spinal systems reported, the incidence of rod/plate fractures for degenerative spondylolisthesis was 0.0 to 7.1 percent (mean = 1.5 percent), for fractures 0.0percent, for degenerative disc disease 0.0 to 4.0 percent (mean = 1.1 percent), for scoliosis 0.0 to 9.1 percent (mean = 0.9 percent), for failed back syndrome 0.0 to 2.7 percent (mean = 0.3 percent), and for spinal stenosis 0.0 to 7.7 percent (mean = 5.0 percent) (Ref. 66). The incidence of screw fractures for degenerative spondylolisthesis was 0.0 to 18.6 percent (mean = 6.2 percent), for fractures 20.0 to 28.6 percent (mean = 22.2 percent), for degenerative disc disease 0.0 to 2.7 percent (mean = 0.6percent), for scoliosis 1.8 percent, for failed back syndrome 0.0 to 3.4 percent (mean = 2.4 percent), and for spinal stenosis 0.0 to 14.3 percent (mean = 3.0 percent). The incidence of screw loosening or pull-out for degenerative spondylolisthesis was 0.0 to 9.3 percent (mean = 0.9 percent), for fractures 0.0 to 5.0 percent (mean = 3.7 percent), for degenerative disc disease 0.0 to 7.4 percent (mean = 0.7 percent), for scoliosis 0.0 to 3.5 percent (mean = 1.8 percent), for failed back syndrome 0.0 to 12.1 percent (mean = 1.6 percent), and for spinal stenosis 0.0 percent. The incidence of connector loosening was 0.0 percent for degenerative spondylolisthesis, fractures, scoliosis, and spinal stenosis, 0.0 to 2.1 percent (mean = 0.4 percent) for degenerative disc disease, and 0.1 percent for failed back syndrome.

A low rate of mechanical failure of pedicle screw fixation devices, when used in multiple indications, is further documented by the medical literature (Refs. 3, 5, 19, 22, 24, 32, 35, 37, 43, 47, 50, 58, 59, 60, 73, 77, 79, 87, 89, 90, 94, 95, 107, 109, 110, 113, 116, 122, 125, 150, 151, 152, 162, 163, 164, 173, 183, 185, 186, 187, 191, 192, 193, and 203). A meta-analysis of 58 clinical studies revealed no differences between pedicle screw fixation (n = 641), hook-rod fixation (n = 1128), anterior fixation (n = 1128)= 255), and sublaminar wire-rod fixation (n = 48) groups in the rate of mechanical device failures (Refs. 51 and 119).

Survivorship analysis of pedicle screw device failures (defined as screw bending or breaking, infection, device loosening, rod or plate hardware problems, or neurologic complication requiring device removal) in patients treated for spondylolisthesis, postlaminectomy instability, pseudarthrosis, trauma, scoliosis, and tumor demonstrated a 90 percent survival of the instrumentation at 20 months, and 80 percent survival at 5 to 10 years (Ref. 124). The cumulative survivorship at 1 year was 84.0 percent and 91.3 percent for two devices used in the treatment of patients diagnosed with degenerative isthmic spondylolisthesis, degenerative segmental instability, and degenerative lumbar scoliosis (Ref. 26). Survivorship analysis performed on thoracolumbar burst fractures treated with pedicle screw fixation also demonstrated high survival rates for the implants: 100 percent at 22.4 months and 75 percent from 22.4 to 32 months (54).

## 2. Soft Tissue Injury

The incidence of device-related soft tissue injuries associated with the use of pedicle screw spinal systems for both degenerative spondylolisthesis and fracture groups is comparable to that associated with nonpedicle screw instrumented fusions and noninstrumented fusions (Refs. 66 and 201). Clinical studies have documented 0.1 percent and 0.2 percent rates of vascular injuries related to the use of pedicle screw spinal systems for the degenerative spondylolisthesis and fracture groups, respectively, and no visceral (intestinal) injuries for those groups. There were no differences found between treatment groups for intraoperative and postoperative neurological injuries, including nerve root and spinal cord injuries, as well as new radicular pain. For the degenerative spondylolisthesis and fracture groups, intraoperative nerve root injuries occurred in 0.4 percent and 0.2 percent of cases, respectively; intraoperative spinal cord injuries occurred in 0.1 percent and 0.2 percent of cases, respectively; postoperative radicular pain or deficits in 4.8 percent and 0.9 percent of cases, respectively; intraoperative device-related dural tears in 0.1 percent and 0.7 percent of cases, respectively; and postoperative dural tears or leaks in 0.3 percent and 0.0 percent of cases, respectively (Refs. 66 and 201).

The data released from the IDE clinical investigations reported an overall vascular injury rate of 0.7 percent; an intraoperative nerve root injury rate of 0.1 percent; a wound infection rate of 3.7 percent; a postoperative radicular pain or deficit rate of 2.2 percent; and a rate of postoperative dural tears or leaks of 0.8 percent. In these investigations, intraoperative spinal cord injuries did not occur (Ref. 66).

The medical literature documents a low incidence of soft tissue injuries related directly to the device when used in the treatment of fractures (Refs. 46, 49, 74, 106, 127, and 153), degenerative spondylolisthesis (Refs. 26, 27, 37, 49, 60, 113, 183, 185, 187, 191, and 192),

isthmic spondylolisthesis (Ref. 147), degenerative disc disease (Refs. 47, 60, 113, 183, 187, 191, and 192), deformities (Ref. 25), scoliosis (Refs. 43 and 116), tumors (Ref. 126), spinal stenosis (Ref. 173), and multiple diagnoses (Refs. 112 and 122). A meta-analysis of the medical literature for treatment of degenerative spondylolisthesis and fracture demonstrates no differences in the rates of intraoperative and postoperative adverse events related to soft tissue injuries among pedicle screw fixation, hook-rod fixation, anterior fixation, and sublaminar wire-rod fixation treatment groups (p < 0.05) (Refs. 51 and 119).

These soft tissue injuries appear to be related to the surgical procedure, rather than the device itself. Misdirected pedicle screws can cause pedicle fracture, screw cutout, or screw penetration of the pedicle, potentially causing nerve root or spinal cord injuries, dural tears, or canal stenosis (Refs. 152, 166, 171, and 189). Meticulous surgical technique and attention to detail appear to minimize these adverse events (Refs. 24, 47, 60, 79, 90, and 190). Pedicle screws too large for the pedicle diameter can cause pedicle fracture. Likewise, over penetration of pedicle screws through the vertebral body from pedicle screws too long for the anterior-posterior dimensions of the vertebrae can cause retroperitoneal vascular or visceral injury (Refs. 101, 106, and 204). Thus, selection of the appropriate size of the pedicle screw is critical to prevent these injuries (Refs. 64 and 190). Operative technique guidelines have been developed to assure accurate placement of pedicle screws and minimize operative complications (Refs. 16, 56, 149, 164, and 172). In addition, the relevant surgical anatomy of the thoracic, lumbar, and sacral spine, including the pedicle dimensions and orientation, as well as surrounding soft tissue structures, have been thoroughly described in the medical literature (Refs. 7, 15, 20, 57, 62, 64, 69, 75, 87, 88, 91, 101, 102, 106, 117, 131, 132, 133, 141, 145, 156, 161, 166, 171, 176, 177, 189, 190, 195, 199, and 204).

## 3. Pseudarthrosis

In the Cohort study, radiographic data were available to determine the fusion status for 1,794 patients in the pedicle screw group and 382 patients in the noninstrumented group for the treatment of degenerative spondylolisthesis, and 506 patients in the pedicle screw group and 184 patients in the nonpedicle screw group for the treatment of fracture. There was a statistically significant reduction in