



PediGuard[®]

Placing Navigation Back in Your Hands

Case Report

Challenges in pedicle screw placement

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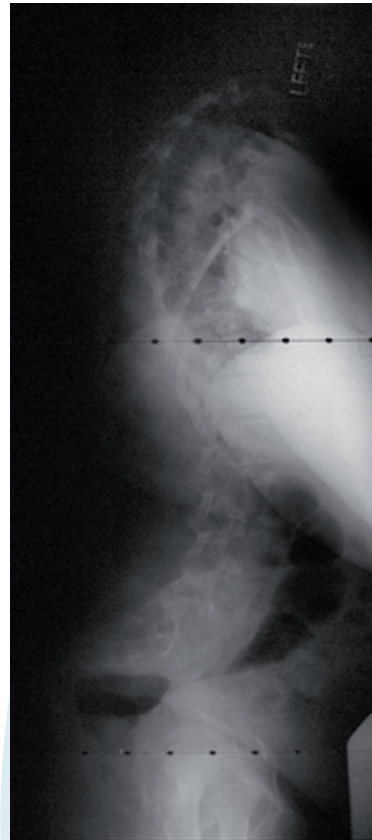
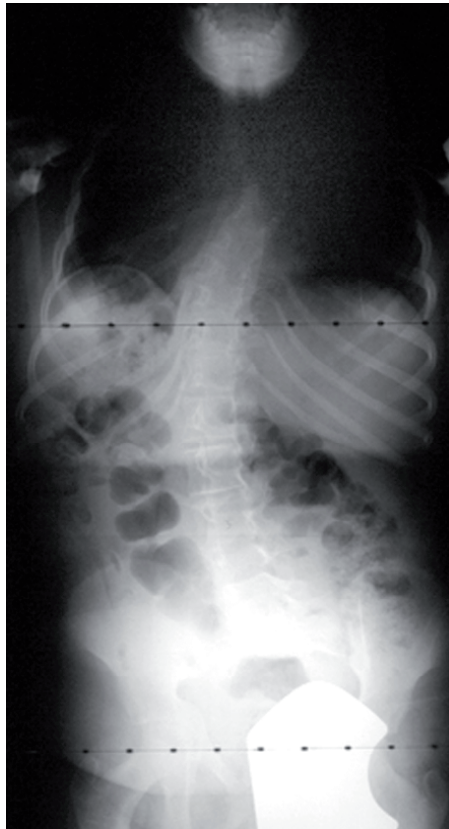
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SpineGuard[™]
Make spine surgery safer



Case

14 y/o male with syndromic kyphoscoliosis



Operative Goal

Correction and fusion from T1-L4 utilizing a pedicle screw and rod system.

Pre-Operative Assessment

Patient's size will limit ability to utilize image intensification intraoperatively to assist in pedicle navigation.

Small sclerotic concave pedicles will reduce or eliminate the use of standard Lenke style probes for pedicle preparation.

Previous fusion at T2-L4 will reduce identifiable anatomic landmarks.





Pedicle Preparation Instrumentation: PediGuard®

Free-hand electronic pedicle preparation instrument requiring no additional equipment or steps.

Analyzes tissue at tip of device (cancellous, cortical or soft tissue) and provides audible and visual feedback to surgeon alerting of possible cortical perforations.

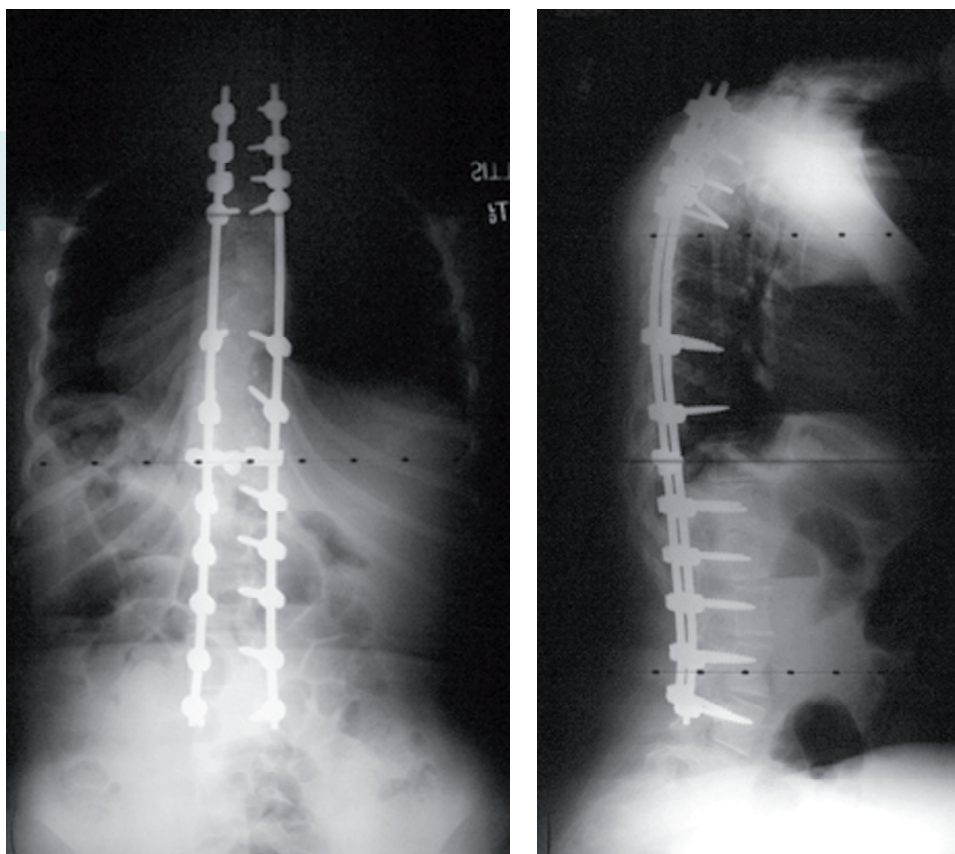


Clinical Summary

Standard Lenke style probe proved too large and with only tactile feel was inadequate to navigate the small sclerotic pedicles.

PediGuard was used to prepare the pedicles and provide tissue type feedback at the end of the instrument to allow adjustment of the device to avoid pedicle perforations.

The need for intraoperative imaging was reduced.



Pedicle screws were placed bilaterally at T1-4, T8, T10, T12, and L1-4.

Approximately four pedicles were too small to allow a complete inside technique and the screws were placed with an in-out-in technique.

Without the PediGuard device, the case would have been extremely difficult to complete due to the patient's large size, very small pedicles, and the inability to use image intensification.



Pedicle preparation technique

Standard technique

Device was passed down the pedicle by applying moderate pressure and rotating handle back and forth in a drilling type motion through the cancellous bone.

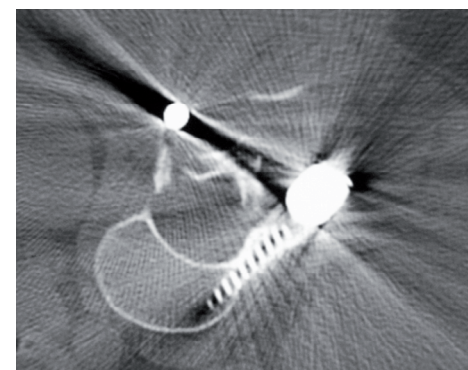
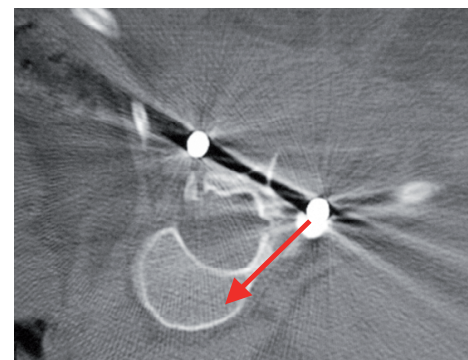
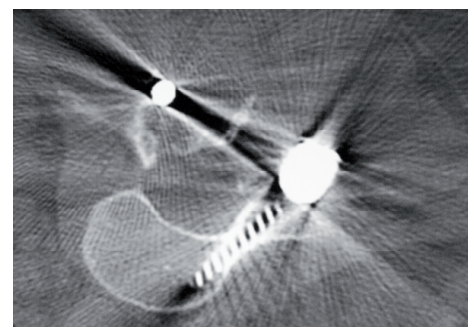
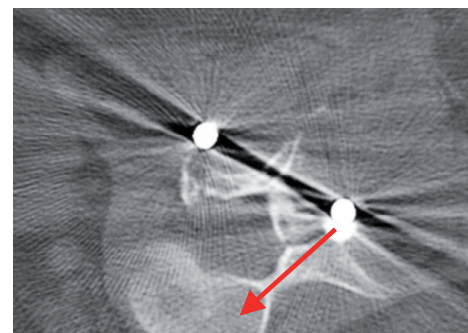
If device signal changed, indicating the tissue at the tip had changed from cancellous bone, the handle was rotated in order to move the tip until the original signal was obtained.

Once original signal was obtained, step one was continued until the proper depth was achieved or signal changed (if signal changed step two was repeated).

In-Out-In technique

When pedicle was too small to pass the PediGuard, the device was slid down the lateral wall of the pedicle starting just beneath the transverse process using the tactile feel and audible feedback to remain against the wall.

Once the pedicle enlarged as it entered the vertebral body, the device was inserted through the cortex and into cancellous bone using tactile feel and audible feedback to assist.



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Caution: See package insert for labeling limitations, intended uses, relevant warnings, precautions, side effects and contraindications.
Federal (USA) law restricts the sale and use of this device to a prescription of a physician.

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