example, defining and following a group of patients with severe lumbar stenosis that has not been treated would yield Level I evidence.

History and Physical Findings

- A sufficiently powered observational study of the predictive value of historical and physical findings in patients with the diagnosis of lumbar spinal stenosis is proposed. The study should utilize validated outcome instruments, such as the Zurich Claudication Questionnaire (ZCQ) and the VAS for back and leg pain, and CT myelography or MRI as the gold standard.

Diagnostic Tests

- Develop reliable and reproducible criteria for the diagnosis by cross-sectional imaging of central, subarticular recess and foraminal stenosis.
- Repeat interobserver and intraobserver variability studies with MRI and CT myelography using dural sac area as a measure of central canal stenosis.
- Evaluate the significance of lateral recess and neuroforaminal size, effacement of perineural fat, nerve root sleeve anatomy and nerve root or ganglion displacement and compression with respect to symptomatic radiculopathy and the outcome with surgical decompression.
- A prospective study is proposed evaluating the significance of additional findings on axial loaded cross-sectional imaging on patient prognosis and surgical decompression in patients with neurogenic intermittent claudication and radiculopathy.

Outcome Measures

- Further studies are needed to validate additional outcome measures for the treatment of lumbar spinal stenosis. Currently, the best and most specific outcome measure for spinal stenosis appears to be the Zurich Claudication Questionnaire (Swiss Spinal Stenosis Questionnaire). In future studies of specific outcome measures for the treatment of lumbar spinal stenosis, this questionnaire could be considered to be a potential gold standard.

Medical/Interventional Treatment

- The role of routine pharmacological treatment including NSAIDs, muscle relaxants and analgesics, used extensively in the treatment of spinal stenosis as well as other back conditions, needs to be investigated in patients with spinal stenosis using untreated control groups with spinal stenosis.
- A large, double-masked, randomized controlled trial with a long-term observation period to examine the potential benefits of intramuscular calcitonin for the treatment of lumbar stenosis.
- An appropriately powered, randomized controlled trial comparing physical therapy to the natural history of lumbar spinal stenosis using standardized techniques and validated outcome measures.
- A controlled trial comparing manipulation to natural history of lumbar spinal stenosis using standardized techniques and validated outcome measures.
- Use of validated outcome measures to compare manipulation to other medical/interventional treatments for spinal stenosis, and assessment of long-term effectiveness and cost effectiveness.
- A large double-masked, randomized, controlled clinical trial with at least one-year follow-up in patients with unilateral leg pain from lumbar spinal stenosis treated by fluoroscopically-guided contrast-enhanced transforaminal epidural steroid injections in which the control group receives saline placebo injections.

- A large double-masked, randomized, controlled clinical trial with at least two-year follow-up in patients with neurogenic claudication from lumbar spinal stenosis treated by fluoroscopically-guided interlaminar or caudal epidural steroid injections in which the control group receives saline placebo injections.
- A randomized, controlled trial comparing the use of individual ancillary treatments to a control, preferably masked, in patients with lumbar spinal stenosis.
- An appropriately powered study containing three groups with symptomatic lumbar spinal stenosis comparing soft bracing, rigid bracing and untreated controls (no bracing). Outcome measures could include the ZCQ, VAS, walking distance and a validated, health-related quality of life measure such as the SF-36 or ODI.
- Future long-term studies of the effects of medical, noninvasive interventions for lumbar spinal stenosis are needed and should include an untreated control group, when ethically feasible. These studies should include results specific to each of the medical/interventional treatment methods utilized.

Surgical Treatment

- A large, multicenter, three-arm, randomized, controlled trial using a well-defined group of patients with moderate clinically symptomatic stenosis, comparing lumbar decompression to a well-defined medical/interventional treatment program and a natural history group of untreated patients.
- A large, multicenter, three-arm, randomized, controlled trial using a well-defined group of patients with moderate stenosis, comparing the use of interspinous spacers to a microlaminotomy decompression and a well-defined medical/interventional treatment program.
- A multicenter, randomized, controlled trial with sufficient power and appropriate validated outcome tools to determine the effectiveness of lumbar decompression as compared to medical/interventional management for moderate to severe lumbar stenosis. This study could include stratification of patients based on demographics and comorbidities.
- A large, multicenter, three-arm, randomized, controlled trial using a well-defined group of patients with mild to moderate clinically symptomatic stenosis, comparing the use of interspinous spacers to a microlaminotomy decompression and a well-defined medical/interventional treatment program.
- A randomized, controlled trial of sufficient power is proposed with validated outcome instruments and long-term follow-up evaluating the results of decompression, decompression with fusion and decompression with fusion and instrumentation.

Cervical Radiculopathy from Degenerative Disorders

Natural History

- A prospective study of patients with cervical radiculopathy from degenerative disorders without treatment, notwithstanding non-prescription analgesics, would provide Level I evidence regarding the natural history of this disorder.
- A systematic study of patients with untreated cervical radiculopathy from degenerative disorders would provide evidence regarding the natural history of the disease in this patient population.

History and Physical Findings

- Further studies are needed to demonstrate the positive predictive value of specific symptoms and physical exam findings in patients with confirmed cervical radiculopathy to demonstrate their usefulness in predicting a good outcome with conservative or surgical treatment.

Diagnostic Tests

- Studies evaluating the accuracy of MRI, CT and CT myelography in detecting and characterizing compressive lesions in the cervical spine in patients with cervical radiculopathy should be repeated using state of the art equipment and imaging techniques and should implement surgical findings and outcomes as gold standards.
- Further studies should be done to evaluate the contribution of EMG to the evaluation of cervical radiculopathy patients with discordant MRI findings and clinical findings using surgical findings and outcomes as gold standards.
- Further studies should be done evaluating the contribution of SNRB to the evaluation of cervical radiculopathy patients with discordant MRI findings and clinical findings, and to the evaluation of cervical radiculopathy patients with findings on MRI at multiple levels ipsilateral to the patient's symptoms using surgical findings and outcomes as gold standards.
- Studies should be done evaluating the contribution of dynamic upright cervical spine MRI to the evaluation of and long term outcome of patients undergoing surgical decompression for cervical radiculopathy with attention to the following question: Does the presence of dynamic central canal stenosis at an adjacent level affect the long term outcome of patients undergoing surgical decompression using an anterior approach with fusion versus a motion preserving posterior approach?

Outcome Measures

- Disease specific outcome measures like the PSFS and the HSQ have been developed and seem to be useful in assessing outcome for the treatment of cervical radiculopathy from degenerative disorders. These measures are limited in that they have not been widely used or accepted. Outcome measures such as these need to be incorporated into Level I studies to confirm their validity and to establish themselves as acceptable research tools to quantitate outcome after cervical radiculopathy from degenerative disorders.

Medical/Interventional Treatment

- Future studies of the effects of pharmacological treatment in the management of cervical radiculopathy from degenerative disorders should include an untreated control group when ethically possible.
- Future outcome studies including patients with cervical radiculopathy from degenerative disorders treated only with pharmacological treatment should include subgroup analysis for this patient population.
- Future studies of the effects of physical therapy/exercise in the management of cervical radiculopathy from degenerative disorders should include an untreated control group when ethically possible.
- Future outcome studies including patients with cervical radiculopathy from degenerative disorders treated only with physical therapy/exercise should include subgroup analysis for this patient population.
- Future studies evaluating the effects of emotional, cognitive and work-related issues would add to our understanding of how these factors affect outcomes in patients with cervical radiculopathy from degenerative disorders.
- Future studies of the effects of manipulation/chiropractics in the management of cervical radiculopathy from degenerative disorders should include an untreated control group when ethically possible.
- Future outcome studies including patients with cervical radiculopathy from degenerative disorders treated only with manipulation/chiropractics should include subgroup analysis for this patient population.
- Future studies of the effects of manipulation/chiropractics in the management of cervical radiculopathy from degenerative disorders should include data and discussion about any complications associated with treatment.
- Future studies of the effects of epidural steroid injections in the management of cervical radiculopathy from degenerative disorders should include an untreated control group when ethically possible.
- Future outcome studies including patients with cervical radiculopathy from degenerative disorders treated only with epidural steroid injections should include subgroup analysis for this patient population.
- Future studies of the effects of epidural steroid injections in the management of cervical radiculopathy from degenerative disorders should include data and discussion about any complications associated with treatment.
- Future studies of the effects of ancillary treatments in the management of cervical radiculopathy from degenerative disorders should include an untreated control group when ethically possible.
- Future outcome studies including patients with cervical radiculopathy from degenerative disorders treated only with ancillary treatments should include subgroup analysis for this patient population.
- Future studies evaluating the effects of emotional, cognitive and work-related issues would add to our understanding of how these factors affect outcomes in patients with cervical radiculopathy from degenerative disorders.

Surgical Treatment

- A prospective, multicenter randomized controlled trial (RCT) with minimum two year follow-up comparing surgical to medical/interventional treatment for the treatment of cervical radiculopathy from degenerative disorders would yield invaluable information regarding the relative outcomes of these two treatment options.
- Future studies evaluating the effects of emotional, cognitive and work-related issues would add to our understanding of how these factors affect outcomes in patients with cervical radiculopathy from degenerative disorders.
- Prospective, blinded, RCT comparing clinical outcomes and radiographic alignment of patients treated for cervical radiculopathy due to single level degenerative disease with ACD compared with ACDF with a uniform surgical technique would generate important information about the relative value of preserving normal alignment.
- A well designed, prospective RCT to compare radiographic and clinical outcomes following ACDF with or without a plate for degenerative cervical radiculopathy would generate meaningful data regarding the potential long term benefits of preserving or restoring sagittal alignment. There should be two cohorts, one with single level disease, and one with multilevel disease.
- Prospective, RCT with long term follow up to evaluate clinical outcomes, perioperative complications, and long term success including need for revision surgery following treatment of degenerative cervical radiculopathy with posterior foraminotomy versus ACDF. The study group would consist of foraminal stenosis only and should include two separate cohorts, including "soft disc" herniation and hard disc or spondylotic disease.
- Continued long term follow-up of patients currently enrolled in previously reported RCTs is necessary to determine if purported advantages of TDA compared with ACDF can be validated, with particular focus on validated clinical outcomes, revision surgery and adjacent segment disease. Subgroup analysis should include soft disc compared with hard disc and foraminal compared with paracentral pathology for cervical radiculopathy patients.
- Additional independent, masked, prospective RCTs comparing ACDF to TDA for the treatment of cervical radiculopathy from degenerative disorders would add substantial unbiased validation to the results of the investigational device exemption (IDE) studies.
- An adequately powered, prospective, comparative study of patients treated with ACDF, ACD, TDA and PLF followed for greater than four years and assessed with validated outcome measures would yield useful information about the long term outcomes of surgery for cervical radiculopathy from degenerative disorders.



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