

Project Walk Atlanta: Spinal Cord Injury Stimulation Treatment

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for

Tissue Regeneration Technologies LLC

Patient (n=10) Characteristics

- Gender: 6M, 4F
- Age range: 17-73 years
- TSI range: 14-112 months
- Injury Sites:
 - C3, C5, C6(2), C7, T3(3), T4, T10
- Laminectomy: 9N, 1Y
- ASIA Score: 6A, 4B
- Para/Quad: 6P, 4Q
- Injury:
 - 6 Complete, 4 Incomplete
- Injury type:
 - 5 moving vehicles
 - 2 gunshots
 - 1 diving
 - 1 post-surgical
 - 1 pedestrian
- Lesion type:
 - 3 bruised
 - 3 squeezed/crushed
 - 2 ruptured
 - 1 compression fracture
 - 1 unknown

Treatment History

- TRT stimulation completed: 10/10
- Time treated range:
 - 7-39 wks (median 12.5 wks)
- # TRT treatments:
 - 5-17 (median 10)
- Total shocks (x1000):
 - 21.75-72 (median 42.45)
- Highest energy (mJ/m²):
 - 0.13-0.23 (median 0.14)
- All study therapy completed as planned
- Other therapies: 4/10
 - 1 hyperbaric and IMT
 - 1 hyperbaric
 - 1 rehabilitation
 - 1 stem cells
- Physical therapy:
 - 4-40 hrs (median 29 hrs)

Project Walk Atlanta

Metric Improvement

- Significant mean improvements (two-sided $p=0.004$, sign test) relative to baseline

#	Baseline	Exit	Change	TSI (m), Lesion	Injury Site	Injury Type
1	3	10.5	+7.5	83, Ruptured	C5	Q, Complete
2	12	16	+4	27, Bruised	T3	P, Complete
3	7	16	+9	15, Thermal	T3	P, Incomplete
4	13	NA	NA	93, Bruised	T10	P, Complete
5	4	6	+2	112, Crushed	C3	Q, Incomplete
6	16	18	+2	38, Comp Fx	C6	Q, Incomplete
7	13	16	+3	27, Ruptured	C6	Q, Complete
8	16	20	+4	66, Squeezed	T3	P, Incomplete
9	11	14	+3	33, Bruised	C7	P, Complete
10	13	17	+4	14, Crushed	T4	P, Complete

Efficacy Scoring

- NA: Not applicable
- -2: Much worse relative to baseline
- -1: Worse relative to baseline
- 0: Same as baseline
- +1: Better than baseline
- +2: Much better than baseline
- +3: Returned to normal

Efficacy Measures

- Spasticity
- Core Strength
- Core Movement
- Core Sensitivity
- Leg Muscle Mass
- Leg Extremity Strength
- Leg Extremity Movement
- Leg Extremity Sensitivity
- Leg Extremity Reflexes
- Bladder Function
- Bowel Function
- Sexual Function
- Lung and Diaphragm
- Perspiration below injury
- Sensitivity to cold
- Nerve pain
- Wounds (not included)
 - Scar appearance
 - Chronic ulcers

Case Specific Best Improvements

- Multi-dimensional improvements for all cases

#	Best 1 st	Best 2 nd	Best 3 rd	TSI (m), Lesion	Injury Type
1	Lung/Diaph +3	6 of 15 others +2		83, Rupture	Q, Complete
2	Core Str +2	Core Mov +2	3 others +2	27, Bruised	P, Complete
3	Leg Ex Se +2	8 of 14 others +1		15. Missing	P, Incomplete
4	Spasticity +2	Leg Ex Mv +2	Leg Ex R +2	93, Bruised	P, Complete
5	8 of 15 measures +1			112, Crushed	Q, Incomplete
6	Core Mov +2	6 of 14 others +1		38, Comp Fx	Q, Incomplete
7	8 of 15 measures +1			27, Rupture	Q, Complete
8	6 of 14 measures +1			66, Squeezed	P, Incomplete
9	2 of 16 measures +1			33, Bruised	P, Complete
10	Lung/Diaph +3	Core S/M +2	All 5 Leg +2	14, Crushed	P, Complete

Degree of Improvement (1)

Efficacy Measure	+3	+2	+1	0
Spasticity (2 rated -1)	0	1	3	3
Core Strength	0	3	5	2
Core Movement	0	4	3	3
Core Sensitivity	0	0	8	2
Leg Muscle Mass	0	2	2	6
Leg Extremity Strength	0	2	5	3
Leg Extremity Movement	0	3	4	3
Leg Extremity Sensitivity	0	2	4	4
Leg Extremity Reflexes	0	2	5	3

Degree of Improvement (2)

Efficacy Measure	+3	+2	+1	0
Bladder Function	0	0	1	9
Bowel Function	0	0	0	10
Sexual Function	0	1	0	9
Lung and Diaphragm (4 NA)	2	0	2	2
Perspiration below injury	0	3	4	3
Sensitivity to cold	0	1	5	4
Nerve Pain (1 rated -1)	0	0	1	6

Best Overall Improvement (3)

Efficacy Measure	+3	+2	+1	0
Spasticity (2 rated -1)	0	1	3	3
Best Core Measure	0	4	6	0
Best Leg Measure	0	4	6	0
Best Function Measure	0	1	1	8
Lung and Diaphragm (4 NA)	2	0	2	2
Perspiration below injury	0	3	4	3
Best Sensory Measure	0	3	5	2
Best Overall	2	4	4	0

Mean # Measures Improving Per Case

- Multidimensional benefits as shown below:

Measure Score	Total Cases With At Least One Such Score	Total # Measures With That Score	Overall Average Per 10 Cases
+3	2	2	0.2
+2	6	24	2.4
+1	10	52	5.2
0	10	72	7.2
-1	2	3	0.3

Overall Efficacy Results Confidence

- All patients experienced improvements
- Lower 95% confidence bounds beyond chance

Best Outcome	Percent Achieving	95% Lower Bound
+3	20%	5.1%
+2 or +3	60%	33.6%
+1 or +2 or +3	100%	74.1%

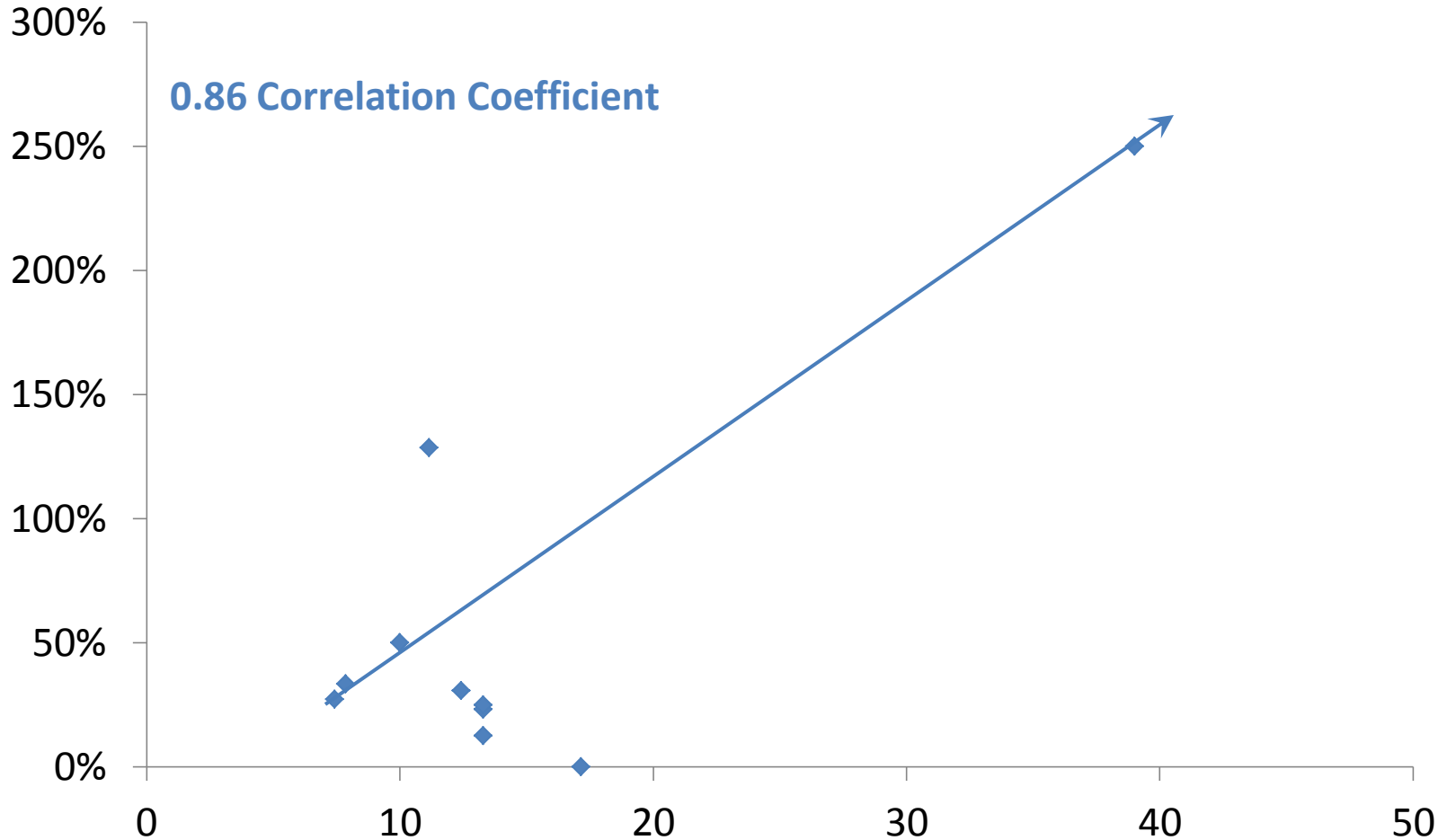
Patient Self Assessment (1-10)

- 1 = baseline with 10 = total recovery
- Favorable self-perception of improvement

Rating	Percent Achieving	95% Lower Bound
At least 2	100%	74.1%
At least 3	90%	65.0%
At least 4	60%	33.6%
At least 5	50%	25.1%
At least 6	20%	5.1%
At least 7	10%	1.0%

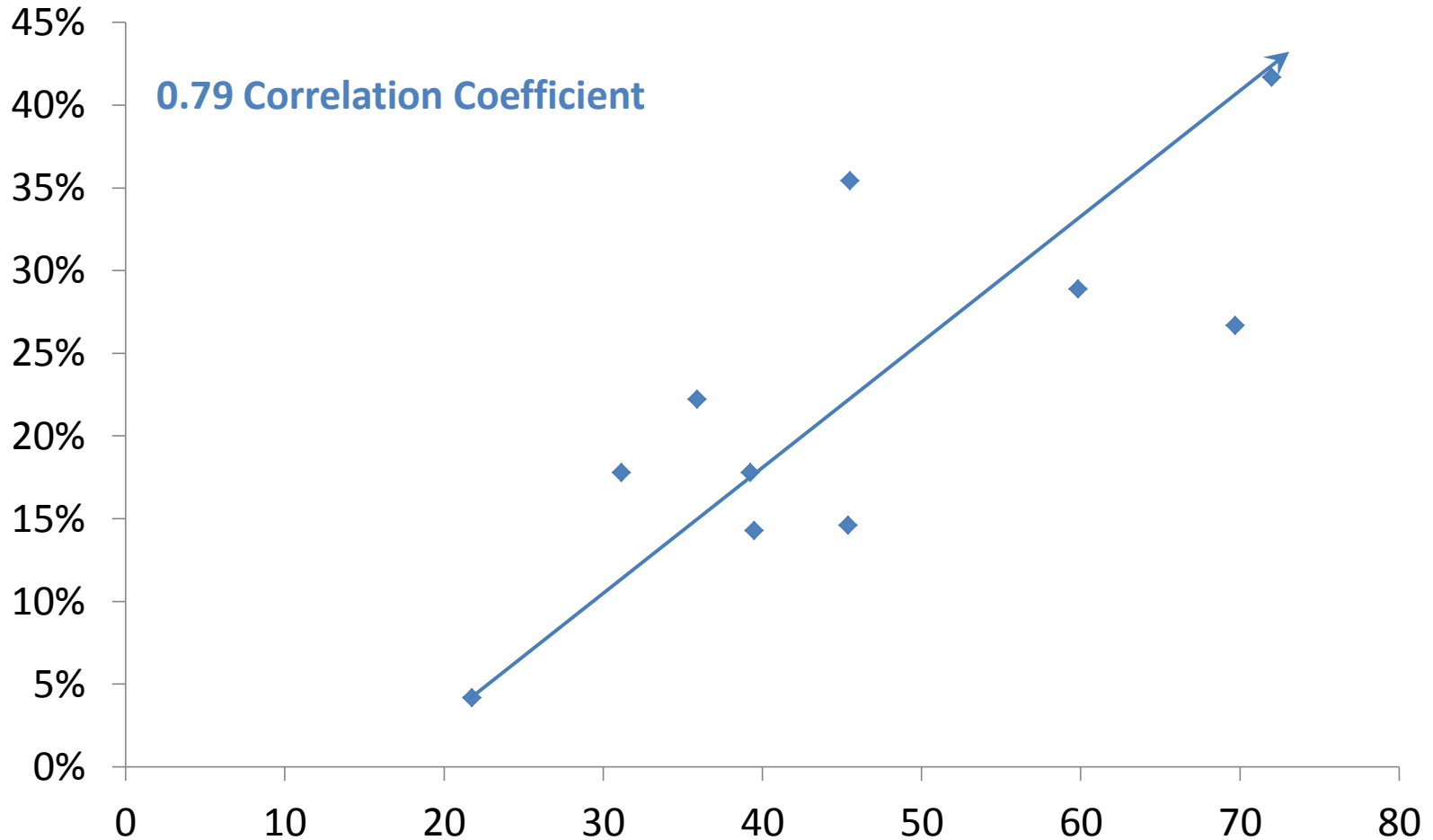
Correlations

% Improvement: From DAS Baseline vs # Weeks Study



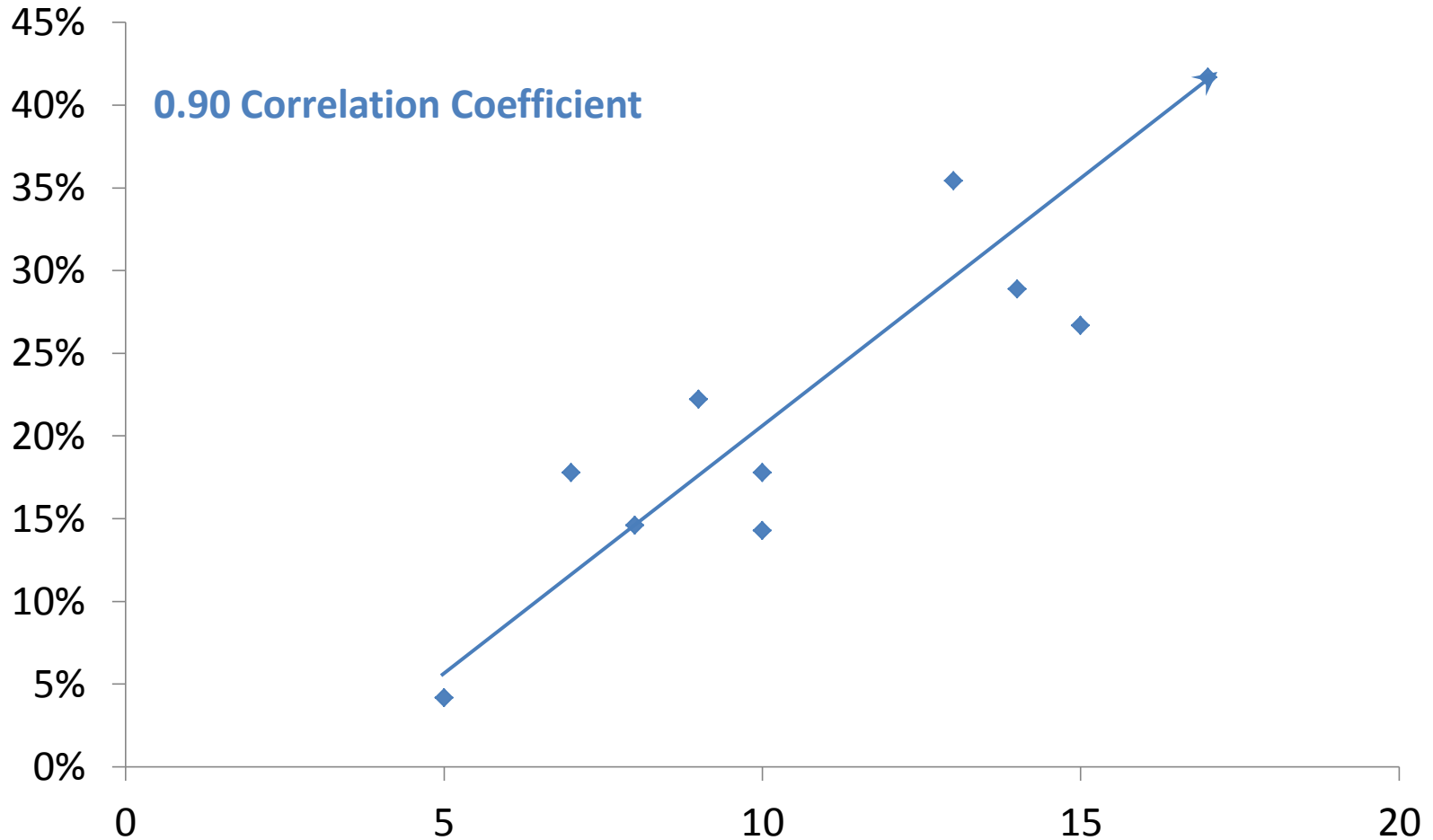
Correlations

% Improvement: Survey vs. Total # of Shocks (X1000)



Correlations

% Improvement: Survey vs of # of Treatments



Correlations

- Number of treatments, & more importantly, weeks since 1st treatment are most significant factors for measurable improvements.

Correlation	Patient/Therapist Survey: % Improvement	DAS Evaluation: % Improvement from baseline to Normal	Project Walk Baseline DAS Score Improvement %	Patient Self Assessment: % Improvement to normal
Correl. to hrs. of Therapy	0.18	-0.19	0.03	0.00
Correl. to # of treatments	0.90	0.27	0.22	0.47
Correl. to # of shock	0.79	0.06	0.02	0.36
Correl. to wks. in study	0.47	0.48	0.86	0.65

DATA

- Median & Mean were similar for data sets
- Most patients received low energy shocks

	MIN	MAX	Median	Mean
Number of weeks in Study	7	39	13	14
Number of Treatments	5	17	10	11
Total # of Shocks	21750	72000	42450	46000
Highest energy (mj/mm ^2)	0.13	0.23	0.14	0.17
Hours of Therapy during study	4	40	29	26
Final Project Walk evaluation	6	20	16	15

What We Can Take from the Data

- # of treatments, # of shocks, & weeks in study:
Positive correlation for assessments
- While relatively similar numbers of each for each patient, the small differences were key
- Time since first treatment was most important
- Positive correlation of at least 0.47 for weeks in study, with independent evaluation = 0.86

Wound Assessments

- Wound healing was also observed for all wounds
- Chronic ulcers healed for all 3 patients with chronic ulcers at baseline
- Scar appearance improved for all 7 patients with scars; the other 3 patients did not have scars
 - much better (+2) for 2 patients
 - improved (+1) for 5 patients

Safety

- 1 case (#3) had small bruises on their foot which was classified as mild and resolved
- No cases had any distal adverse events

Moving Forward

- All experienced improvement from baseline
 - Mean number of improvements: 0.2 resolved, 2.4 much better, and 5.2 improved => 7.8 per case
- Multi-dimensional treatment benefit
 - 20% +3, 60% +2, and 100% +1 relative to baseline
 - 4 of 6 completes and 2 of 4 incompletes experienced +2 or +3
 - Project Walk metric confirmation
 - Patient self assessment confirmation
- No safety issues
- All willing to continue treatment

DATA

- The Median & Mean were equivalent for virtually all forms of assessment
- While treatments were relatively similar for each patient, all saw an improvement!

	MIN	MAX	Median	Mean
Patient/Therapist: % Improvement	4%	42%	20%	22%
Independent: % Improvement	5%	23%	10%	11%
Improvement % Patient Self Assessment	13%	250%	31%	65%
	20%	70%	45%	43%

The End

www.projectwalkatlanta.org