the incidence of pseudarthrosis in the degenerative spondylolisthesis group when treated with pedicle screw fixation (3.7 percent) compared to treatment without instrumentation (17.0 percent) (p < 0.001). However, there was no significant difference in the incidence of pseudarthrosis associated with the use of pedicle screw fixation in treating fractures (1.8 percent) compared to treatment with nonpedicle screw fixation devices (3.3 percent) (p = 0.18) (Refs. 66 and 201).

In the data released from the IDE clinical investigations, the incidence of pseudarthrosis for degenerative spondylolisthesis was 0.0 to 44.0 percent (mean = 12.6 percent), for fractures 10.0 to 14.3 percent (mean = 11.1 percent), for degenerative disc disease 0.0 to 37.0 percent (mean = 8.4 percent), for scoliosis 0.0 to 36.4 percent (mean = 3.7 percent), for "failed back syndrome" 0.0 to 47.2 percent (mean = 12.6 percent), and for spinal stenosis 5.1 to 14.3 percent (mean = 13.0 percent) (Ref. 66).

The medical literature similarly documents a low incidence of pseudarthrosis in those treated with pedicle screw spinal systems for fractures (Refs. 3, 17, 34, 35, 36, 47, 80, 153, and 154), degenerative spondylolisthesis (Refs. 32, 37, 96, 125, 173, and 174), deformities (Ref. 25). degenerative spondylosis (Refs. 22, 24, 169, and 194), degenerative disc disease (Ref. 205), and tumor (Refs. 50 and 126). Survivorship analysis for pseudarthrosis demonstrated a 98 percent fusion rate at one year, 97 percent at 12 to 20 months, 96 percent at 21 to 30 months, and 93 percent at 31 to 40 months (Ref. 124).

## 4. Reoperation

Reoperations were necessary in 17.6 percent and 23.2 percent of cases, respectively, for the degenerative spondylolisthesis and fracture groups in the Cohort study (Refs. 66 and 201). Device removals constituted the vast majority of reoperation procedures: 270 of 379 (71.2 percent) patients with reoperations in the degenerative spondylolisthesis group, and 109 of 136 (80.1 percent) patients with reoperations in the fracture group. Most device removals were performed for pain, irritation, or prominence of the device (6.3 percent and 7.2 percent in the degenerative spondylolisthesis and fracture groups, respectively). Only a small percentage of the devices were removed for device failure (0.6 percent and 1.5 percent in the degenerative spondylolisthesis and fracture groups, respectively).

In the data released from the IDE clinical investigations, the rates of

reoperations reported for degenerative spondylolisthesis were 1.4 to 13.2 percent (mean = 5.0 percent), for fractures 10.0 to 14.3 percent (mean = 11.1 percent), for degenerative disc disease 1.4 to 10.5 percent (mean = 2.3percent), for scoliosis 2.3 percent, for failed back syndrome 1.1 to 8.8 percent (mean = 1.6 percent), and for spinal stenosis 5.1 to 5.6 percent (mean = 5.0percent) (Ref. 66). The medical literature documents rates of device-related and nondevice related reoperations of 7.0 percent to 24 percent for pedicle screw fixation cases for a variety of conditions (Refs. 50, 60, 86, and 173). Metaanalysis of the literature demonstrated that the reoperation rate for the treatment of fractures with pedicle screw spinal systems (5.8 percent) are comparable to the reoperation rates associated with hook-rod devices (8.9 percent) and anterior devices (2.7 percent) (Refs. 51 and 119).

## 5. Fusion

Comparing the degenerative spondylolisthesis and fracture groups in the Cohort study, patients treated with pedicle screw fixation had a significantly higher fusion rate (89.1 percent and 88.5 percent, respectively) than the nonpedicle (70.8 percent and 81.0 percent) and noninstrumented (70.4 percent and 50.5 percent) groups (p < 0.0001). Using actuarial analysis, the time-adjusted rates of fusion for the degenerative spondylolisthesis group demonstrated that treatment with pedicle screw fixation was associated with a significantly greater rate of fusion than treatment with no instrumentation (82.5 percent versus 74.5 percent, p <0.001). The time-adjusted rates of fusion for the fracture patient group demonstrated that there was no significant difference in the rates of fusion when comparing pedicle screw fixation and nonpedicle screw fixation. For the degenerative spondylolisthesis group, the rate of fusion was higher in those treated with pedicle screw fixation than in those treated without instrumentation at every time interval beyond 3 months. These rates are evidence that fusion occurs faster in the pedicle group (Refs. 66 and 201).

In the data released from clinical investigations performed under IDE's, fusion rates associated with pedicle screw spinal systems were comparable to those associated with nonpedicle screw instrumentation and noninstrumentation. The fusion rates in patients with pedicle screw fixation were 82.1 to 89.5 percent (mean = 87.8 percent) in the treatment of degenerative spondylolisthesis, 71.4 to 80.0 percent (mean = 77.8 percent) for fractures, 82.9 to 93.1 percent (mean = 85.9 percent) for degenerative disc disease, 96.5 percent for scoliosis, 88.6 to 94.7 percent (mean = 91.9 percent) for "failed back syndrome," and 85.7 to 92.3 percent (mean = 91.3 percent) for spinal stenosis (Ref. 66).

A high incidence of successful fusion after pedicle screw fixation is documented in the medical literature. The fusion rates for the treatment of spinal deformity was 100 percent (Ref. 86); for low back syndrome 100 percent (Ref. 109); for postlaminectomy instability 94 percent (Ref. 113); for fracture 88.5 percent to 100 percent (Refs. 55, 66, 80, and 201); for postsurgical failed back syndrome 91.6 percent (Ref. 173); for pseudarthrosis 80 percent to 94 percent (Refs. 113 and 186); for degenerative spondylosis 87 percent to 100 percent (Refs. 22, 169, 185, and 187); for spinal stenosis 96 percent to 100 percent (Refs. 113, 163, and 173); for scoliosis 100 percent (Ref. 163); for spondylolisthesis 78 percent to 100 percent (Refs. 27, 37, 49, 96, 113, 125, and 173); and for multiple diagnoses 77 percent to 100 percent (Refs. 49, 95, 110, 183, 192, 200, and 202). A randomized prospective trial comparing pedicle screw fixation with noninstrumented fusion demonstrated a significant improvement in the rate of successful fusion when pedicle fixation was utilized (94 percent fusion rate with rigid pedicle screw instrumentation versus 65 percent without instrumentation) (Ref. 202)

Meta-analyses of the medical literature compared the treatment outcomes with pedicle screw fixation with three types of class II spinal fixation systems, i.e., posterior hook-rod devices, anterior instrumentation, and sublaminar wire-rod instrumentation. For thoracolumbar spine fractures, patients treated with pedicle screw fixation had a significantly higher rate of successful fusion (99.4 percent) than those treated with hook-rod fixation (96.9 percent) or anterior fixation (94.8 percent), p < 0.05 (Ref. 51). There were no significant differences in the fusion rates for patients with degenerative spondylolisthesis treated with pedicle screw fixation (93 percent) and those treated with hook-rod/sublaminar wirerod fixation (96 percent) or anterior fixation (94 percent) (Ref. 119).

## 6. Pain

For the degenerative spondylolisthesis patients in the Cohort study, the rate of improvement in back pain was significantly greater in the pedicle group (91.5 percent) when compared to the noninstrumented group (84.0 percent), p < 0.001. In contrast, the