



## Orthopedic Surgery (Spine)

In recent years, the outcome evaluations and healthy life expectancy that are discussed in the context of medical administration, are strongly related to lifestyle-related diseases and medical disorders. Meanwhile, no matter how healthy the internal body is, if the musculoskeletal function supporting it is not in good condition, a patient is not truly in good physical health. Looking at the future social structure of Japan, it is very important that people stay active suitable to their age and lifestyle. Daily activities such as walking, standing straight, sitting on a bed or wheelchair, swallowing and breathing without problems are all deeply related to the vertebra (spine). To achieve true quality of life, the spine literally functions as a backbone.

To deliver optimal and safe treatment for patients with spinal disorders, the spinal surgery field, and the medical devices and systems for such use, have evolved significantly over the past decade. The following three innovations are introduced:

### 1. Innovation for minimally invasive surgery

Traditionally, it was necessary to approach spinal surgery with a large incision and opening up of skin and muscle (Figure 1). However, with the development of minimally invasive surgery that reduces damage to the body, the development and improvement of medical devices for such surgery are now in their advanced stage. Typical examples are a discectomy of a lumbar disc herniation under endoscopy and microscopy, percutaneous pedicle screw fixation using a cylindrical surgical instrument (Figure 2), and percutaneous vertebroplasty that performs percutaneously balloon dilation and cement injection for spinal compression fractures. These minimally invasive surgical procedures significantly reduce operation times and blood loss, contributing to shortened post-operative hospital stays. Medical device manufacturers are shifting their efforts from simply selling the products to the industry-government-academia initiatives to offering training for introducing new technology and calling for safety in cooperation with academic societies and the PMDA.

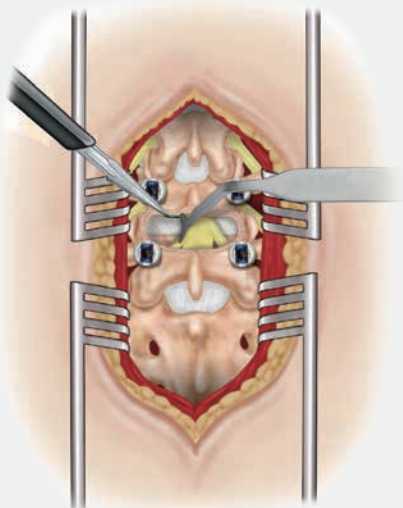


Figure 1

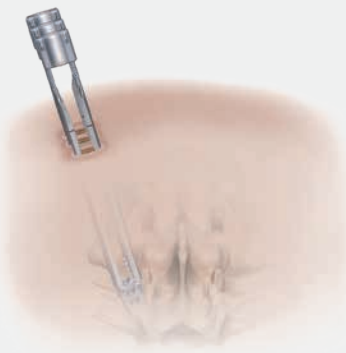


Figure 2

### 2. Innovations for improving surgical safety

As surgery has become less invasive and the patient population undergoing spinal surgery continues to expand, improvement of safety has become increasingly more important. In order to achieve more accurate surgery, navigation systems assisted by computer technology are gaining ground. Based on image data taken before surgery with an X-ray fluoroscopic apparatus, a 3D simulation is performed to determine the insertion position and angle of spinal screws. Benefits during surgery include accurate surgical operations by overlapping the operation site with a planning image displayed on a monitor, and lower radiation exposure to both the patient and physician due to reduced use of fluoroscopy. In order to mitigate the post-operative risk of nerve paralysis, a nerve monitoring device was developed to observe changes in neurological symptoms during surgery. Devices and software aimed at improving the safety of spinal surgery continue to advance.

### 3. Innovation for maximizing clinical outcomes

Innovations for maximizing clinical outcomes obtained from spinal surgery derive from the products and from evidence-building. Examples derived from products include vertebral cages that are surface-treated with titanium for better fusion with patients' bones, cervical artificial vertebra discs that preserve cervical spine mobility, and new bone grafting materials (human demineralized bone matrices) with osteoinductive characteristics. Examples derived from evidence-building include a surgical database in the form of a registry, which the Neurospinal Society of Japan and the Japanese Spinal Instrumentation Society are working on. These efforts of collecting big data in the spinal field facilitate Japanese evidence-building and global transmission of the information.

Innovation in the field of spine surgery outlined above will contribute to preventing people from becoming bedridden, an urgent issue for Japan, and to the shift from hospitalization to home care and nursing. Comprehensive innovation in the spinal field that combines hardware including medical devices, and software including education, evidence-building, and patient awareness, are indispensable for healthy Japanese life expectancy.