



# **ROTEM-guided Transfusion during Lumbar Pedicle Subtraction Osteotomy for Adult Spinal Deformity: Preliminary Findings from a Matched Cohort Study**

**Eurospine Barcelona  
September 2018**

**Thomas J. Buell MD**

**Thomas J. Buell MD, Davis G. Taylor MD, Ching-Jen Chen MD, Lauren K. Dunn MD, Jeffrey P. Mullin MD, Marcus D. Mazur MD, Chun-Po Yen MD, Mark E. Shaffrey MD, Christopher I. Shaffrey MD, Justin S. Smith MD PhD, Bhiken I. Naik MBBCh  
(Manuscript submitted to JNS Spine)**



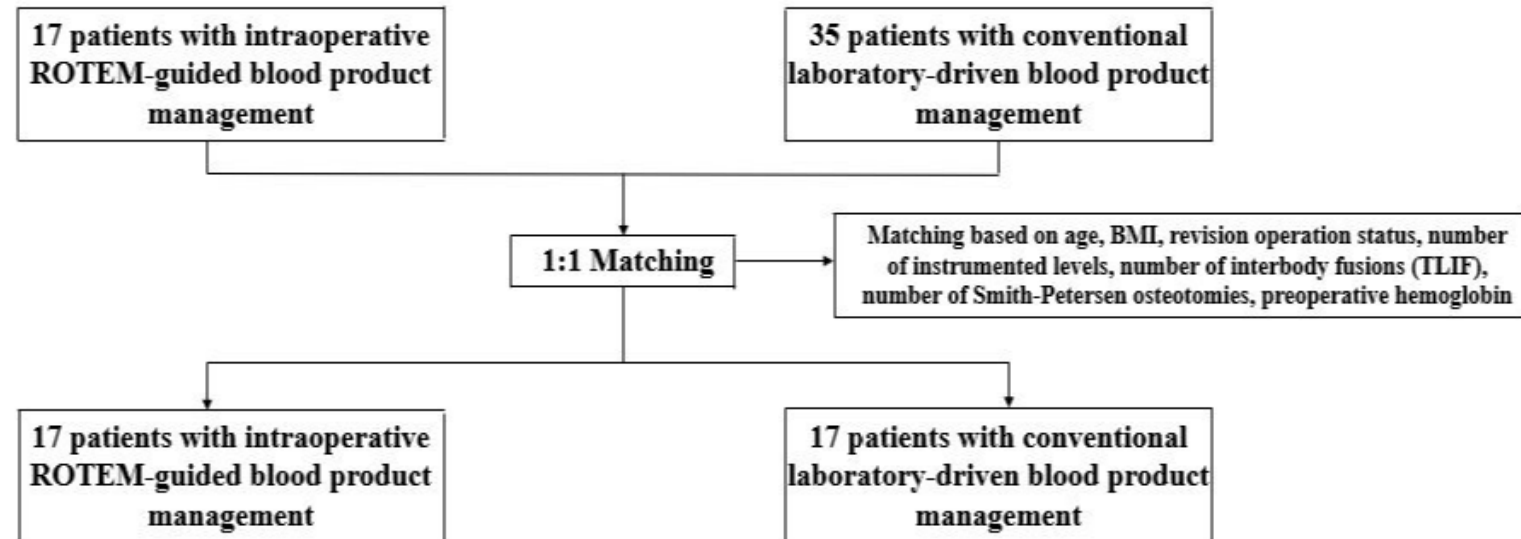
# Background & Study Objective

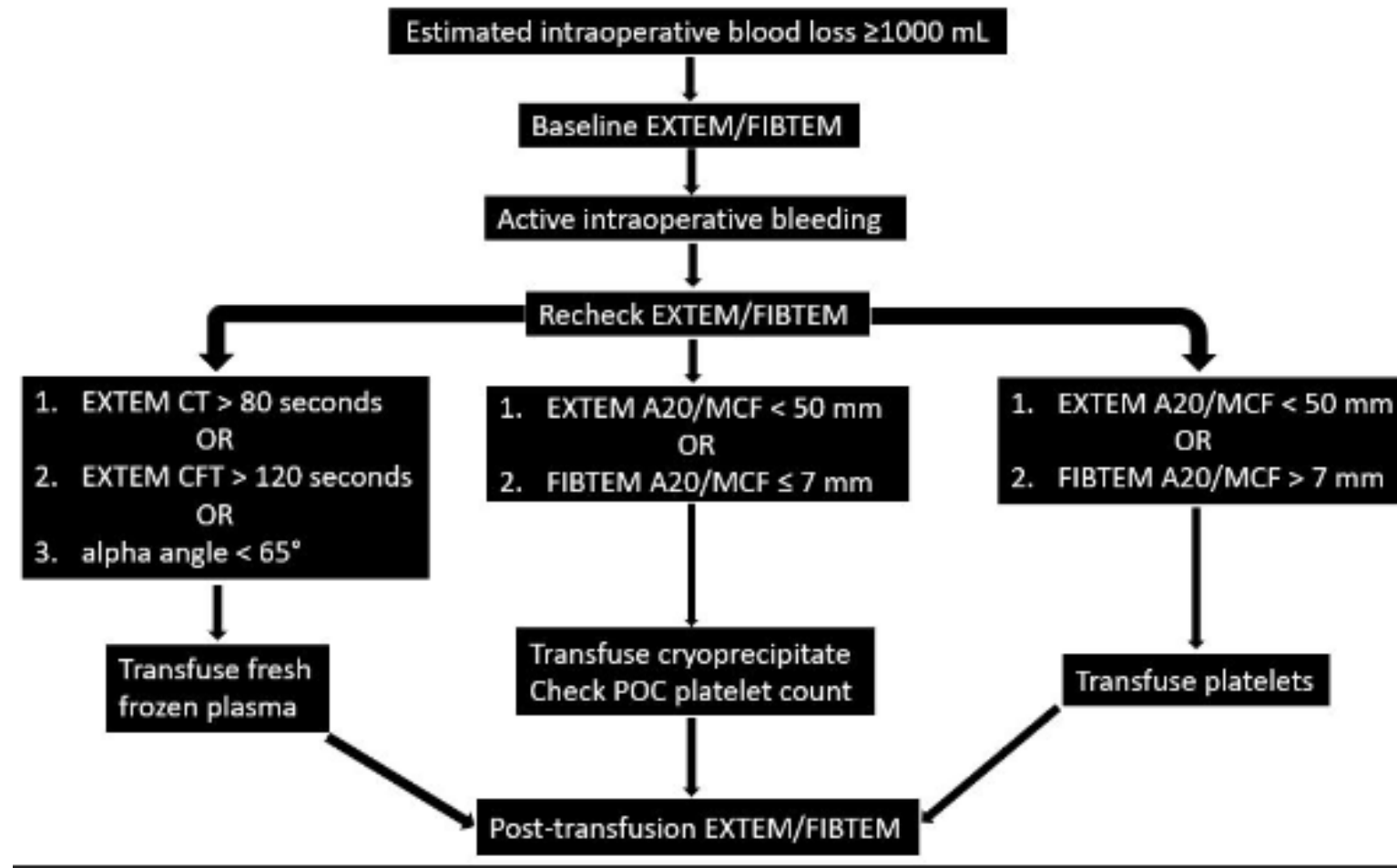
- Significant blood loss and coagulopathy are often encountered during adult spinal deformity (ASD) surgery and optimal intraoperative transfusion algorithm is debatable.
- Rotational thromboelastometry (ROTEM), a functional viscoelastometric method for real-time hemostasis testing, may allow early identification of coagulopathy and improve transfusion practices.
- The objective of this study is to investigate the effect of ROTEM-guided blood product management on perioperative blood loss and transfusion requirements in ASD patients undergoing surgical correction with pedicle subtraction osteotomy (PSO).



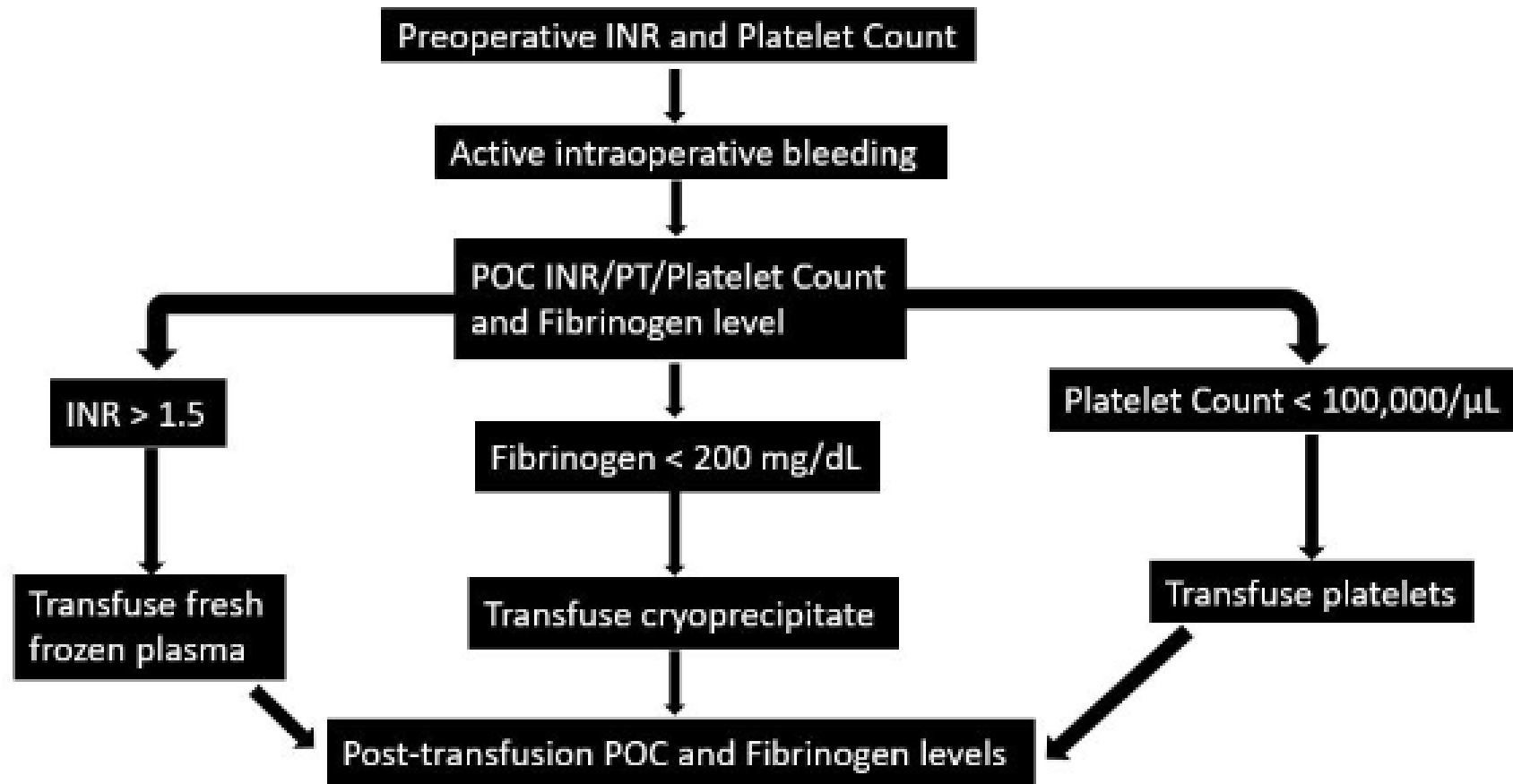
# Study Objective & Methods

- We retrospectively reviewed ASD patients who underwent single-level, lumbar PSO at our institution.
- All patients who received ROTEM-guided blood product transfusion between 2015 and 2017 were matched in a 1:1 ratio to a historical cohort treated using conventional laboratory testing (control).
- Co-primary outcomes: intraoperative estimated blood loss (EBL) and total blood product transfusion volume.
- Secondary outcomes: perioperative transfusion requirements and postoperative subfascial drain output.





Predefined treatment algorithm for patients receiving intraoperative ROTEM-guided transfusion therapy (recreated from Naik et al. ROTEM study). ROTEM assessment includes EXTEM (external temogram) and FIBTEM (fibrinogen temogram) assays. Algorithm variables reported by these assays are clotting time (CT), clot formation time (CFT), alpha angle, amplitude at 20 minutes (A20), and maximum clot firmness (MCF). Prolongation of EXTEM CT (> 82 seconds) is related to extrinsic pathway abnormalities (due to functionally low levels of factors II, VII, and X), which is treated with fresh frozen plasma. Low EXTEM A20 and MCF (<52 mm) indicate poor clot strength, which may be related to either platelet abnormalities (when FIBTEM MCF is normal [7-24 mm]; treated with platelet transfusion) or low fibrinogen (when FIBTEM MCF is low [<7 mm]; treated with cryoprecipitate transfusion).



Predefined treatment algorithm for patients receiving intraoperative transfusion therapy guided by conventional testing (recreated from Naik et al. study). Conventional lab testing for prothrombin time (PT), international normalized ratio (INR), and platelet count were performed in the blood bank. Assessment of fibrinogen levels was performed via standard laboratory testing.

# Results



- The matched groups (ROTEM and control) comprised 17 patients each.
- Comparison of matched group baseline characteristics demonstrated differences in female sex and total intraoperative dose of intravenous tranexamic acid (TXA).

**Table 1. Pre-operative baseline demographic and surgical parameters**

	ROTEM (n=17)	Conventional (n=17)	<i>P</i>
Age at surgery (years)	62.94±11.58	64.29±11.80	0.62
Female	16 (94)	10 (59)	<b>0.04</b>
Body mass index (kg/m <sup>2</sup> )	30.14±7.68	30.22±4.49	0.27
ASA physical status	3 [2-3]	3 [2-3]	1.00
Revision operation	16 (94)	16 (94)	1.00
No. of instrumented levels	11.47±3.10	12.47±3.45	0.67
TLIF	0.59±0.80	0.53±0.62	1.00
Smith-Petersen osteotomy	1.47±1.87	1.71±2.39	0.96
Iliac fixation	16 (94)	16 (94)	1.00
Operative duration (minutes)	382.71±80.15	382.94±67.85	0.59
TXA (mg)	3534.38±2443.90	1916.93±1862.77	<b>0.03</b>

# Results



- EBL was lower in the ROTEM group (3200.00±2106.24 vs. 3874.12±2224.22 mL,  $p=0.36$ ), and the effect size was small-to-medium (Cohen's  $d = 0.31$ ).
- ROTEM group had less total blood product transfusion volume (1624.18±1774.79 vs. 2810.88±1847.46 mL,  $p=0.02$ ), and the effect size was medium-to-large (Cohen's  $d = 0.66$ ). This difference was no longer significant after adjusting for TXA ( $\beta = -0.18$ , [-1995.78–671.64],  $p=0.32$ ).

**Table 2. Primary outcomes of intraoperative blood loss and total blood product transfusion requirements**

	ROTEM (n=17)	Conventional (n=17)	<i>P</i>	Cohen's <i>d</i>	Beta [95% CI]*	Adjusted <i>P</i> *
Blood loss (mL)	3200.00±2106.24	3874.12±2224.22	0.36	0.31	-0.07 [-1858.67-1330.13]	0.74
Total blood product transfusion volume (mL)	1624.18±1774.79	2810.88±1847.46	<b>0.02</b>	0.66	-0.18 [-1995.78-671.64]	0.32

# Results

- More cryoprecipitate and less fresh frozen plasma (FFP) were transfused in the ROTEM group (cryoprecipitate units:  $1.24 \pm 1.20$  vs.  $0.53 \pm 1.01$ ,  $p=0.03$ ; FFP volume:  $119.76 \pm 230.82$  vs.  $673.06 \pm 627.08$  mL,  $p < 0.01$ ), and this remained significant after adjusting for TXA (cryoprecipitate units:  $\beta = 0.39$ , [0.05–1.73],  $p=0.04$ ; FFP volume:  $\beta = -0.41$ , [-772.55– -76.30],  $p=0.02$ ).

**Table 3. Secondary intraoperative outcomes compared between the matched cohorts**

	ROTEM (n=17)	Conventional (n=17)	<i>P</i>	Beta [95% CI]*	Adjusted <i>P</i> *
pRBC transfusion (units)	3.24±2.68	5.29±3.37	<b>0.05</b>	-0.88 [-3.03-1.21]	0.39
pRBC volume (mL)	1023.59±849.84	1575.41±971.26	0.09	-0.12 [-861.14-422.63]	0.49
Autologous blood transfusion (mL)	1148.76±890.51	1173.76±712.15	0.67	0.07 [-510.72-721.20]	0.73
Cryoprecipitate transfusion (units)	1.24±1.20	0.53±1.01	<b>0.03</b>	0.39 [0.05-1.73]	<b>0.04</b>
Cryoprecipitate volume (mL)	163.88±167.17	78.41±149.61	<b>0.04</b>	0.34 [-13.18-229.04]	0.08
FFP transfusion (units)	1.29±3.65	3.94±3.29	<b>&lt;0.01</b>	-0.30 [-4.92-0.48]	0.10
FFP volume (mL)	119.76±230.82	673.06±627.08	<b>&lt;0.01</b>	-0.41 [-772.55- -76.30]	<b>0.02</b>
Platelet (units)	0.47±0.87	0.53±0.80	0.72	0.10 [-0.47-0.79]	0.61
Platelet volume (mL)	105.18±196.69	121.24±184.18	0.73	0.08 [-113.58-173.12]	0.67
Crystalloid (mL)	3070.59±1079.36	3098.76±1227.84	0.94	0.01 [-890.97-918.47]	0.98
Colloid (mL)	2329.41±1217.84	1411.76±744.46	<b>0.01</b>	0.37 [23.86-1598.08]	<b>0.04</b>



# Results



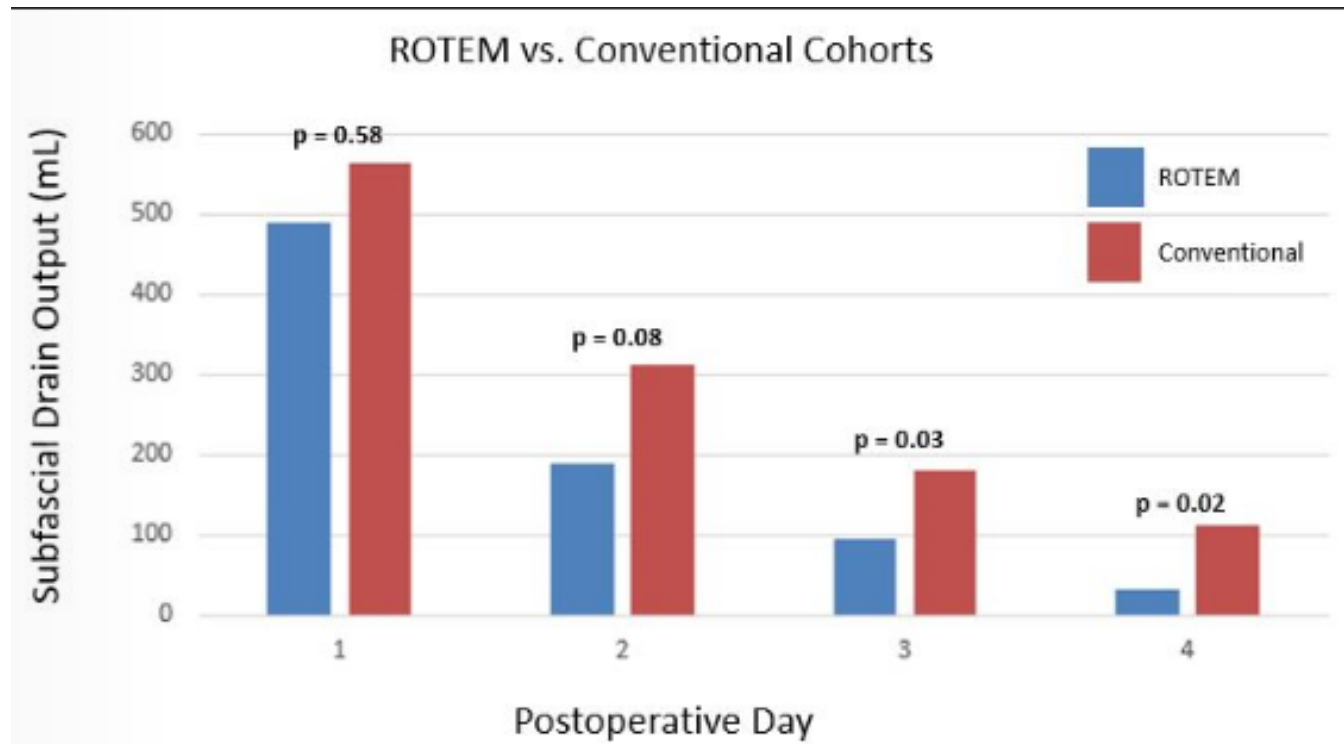
- Drain output was less in the ROTEM group and remained significant after adjusting for TXA.

**Table 4. Secondary postoperative outcomes compared between the matched cohorts**

	ROTEM	Conventional	<i>P</i>	Beta [95% CI]*	Adjusted <i>P</i> **
Drain output (mL)					
POD1	491.54±210.19	564.59±215.00	0.37	-0.12 [-225.92-128.74]	0.58
POD2	170.92±160.20	313.28±156.55	<b>0.02</b>	-0.34 [-236.34-14.57]	0.08
POD3	71.42±83.19	180.00±116.91	<b>0.01</b>	-0.43 [-171.17- -10.47]	<b>0.03</b>
POD4	22.85±47.87	111.44±95.98	<b>&lt;0.01</b>	-0.47 [-141.58- -14.97]	<b>0.02</b>
Total blood product transfusion volume (mL)	923.00±414.90	1147.82±896.67	0.37	-0.11 [-732.65-435.29]	0.61
pRBC (units)	2.31±1.38	2.18±1.55	0.81	-0.05 [-1.33-1.05]	0.81
pRBC volume (mL)	714.00±427.16	678.18±476.83	0.83	-0.04 [-407.59-332.59]	0.84
Cryoprecipitate (units)	0.23±0.44	0.18±0.53	0.77	0.06 [-0.35-0.47]	0.77
Cryoprecipitate volume (mL)	27.85±53.65	23.41±71.21	0.85	0.06 [-48.31-59.05]	0.84
FFP (units)	0.15±0.38	0.65±1.17	0.12	-0.12 [-0.68-0.36]	0.53
FFP volume (mL)	44.31±108.71	187.29±327.89	0.11	-0.12 [-192.19-99.53]	0.52
Platelet (units)	0.54±0.66	1.12±1.27	0.12	-0.17 [-1.20-0.49]	0.40
Platelet volume (mL)	136.85±166.33	258.94±285.56	0.15	-0.15 [-263.81-123.39]	0.46
Ambulation	2.82±1.94	2.54±1.20	0.67	--	--
ICU	3.00±1.41	2.36±1.01	0.18	--	--
Days to DC	6.92±2.02	7.94±2.05	0.19	--	--

# Results

- Drain output was less in the ROTEM group and remained significant after adjusting for TXA.



# Conclusions



- For ASD patients treated with lumbar PSO, more cryoprecipitate and less FFP were transfused in the ROTEM group compared to the control group that utilized conventional lab testing to guide blood product transfusion.
- ROTEM-guided therapy may allow for early identification of hypofibrinogenemia, and aggressive management of this may reduce blood loss and total blood product transfusion volume.
- Lack of significance in primary outcomes may likely be from small cohort size. However, the importance of this pilot study is that its preliminary results may help power future prospective randomized controlled trials.

# Disclosures



Christopher I. Shaffrey MD

Consultant: Medtronic, Nuvasive, Zimmer-Biomet, K2M

Royalties: Medtronic, Nuvasive, Zimmer-Biomet

Stock holder: Nuvasive

Grant: NIH, DOD, NACTN

Justin S. Smith MD PhD

Royalties: Zimmer Biomet

Consultant: Zimmer Biomet, Cerapedics, Nuvasive, K2M, AlloSource

Honorarium: Zimmer Biomet, Nuvasive, K2M

Research support: DePuy Synthes, ISSGF

Fellowship support: NREF, AOSpine