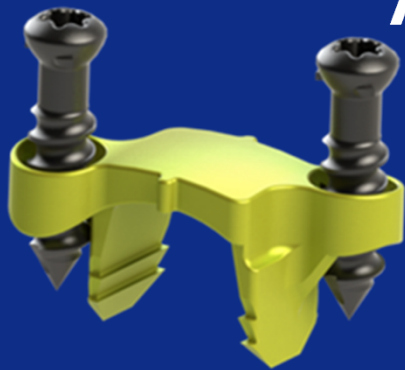


A Prospective Clinical Trial on a Scoliosis Growth Modulation Clip/Screw Device: Initial Safety Results

Wall E, Reynolds J, Jain V, Bylski-Austrow D, Ferris A, Samuels P, Alonso M, Crawford A



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Disclosure



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Approved IDE Study

- Prospective Initial Safety Trial
 - (www.clinicaltrials.gov NCT01465295)
- Non-fusion Growth Modulation
- Adolescent and Late Juvenile Scoliosis
- 6 Patients

Inclusion

- Lenke: 1A, 1B
- Cobb: 25°-40°
- Levels:T3-L1
- Age: ≥ 10 years
- Bone Age: < 13 ♀ < 15 ♂
- Open Triradiate, Risser 0, pre-menarchal
- ☑ High risk progression to >50

A photograph of a surgical team in an operating room, performing a procedure. The team is wearing blue scrubs and masks. A patient is lying on the table, and the surgical site is visible. A monitor in the background shows a close-up of the surgical site. The text "HemiBridge Study Clip Insertion" is overlaid on the image.

HemiBridge Study Clip Insertion

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Safety Results

- No device misplacement, loosening, breakage, migration, autofusion
- No disc contact
- No spinal canal intrusion
- No neuromonitoring changes
- No device related Adverse Events
- No return to OR

Procedure Related AEs

- Mucous Plug 1 patient
- Chylous Effusion tx with diet (NPO) and pigtail catheter 1 patient
- Minor AEs of nausea, dizziness, pain, atelectasis, effusion, slight pneumothorax

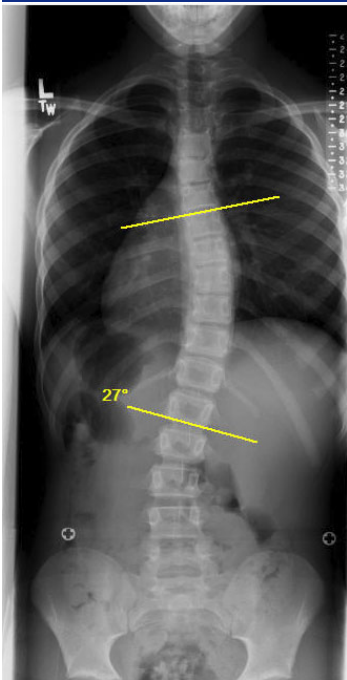
Results

- Hospital Stay <4 days
- EBL 75ml
- Surgical time 90 min (57-124 min)
- Cobb 34.4° preop, 24.6 postop ($p<0.05$)

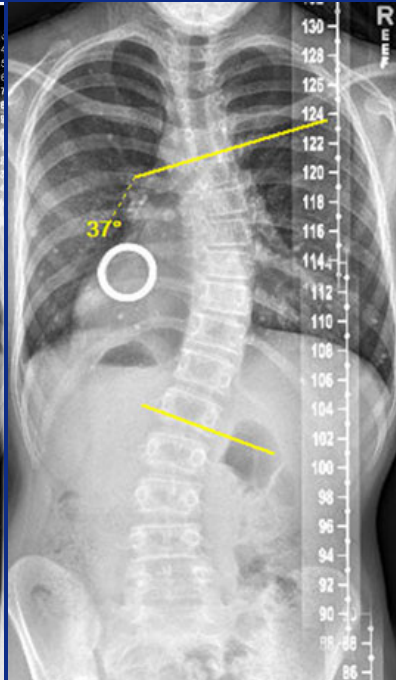
HemiBridge Study Case 1

37°

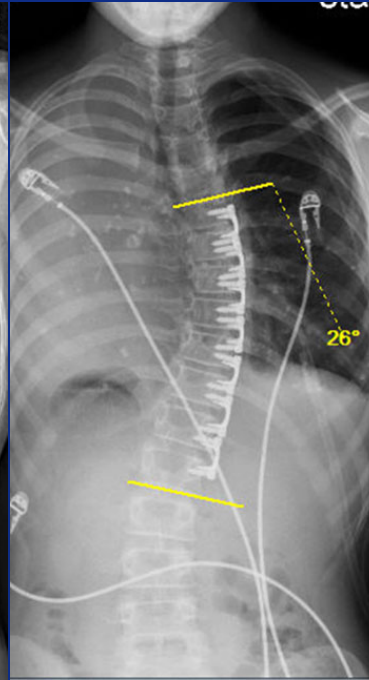
29°



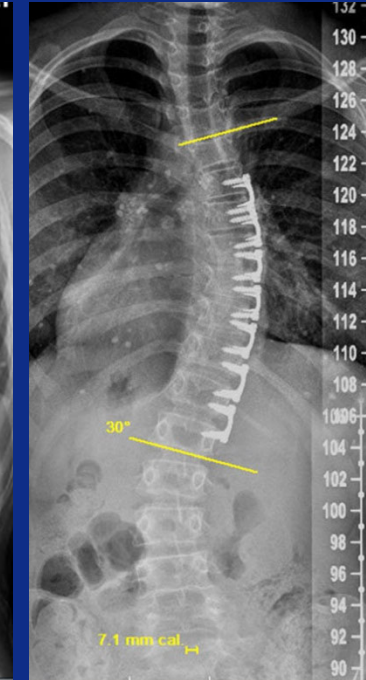
27° 4 mos
Pre-Rx



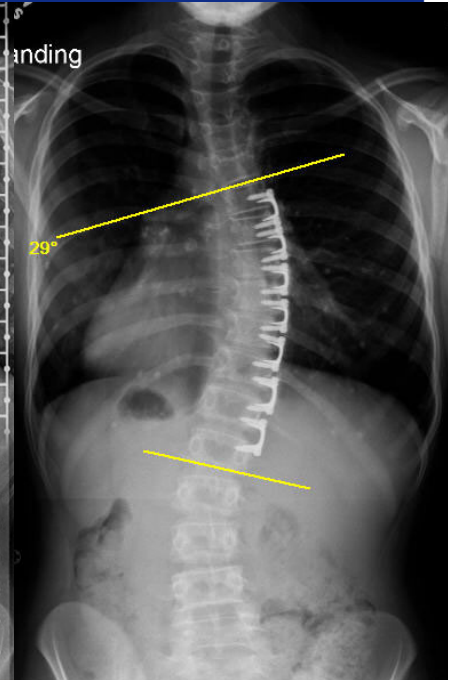
3 months later
37°; 10° rapid
progression



Rx 27°



3 mos post
Rx 29°



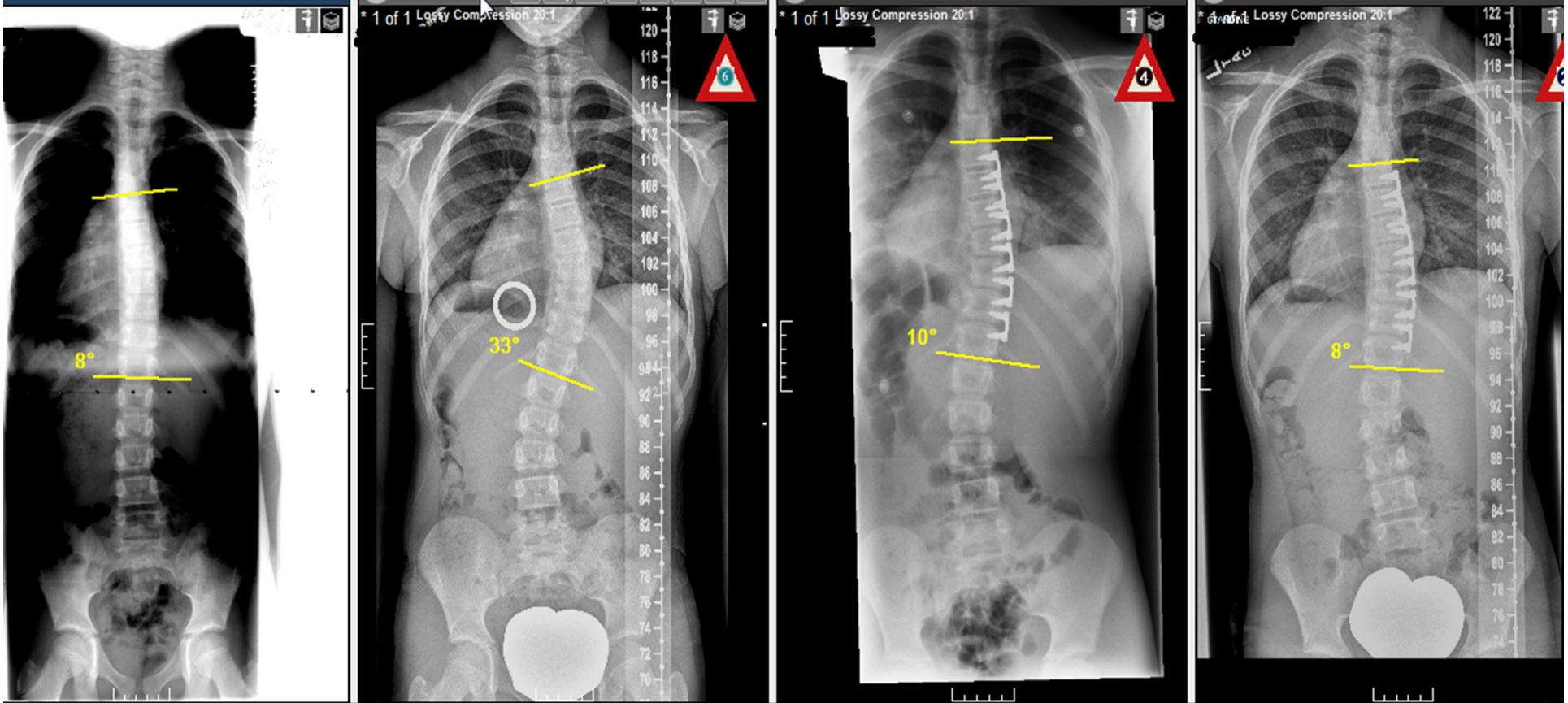
6 mos post
Rx 29° stable

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HB #2

33°

16°



2 years preop

Pre-op

1 month

3 months

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HemiBridge™ Study Case #3

Baseline
35°

Rx
36°

3 mos
41°

6 mos
43°

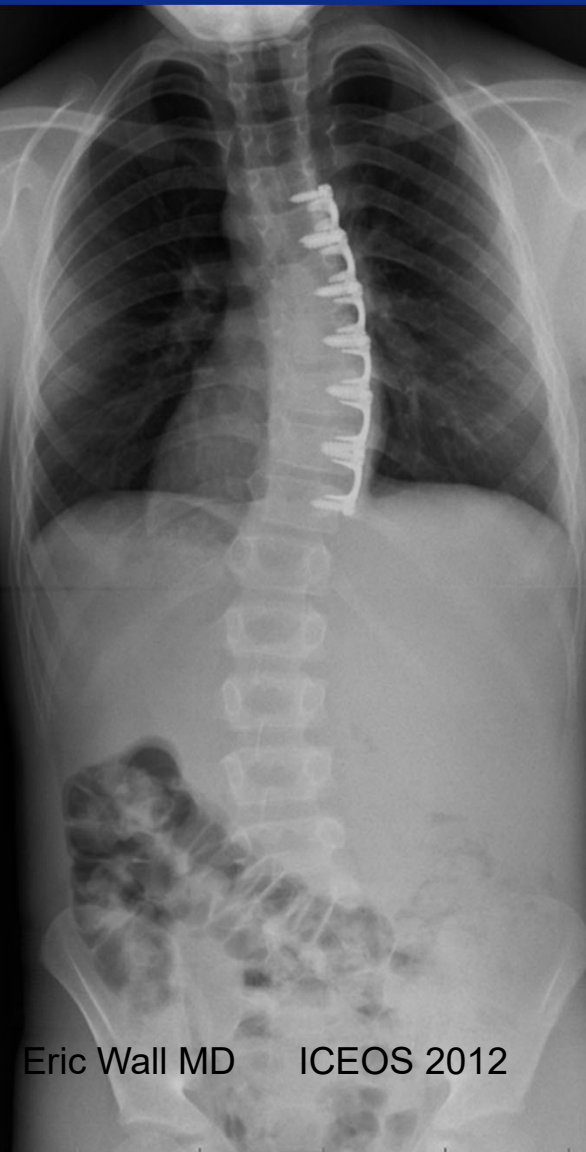


HemiBridge™ Study Case #4

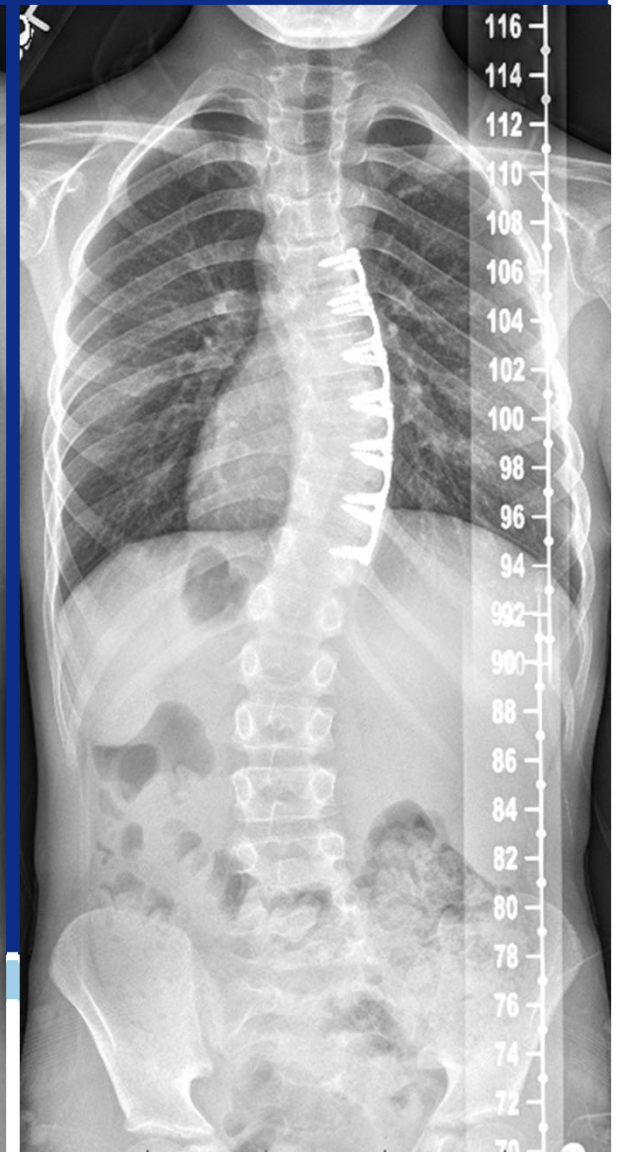
Baseline 36°



Rx 20°



3 mos 29°



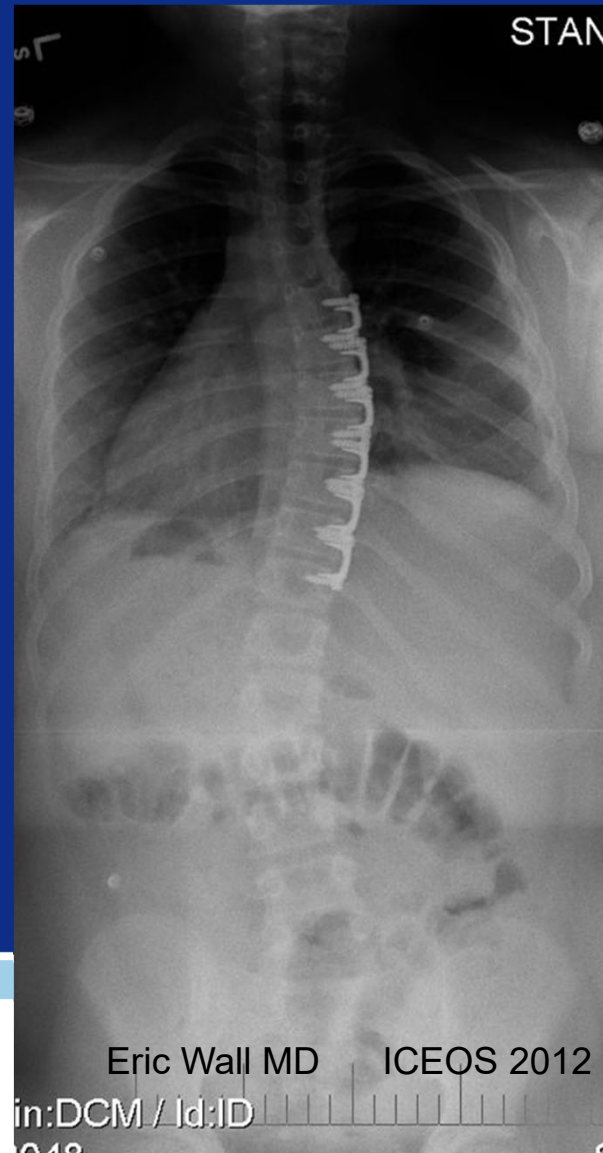
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HemiBridge™ Study Case #5

Baseline 31°

Rx 27°

3 mos 23°



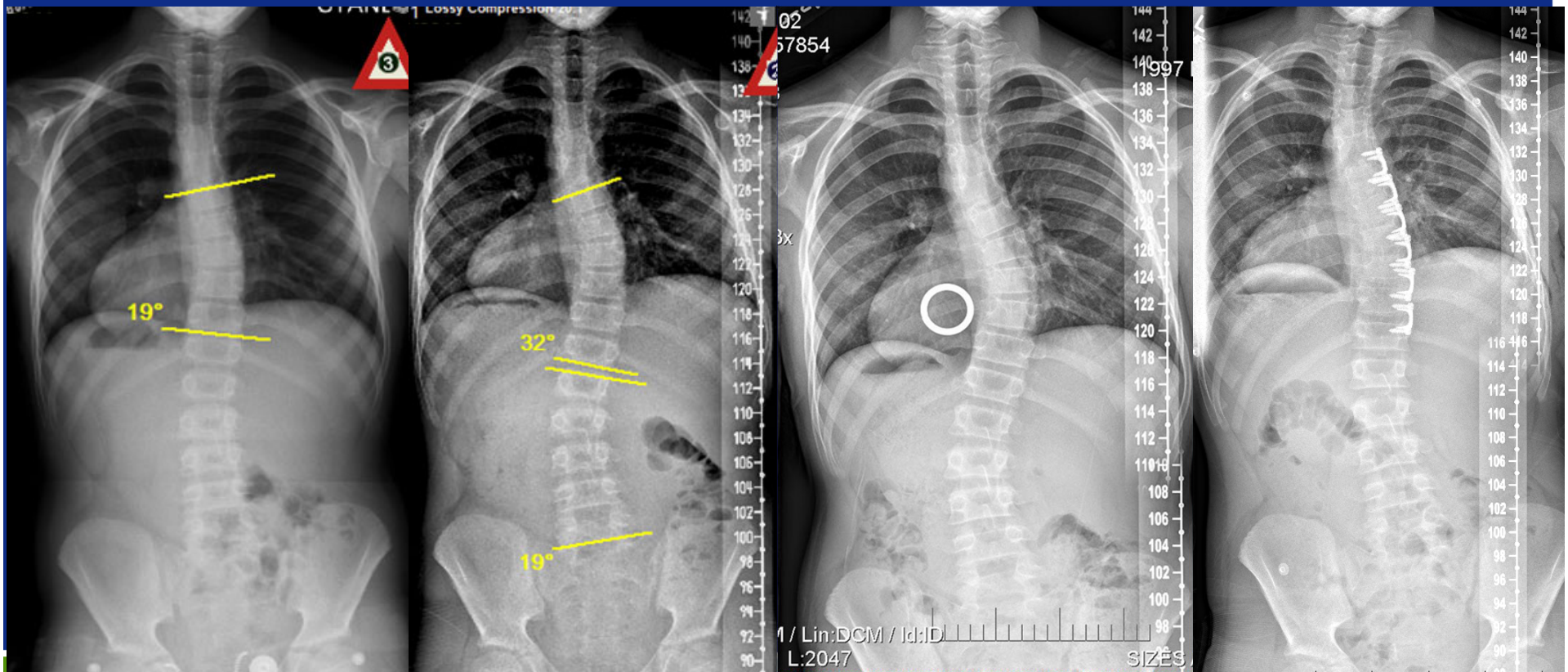
HemiBridge Study Case # 6

1 year pre
Rx MT 19°

2.5 mos pre Rx 32°;
13° Progression in 9
mos

Baseline Screening: 39°
20° Progression in One
Year and 7° in 2 mos

Post Rx 15°



Conclusion

- Enrollment completed on FDA IDE study
- No serious device-related AEs
- Statistically significant improvement in primary curve magnitude at 1 month