Final Program and Meeting Guide 9th International Symposium

Live Instructional Non-Fusion Spine Course

Interactive surgery via satellite

New York University School of Medicine Washington Square, New York United States of America

Tuesday 3rd of May 2005



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Welcome letter

New York, May 3rd, 2005

Dear Participants and Guests

Welcome to New York City and the Swiss Spine Institute and New York University.

We are excited about this collaboration and hope that this one-day symposium will give you much satisfaction. Live instructional courses have become one of the Swiss Spine Institute specialties and the Course Chairman Dr. Tom Errico, Chief Spine Services, Departments of Orthopaedics; School of Medicine, New York University has put together an impressive faculty.

The day is meant to enhance knowledge, discuss findings and ask questions to the faculty and to your peers. Please give us suggestions of further topics in the evaluation forms that you would like to see as seminars. Do not be shy this is a collaborative effort for you and with you.

We hope you will enjoy the seminar and Spring in New York 2005.

Sincerely

Margareta Nordin Dr. Sci. President Swiss Spine Institute New York, May 3rd, 2005

Dear Participants and Guests

Lumbar Arthroplasty has reached a new beginning with the FDA approval of the Charite Artificial Disc this past year. Early usage has commenced in the U.S. and continues in Europe. Motion Sparing Technology also involves other new implants currently in the regulatory process as well as other forms of motion preservation. This program is designed to bring together into one format the broad spectrum of thought represented by the leaders in motion preservation. The symposium with live instructional surgical demonstrations brings to the attendees actual surgical experience and concepts from leaders in the field. Live surgeries in conjunction with didactic lectures will delve into the all-important surgical indications and contra-indications to these techniques. There is adequate time for questions and answer sessions simultaneously live between Switzerland and New York. This live real time format allows for extraordinary learning experiences for all involved.

Sincerely

Dr Thomas Errico, MD Course Chairman NYU Hospital for Joint Disease



Synthes Spine is a leading international spinal device company, specializing in the development, manufacturing, and marketing of technologies for the surgical treatment of spinal disorders. Synthes Spine features a comprehensive and diverse portfolio of products for fusion and non-fusion surgical techniques with the objective of providing the patient with the best possible outcome. Close collaboration with many surgeons, including the AO Foundation, allows Synthes Spine to provide the highest quality products and services to our customers and the patient.

Registration

Tuesday morning, May 3rd, 2005 from 07:30am

Congress location

New York University School of Medicine Kimmel Center 60 Washington Square South, 4th Floor New York, NY 10012 United States of America

Congress contact person

Ms Jolanda Meury Event Coordinator Engelgasse 77 4052 Basel, Switzerland Phone: +41 (0) 61 373 23 03 Fax: +41 (0) 61 373 23 02 E-mail: jolanda.meury@swiss-spine.ch

Swiss Spine Institute sponsorship information

Mr Bill Chambers General Manager Engelgasse 77 4052 Basel, Switzerland Phone: +41 (0) 61 373 23 03 Fax: +41 (0) 61 373 23 02 E-mail: bill.chambers@swiss-spine.ch Web: www.swiss-spine.ch

About the Live Instructional Non-Fusion Spine Course

The course will be chaired by Dr Thomas Errico, MD, Professor at the New York University School of Medicine. An interactive and instructional course will feature six (6) spine surgeries transmitted live from the Swiss Spine Institute reference clinic via satellite to the New York University School of Medicine, with instructional saw bones courses in parallel to the surgery.

This course is designed to not only demonstrate the latest motion preserving technics; moreover it will allow delegates to have hands on experience in the surgeries they are observing. In just one day, surgeons will be able to experience surgeries on dynamic stabilisation, and disc replacement technology for the cervical and lumbar spine as well as practical hands on instruction in the auditorium.

Swiss Spine Institute

The Swiss Spine Institute founded in Switzerland in 1999, is a non-profit foundation and association for international spine medicine based on a decentralized network of spine specialists and centres of competence around the world.

Objectives

The Institute's objective is to trace precisely the relevant conservative and operative treatment methods in a central data base and improve treatment quality based on this documentation. This evidence based documentation provides a platform for education, research, development and information to medical doctors and allied Health care professionals involved in spine medicine around the world.

Mission

Our mission is dedicated towards advancing the specialty of spine surgery in order to provide the highest quality of spine care to the public.

Swiss Spine Institute-Association Membership

Membership is open to all individuals and legal entities. The activities of the association are geared to the needs of spine specialists, Healthcare and rehabilitation in spinal medicine. Your membership support will assist the Institute in advancing the specialty of spine surgery in order to provide the highest quality of spine care to the public.

Benefits

Swiss Spine Institute Membership offers valuable benefits to meet your professional goals.

- Free live surgery DVD
- 20% off meeting registration fees
- Access to legal and patent advisory service
- · Partake in Swiss Spine Institute research projects
- Invitation to appear as faculty
- Advance access to training courses
- Free copies of the patients' magazine Colonna
- Membership directory
- · Certificate of membership

Fees

Membership is limited and fees of \$375.00 are charged annually. Application forms can be downloaded from our web site, or from the Institute direct at institute@swiss-spine.ch

Web site

The Swiss Spine Institute has a web site at the address www.swiss-spine.ch and provides comprehensive and up-to-date information on all of the Institutes activities.

3rd Trans Atlantic Spine Congress "Innovations in Spine Surgery"

4th & 5th of November 2005 Dallas, USA and Zürich, Switzerland Held in cooperation with the Texas Back Institute Full registration \$995.00 Registration for Swiss Spine Institute members \$795.00

SWISS SPINE INSTITUTE

Attendance

This multidisciplinary spine course is intended for orthopaedic surgeons, neurosurgeons, physiatrists, pain specialists, neurologists, radiologists, physical therapists, rheumatologists, anaesthesiologists, osteopathic physicians, researchers, nurse practitioners, chiropractors and other physicians and allied Health professionals involved in spine care. Attendance at the Live Instructional Spine Surgery Course is open; membership to the Swiss Spine Institute is not required.

Accreditation Statement

The Swiss Spine Institute through the co-sponsor the NYU Post-Graduate Medical School is providing accreditation for delegates attending this meeting.

The NYU Post-Graduate Medical School is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

Credit Designation Statement

The NYU Post-Graduate Medical School designates this educational activity for a maximum of (6) category 1 credit toward the AMA Physician's Recognition Award. Each physician should claim only those credits that he/she spent in the activity.

Disclosure Statement

The NYU Post-Graduate Medical School adheres to ACCME Standards regarding industry support of continuing medical education. Disclosure of any commercial relationships as well as discussion of off-label or investigational use of any drug, device or procedure by the faculty will be made known at the symposium.

The Swiss Spine Institute with their designated sponsor of continuing medical education, the NYU Post-Graduate Medical School must comply with the Essentials and Standards set by the Accreditation Council for Continuing Medical Education (ACCME) for commercial support of continuing medical education.

It is a requirement that the following Standards are met for each continuing medical education activity:

- All activities must be free of any commercial bias.
- Commercial supporters of CME activities shall not control the planning, content or execution of the activity.
- Presentations must give a balanced view of therapeutic options. If trade names are used, those
 of several companies should be used rather than only that of a single supporting company.
- An offer by a commercial entity to provide a presentation reporting the results of scientific research shall be accompanied by a detailed outline of the presentation for use by the accredited sponsor to confirm the scientific objectivity of the presentation.



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- When an unlabeled use of a commercial product is discussed, the speaker must disclose that the product is not labelled for the use under discussion or that the product is still investigational. This is mandatory by the ACCME.
- No commercial promotional materials shall be displayed or distributed in the same room, before, during or immediately after an educational activity for credit.
- Representatives of commercial supporters may attend an educational activity, but may not engage in sales activities while in the room where the activity takes place.
- Funds from a commercial source must be in the form of an educational grant made payable to the accredited sponsor for the support of the program.
- Commercial support may be acknowledged in printed announcements and brochures; however, reference must not be made to specific products.

All faculties in a CME activity must disclose the existence of any significant financial interest or other relationship with the manufacturer(s) of any commercial product(s) discussed in an educational presentation. This must be disclosed to the participants prior to the activity in brief statements in conference materials such as brochures, syllabi, exhibits, poster sessions or postmeeting publications.

Badge distribution

Registration badges may be picked up on site at the registration desk. Representatives without a badge will not be admitted in the exhibit or congress hall. Badges are personal and non-transferable and must be worn in the exhibit and congress area at all times. Defacing badges by inserting business cards, photocopying, attaching ribbons or other items to badges is not allowed.

Smoking policy

No smoking is permitted within the exhibit or congress hall at any time including installation, exhibit hours, and dismantling.

Photography

No photography is allowed. Only the official photographer may take photographs or video in the exhibit and congress hall. Filming or photographing of the live surgery telecast is not allowed. Exhibitors taking photographs in the exhibit or congress hall will have their film confiscated.

Children

No children under 18 years of age will be permitted to enter the course.

Exhibition

A supporter exhibition will take place during the Live Instructional Non-Fusion Spine Course on Tuesday, May 3rd, 2005 from 07:30am to 04:00pm. The function of this exhibition is to inform attendees about products and services relevant to the practice of spine medicine.

Collaboration works.





Ingenuity. Integrity. Infinite possibilities."

Mini seminars

Break out workshop/mini seminar sessions will be held during the day in room 914 on the 9th floor. These seminars are free of charge for registered delegates of the Live Instructional Non-Fusion Spine Course and are intended for orthopaedic surgeons, neurosurgeons, physiatrists, neurologists, radiologists, rheumatologists and osteopathic physicians who are involved in spine care. Registration to the mini seminars are free, and will be accepted online and at the venue on a first-come, first-served basis.

Mini seminar time table

| 10:30 am — 11:00 am | Stryker Spine |
|---------------------|--|
| 12:30 pm – 01:30 pm | Zimmer Spine; Lunch will be served in the room |
| 02:30 pm – 03:00 pm | St. Francis Medical Technologies |
| 04:00 pm – 04:30 pm | DePuy Spine |

Instructional sawbones courses

The instructional sawbones courses will be held in the auditorium on stage in parallel to the live surgeries with delegates receiving hands on education on the procedure they are watching. These courses will allow delegates to have hands on experience in the surgeries they are observing.

Instructional sawbones course time table

| 08:00 am | - 08:45 am | Zimmer Spine | |
|----------|------------|---------------------|--------------|
| 08:45 am | – 09:30 am | DePuy Spine | |
| 10:15 am | – 11:00 am | St. Francis Medical | Technologies |
| 11:00 am | - 11:45 am | Stryker Spine | |

Program of the Live Instructional Non-Fusion Spine Course

Morning Session

| NY Time | Surgery from Switzerland | Surgeon | Moderator |
|----------|---|----------------------------------|--------------------|
| 07:30 am | Open: Registration and morning coffee | | |
| 08:00 am | 1 st Live Surgery: Dynamic stabilisation of the posterior column | O. Schwarzenbach, Switzerland | R. Davis, USA |
| 08:45 am | 2 nd Live Surgery: Total artificial disc prothesis lumbar | R. Guyer, USA M. Morgan, USA | P. McAfee, USA |
| 09:30 am | 3 rd Live Surgery: Total Artificial Disc Prothesis | J. Zigler, USA M. Morgan, USA | R. Delamarter, USA |
| 10:15 am | 4 th Live Surgery: Interspinous decompression system | J. Zucherman, USA | S. Blumenthal, USA |
| 11:00 am | Pre-recorded surgery: Total artificial disc prothesis lumbar | S. Rasmussen, Denmark | T. Errico, USA |
| 11:45 am | 5 th Live Surgery: Dynamic stabilization system | N. Boeree, UK | P. McAfee, USA |
| 12:30 pm | Buffet Lunch: Rosenthal Pavilion, 10 th Floor | | |

| Afternoon Session | | | | |
|-------------------|---|------------------------|----------------|--|
| NY Time | Lectures | Speaker | Moderator | |
| 01:30 pm | Panel interview with all surgeons via satellite from Switzerland | All surgeons | T. Errico, USA | |
| 02:30 pm | Outcome Assessment in New Non Fusion Technologies | M. Nordin, USA | T. Errico, USA | |
| 02:40 pm | Dynamic Stabilization: Preliminary US IDE Clinical Results | R. Davis, USA | T. Errico, USA | |
| 02:50 pm | Dynamic lumbar stabilization with Dynesys5 year follow-up of 150 patients, a prospective multi-center study | T. Stoll, Switzerland | T. Errico, USA | |
| 03:00 pm | Mechanical Interspinous Normalization System Rationale and 16 Year Results From Europe | P. McAfee, USA | T. Errico, USA | |
| 03:10 pm | X STOP (IPD) Interspinous Process Decompression | S. Blumenthal, USA | T. Errico, USA | |
| 03:20 pm | Revision Surgery in the Motion Preservation Arena | P. McAfee, USA | T. Errico, USA | |
| 03:30 pm | Coffee break | | | |
| 04:00 pm | Multi-level Lumbar Artificial Disc Replacement: The U.S. Experience | R. Delamarter, USA | T. Errico, USA | |
| 04:10 pm | Indication Algorithm for Non-Fusion Technology | R. Bertagnoli, Germany | T. Errico, USA | |
| 04:20 pm | Metal-on-Metal artificial lumbar disc replacement versus circumferential fusion for the treatment of discogenic pain: A prospective randomized study | R. Sasso, USA | T. Errico, USA | |
| 04:30 pm | Introduction to Goals of Cervical Arthroplasty | T. Errico, USA | T. Errico, USA | |
| 04:50 pm | Panel discussion | | T. Errico, USA | |
| 05:20 pm | Close of day | | T. Errico, USA | |

Faculty Member List

Chairman

Dr Tom Errico, MD, USA

Surgeons

Dr Nicholas Boeree, MD, United Kingdom Dr Christian Etter, MD, Switzerland (Medical Director) Dr Rick Guyer, MD, USA Dr Mickey Morgan, MD, USA Dr Sten Rasmussen, MD, Denmark Dr Othmar Schwarzenbach, MD, Switzerland Dr Jack Zigler, MD, USA Dr James Zucherman, MD, USA

Speakers

Dr Rudolf Bertagnoli, MD, Germany Dr Scott Blumenthal, MD, USA Dr Reginald Davis, MD, USA Dr Rick Delamarter, MD, USA Dr Tom Errico, MD, USA, (Chairman) Dr Paul McAfee, MD, USA Prof Margareta Nordin MD, Sci, CIE, USA (Host) Dr Rick Sasso, MD, USA Dr Thomas Stoll, MD, Switzerland

Surgeons CV

Dr Nicholas Boeree, MD, United Kingdom

Practice

Consultant Orthopaedic Spinal Surgeon Southampton University Hospital Department of Orthopaedics Southampton, Hampshire, United Kingdom

BUPA Chalybeate Hospital Chalybeate Close Southampton, Hampshire, United Kingdom

Education 1976–82 Medical Education at the London Hospital Medical College

Publications

11

Presentations

- 1 Can Adcon-L be used safely and to advantage in the all forms of surgery for degenerative lumbar disease? Eurospine, Oct 2000
- 2 The Outcome of Anterior Lumbar Interbody Fusion using the Hartshill Horseshoe Cage vs. Single Level Graf Ligament Stabilisation. Combined Meeting of BSS and Nordic Spine Society, April 2000 Awarded prize for best paper
- 3 The Outcome of Posterior Lumbar Interbody Fusion (PLIF) vs. Posterolateral Fusion for Spondylolytic Spondylolisthesis. Combined Meeting of BSS and Nordic Spine Society, April 2000
- 4 Does Provocative Discography Help in Low Back Surgery? Eurospine, Oct 2000
- 5 ECG of Surgeons During Scoliosis Surgery. BSS Leeds 2003

Dr Christian Etter, MD, Switzerland Practice

Head Department of Spine Medicine Head Department of Pain Therapy Hirslanden Clinic Aarau 5001 Aarau, Switzerland

Member of the Board Spina Sana Patient organisation Dates: 1999 to present

Chairman Membership committee Spina Arthroplasty Society Dates: 2003 to present

Education

University of Basel Switzerland Graduated: 1979 Degree: Medical Practitioner

University of Basel Switzerland Graduated: 1983 Degree: M.D.

University of Berne Switzerland Graduated: 1988 Degree: FMH Specialist of Orthopaedic Surgery

Publications

NA

Presentations

61

Dr Rick Guyer, MD, USA

Practice

Orthopaedic Spine Surgeon Texas Back Institute Plano, Texas, USA

Education

- 1964–67 Wissahickon High School Ambler, Pennsylvania, USA
- 1967–71 Ursinus College Collegeville, Pennsylvania, USA
- 1971–75 University of Pennsylvania School of Medicine Philadelphia, Pennsylvania, USA

Publications

74

Presentations

77

Dr Mickey Morgan, MD, USA

Practice General and Vascular Surgery Frisco, TX, USA

Education Coronado High School Lubbock, TX, USA

Texas Tech University Lubbock, TX, USA B.S. Zoology 1974

University of Texas Health Science Center San Antonio, TX, USA M.D. 1980

Publications

2

Presentations

NA

Dr Sten Rasmussen, MD, Denmark

Practice

Chief Director of Accelerated Stay Programmes in Orthopaedic Surgery Consultant Spine and Pelvic Surgery Northern Orthopaedic Division Århus University Aalborg Hospital Hobrovej Aalborg, Denmark

Education

| Aalborg 1975 | Graduation in mathematics, physics and biology from Hasseris College |
|--------------|--|
| June 1982 | Medical candidate from Aarhus University |
| January 1984 | Authorisation as medical doctor from The Danish Board of Health |
| April 1989 | Master of Economy and Organisation |
| January 1993 | Authorisation as orthopaedic surgeon from The Danish Board of Health |
| Publications | |

25

Presentations

34

Dr Othmar Schwarzenbach, MD, Switzerland

Practice Das Rückenzentrum Bahnhofstrasse 3 3600 Thun, Switzerland

Education 1978–83 University of Basel

Residency

- 1984/85 Laboratory for experimental Surgery, Davos (Prof. S.M. Perren)
- 1986 Mount Sinai Hospital, Toronto, Canada, Research Department (A.A. Czitrom, MD, PhD)
- 1987 Inselspital Bern Clinic for Visceral Surgery University of Bern (Prof. L.H. Blumgart)
- 1988 Inselspital Bern Clinic for Orthopaedic Surgery (Prof. R. Ganz)

Dpt. for Hand Surgery (Prof. U. Büchler)

Dpt. for Anaesthesiology (Prof. D. Thomson)

1989/90 Inselspital Bern Clinic for Orthopaedic Surgery University of Bern (Prof. R. Ganz)

Membership

Swiss Orthopaedic Society (SGO) Swiss Spine Institute European Spine Society Group International Cotrel-Dubousset (GICD)

Dr Jack Zigler, MD, USA

Practice

Spine Surgeon Co-Director Spine Fellowship Program Texas Back Institute Plano, Texas 75093

Clinical Associate Professor of Orthopaedic Surgery UT-South western School of Medicine

Education

Bachelor of Science, with Distinction – 1973 Cornell University Ithaca, New York 14850

M.D. Cum Laude – 1977 SUNY Upstate Medical Center Syracuse, New York 13210

July 1977 – June 1978 Resident in Surgery Long Island Jewish – Hillside Medical Center New Hyde Park, New York

July 1978 – June 1981 Resident and Chief Resident in Orthopaedic Surgery Mount Sinai School of Medicine New York, New York 10029

July 1981 – June 1982 Arnold Fellow in Spine Surgery Henry H. Bohlman, M.D., Preceptor Department of Orthopaedic Surgery Case Western Reserve Univ. School of Medicine Cleveland, Ohio 44106

Publications

28

Presentations

57

Dr James Zucherman, MD, USA

Practice

St. Mary's Hospital and Medical Center, S.F., CA

Education

June 1970 University of California at Berkeley University of Southern California BA, with Honours, Varsity Tennis Letter

April 1974 Graduate Baylor College of Medicine Houston, Texas, MD

July 1974 to Postgraduate June 1975 Los Angeles County – USC General Hospital, Internal Medicine Intern

- July 1975 to Mt. Zion Medical Center June 1977 General Surgery Resident
- July 1977 to San Francisco Combined June 1981 Orthopaedic Residency Program Orthopaedic Surgery Resident
- July 1981 to University of Hong Kong Dec. 1981 Duchess of Kent Children's Orthopaedic Hospital Paediatric – Spine Orthopaedic Surgery Fellowship

Publications

109

111

Presentations

11th International Symposium

Two Decades of Instrumented Fusion "An in depth analysis" In Cooperation with AO Spine International

Zürich, Switzerland Friday 20th & Saturday 21st of January, 2006

Invitation

Following the "Harrington rod era" the introduction of transpedicular screw and cage systems about two decades ago, led to the widespread use of spinal fusion in daily practice. The progress made in implant technology and the development of less invasive surgical approaches opened new dimensions in spinal instrumentation and fusion. However, the enormous boost of new fixation techniques, and the great variety of new products can also be confusing. In addition spine surgeons today are confronted with non-fusion technology, CT-guided surgery and the proliferation of biomaterials to augment the basic spinal fusion. With these new surgical procedures and implants, continuous critical discussion about the benefits and risks of existing and new fusion techniques is mandatory.

The objective of this symposium is to present a state of the art review by a distinguished international faculty, of the history as well as the present knowledge in the field of spinal fusion after two decades of spinal instrumentation. This symposium will also address other important issues, such as imaging of spinal fusion, bone substitutes and clinical outcomes assessments. As a highlight several opinion leaders will present their experience on specific topics in an introductory guest lecture session. A case presentation session with voting and live projected results on the screen should stimulate interaction between participants and the faculty and provoke practise related discussions.

Special registration rate for Swiss Spine Institute and AOSpine International members.

Register online at www.swiss-spine.ch or for further information please contact Jolanda Meury at the Swiss Spine Institute +41 61 373 2303.





Presentations

Dr Rudolf Bertagnoli, MD, Germany

Practice

Since 1994 Head of Spine Center Straubing Spine Center Straubing Straubing, Germany

> Chief of St. Wolfgang Spine Center St. Wolfgang Clinic Bad Griesbach Bad Griesbach, Germany

Chief of Spine Center Johannesbadklinik Bad Füssing Bad Füssing, Germany

Since 2005 Head of Spine Center Bogen Bogen, Germany

> Founder, charter member, member of the Board of Directors and President of the Spine Arthroplasty Society (SAS)

Education

- 1984 Graduation & Promotion University of Vienna Vienna, Austria
- 1984–85 Institute of Anatomy University of Vienna Vienna, Austria (Director: Prof. Dr. W. Firbas)

Publications

52

Presentations

570

Indication Algorithm for Non-Fusion Technology

There are currently two main strategies for the surgical treatment of lumbar discopathy: decompressive and fusion procedures. The first one is less invasive to collateral structures with the main objective of direct or indirect decompression of neural structures. However, the percutaneous endoscopic methods can not successfully be used in all conditions with decompressive needs. Although open surgery is characterized by a usually higher degree of spinal decompression, the approach causes more unavoidable surgically induced trauma. This results in a typically much greater destabilizing effect on the motion segments than those observed in the percutaneous techniques. Overall, a total of 3-14% of all patients undergoing simple disc surgery have to be operated again due to persistent or recurrent complaints. Therefore intersegmental fusion techniques have been focused on in recent years with the development of new implants and advanced surgical methods. But one main disadvantage of spinal fusion surgery still remains: the complete elimination of intersegmental motion, which leads to load shifting and an increase of the stress on the adiacent spinal motion segments.As a complete return to Health cannot be achieved using any of the existing treatments, therapy should ideally consist of a reasoned series of small treatment steps, also taking Arthroplasty Surgeries (partial or total disc replacements) and Posterior Dynamic Spinal Stabilization into account. The aim of this treatment design is to minimize the absolute number of patients ultimately operated upon. This means both that the collateral trauma and the risk of the procedure can be kept to a minimum along this pathway, and that if one therapy concept fails, the patient can be offered a further treatment step in this reasoned stepwise sequence. As the overall results of conservative treatment are considered by most physicians to be good in the majority of patients, a conservative regimen should first be undertaken consistently and diligently before resorting to surgery in those few patients in which all reasonable non-surgical options fail.

Dr Scott Blumenthal, MD, USA Practice

President Texas Back Institute, Medical Staff, Presbyterian Hospital of Plano Plano, Texas, USA

Active Staff

Parker Road Surgery Center Plano, Texas, USA

Courtesy Staff Medical Arts Hospital Dallas, Texas, USA

Consulting Staff

Parkland Hospital Dallas, Texas, USA

Education

| 1972–76 | Beverly Hills High School Beverly Hills, California, USA |
|---------|--|
| 1976–78 | Northwestern University Evanston Illinois, USA Bachelor of Science in Medicine |

1978–82 Northwestern University Medical School Doctor of Medicine

Publications

15

Presentations

108

X STOP (IPD) Interspinous Process Decompression

The mechanism of neurogenic intermittent claudication (NIC) secondary to lumbar spinal stenosis is well understood. Patients' symptom are exacerbated in extension and relieved in flexion. Biomechanical studies demonstrate that extension decreases the dimensions of the spinal canal and neural foramina while flexion increases these dimensions. Based on this fundamental mechanism, the X STOP was developed to limit extension at the stenotic levels, relieving the symptoms of NIC.

Pre-clinical testing of the X STOP demonstrated that the implant increases the dimensions of the spinal canal and neural foramina, decreases the pressure on the posterior annulus, and decreases the loading of the facet joints. In addition, the X STOP has no significant affect on adjacent levels.

The X STOP is placed under local anaesthesia between the spinous processes using a minimally invasive technique. The typical procedure takes less than one hour and patients return home the same day. 100 X STOP patients were treated in the US IDE study and outcomes were measured using a validated claudication questionnaire developed by Stucki & Katz. On a 100 point scale, the mean pre-operative score was 51.5 and the mean post-operative score was 25.9 at 24 month follow-up – a 49.7% relative improvement. Physical functio n domains of the SF-36 also significantly improved.

The IDE study demonstrated the X STOP is significantly more effective than non-operative therapy. The X STOP also appears to have outcomes comparable to laminectomy in treating NIC patients with considerably lower risk of major complications.

Dr Reginald Davis, MD, USA

Practice

Head, Division of Neurosurgery Greater Baltimore Medical Center Physicians Pavilion West Baltimore, MD, USA

Education

| 1970-73 | Mansfield Senior High School |
|---------|--|
| 1973–76 | B.S. in Chemistry and Biology (Cum Laude) Marietta College Marietta, OH, USA |
| 1976–80 | M.D. Degree from The Johns Hopkins University School of Medicine Baltimore, MD, USA |

Publications

Davis RJ, North RB, et al: Head and Spinal Cord Injury. In Textbook of Paediatric Intensive Care, Mark Rogers, ed., William & Wilkins, Baltimore, 1987, pp 649-700

Uematsu S. Brophy B, Davis RJ: Carotid Blood Flow in Subarachnoid Haemorrhage. The Detection of Vasospasm by an Ultrasonic Flow Meter. Abstract at Symposium of XIIIth International Congress of Neurology: 18

Presentations

NA

Dynesys Spinal System: U.S. IDE Preliminary Data From Single Investigator Cohort.

By Reginald J. Davis, M.D., F.A.C.S.

Reported are preliminary data from a single center cohort of an ongoing prospective randomized multicenter trial of the Dynesys Dynamic Stabilization Spinal System.

Patients with stenosing lesions of the spine causing significant leg symptoms with or without back symptoms were enrolled and prospectively randomize to treatment utilizing decompression and either posterior lateral fusion with rigid pedicle screw fixation, or stabilization using the Dynesys Spinal System. The Dynesys Spinal System was implanted in 27 patients.

Twelve females and 15 males mean age 55.3 yrs. were treated using the Dynesys Spinal System.

Spinal stenosis was present in 18/27 or 66.7%. Remaining diagnoses included DDD, HNP and Spondylosis.

Instrumentation occurred at L4- 5 in 9/26 or 34.6% and at L4-S1 in 6/26 or 23.1%

Neurological status, patient satisfaction, SF 12 mental and physical Health, VAS back and leg pain, Oswestry, were evaluated at 3wks (24), 3mos (20), 6mos (16), 12mos (10), and 24mos.

These preliminary data show results very similar to those already reported by Dynesys surgeons.

Dr Rick Delamarter, MD, USA

Practice

Medical Director and Orthopaedic Surgeon The Spine Institute at Saint John's Health Center Santa Monica, CA, USA

Education

| 1981–82 | Surgical Internship |
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| | UCLA Medical Center |
| | |

1982–85 Orthopaedic Residency UCLA Medical Center

| 1985–86 | Chief Resident, Orthopaedic Surgery, |
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| 1985–87 | UCLA Medical Center |
| 1986–87 | Spine Fellowship, Case Western Reserve University and Acute Spinal Cord Injury Unit, Cleveland Veterans Hospital Cleveland, Ohio, USA Dr. Henry Bohlman |
| Apr–May 1987 | Visiting Fellowship, Groupe Hospitalier Pitie-Salpetriere, Paris, France Prof. Raymond Roy-Camill |
| | |

Publications

65

Presentations 268

Dr Tom Errico, MD, USA Practice

Attending Physician Tisch Hospital NYU Medical Centre New York, NY, USA

Attending Physician Bellevue Hospital N.Y.U. Medical Centre New York, NY, USA

Attending Physician Manhattan Veterans Administration Hospital New York, NY, USA

Attending Physician Orthopaedic Institute Hospital for Joint Diseases New York, NY, USA

Education

1972

BA, Zoology Rutgers University

| 1976 | Medicine University degli Studi di Bologna |
|--------------|--|
| 1978 | MD Medicine New Jersey Medical School |
| 1978–79 | Surgical Internship New Jersey Medical School |
| 1979–83 | Orthopaedic Residencies New York University MedicaCenter |
| 1983–84 | Fellowship Training John P. Kostuik, MD FRCS University of Toronto |
| Publications | |

56

Presentations

110

Introduction to Cervical Arthroplasties

Overview: Currently the standard of care for the surgical treatment of cervical radiculopathy is Anterior Cervical Decompression and Fusion. New cervical arthroplasty devices seek to supplant fusion as a method to achieve similar excellent results but with the promise of diminishing the incidence and severity of adjacent segment degeneration and symptomatic disease. There are however different considerations in cervical arthroplasty versus fusion. For example with fusion residual osteophytes may continue to develop rather than remain static or possibly resorb. Because of persistent motion we may have to perform wider bony decompressions than with a standard fusion. Biomechanical data reveals that the foraminal area available for the root from the neutral position increases 28% in flexion and diminishes 17% in extension. This wide fluctuation of room for the exiting neural elements begs the question as to whether the surgeon can perform the same decompression with a fusion as he does with an arthroplasty or does the surgeon need to perform a wider bony resection. Other arthroplasty complications such as device migration, subsidence and heterotopic ossification need to be monitored.

Cervical Biomechanics: The cervical spine functions completely different biomechanically than the lumbar spine. Rather than one center of rotation the cervical spine has two separate centers of rotation. One in the lower vertebral body for flexion and extension and one in the upper cervical spine for lateral bending. Furthermore coupled motion required for axial rotation results in effective distraction of the intervertebral space and foraminal enlargement.

Material Decisions: Arthroplasty designs are differentiated by the surface bearing materials used in the designs. Present devices use hydro elastic materials, metal on plastic, or metal on metal devices. The geometry of the articulations determines their biomechanical behavior while the materials affect their ultimate wear characteristics. Wear debris and the biologic response have been extensively studied.

Cervical Disc Replacements: This presentation will discuss the key features and early clinical results when available for the Bryan Disc, Prestige Disc, ProDisc-C, PCM, and the CerviCore device. These devices with the earliest developed in the mid 1980's are in varying stages of regulatory approval in the U.S. with wider usage in Europe and around the world. Early current cervical design positives include maintenance of segmental motion, similar early complication rates and revision strategies to fusion but with the yet unforfilled promise that maintenance of proper motion will improve the incidence of adjacent segment disease. Current design negatives include surgeons learning new methods of cervical decompression and implantation, incidence of spontaneous ossification, device-related technical and malposition problems, as well as unanswered questions about optimal bearing surfaces and extent of decompression.

Dr Paul McAfee, MD, USA Practice

Orthopaedic Surgeon Towson Orthopaedic Associates, P.A. O'Dea Medical Arts Building Baltimore, Maryland, USA

Education

University of Rochester Rochester, NY, USA BA with Distinction, June 1975 Senior year in absentia (participated in an accelerated program that allowed matriculation to medical school one year early)

State University of New York Upstate Medical Center Syracuse, NY, USA Doctor of Medicine September 1974 – June 1978

Publications

150

Presentations

NA

Mechanical Interspinous Normalization System Rationale and 16 Year Results From Europe

In lumbar degenerative disc disease (DDD), between early stages when conservative treatment is indicated and advanced stages calling for fusion or disc replacement, spine surgeons once had no viable therapeutic options to propose to their patients. The working hypothesis was that if one could correct the abnormal mechanical conditions that lead to DDD, by implanting a dynamic system of support, the degenerative process and the accompanying low back pain could be halted. The implant has been developed with the idea of creating a tension-band system, including an interspinous spacer and bands made of woven polyester. This obviates the need for bony purchase, avoiding the risk of loosening.

Biomechanical studies have confirmed the effectiveness of this implant in increasing intervertebral stiffness, reducing mobility in flexion and extension, and unloading the facet joints and posterior portion of the disc.

Depending on the indication, the Wallis implant is placed either subsequent to a decompressive procedure or in isolated fashion through a midline incision. The Wallis system is technically simple and straightforward, with a short learning curve and reduced perioperative and postoperative morbidity.

The Wallis system treats low-back pain that accompanies degenerative lesions of grade II, III and IV in lumbar segment down to L4-L5 in the following indications: voluminous herniated disc, recurrent herniated disc, herniated disc accompanying an L5 sacralization transitional anomaly, DDD at a segment adjacent to fusion, symptomatic modic I change and lumbar canal stenosis.

Prof Margareta Nordin, MD, Sci, CIE, USA Practice

Program Director and Director of Occupational and Industrial Orthopaedic Center (OIOC) NYU Hospital for Joint Diseases New York, NY, USA

Professor (Research) at the Departments Orthopaedics and Environmental Medicine Graduate School of Arts and Science and New York University School of Medicine New York, NY, USA

Program Director of the Program of Ergonomics and Biomechanics

President for Swiss Spine Institute Basel Switzerland

Education

| 1966 | Matriculation Certificate |
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| | Sigrid Rudebecks Gymnasiu |
| | Flickor Gothenburg, Sweder |
| 1969 | Physical Therapist |
| | School of Occupational and |
| | Physical Therapy |
| | School of Health Education |
| | Gothenburg, Sweden |
| 1982 | Medical Doctor of Science |
| | Department of Orthopaedic |
| | Sahlgren Hospital |
| | School of Medicine |
| | University of Gothenburg |
| | Gothenburg, Sweden |

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Publications

140

Presentations

NA

Outcome Assessment in New Non Fusion Technologies

Outcome assessment evaluations are essential to understand the efficacy of a procedure and/or a treatment. Out come assessments are performed at several levels reflecting the interest of the assessor. The assessment choice in turn reflects the interest of the stakeholders (the patient, the Healthcare provider, the manufacturer of the device, the payor and possible others). The stakeholders may not have similar goals or interests in similar outcomes. To be valid and reliable the assessment of a procedure must

- 1 Have clear hypotheses and/or research question(s)
- 2 Be blind to the extent possible from stakeholder(s)
- 3 Use reliable and valid outcome tools
- 4 Include patient outcomes such as pain ratings, functional outcome and satisfaction with the procedure. The change pre and post procedure in outcomes must be of clinical significant amplitude to determine success or failure.
- 5 Include cost if possible

The Healthcare provider is coming under increased scrutiny for determining success or failure. It is therefore of importance to determine as a first step what kind of quantitative study is proposed for example cross sectional study, clinical series, cohort study or randomized controlled trial (RCT). RCT is considered the gold standard to answer if a proposed treatment or procedure is superior to a different treatment or/ and to a control group. Outcomes to measure treatment success or failure for a treatment are usually divided in four major constructs: patient outcomes (pain, function, and satisfaction), surgical outcomes (complications, imaging), implant survival (implant defect, time of survival) and cost outcomes (procedure, hospitalization, other treatments, work absence). In answering a research question the choice of study design and tools to measure outcomes is a daunting task and should never be underestimated.

Dr Rick Sasso, MD, USA

Practice

Spine Surgeon President Indiana Spine Group Indianapolis, Indiana, USA

Education

| May 1982 | Undergraduate Education B.A. Wabash College Crawfordsville, Indiana, USA |
|----------|--|
| May 1986 | Graduate Education M.D. Indiana University School of Medicine Indianapolis, Indiana, USA |

Publications

45

Presentations

197

Metal-on-metal artificial lumbar disc replacement versus circumferential fusion for the treatment of discogenic pain:

A prospective randomized study Rick Sasso, MD1, Mike Hahn, MD2

Background Context: Metal-on-metal lumbar artificial disc replacements are undergoing evaluation in United States FDA IDE studies for the treatment of discogenic pain due to degenerative disc disease. The FlexiCore study recently completed enrolment of a prospective, randomized trial with a 2:1 ratio of the artificial disc to control. We are reporting the initial results from 2 surgeons.

Purpose: The purpose of this study is to examine the role of the FlexiCore artificial lumbar disc compared to standard circumferential fusion for the treatment of discogenic pain.

Study Design/Setting: This study represents pooled data from 2 surgeons involved in the multicenter prospective, randomized FDA IDE study comparing

the FlexiCore artificial lumbar disc to circumferential fusion for discogenic pain due to one-level degenerative disc disease unresponsive to non-operative treatment. The randomization ratio is 2:1.

Patient Sample: 59 patients were enrolled (40 artificial disc, 19 control). Sufficient follow-up data is available for 49 (32 disc and 17 control). The average age of the FlexiCore group is 38 with average body mass index (BMI) of 28. 17 males and 15 females. 5 are smokers (16%). 23 were done at L5-S1 and 9 at L4–5. The 17 controls were circumferential fusions using an anterior femoral ring and posterior pedicle screw instrumentation and autogenous iliac crest bone graft. The average age is 42 with an average BMI of 29. 9 males and 8 females. 3 are smokers (18%). 15 were done at L5-S1 and 2 at L4-5.

Outcome Measures: Oswestry Disability Index (ODI); Back pain visual analog pain score (VAS); Range of motion: flexion/extension and lateral bending.

Methods: Prospective data was collected preoperatively and at defined intervals postoperatively.

Results: Oswestry Disability Index (ODI) preoperatively was 61 (FlexiCore) and 57 (control). At 6 week follow-up FlexiCore-34, control-51; at 3 months FlexiCore-28, control-25; at 6 months FlexiCore-20, control-14; at 12 months FlexiCore-6, control-22. Visual analog pain score (VAS) preoperatively was 86 (FlexiCore) and 84 (control). At 6 week follow-up FlexiCore-28, control-47; at 3 months FlexiCore-33, control-28; at 6 months FlexiCore-18, control-16; at 12 months FlexiCore-8, control-38. Range of motion in flexion/extension preoperatively was an average of 8 degrees; the FlexiCore group postoperatively was 5 degrees. Lateral bending averaged 4 degrees preoperatively and 3 degrees after FlexiCore disc replacement.

Conclusions: These initial results demonstrate the FlexiCore artificial disc to compare very favourably to circumferential fusion for the treatment of lumbar degenerative disc disease unresponsive to non-operative treatment. These results are not intended to represent the overall study results.

Dr Thomas Stoll, MD, Switzerland

Practice

Head of Orthopaedic Spine Surgery at the Spine Centre of Bethesda Hospital, Basel, Switzerland with main focus on degenerative spinal disease.

Education

Medical school and degree of MD at the University of Basel.

Basic surgical training in Switzerland, specialisation in orthopaedic surgery with Professor Erwin Morscher.

Clinical and research fellowship in Adelaide, Australia with Professor Sir Dennis Paterson in 1990, research on scoliosis surgery.

From 1991 till 1996 staff member at the Orthopaedic Department (Prof. Erwin Morscher, Prof. Walter Dick), specialising in spine surgery.

Publications

NA

Presentations

Dynamic Lumbar Stabilization with Dynesys 5 Year Follow-up of 150 Patients, a Prospective Multi-center Study Thomas M. Stoll, Gilles Dubois and Othmar Schwarzenbach

Introduction: Various forms of lumbar instability require a surgical stabilization. As an alternative to fusion, a mobile, dynamic stabilization restricting segmental motion would be advantageous in various indications. The dynamic neutralization system for the spine (Dynesys(r)) is a pedicle screw system for mobile stabilization. It can routinely be combined with direct decompression.

Patients and methods: This prospective multi-center study evaluated the outcome of Dynesys in the treatment of lumbar instability conditions, evaluating pre- and post-operative pain, function, and radiological data on a consecutive series of 150 patients.

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Indications were: Unstable segmental conditions, mainly combined with spinal stenosis (60.0%) and with degenerative discopathy (31.3%), in some cases with disc herniation (6.7%), and with failed back syndrome (2.0%). 64 (43%) patients additionally had degenerative spondylolisthesis and 46 (31%) patients had undergone previous lumbar surgery. In 85 (57%) patients instrumentation was combined with direct decompression. The mean age at operation was 58.1 (±14.4) years, the mean follow-up time was 61.4 months (±29.6) and the minimum follow-up time was 24 months.

Results: 135 patients (90.0%) were available for followup. The complication rate was low. When later additional surgery was performed it was in the majority of cases for non-index segments. Mean pain and function scores improved significantly from baseline to follow-up as follows: back pain score (o-10) from 7.2 to 2.4, leg pain score from 6.4 to 1.6, and Oswestry Disability Index from 48.8% to 19.8%.

Conclusion: These study results compare favourably with to those obtained by conventional procedures especially in cases where direct decompression is needed; however, dynamic posterior stabilization is less invasive than most fusion procedures. It can directly be combined with decompression.

Dynamic neutralization proved to be a safe and effective alternative in the treatment of unstable lumbar conditions.

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