rate of back pain improvement was greater in the nonpedicle group (95.2 percent) than the pedicle group (90.1 percent) for the fracture patient group, p < 0.023. The rate of improvement in leg pain was significantly greater in those degenerative spondylolisthesis patients treated with pedicle screw fixation (91.5 percent) than those treated without instrumentation (88.2 percent), p < 0.027. There were comparable improvements in pain in patients treated with pedicle screw fixation (90.1 percent) and nonpedicle screw instrumented fusion (95.2 percent) for the fracture patient group (Refs. 66 and

Clinical investigations performed under IDE protocols have demonstrated rates of improvement in pain ranging from 79.1 to 89.3 percent (mean = 85.7 percent) in the treatment of degenerative spondylolisthesis, 70.0 to 85.0 percent (mean = 74.1 percent) for fractures, 71.7 to 86.2 percent (mean = 78.2 percent) for degenerative disc disease, 44.2 percent for scoliosis, 72.4 to 81.6 percent (mean = 76.8 percent) for failed back syndrome, and 71.4 to 84.6 percent (mean = 82.6 percent) for spinal stenosis (Ref. 66).

The medical literature also documents successful outcomes for pain in patients treated with pedicle screw fixation with success rates ranging from 67 percent to 100 percent (Refs. 2, 19, 27, 37, 80, 86, 95, 97, 109, 110, and 147). A metaanalysis of these data showed that the 83.3 percent rate of improvement in pain for patients treated with pedicle screw instrumentation was comparable to the 83.3 percent rate for hook-rod instrumentation and the 77.0 percent rate for anterior instrumentation in the treatment of fractures (Ref. 51). Similarly, the rate of satisfactory clinical (pain and function) outcomes in patients treated for degenerative spondylolisthesis with pedicle screw instrumentation was 85.7 percent, which was comparable to those treated with nonpedicle screw instrumentation (89.6 percent) or noninstrumented fusions (89.6 percent) (Refs. 51 and 119).

7. Function

In the Cohort study, data on functional status was available from 2,132 patients in the pedicle screw group and 451 patients in the noninstrumented group for the treatment of degenerative spondylolisthesis, and from 569 patients in the pedicle screw group and 211 patients in the nonpedicle screw group for the treatment of fracture. In the degenerative spondylolisthesis group, there was a significantly greater

incidence of functional improvement associated with the use of pedicle screw fixation (90.4 percent) compared to treatment without instrumentation (86.7 percent) (p < 0.02). In contrast, in the fracture group, there was a significantly lower incidence of functional improvement associated with the use of pedicle screw fixation (87.9 percent) compared to treatment with nonpedicle screw fixation (93.4 percent) (p < 0.027) (Refs. 66 and 201).

In the IDE clinical investigations, the rate of functional status improvement for degenerative spondylolisthesis treated with pedicle screw instrumentation was 79.1 to 86.8 percent (mean = 84.4 percent), fractures 75.0 to 85.7 percent (mean = 77.8 percent), degenerative disc disease 74.1 to 75.7 percent (mean = 75.4 percent), scoliosis 34.9 percent, failed back syndrome 69.3 to 73.6 percent (mean = 71.6 percent) and spinal stenosis 71.4 to 74.4 percent (mean = 73.9 percent) (Ref. 66).

In the medical literature, the rate of successful functional outcomes in the treatment of spinal stenosis was 78 percent (Ref. 173); isthmic spondylolisthesis 90.9 percent (Ref. 147); postsurgical failed back syndrome 80.2 percent (Ref. 173); degenerative disc disease 60 percent (Ref. 206); and low back pain 72 percent (Ref. 109). A meta-analysis of these data showed that the 82.0 percent rate of improvement in functional outcomes of patients treated with pedicle screw instrumentation was comparable to the 74.8 percent rate for hook-rod instrumentation and the 73.2 percent rate for anterior instrumentation in the treatment of fractures (Ref. 51).

8. Neurologic Status

In the Cohort study, in the degenerative spondylolisthesis group, the rate of improvement of spinal cord neurologic function was comparable for those treated with pedicle screw fixation (3.6 percent) and those treated with noninstrumented fusion (1.2 percent). For the fracture group, there were no significant differences in the rates of improvement of spinal cord neurological assessments between the pedicle screw (13.3 percent) and nonpedicle screw instrumentation (13.0 percent) groups (p < 0.91) (Refs. 66 and 201).

For the degenerative spondylolisthesis group, the rate of root status improvement by one grade or more was significantly greater in patients treated with pedicle screw fixation (36.8 percent) than in patients treated without instrumentation (29.2 percent), or with nonpedicle screw fixation (25.5 percent), p < 0.002. In the

fracture group, the rates of improvement in root neurological assessments were comparable in the pedicle screw instrumented group (24.1 percent) and the nonpedicle screw instrumented group (18.2 percent) (p < 0.08) (Refs. 66 and 201).

In the IDE clinical investigations, there was improved neurological root status in 11.8 to 32.6 percent of patients (mean = 19.3 percent) with degenerative spondylolisthesis, in 7.5 to 30.7 percent of patients (mean = 17.6 percent) with degenerative disc disease, in 12.2 to 32.2 percent of patients (mean = 20.5 percent) with failed back syndrome, in 5.8 percent of patients with scoliosis, in 28.6 percent of patients with spinal stenosis, and in 14.3 percent of patients with fracture (Ref. 66).

Improvement in the neurological status of patients treated with pedicle screw fixation in the medical literature ranged from 18.8 percent to 100 percent, and was found to be comparable to that resulting from nonpedicle screw instrumented fusions and noninstrumented fusions (Refs. 39, 49, 55, 80, 107, 153, 154, and 164). Metaanalysis of the literature for the treatment of thoracolumbar fractures demonstrated a statistically higher rate of neurologic improvement in the anterior instrumentation (51.4 percent) and hook-rod instrumentation (40.7 percent) treatment groups compared to the pedicle screw instrumentation group (24.3 percent) (p < 0.05). However, the pedicle screw treatment group had a significantly greater proportion of neurologically intact (Frankel E) preoperative neurological profiles compared to all other treatment groups and, hence, no potential for neurological recovery (Ref. 51). There were no significant differences between treatment groups in the number of patients who were neurologically worse or who had neurological complications (Ref. 51).

9. Potential Effects on Bone Density

Experimental work has demonstrated decreased pedicle screw fixation strength in bone with decreased bone mineral density (Refs. 40 and 167), and care must be taken, therefore, in patients with osteoporosis (Ref. 170). Animal studies have demonstrated significant device-related decrease in bone density following arthrodesis with rigid spinal instrumentation (Ref. 123). However, rates of successful fusion increase with increased mechanical rigidity of the spinal fixation systems used to stabilize the spine. The significance of these findings in the clinical setting has not been resolved.