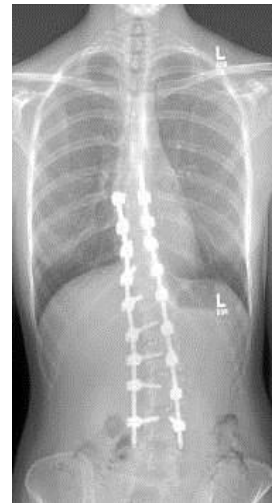
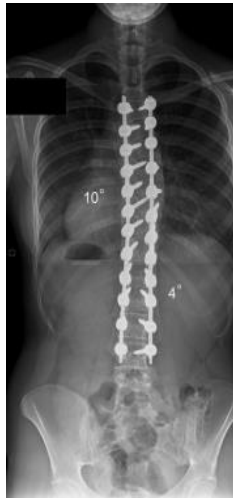


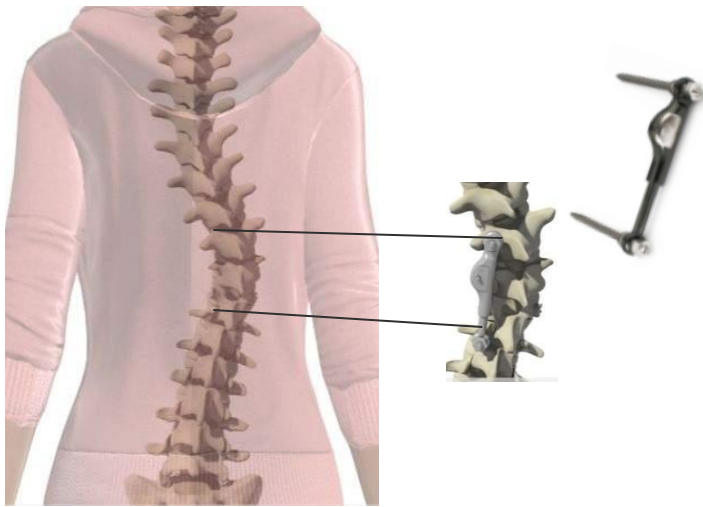


**MID-C System for AIS
Clinical Summary
July, 2016**

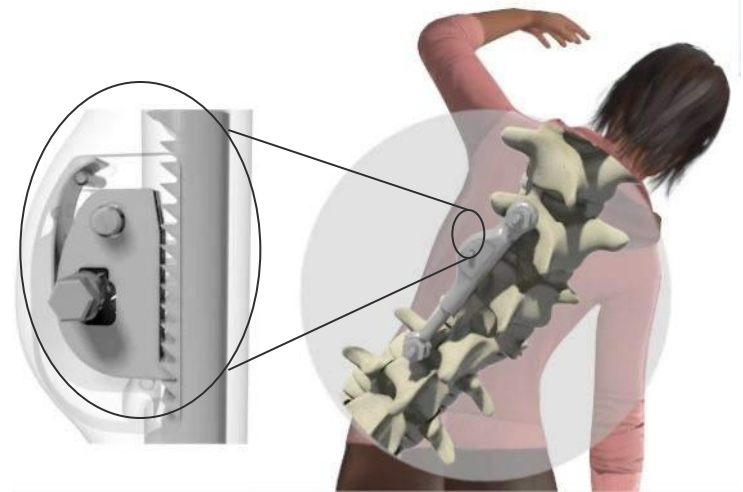


Long Posterior Spinal Fusion (PSF) is considered the 'gold standard' in the treatment of progressive Adolescent Idiopathic Scoliosis (AIS). The procedure involves Screws, Hooks or Hybrid constructs, with long Titanium or Cobalt Chrome rods. On average, 10 motion segments are being fused for life.

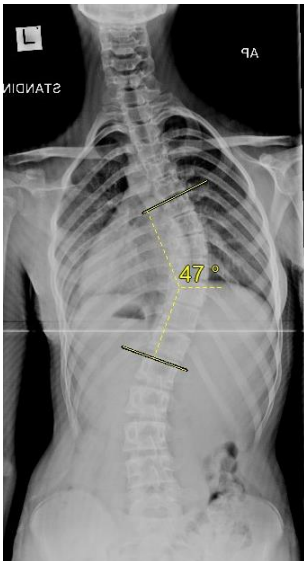




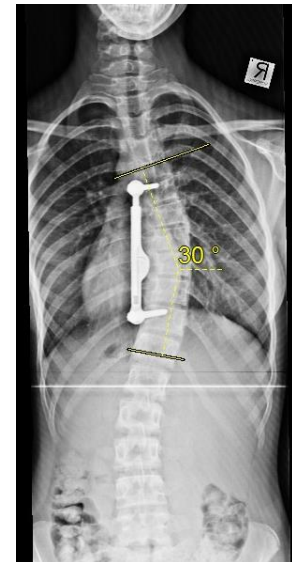
ApiFix system requires only 2 screws and an expandable rod



A Miniature ratchet mechanism is activated when the patient performs lateral bending



Post operative physical therapy gradually gain additional correction



- System is a ratchet based expandable rod, connected to two bone screws located at the concave side of a scoliotic deformity.
- Device designed to increase its length as patient bends to the corrective direction, and maintain the correction as patient returns to reference.
- Screw-Implant connection is a poly-axial joint and therefore no moment can be delivered to the implant; loading is pure axial compression.
- Polyaxial joint allows system to be aligned after any incremental correction.
- The polyaxial joints use ADLC ceramic coating to minimize wear
- Incremental correction begins 3 weeks after the procedure.
- Percutaneously accessible Control Pin provides the option of switching the mechanism between Ratchet, Idle and Locked positions.



- Maintain Cobb angle below baseline, and $< 50^\circ$, minimal risk of curve progression ⁽¹⁷⁾
- Limit number of motion segments involved
- Use fewer screws
- Minimize incision size
- Intended benefits compared to long fusion:
 - Shorter operative and hospitalization time
 - Unilateral approach minimize invasiveness
 - Minimal blood loss
 - All options remain available; “no bridges are burned”



Long fusion



MID-C

	Typical Standard Scoliosis Case	Typical ApiFix Case
Incision size	~ 40 cm	~12 cm
Blood loss	800-1200 CC	~50 CC
Surgery time	4-6 hours	~1 hour
Hospitalization	6-7 days	2-3 days



- The MID-C System is intended to be used for treatment of Adolescent Idiopathic Scoliosis (AIS) patients having:
 - Age of 11 to 17 years.
 - Cobb angle up to 60 degrees.
 - Classified as Lenke type 1 & 5.
 - Flexible curve, reducible to below 35° on lateral bending X-rays taken in the supine position.

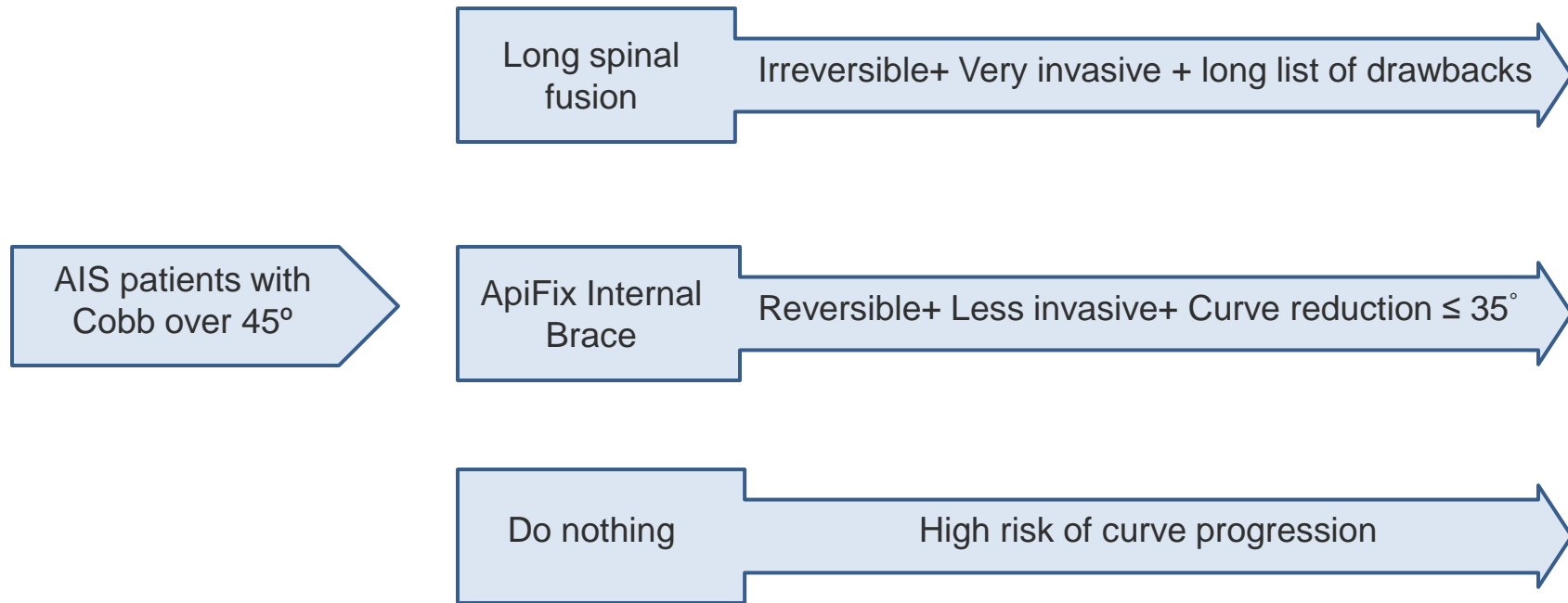
Long spinal
fusion

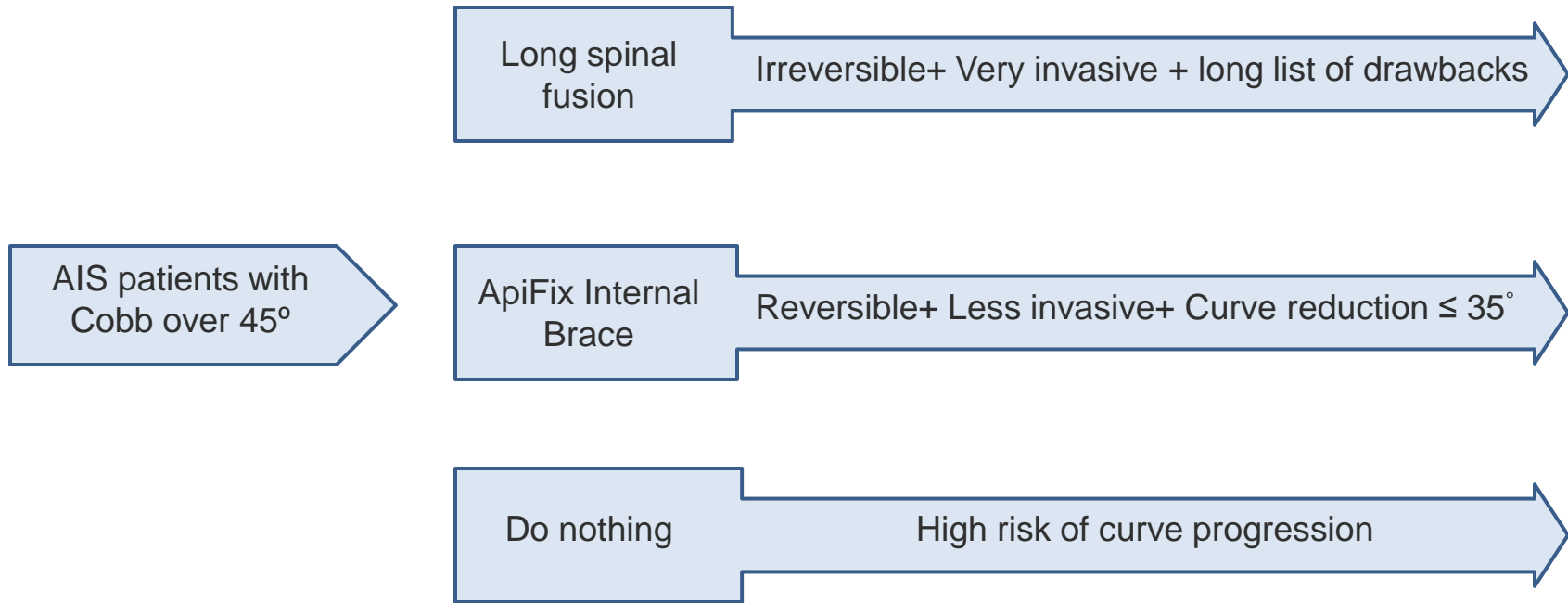
Irreversible+ Very invasive + long list of drawbacks

AIS patients with
Cobb over 45°

Do nothing

High risk of curve progression





ApiFix Benefit:

Curve reduction to the point progression is unlikely after skeletal maturity, avoiding the need for the irreversible long spinal fusion.

- Device received CE-Mark in December 2012
- Clinical Status to date:

Total of 89 patients treated in 9 countries (14 sites)

Patient Follow Up to date:

- 3 patients > 4 years
- 13 patients > 3 years
- 30 patients > 2 years, 24 of them reached skeletal maturity
- 54 patients > 1 year , 28 of them reached skeletal maturity
- 66 patients > 6 months

Total Clinical Experience: 1920 patient-months

Adverse Events:

- No device breakage
- No screw breakage
- No neurological damage
- No over-correction
- Two infections that resolved with device removal
- Four revisions to long spinal fusion, due to inability to reduce the curve to a satisfactory level; all in patients that were outside the current indications.
 - Two of the four patients revised to long fusion also had mini re-operations due to Control Pin left in the Idle position.
- Five re-operations due to screws positioned outside the pedicle
(5 of total 196 screws placed is in line with the general statistics of 5% pedicle screws misplacement)
- Two wound seromas, resolved spontaneously.

Total patients re-operated	11/89 (12%)
Pts Re-Op among all pts per current indications	6/84 (7%)
Pts Re-Op post first 25 pts, per current indications	4/64 (6%)

- Two main changes that improved outcomes:
 - Increasing number of levels spanned from 3-4 to 5-6
 - Refining indications to limit use to patients with non-flexible curves

Demographic and Statistics of the first 25 patients:

	Average	Min.	Max
Age @ surgery	14	8	17
Risser	3	0	4
Pre-Op Cobb of the major curve	49	40	78
Cobb of the major curve @ last F/U	35	16	70
Pre-Op Cobb of the secondary curve	34	12	52
Cobb of the secondary curve @ last F/U	27	10	48

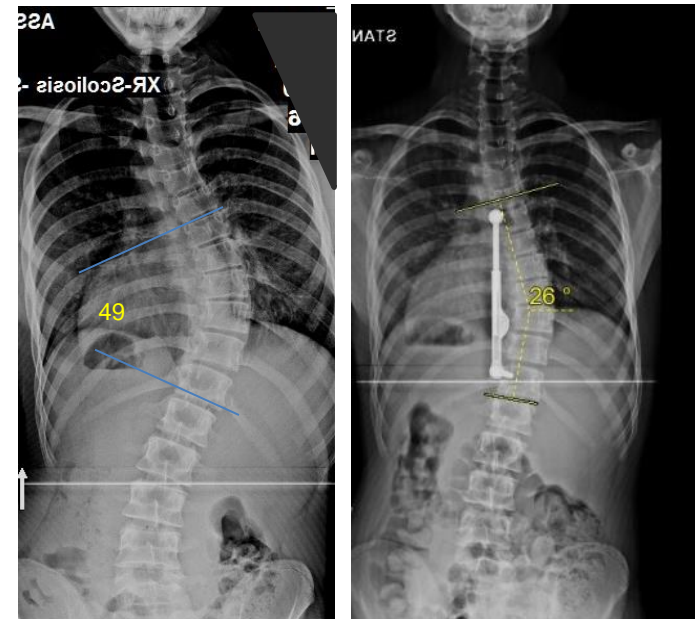
Lenke type: Lenke type 1- 22 patients. Lenke type 5- 3 patients.
Females- 24, Male- 1
Number of patients where the main curve was reduced to $\leq 35^\circ$: 11 **(44%)**

Demographic and Statistics of patients 26 - 75:

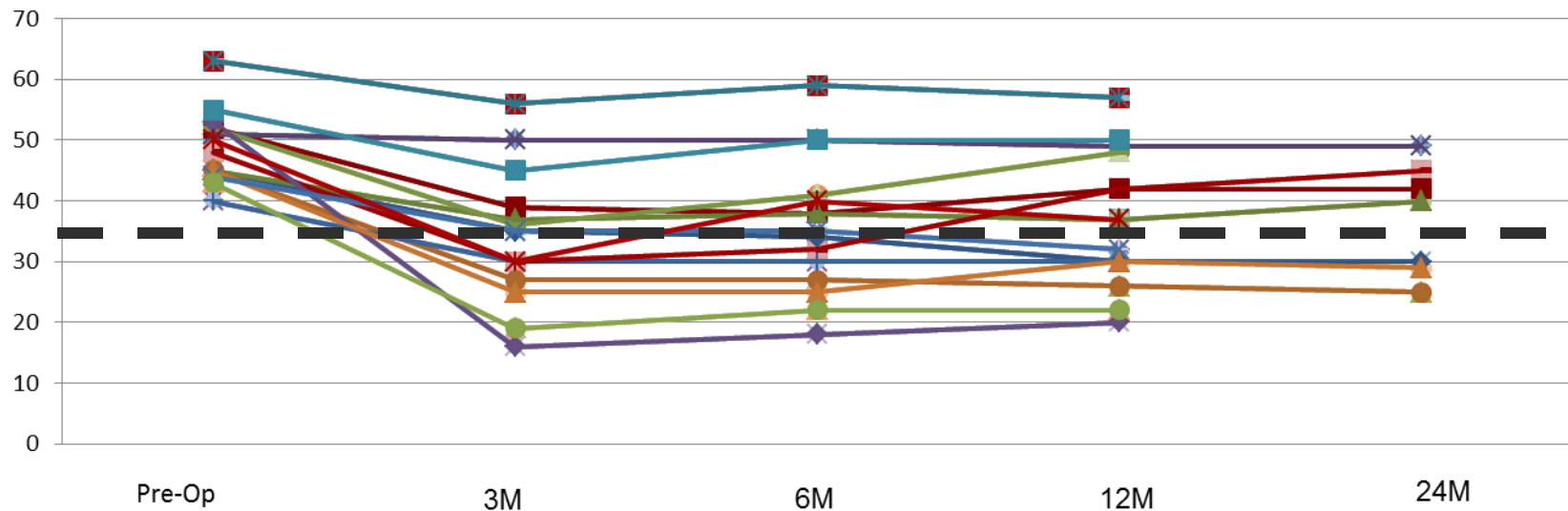
	Average	Min.	Max
Age @ surgery	14	11	24
Risser	3	0	5
Pre-Op Cobb of the major curve	44	30	60
Cobb of the major curve @ last F/U	27	8	50
Pre-Op Cobb of the secondary curve	29	18	45
Cobb of the secondary curve @ last F/U	19	5	35

Lenke type: Lenke type 1- 43 patients. Lenke type 5- 7 patients.
Females- 48, Male-2
Number of patients where the main curve was reduced to $\leq 35^\circ$: 45 **(90%)**

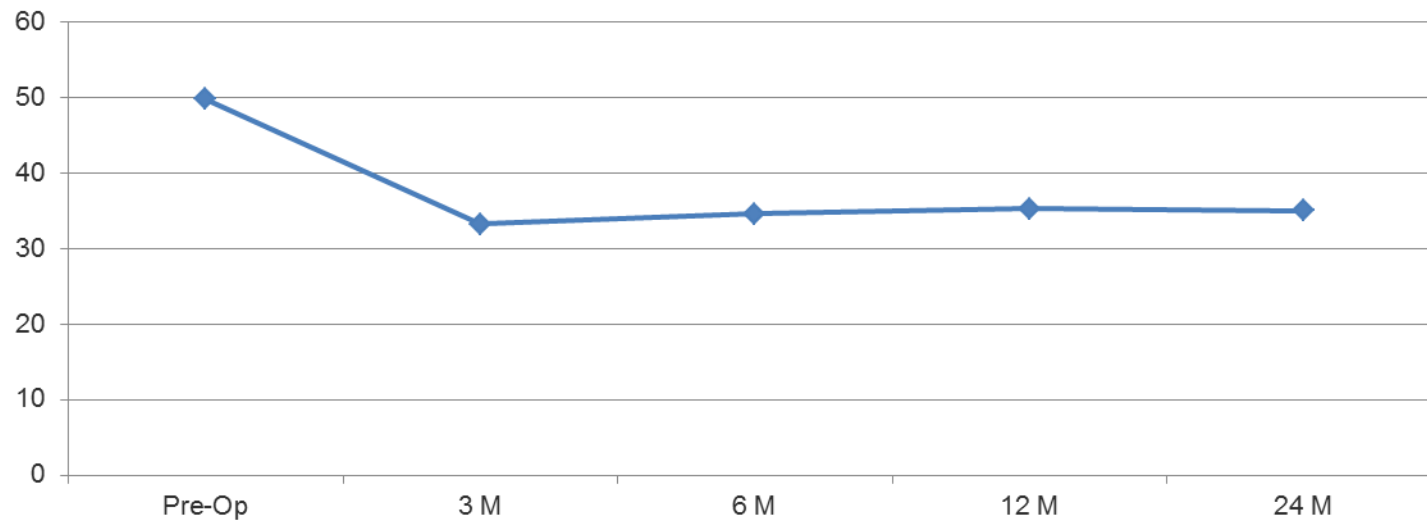
Measurements performed by ApiFix
with no independent validation



- None of the curves progressed above baseline
- Only one curve was above 50 degrees at last follow-up
- All curves above 35 degrees are due to wrong indications or wrong implants used

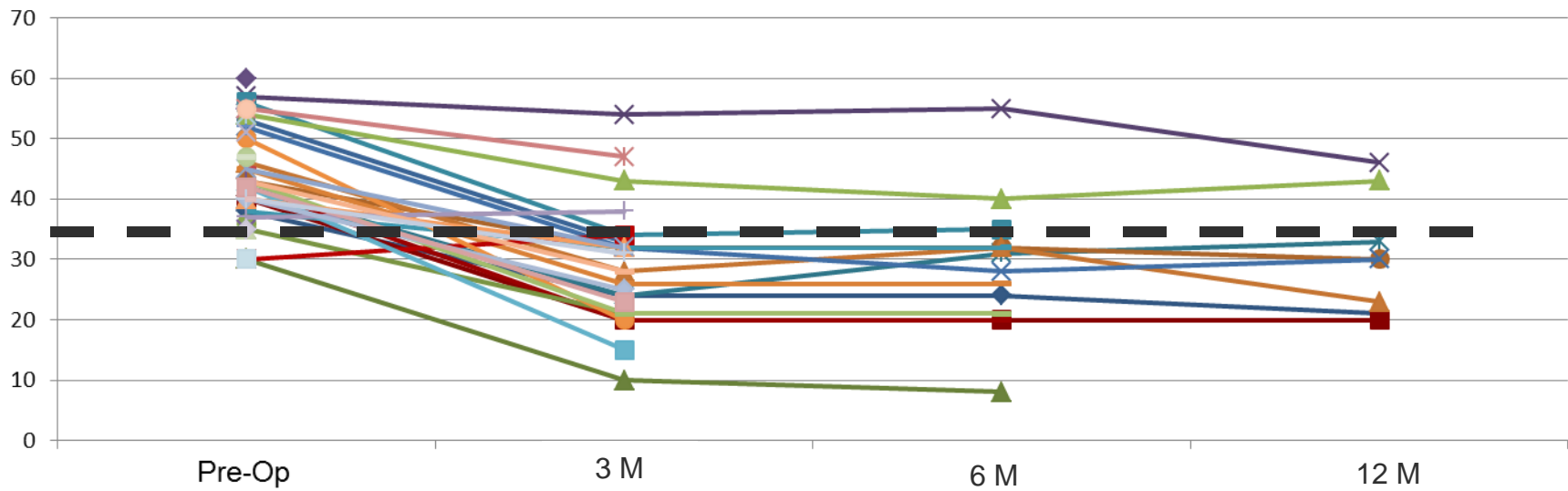
Major Curve- First 25 patients

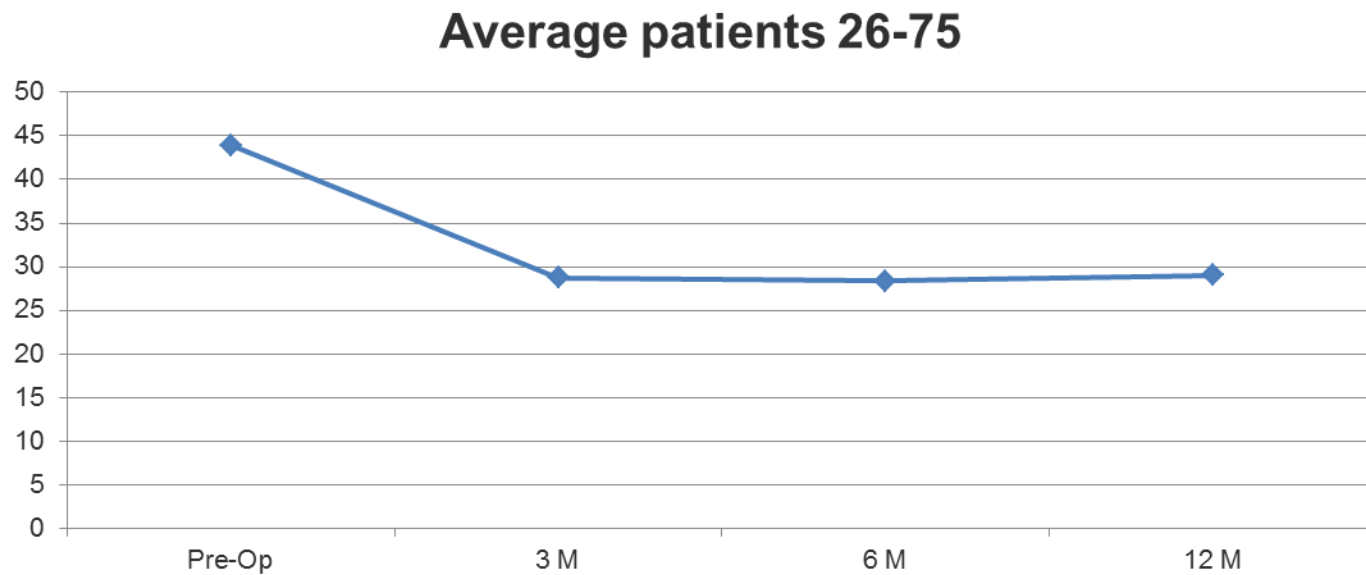
Average of First 25 patients



High degree of stability in curve correction beyond 3 months

- None of the curves progressed compared to baseline (within measurement error)
- No curve above 50 degrees
- Four curves above 35 degrees are due to wrong indications or surgical errors

Major curve- Patients 26 to 75



Data show good stability of curve correction beyond 3 months

Thank you!

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