

Study Title: A Prospective Cohort Study of the Surgical Treatment of Early Onset Scoliosis using a remotely expandable device for non-invasive lengthening of a growing rod (Magec™) and its performance in prevention of progression of scoliosis.

Ethics Ref: 11/SC/0360

Clinicaltrials.gov number: NCT01362881

Protocol number: SC-11-001

TRIAL + NON-TRIAL GROUP

PRESENTATION OF NON-TRIAL PATIENTS ‘MID-TERM RESULTS’

COLIN NNADI

CONSULTANT SPINE SURGEON

OXFORD UNIVERSITY TEACHING HOSPITALS UK

ICEOS MEETING HOLLAND 2016

ACKNOWLEDGEMENTS

- Jeremy Fairbank
 - James Wilson-MacDonald
 - Thejasvi Subramanian
 - Pavlos Panteliades
 - David Mayers
 - Chrish Thakar
 - Daniel Rolton
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- Disclosures – Nuvasive, DePuy-Synthes

OXFORD MAGEC STUDY

- Prospective Cohort Study
- Subjects with Early onset scoliosis
- Minimum of 20 and maximum of 50 participants
- Planned Trial period – 1 yr recruitment + 2 yr Follow up. End date April 2016
- **Primary Objective** - Evaluate performance and safety of device in preventing progression of scoliosis
- **Secondary Objectives**
- Evaluation of clinical outcome
- Assess impact on re-operation rate
- Evaluate complication rates
- Evaluate durability of correction

DEMOGRAPHICS

- 35 Patients
- Prospective data collection from December 2011
- 17 M 18 F
- Average age 7.4 (2-14)
- Average no. of distractions 9.4 (2-17)
- Idiopathic (9) Congenital (4) Syndromic (17) Spinal Cord Injury (1) Neuromuscular (3) Chromosomal abnormality (1)
- Achondroplasia (2) excluded
- Average Follow up 30 months (5-57)

COBB AND ANCHOR POINT CHARACTERISTICS

	R ANCHOR		L ANCHORS		COBB ANGLE VERTEBRAE		COBB ANGLE MAJOR					
	PROXIMAL	DISTAL	PROXIMAL	DISTAL	PROXIMAL	DISTAL	PRE-OP	POST-OP	6M	12M	24M	LATEST
1	T4, 5	L1, T12	T4, 5	L1, T12	T6	T12	30	18	24	22	18	18
2	T4, 5	L5, 4	NA	NA	T5	L1	78	61	NA	59	47	61
3	T2,3	T11, 12	T2, 3	T11, T12	T3	T12	34.9	13	15.1	16.8	18.4	31
4	Ribs 2,4,6	L3,4	NA	NA	T2	T10	41	32	36	NA	NA	36
5	T4,5	L4,5 (HOOK)	T4,5	L4,5	T4	T11	51	45	49	43	44	45
6	T3,4	T11, T12	T3,4	T12,L1	T4	L1	41	32	25.4	27	31	36
7	T3,4	T3,4	L4,5	L4,5	T5	L1	68.7	31	38.1	31	39	28
8	T3,4 (HOOKS)	L1,3	T3,4	L1,2,3	T5	L1	85	63.2	45	47	48	43
9	T2,3	L2,3	T2,3	L2,3	T4	L1	49	30.8	28	32	NA	32
10	T3,4	L3,4	T3,4	L3,4	T4	T11	61.4	27.2	26	33.8	NA	33.8
11	T3,4	PELVIS	T3,4	PELVIS	T10*	L3*	AGE NOT AVA	49	47	57.8	51	34
12	T4,5	T12, L1	T4,5	T12, L1	T4	T12	31	17	11.2	NA	NA	11.2
13	T2, 4	L3,4,5	T2,4	L4,5	T9	L3	90.8	80.5	60.5	65	61	66.7
14	T3,4	L3,4	T3,4	L3,4	T5	L1	68.1	32.2	50.8	39.2	42.8	42.8
15	T2,4	L5, S1	T1	L5, S1	T10	L4	52.3	35.2	31.3	49.5	47.5	54
16	T3,4	L1,2	T3,5	L1,2	T7	T12	13.8	11.2	9.43	7.75	NA	7.75
17	T5,6	L4,5	T5,6	L4,5	T11	L5	45	33	31	29.1	30.6	30.6
18	T3,4	L4,5	T3,4	L4,5	T8	L2	59.8	37.2	38	32.4	35.7	47
19	T3,4	L2,3	T3,4	L2,3	T5	T12	46.3	20.9	21.8	23.2	31.7	48
20	T1,2	L2,3	T1,2	L2,3	T4	T9	69	34.9	39.2	43.3	NA	43.3
21	T2,3	L4,5	T2,3	L4,5	T6	L2	69.8	47.7	33.1	27	8.36	43
22	T3,4	L3,4	T3,4	L3,4	T5	L1	61	58.1	43.9	31.4	27	27
23	T3,4	T12,L1	T3,4	T12,L1	T6	T12	44.9	28.4	29.9	29.2	33	35
24	T2,3	L4,5	T2,3	L4,5	T6	T11	56	63	50.1	54.3	61	66
25	T3,4	L3,4	T3,4	L3,4	T5	L2	67	65.5	56.6	54.4	53	53
26	T3,4	L2,3	T3,4	L2,3	T5	T11	55.8	NA	24	31.5	NA	31.5
27	DOK T3, DRILL	L4,5	DOK T4, DRILL	L4,5	T6	T11	35	24.7	33.2	36.4	24.9	26.7
28	OOR QUALIT	L1,2	OOR QUALIT	L1,2	T3	L2	59	40.4	40	37.2	40	50.4
29	T3,4	T12,L1	T3,4	T12,L1	T6	T11	37.3	49.9	47.6	47.1	58	58
30	T3,4	L4,5	T3,4	L4,5	T2	T9	63	40	52.9	54	NA	54
31	T3,4	L1,2	T3,4	L1,2	T6	L1	46.5	23.2	16.6	15	20	13
32	T3,4	L1,2	T3,4	L1,2	T6	T11	40	26.2	19.3	24.6	NA	24.6
33	T4,5	L1,2	T4,5	L1,2	T7	L2	26.5	18.2	12.9	14.2	19	19
34	T3,4	T11,12	T3,4	T11,12	T5	T12	56	25	27	27.1	33.8	31.9
35	T2,3,4	L3,4,5	T2,3,4	L3,4,5,	T4	L4	43	49	59	NA	47	73

SUMMARY TABLE

Timing	Pre op	3 months	6 month	12 mnths	24 mnths	Latest
Cobb	52	37	34	35	37	38
TK	43	35	42	39	42	40
PJK	15	12	13	15	16	16
T1-T12	127	131	127	142	129	143
T1-S1	222	228	213	236	235	243

Comparison of Rod Distraction Gaps (R vs L)(mm)

Timings	Post-op	6 months	12 months	24 months	Latest
Left	3.7	5.9	6.7	9.9	8.3
Right	3.5	6.2	7	11.2	8.7

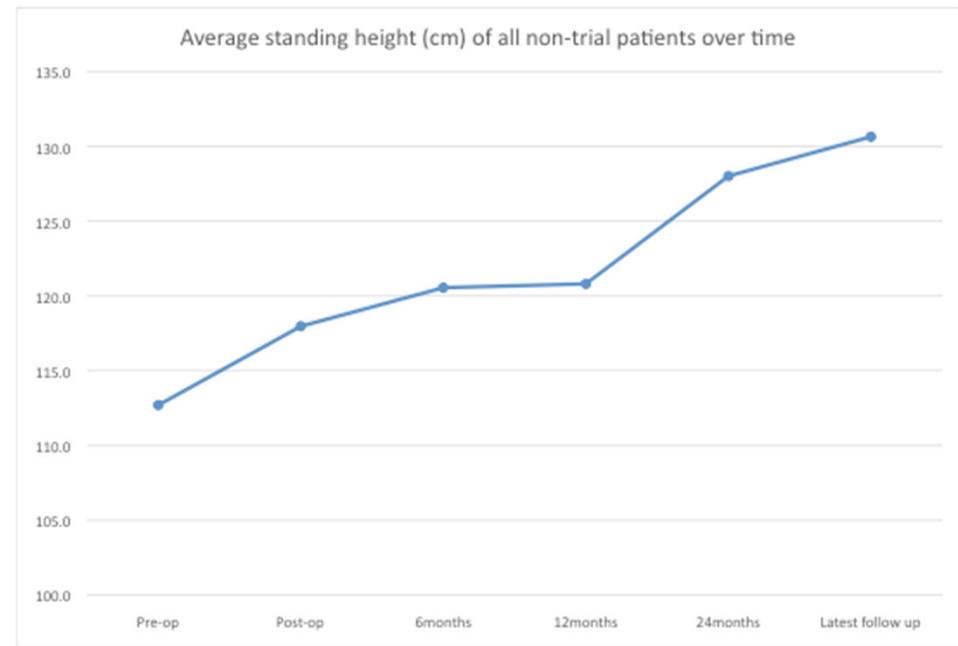
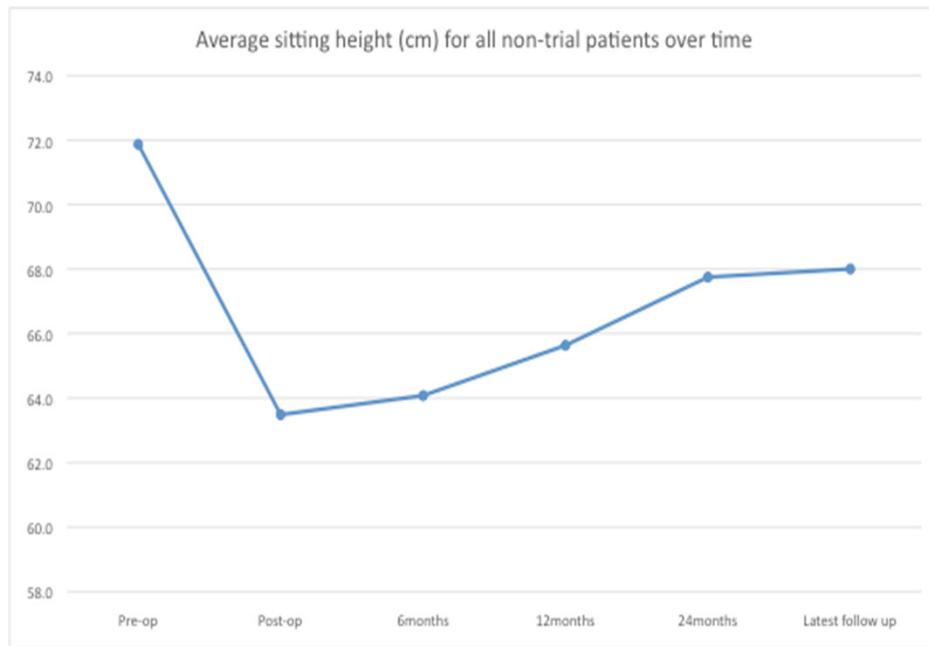
GROWTH PARAMETERS

Timings	No. of pts	Distract. number	Sitting Hgt (cm)	Standing Hgt (cm)	Weight (Kg)
Pre-op		n/a	71.9	112.7	19.6
Post-op	35	1	63.5	118	24.4
6 months	35	2	64.1	120.5	25.3
12 mnths	35	4	65.6	120.8	27.5
24 mnths	35	8	67.8	128	30.8
Latest	35	10	68	130.6	31.3

60% increase in body weight

Sitting/standing height ratio 1:1.9

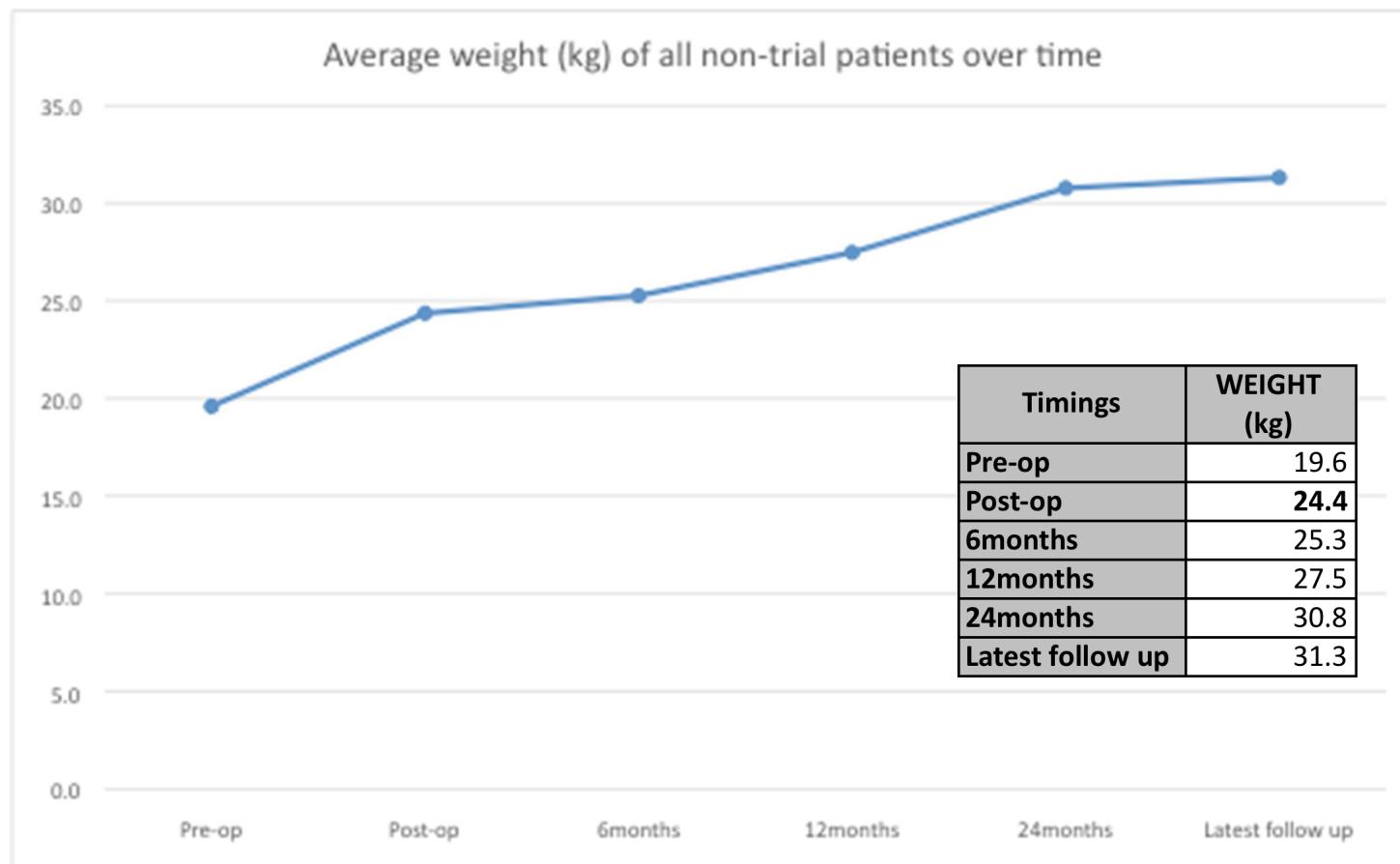
SITTING/STANDING HEIGHT



Timings	SITTING HEIGHT (cm)
Pre-op	71.9
Post-op	63.5
6months	64.1
12months	65.6
24months	67.8
Latest follow up	68.0

Timings	STANDING HEIGHT (cm)
Pre-op	112.7
Post-op	118.0
6months	120.5
12months	120.8
24months	128.0
Latest follow up	130.6

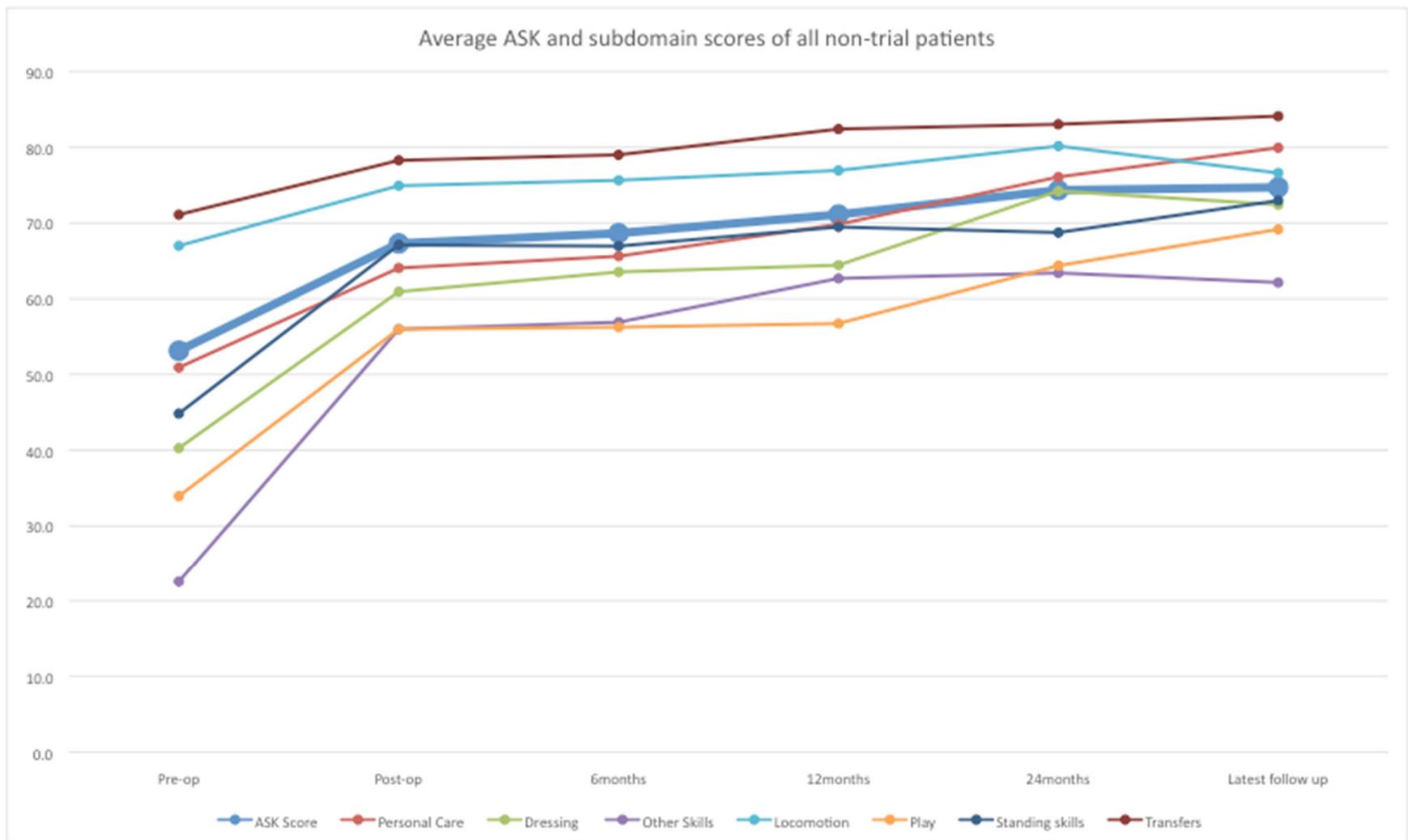
WEIGHT GAIN



Growth Rates per year

	AVERAGE LENGTH OF FOLLOW UP (years)	AVERAGE CHANGE IN SITTING HEIGHT		AVERAGE CHANGE IN STANDING HEIGHT		AVERAGE CHANGE IN WEIGHT	
		ACTUAL (cm)	PER YEAR (cm/year)	ACTUAL (cm)	PER YEAR (cm/year)	ACTUAL (kg)	PER YEAR (kg/year)
Average	2.5	4.17	1.57	12.59	4.66	6.28	2.54
Max value	4.6	12.70	4.00	27.60	7.43	19.00	7.38
Min value	0.7	-1.80	-1.80	2.40	1.20	-4.06	-1.32

FUNCTIONAL OUTCOMES



FUNCTIONAL OUTCOME

Timings	ASK Score	Personal Care	Dressing	Other Skills	Locomotion	Play	Standing skills	Transfers
Pre-op	53.1	50.9	40.3	22.6	67.0	33.9	44.8	71.1
Post-op	67.3	64.1	60.9	56.0	74.9	56.0	67.1	78.3
6months	68.7	65.6	63.5	56.9	75.6	56.3	67.0	79.0
12months	71.1	69.8	64.4	62.7	76.9	56.7	69.5	82.4
24months	74.3	76.1	74.2	63.4	80.2	64.4	68.8	83.0
Latest follow up	74.7	79.9	72.4	62.2	76.6	69.2	73.0	84.1

ASK increased across all domains with biggest increase in play activity

COMPLICATIONS

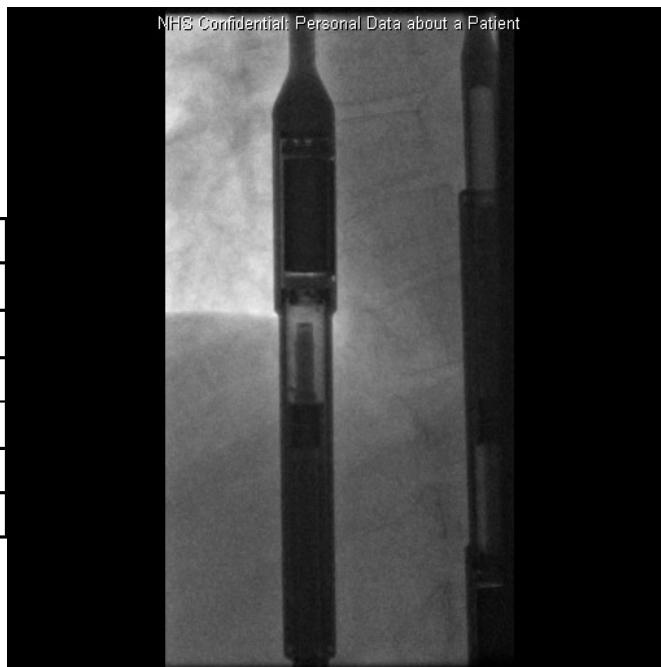
Infection

	Age	M/F	Diagnosis	Organism	LOS 1	LOS 2	LOS 3	Theatre Visits (including revision)	Date of Diagnosis Of infection	Days from index Surgery
1 C	8	M	Syndrome	1. Staph A 2. Serratia Marcescens	6 d	5 d		2	14.9.16	15 d
2	7	F	Syndrome	Staph A	4 d	5		1	23.9.16	43 d
3 C	8	F	Syndrome	Staph Epidermis	3 d	11 d		2	30.6.16	1642 d (4.5 yrs)
4	13	F	Syndrome	-- ve growth	6 d	7 d	6 d	3	28.7.16	49 d
5 C	10	M	Syndrome	Staph A	5 d	5 d		5	13.2.14	730 d (2 yrs)
6	7	M	Syndrome	Staph A	5 d	15 d		1	15.11.15	10 d

13 Revision cases in the last year (6/13 infections). 0 Infections in primary cases

Risk assessment on-going

Broken Actuator Pin



Subject	Age	Gender
1	6	M
2	11	F
3	13	F
4	11	M
5	5	M
6	7	F

Revision	Broken Actuator Pin
g	Y
s	Y
s	Y
s	Y
g	Y
s	Y

Average time to Actuator Pin Breakage 39 mnths

Other complications

Subject	Age	Gender	Diagnosis	
1	13	F	Idiopathic	fusion (loosening of proximal
2	15	F	Syndrome (G mutation)	fusion
3	13	F	Goldenhar Sy	fusion for broken Rod
4	13	F	Neurofibrom	Curv
5	11	F	Syndrome	Curv
6 C	10	M	Di George Sy	proximal construct
7	13	M	Achondropla	of distal anchor
8 C	11	F	Goldenhar Sy	proximal anchor (SR)



Average time to revision from other complications 28.7 mnths

SUMMARY

PROS

- Revolutionised Rx of EOS
- Obvious psychosocial benefits
- Cost savings (NICE data)
- ↓ Infection rates in 1^o Surgery
- Importance of growth factors as main outcome measures established
- ?Advantages of targeted distraction principle (Tail-gating) vs Maximum distraction

CONS

- Cost of failure (revision)
- Fear of the unknown (child)
- Device failure
- Metallosis
- What to do with infected MAGEC Rod?
- Intended distraction vs True distraction
- Lumbar curves

14/35 unplanned returns to theatre

6/13 infected revisions

?Amend Goals of Rx of EOS to include.....

- Control of spinal deformity to facilitate sustained physical and psychological development of the child
 - +
- Optimise Lung Function and Spinal Growth
- Avoidance of complications