



FIREFLY® Case Study

Revision

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Chief Medical Officer and Founder
Mighty Oak Medical, Manufacturer of FIREFLY



Patient History:

- 25 year old / Male
- Primary Diagnosis:
 - Idiopathic scoliosis
 - Failed PSF at T3 - L2
 - Migrated, malpositioned pedicle screws
- Increased thoracic kyphosis

Treatment Plan:

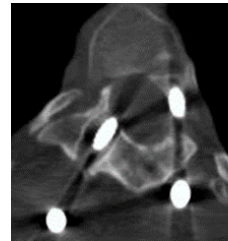
- FIREFLY Utilization at:
 - T1, T4, T5, T6, T8, L3
 - L4 TBD intra-operatively

Concierge Pre-Surgical Planning:

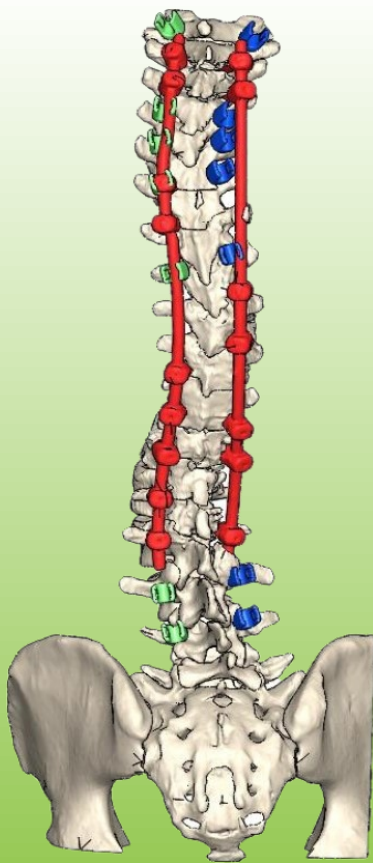
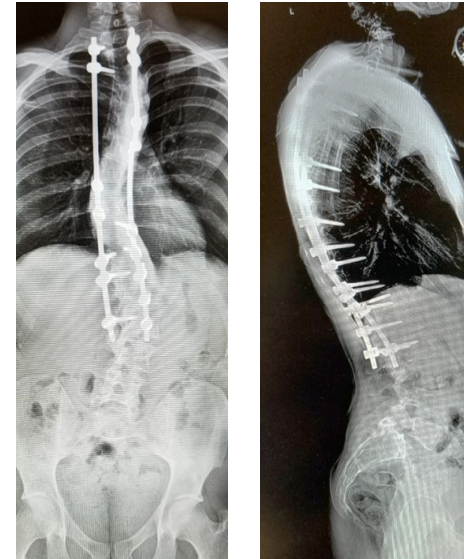
This is a case of a 25 year old male with a history of idiopathic scoliosis. Previous PSF failed in the upper thoracic spine.

The 3D modeling provided by Mighty Oak allowed for a thorough analysis of the pre-existing trajectories. This analysis determined that existing screw trajectories were acceptable and would be retained at T2, T3, T7, T9, T10, T11, T12 and L1. Trajectories deemed unacceptable will be redirected using FIREFLY guides.

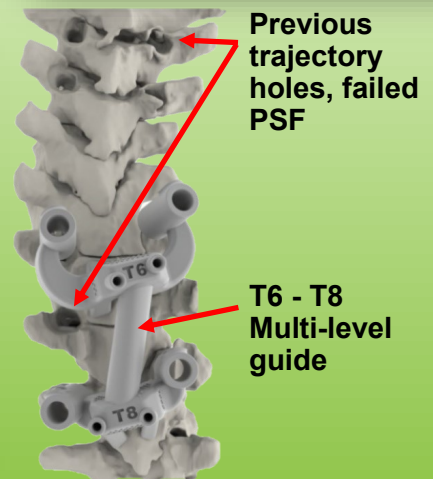
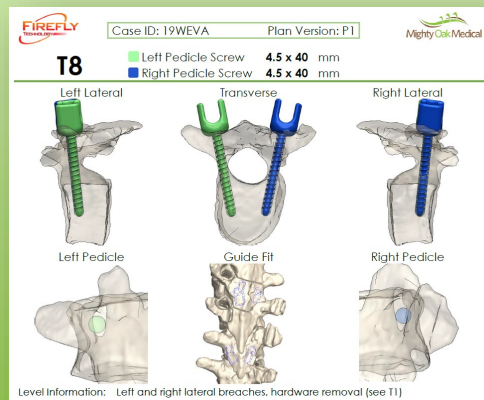
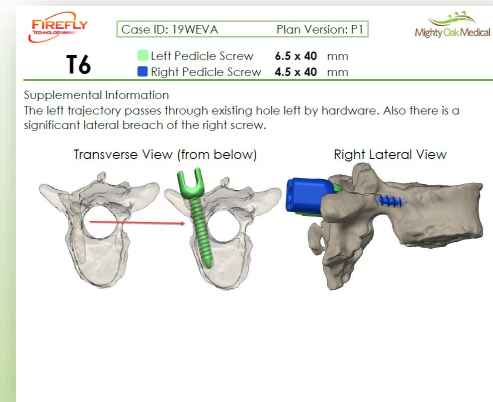
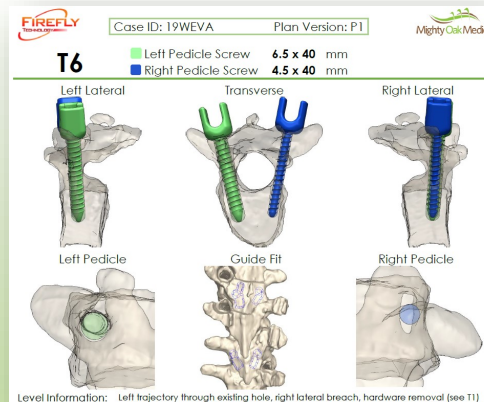
Multi-level guides were created for T4/T5 and T6/T8 with single-level guides for T1 and L3 to extend the existing construct.



*Existing trajectory breaches medial cortical margin



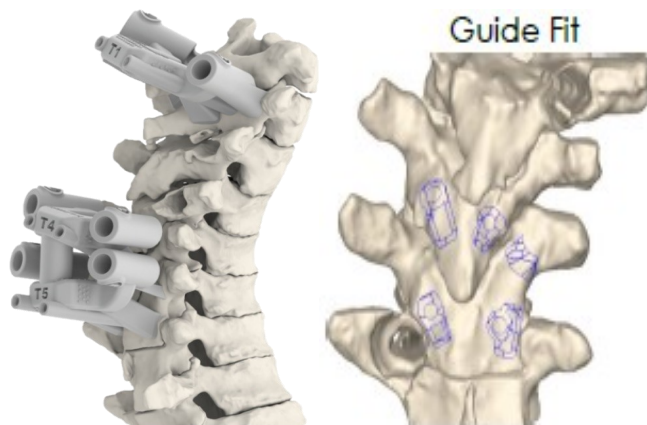
*New screw placement overlaid with existing failed hardware (Red) to help surgeon assess hardware interference



Intra-Operative:

A thorough soft tissue dissection was performed from T1 - L3. Next the existing instrumentation was removed, with extreme care for the upper right thoracic pedicle screw construct. These screws were severely angulated into the spinal canal as determined by the pre-operative analytics. Additionally, specific pedicle screws which were seen to be breaching the medial cortical margins based on pre-operative analytics were removed or redirected using FIREFLY Guides.

The exposed bone surface was meticulously compared to the 3-D printed bone model to exactly identify levels. Three areas of pseudo arthrosis were identified, at T2-3, T3-4, T7-8. The multilevel FIREFLY patient-specific drill guides were applied to the spinal segments of T4/T5, and T6 /T8 that are within the fusion mass. The single level guides were applied at T1 and L3, adjacent to the fusion mass. In each instance, the guide was meticulously approximated to the dorsal bony contours by “corking” the guide into position. Fidelity of the patient-contacting surfaces was visually assessed. The guide was then transfixated to the bone with a depth controlled fixation screw. A series of drill and tap sleeves were then applied to the guide, with the pedicle then being cannulated to a high degree of accuracy and specificity using the 3.2 mm drill bit to the indicated depth. The qualified tap of the appropriate diameter was then used for the pre-operatively determined screw dimension. The guide was then removed and the pedicle screw of the pre-determined dimensions was driven into position. The drilling, tapping and screw placement were all done using power.



*Guide docking locations as identified in the Patient-Specific Plan



Results:

Total time required to perform the pedicle navigation and screw placement steps for 20 screws in the revised construct was 29 minutes and 24 seconds. No intra-operative fluoroscopy was required during the procedure. A post-operative x-ray was obtained to confirm screw placement.

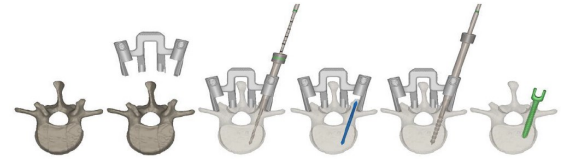
LEVEL	RIGHT TIME	LEFT TIME	TOTALS
T1	1:16	1:16	2:32
T4	1:27	1:27	6:00
T5	1:33	1:33	
T6	1:35	1:35	6:22
T8	1:36	1:36	
L3	1:06	1:06	2:12
New Screws Total (12)			17:06
Retained Screws Total (8)			12:18

*Time includes guide fit, pedicle cannulation and screw placement

The correction of the deformity was achieved through osteotomies of the non-union sites as well as a 2 segment (UIV and LIV) fusion extension. Strategic selection of the pedicle screw sites relative to the non-unions and the osteotomies enabled the corrective forces to be effectively applied. Degrees of correction are indicated to the right:



CURVATURE RANGE	PRE-OP DEFORMITY	POST-OP DEFORMITY
T1-T7	36°	27°
T7-T11	48°	30°
T11-L3	39°	26°



Discussion:

The surgeon was able to review and approve a detailed FIREFLY Patient-Specific Plan that identified specific levels of pedicle screw fixation, levels of concern, and/or “pedicles of opportunity for fixation”. Effective presurgical planning using the power of the FIREFLY 3D images and analytics allowed the surgeon to thoroughly dry run the operation prior to surgery. The surgical plan developed pre-operatively could then be executed precisely in the operating room using FIREFLY Patient-Specific Navigational Guides.

Furthermore, the instrumentation performed with FIREFLY Patient-Specific Navigational Guides provided numerous efficiencies without the use of fluoroscopy. These efficiencies allowed the surgeon to dedicate their time and efforts to other critical aspects of the procedure such as osteotomies and the deformity correction.

What is FIREFLY?

FIREFLY Guides are FDA-cleared and enable optimal screw placement by incorporating planned screw diameter, trajectory, length, and entry point into the guide design.

A preoperative CT is used to make a 3D virtual model of the patient’s spine, which is then used to create a detailed presurgical plan. The guides are then designed around the surgeon’s approved trajectories. This makes each guide not only patient-specific, but level-specific as well.

A 3D printed, anatomically exact bone model of the patient’s spine is also provided for intraoperative use and patient education.

- ◆ FDA cleared and CE marked for use in adult and pediatrics
- ◆ Cleared for use without intraoperative fluoroscopy
- ◆ Predetermined screw sizes and mechanical constraint contribute to faster screw placement
- ◆ Validated to 99.7% accuracy¹
- ◆ No capital expenditure cost

Navigate. Don't Complicate.™

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