Proceedings - 19th International Conference - IEEE/EMBS Oct. 30 - Nov. 2, 1997 Chicago, IL. USA

SPINAL IMPLANTS: PAST, PRESENT, AND FUTURE

Hassan A. Serhan, Ph.D.
Manager, Research and Testing,
AcroMed Corporation
3303 Carnegie Ave. Cleveland, Ohio 44115

I. Introduction:

All the constituent elements of the normal human spine interact simultaneously to provide flexibility of motion, protection of the spinal cord, and structural support for the musculoskeletal torso. Spinal disc herniation, arthritis, and spinal stenosis as well as congenital, idiopathic, and neuromuscular deformities are some of the widespread spinal diseases. These spinal disorders are frequently associated with back pain. Injuries, muscle dysfunction, and surgical procedures may also disturb the normal interactions of the spinal elements, the end result being an alteration in the behavior of the spine which may lead to spinal instability and back pain.

Disease and fractures of the spine present challenging clinical and biomechanical problems to spine surgeons. Spinal cord decompression often results in an extensive destabilization of the spine. Historically, the spine surgeon walked a fine line when performing back surgery. Adequate neural decompression and subsequent relief from pain had to be weighed against destabilization of the spine by extensive cord decompression.

Spinal fusion has become a widely used technique to treat a variety of spinal instability syndromes including those due to trauma, tumor, infection, degeneration, and deformity. Spinal fusion is always performed using bone graft with or without stabilizing implants. The degree of the associated instability usually determines the necessity of implants.

Instrumentation of the spine has undergone revolutionary changes over the past decade. It has evolved from the use of only wire, to wire holding rods, to rods with hooks, to universal systems which include hooks, wires, pedicle screws, and rods or plates. Rods and plates can be contoured to enable segmental maneuvering of the individual vertebrae.

II. Historical Background:

Most of the early research on spinal fusions was built on the search for a treatment for spinal curvature (scoliosis) due to polio and Potts' disease (tuberculosis of the spine). This application was eventually expanded to include idiopathic scoliosis, kyphotic and lordotic deformities, as well as degenerative diseases and spinal fractures.

In 1909, Lange reported his technique for spinal fixation using steel rods which were attached to the vertebrae posteriorly. Posterior surgery was the procedure of choice until the mid-1930's. During this period, anterior surgery became available as an alternative to address Pott's disease degenerative disorders and spondylolisthesis (Burns,1933, Speed 1938). King, in 1944, achieved fixation via facet screws. In 1962, Harrington introduced his technique for spinal fixation by using stainless steel rods and hooks. In the 1970's Luque used sublaminar wires attached to rods to achieve segmental fixation.. Dwyer and Zielke both approached the spine anteriorly using screws inserted laterally into the vertebrae. Dwyer used a tension cable and Zielke used a threaded rod to achieve the scoliosis reduction.

In France, Roy-Camille used screws and plates posteriorly to immobilize and maintain lordosis in the lumbar spine. In 1983, Dr. Arthur Steffee further developed pedicle screw fixation in the USA with his Variable Screw Placement System (VSP). The slotted plates allowed for variable screw placement and did not rely on a fixed distance between adjacent pedicles as did the Roy-Camille thereby, enabling the surgeon to fit the instrumentation to the patient and not visa versa. In 1985, Dr. Marc Asher and associates expanded upon the work of Steffee, Luque, Cotrel and Dubousset and introduced the rod based ISOLA posterior spinal system. In the past seven years over 16 different rod systems have been introduced to the market.

The choice of an implant is based on several factors including *in vivo* and *in vitro* studies. Experimental and clinical studies of spinal fixation devices usually provide the surgeon with an analysis of the risks and benefits associated with each implant. Experimental studies include mechanical testing and analysis of components, connections, and implant constructs to determine their biomechanical characteristics including, stability, fatigue life performance, pullout strength, stiffness, and yield and ultimate strength.

Material biocompatibility and imaging characteristics also play a major role in implant selection. Acceptable and FDA recognized materials include cobalt, stainless steel, and titanium alloys, although several polymer based materials are being standardized. Clinical studies combine functional evaluation and biomechanical

(0-7803-4262-3/97/$10.00 (C) 1997 IEEE)

behavior of the implant. This includes instrumentation performance in vivo and in vitro, method of application, quality of instrumentation, and the safety (FDA) approval. Obviously, surgical philosophy and the basic advantage and benefit of the device as well as implant approval and safety record may be the most important factors in selecting a given implant. Patient bone quality and compliance, experience and knowledge of the various spinal devices and pathology influence the surgeon.

III. Spinal Fusion Devices:

The use of internal fixation implants for spinal fusion has gained increasing acceptance over the last 10 years. Specialized implants have been developed for each region of the spine, often based on surgical philosophy and treatment methodology developed by surgeons. Typically there are several techniques and products for the treatment of each pathology. Surgeon preference is based on clinical performance, ease of use, training, and cost. However, many procedures are still accomplished without spinal instrumentation, usually with bone graft. Hospitalization time and the ability of the patient to return to work may also be influenced by the choice of surgical procedure.

Fixation devices can be divided into four major groups based on the area or pathology being treated: 1) Cervical, 2) Deformity, 3) Degenerative, and 4) Trauma/Tumor.

1. Cervical:

There are several commercially available systems and techniques available for the spine surgeon to treat cervical pathologies. Depending on the pathology, the technique can be relatively simple posterior wiring to more complicated total vertebral replacement. Anterior cervical plates can be divided into locking and non-locking systems. The non-locking systems such as AcroMed's Acroplate (Figure 1), and Aesculap's Caspar plate, have shown higher fusion rates in single level fusions and an equivalent rate for two levels. However, in multi-level fusions, locking systems such as the AcroMed anterior cervical stabilization system, Synthes's cervical plate and Danek's Orion system have shown higher fusion rates.

Several posterior lateral mass plate systems are also available in the market. These plates that are not yet approved by the FDA are being used "off-label" to stabilize cervical motion segments and accomplish fusion. Surgeons in both Japan and Korea have successfully treated cervical pathologies using cervical pedicle screws.

Single strand wires and multiple strand wires (cables) have an extensive clinical history. Multi strand cables are flexible thereby reducing the chance of inadvertent penetration of soft tissues. Surgical cables such as Songer cable and wires have been used in conjunction with bone graft for posterior stabilization of the cervical spine.

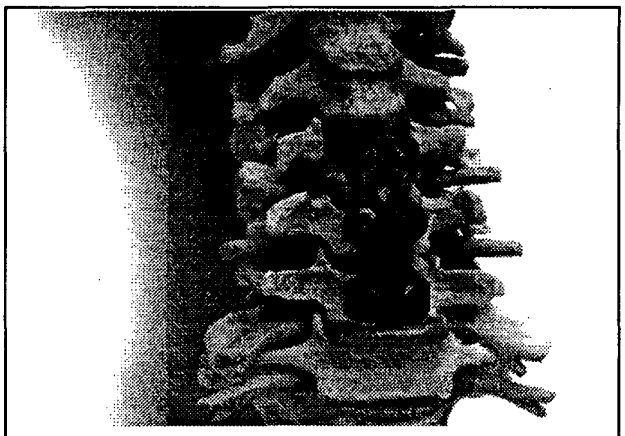

Figure 1: The AcroMed Acroplate Cervical System

External fixation with a halo can be used as a conservative non-surgical treatment method for spine stabilization. Halo's achieve stabilization by rigidly fixing (securing) the head to the trunk with the tenet that the neck remains immobile.

2. Deformity:

Scoliosis is a three dimensional deformity resulting in trunk imbalance, reduction of height and cosmetic appearance. It may also result in pelvic imbalance, compromise of pulmonary function and back pain. External bracing was the treatment of choice before Paul Harrington introduced his hooks and rod system in the early 1960's. The Harrington system became the gold standard for deformity and several other pathologies for several decades and is still used, generally overseas. The longevity of this system is a testimony to its design.

The basis for several posterior instrumentation systems including the Harrington system for treatment of coronal plane deformities is to provide distractive forces on the concave side of the spine and compressive forces on the convex side. This type of deformity is often corrected using posterior-lateral bony fusion and posterior instrumentation. Other existing systems rely on segmental treatment of the deformity together with the application of lateral and A-P forces and movement to achieve 3-D correction (e.g. ISOLA system , Figure 2).

Kyphotic or other sagittal plane deformities are treated by applying distractive forces to resist the compressive loads on the spine, and whenever possible, segmental fixation to decrease sagittal bending moments, combined with interbody bony fusion. Some deformities can be treated quicker, with reduced blood loss

and less muscle distraction using anterior systems. There are several FDA approved anterior deformity systems including: AcroMed's single rod ISOLA system, Kostuik-Harrington system, Zeilke, Dwyer and others. Some of these systems can also be used for the treatment of trauma and tumors in the thoracic and thoracolumbar spine.

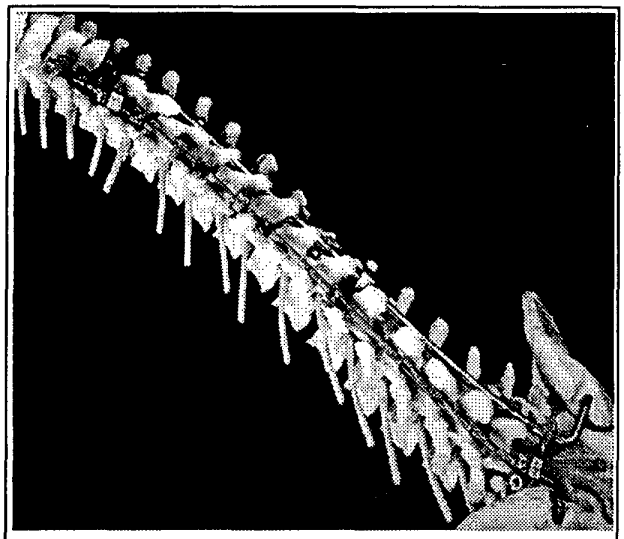

Figure 2: ISOLA® System

3. Degenerative:

Currently, the most common spinal surgery procedure is a discectomy, performed 300,000 - 400,000 times a year in the United States alone. The intervertebral disc is vulnerable to herniation due to the high loads involved in bending and twisting motions. The spinal cord and the nerve system protected by the spine's bony structure are sensitive to compression, causing sciatica that may result in severe pain syndromes.

With aging and continual loading of the spine, the fibrosis tissues in the intervertebral disc are broken into short chains that retain less water and thus do not inflate the disc as much. This segmental instability might cause spinal nerve compression and spinal instability, causing chronic pain.

Facet degeneration could also increase spine stenosis and segmental instability. The lumbar spine is the most common site for degeneration. This is primarily due to the high loads in this region from the transfer of loads from the spine to the pelvis. Uninstrumented treatment of facet joints and/or disc degeneration or herniation include laminectomy and discectomy. Either treatment may cause further instability in the joint, possibly requiring further treatment or instrumented fusion.

Today, pedicle fixation systems for the treatment of degenerative spine is considered to be a necessary tool to treat deformity and degenerative pathologies. Currently, there are several pedicle screw fixation devices with FDA clearance for specific applications while many others are being used "off label". The Variable Screw Placement System (VSP) was introduced by Dr. Steffee in 1984 (Figure 3). The goal of this system was to segmentally treat the spine by using forces to realign and fix the spine in a low profile manner until fusion occurs. As with most posterior systems, success is often achieved by using a Posterior Lumbar Interbody Fusion (PLIF) or Anterior Lumbar Interbody Fusion (ALIF) graft to reduce loads through the instrumentation and transferring loads through the vertebral column. Rod based systems such as ISOLA, TSRH, Fixateur Intern, CD, etc. have been developed and will have specific nuances and techniques to help achieve fusion.

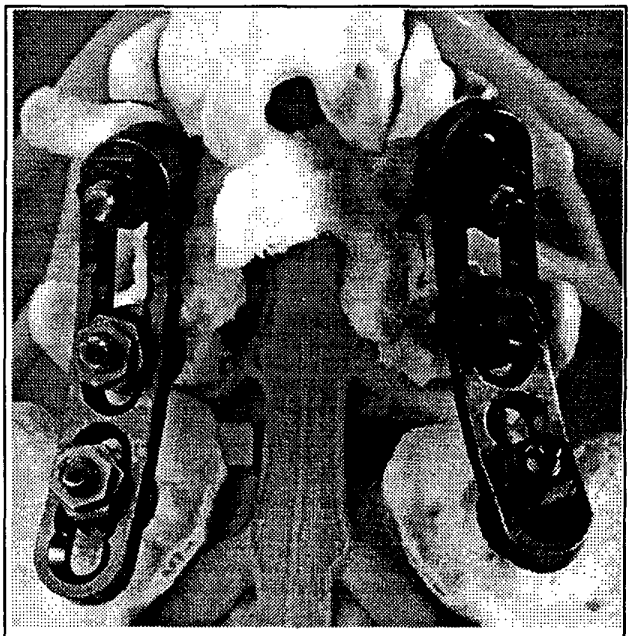

Figure 3: VSP® System

In the last five years, metallic and composite spinal interbody fusion devices have been used in ALIF and PLIF operations to reduce the morbidity of the bone graft donor site or reduce the chance of disease transfer from allograft. The carbon fiber composite Brantigan ALIF and PLIF cages have been used in Europe and the Pacific Rim for the past six years and have shown a high rate of fusion. Unlike the BAK, Ray and Stryker Titanium cages, the Brantigan cages are made from radiolucent carbon fiber/polymer composite material. This material facilitates the assessment of bony fusion and prevents stress shielding because its modulus of elasticity is similar to that of cortico-cancellous bone (Figure 4).

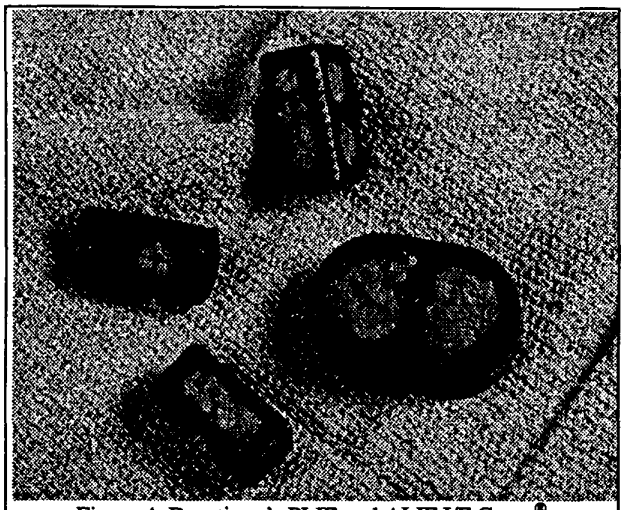

Figure 4: Brantigan's PLIF and ALIF I/F Cages®

4. Trauma/Tumor:

Fractures of vertebral bodies and posterior elements can lead to damage or compression of the spinal cord, and it may cause spinal instability, especially when ligamentous injury is present. Treatment of traumatic injury of the spine varies from external fixation such as bracing to surgical intervention using anterior or posterior fixation devices. The choice of implant is based on the type of injury and the surgeon's choice of implant.

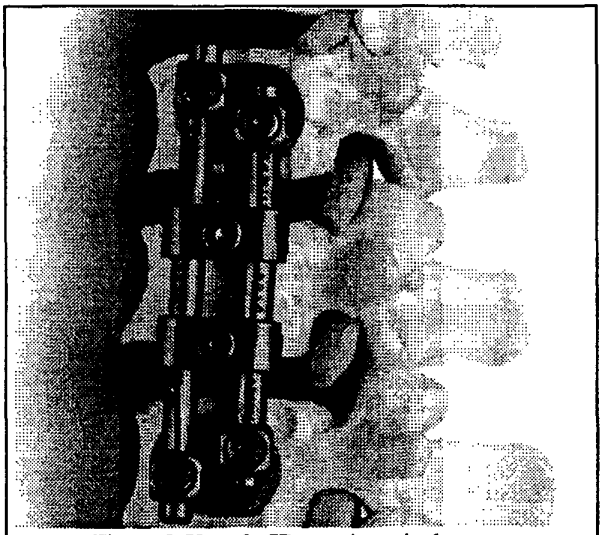

Figure 5: Kaneda SR anterior spinal system

Anterior trauma and tumor systems are either rod or plate based (with the exception of cable based Dwyer system). As with posterior systems, the profile of the system must be low enough to reduce tissue or vessel impingement yet strong enough to accommodate spinal loads. Most systems are designed for mid thoracic to upper lumbar and few exist which can be successfully used to the sacrum.

VI. Future of Spinal Instrumentation:

Eliminating pain or deformity of the spine and maintaining flexibility of motion will be the ultimate goal in any future spinal treatment. Paul Harrington's goal in his first attempts was to correct spinal deformities without fusion. With this goal in mind, non-fusion treatments of the spine such as artificial disc replacements, genetic engineering, artificial ligaments, and hydrogel treatment have gained more attention in the past five years and will continue to be of great interest to spine surgeons.

In the interest of eliminating donor site morbidity and accelerating the fusion process, bone morphogenic protein (BMP), bioactive ceramics, and biodegradable or bioresorbable materials are also being investigated for spinal application.

In general, the future goals of spinal instrumentation will be to treat and restore the functionality of diseased spine.

V. References:

1. Hitchon PW, Traynelis VC, Rengachary s, Techniques in Spinal Fusion and Stabilization, Thieme Publisher, Inc. 1995.
2. Fessler RG, Haid RW, Current Techniques in Spinal Stabilization, McGraw-Hill, 1996.
3. White AA, Panjabi MM, Clinical Biomechanics of the Spine, 2nd Edition J.B. Lippincott Co., 1990.
4. Lin PM, Gill K, Lumbar Interbody Fusion, An Aspin Publication, 1989.
5. Orthopedics Today, The history of FDA Regulation of Spinal Fixation Devices, 1994.
6. "The Classic" Wiring of the Vertebrae as a Means of Immobilization in Fracture and Potts' Disease, Hadra BE, Clinical Orthopaedics and Related Research Journal, pp. 4-8, No. 112, Oct. 1975.
7. "The Classic" Support of the Spondylitic Spine by Means of Buried Steel Bars, Attached to the Vertebrae, Lange F, Clinical Orthopaedics and Related Research Journal, pp. 3-6, No. 203, Feb. 1986.
8. "The Classic" Transplantation of the Tibia Into the Spine of Potts' Disease A Prelilinary Report, Albee FH, Clinical Orthopaedics and Related Research Journal, pp. 5-8, No. 87, Sept. 1972.
9. "Spinal Surgery Update, Guest Speaker" Colter JM, Surgical Rounds for Orthopaedics, pp. 10-11, 1989.