

Patient: _____

Date: _____

Position Statement Pedicle Screw Fixation Devices

Treating a painful, deformed, or unstable spine may require fusion surgery to hold a portion of the spine permanently in a desirable position. A bone fusion must mature for several months before it is secure. During that time, a device that is affixed to vertebrae and implanted within the body may hold the best position. While not all spine fusions required implants, many patients whose spines are weakened by injury or disease, or whose deformities must be corrected, are treated best if the operation includes internal fixation.

Surgeons have positioned and held the spine with many different internal devices, most often metal rods or plates that span two or more vertebrae. Such devices must be fixed to the vertebrae in ways that are strong, safe, and as much as possible, harmless to the patient.

For many years, wires and hooks were used to affix rods or plates to the spine. In the 1960's, Canadian, American, and French surgeons independently developed techniques to insert bone screws through the sturdy side pillars of the vertebrae, the pedicles. When operating from the back of the spine, the safest access to the vertebrae bodies is through the pedicles. The stable hold on a vertebrae achieved by screw fixation permits greater correction of deformity and more rigid fixation, and often spares adjacent healthy vertebrae that would have been included in the fusion were less stables or hooks used.

Spine fusions are performed for many disorders. A great variety of technical challenges exist. Passing a bone screw into a vertebrae through its pedicle is only one small step common to many complex procedures. Placing a screw into a pedicle, therefore, does not, in itself, define an operation, nor is it an act that a sophisticated judge of surgical care would be generally "for" or against.

As with all operations, error can occur in application and in such selecting patients for new techniques. Seeking to eliminate such errors, leaders of the spine care community have sponsored research and given many training courses and seminars so that those already specialized in spine surgery may learn to properly and safely use screws for fixation to the spine. A large number of peer-review articles describe laboratory and clinical research that document the efficacy and safety of spinal screw fixation. Extensive testing, worldwide use, more than two decades of experience, and availability of training to all qualified surgeons

means that inserting screws into the vertebral pedicles of properly selected patients by qualified trained surgeons is within the standard of good practice and is not experimental.

For many patients, the best treatment requires using bone screws fixed to their vertebrae through the pedicles. Since the skills and technology are available, treating those patients otherwise would be suboptimal for many and simple wrong for some. The surgeon's obligation is to provide the best treatment available.

Critical analysis of how and for who internal fixation of the spine is best used must continue. Meanwhile, those patients for whom spinal fixation with screws inserted through the pedicles is the best treatment, should have the opportunity to receive that treatment.

Patient Signature: _____

Physician Signature: _____