metals and metallic alloys (Refs. 65 and 66).

2. Mechanical Properties of the Device

It has been demonstrated that the multiple component pedicle screw spinal systems perform as well as other commercially available spinal fixation device systems in various modes and frequencies of loading (Refs. 8, 21, 45, 63, 67, 71, 73, 77, 98, 99, 100, 136, 137, 138, 142, 143, 144, 146, and 184).

Sufficient test methods exist to enable the evaluation of fatigue strengths and tensile, torsional, and bending strengths of the pedicle screw spinal fixation systems to assure its safety and effectiveness during the period of time needed for fusion to occur (Refs. 8, 13, 21, 45, 66, 72, and 78). There is adequate mechanical testing data for the pedicle screw spinal system for which clinical data was presented at the July 22, 1994, panel meeting. For example, one of the pedicle screw-plate systems had a static bending strength of 807.8 N, stiffness of 123.7 KN/M, and flexibility of 8.18×10^{-3} M/KN (Ref. 45). In cyclic fatigue testing, the same system endured 10⁶ cycles with a 400 N load, 10⁶ cycles with a 500 N load, and 212,960 cycles with a 600 N load (Ref. 45). Pedicle screw-rod systems have reported static bending strengths ranging from 544.9 to 1,289 N, stiffnesses ranging from 136.9 to 153.2 KN/M, and flexibilities ranging from 6.53 to 7.32 ($\times 10^{-3}$) M/KN (Ref. 45). In cyclic fatigue testing, the pedicle screw-rod fixation device systems have endured 10⁶ cycles with a 400 N load, 202,769 to 10⁶ cycles with a 500 N load, and 135,017 to 799,544 cycles with a 600 N load (Ref. 45).

B. Safety and Effectiveness: Clinical

The Panel based its recommendations on valid scientific evidence from the Cohort study, IDE clinical investigations, and the medical literature. These data sources allowed the Panel to evaluate the safety and effectiveness of pedicle screw spinal systems in terms of mechanical failure, soft tissue injury, pseudarthrosis, reoperation, fusion, pain, function, and neurologic status, as well as other potential harmful and beneficial effects of these devices.

Representatives of the SIMG presented the results of the Cohort study at the July 22, 1994, panel meeting. The Cohort study was an open, nonblinded, historical cohort study (Ref. 201). It was designed to recruit a maximum number of surgeons who would voluntarily participate by collecting clinical data on patients who had undergone spinal fusions. Physicians were recruited through announcements at professional society meetings and direct mailings to professional society memberships. Clinical data were collected from medical records of patients who had undergone spinal fusions during the period January 1, 1990, to December 31, 1991. This window was chosen to allow an adequate number of patients with a theoretical minimum followup of 2 years up to the time of the study onset. The concurrent control groups consisted of patients with identical entry criteria who had been operated on during the same time window (1/1/90-12/31/91). These control patients were either fused without instrumentation (noninstrumented) or were fused and instrumented with a control device (nonpedicle screw instrumentation). The data collection protocol was identical to that used for the study group.

Three hundred fourteen surgeons voluntarily participated in this study and contributed a total of 3,500 patients: 2,685 patients in the Degenerative Spondylolisthesis group and 815 patients in the Fracture (spinal trauma) group. In the Degenerative Spondylolisthesis group, the 2,685 patients were stratified by treatment: 2,177 patients were treated with pedicle screw instrumented fusions, 51 patients with nonpedicle screw instrumented fusion, and 457 patients with noninstrumented fusion. Similarly, in the Fracture group, the 815 patients were stratified by treatment: 587 patients were treated with pedicle screw instrumented fusions, 221 patients with nonpedicle screw instrumented fusion, and 7 patients with noninstrumented fusion.

Data from three clinical evaluation periods were collected from each patient record: Preoperatively, immediately postoperatively, and at the final evaluation which ranged from six months to two years postoperatively. The preoperative data included the patient's age, gender, weight, primary diagnosis, involved levels, identification of known prognostic variables (e.g., prior back surgery), and levels of pain, function, and neurologic status. Information regarding the operative procedure included the date of operation, type of bone grafting (if any), the levels instrumented and fused, the name of the pedicle screw device, and the number of each of the relevant components (e.g., rods, screws, connectors). Data collected at the final evaluation time point included the date of the last clinical and radiographic evaluations; fusion status; the date fusion was first diagnosed; maintenance of alignment; and neurologic, functional, and pain assessments.

Intraoperative and postoperative adverse events and the incidence and cause of reoperations were recorded.

Ten prospective IDE clinical trials for multiple indications were analyzed. Five studies involving the treatment of degenerative spondylolisthesis (n = 268) and two studies involving the treatment of spinal fracture (n = 27) were compared to the results of the Cohort study and were presented to the Panel (Ref. 66).

A comprehensive search of the English-language medical literature from 1984 to the present was performed. One hundred one articles pertained to clinical performance of pedicle screw devices and were selected for inclusion in this review (Ref. 66). Only articles appearing in peer-reviewed journals were included. Meta-analyses of the medical literature for degenerative spondylolisthesis and spinal trauma were conducted and presented (Refs. 51, 66, and 119).

These data were analyzed and presented at the July 22, 1994, panel meeting.

1. Mechanical Failure

The Cohort study provided the incidence of mechanical device failures related to treatment with pedicle screw spinal systems, nonpedicle screw instrumentation, and noninstrumented fusion (Refs. 66 and 201). For the fracture group (n = 586), the pedicle screw group had a mechanical failure rate of 9.7 percent, compared to a 1.9 percent failure rate in the nonpedicle screw group. For the pedicle screw group, the incidence of screw fracture was 6.7 percent, screw loosening 2.1 percent, rod/plate fracture 0.3 percent, and connector loosening (slippage) 0.2 percent. For the nonpedicle screw group (n = 221), the incidence of rod/plate fracture was 0.9 percent, hook pull-out 0.5 percent, and connector slippage 0.5 percent

For the degenerative spondylolisthesis group, the device mechanical failure rate was 7.8 percent in the pedicle screw group (n = 2,153). The most frequent events for the pedicle screw group were screw loosening (2.8 percent), screw fractures (2.6 percent), rod or plate fractures (0.7 percent), and connector loosening (slippage) (0.7 percent). Mechanical device failures were not possible in the noninstrumented group because a surgical technique, not an instrument technique, was utilized.

The overall incidence of mechanical device failures in the IDE clinical investigations (n = 2,431) was 0.7 to 3.7 percent (mean = 1.2 percent) (Ref. 66). For all investigational pedicle screw