Functional outcomes for patients with lumbar spinal stenosis treated with MinuteMan™ minimally invasive fusion monotherapy compared to combination therapy with spinal cord stimulation in a real-world pain clinic

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Introduction

The MinuteMan™ interspinous fusion device is a newer minimally invasive combination interspinous spacer and fusion system used to treat lumbar dysfunction, including lumbar spinal stenosis. This device is being used more commonly by interventional pain physicians to treat patients.[1,2] We used the MinuteMan fusion device to treat patients in our pain clinic diagnosed with lumbar spinal stenosis at levels L2-3 – L4-5 from January 2021 to March 2023. Spinal cord stimulation (SCS) is a well-established treatment for patients with lumbar-related pain complaints.[3–5] The study objective is to determine if there are differences in pain and disability scores for spinal stenosis treated with MinuteMan monotherapy compared to those with a combination of MinuteMan and spinal cord stimulation therapy.

Materials and Methods

We reviewed the medical records for all patients treated with the MinuteMan procedure for clinical lumbar spinal stenosis from January 2021 until March 2023 (n=56). Of these patients, 46.4% reported improvement in quality of life and disability categories on the Oswestry Disability Index (ODI) and EuroQol-5 Dimension (EQ5D) at the 2–12-month follow-up visit, average of 4.77 months. This cohort was then divided into patients with combined spinal cord stimulator therapy and MinuteMan (n=27) versus patients treated with MinuteMan monotherapy (n=29). We analyzed the data for self-reported improvement in specific ODI and EQ5D categories and reported whether the patient reported improvement versus no change or negative change.

Our patient population is very representative of patients in a traditional pain clinic. We did not control other variables such as medication use, prior surgery, activity, smoking, etc.

Total population (n=56)		Standard deviation
Average age	70.88	9.89
Months s/p MinuteMan	16.36	6.89
Female	62.5%	
Average female age	69.21	11.05
Months s/p MinuteMan	15.85	7.50
Male	37.5%	
Average male age	73.68	6.94
Months s/p MinuteMan	17.21	5.82
Cohort with stimulator (n=27)		Standard deviation
Avg age	69.83	10.09
Months s/p MinuteMan	17.79	5.98
Month s/p SCS implant	32.66	26.07
Female	63.0%	
Avg female age	68.25	11.16
Months s/p MinuteMan	18.33	6.31
Months since SCS implant	30.73	24.43
Male	37.0%	
Avg male age	72.51	7.74
Months s/p MinuteMan	16.87	5.55
Months since SCS implant	35.95	29.73
Cohort without SCS (n=29)		Standard deviation
Average age	71.86	9.77
Female	62.1%	
Avg female age	70.11	11.19
Months s/p MinuteMan	13.51	7.93
Male	34.5%	
Avg male age	74.73	6.32
Months s/p MinuteMan	17.53	6.31

Table 1: Subject demographic information.

Results

Patients with dual therapy reported a statistically significant improvement in EQ5D improved usual activities (40.7% dual therapy versus 17.24% monotherapy, P=0.05). Other subgroups of the EQ5D approached statistical significance between the dual therapy and monotherapy: EQ5D self-care (33.3% dual therapy versus 13.8% monotherapy, P=0.09), EQ5D Pain (29.6% dual therapy versus 10.3% monotherapy P=0.07) and EQ5D improved mobility (29.63% dual therapy versus 20.69% monotherapy, P=0.45). We also tested the overall magnitude change in ODI and EQ5D scores using single-factor ANOVA, which showed statically significant EQ5D improvement in self-care (P=0.01), pain, and self-perceived health status (P=0.05). EQ5D discomfort approached statistical significance (P=0.08). No statistically significant difference was seen in other parameters.

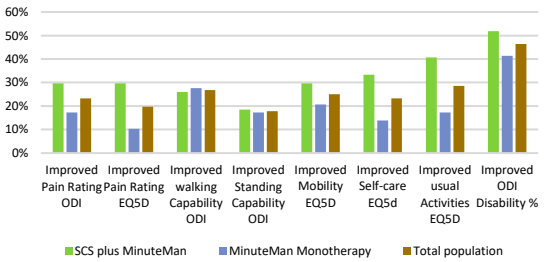

Figure 1: Percentage of subjects who reported improvement in various areas of disability and quality of life as measured by ODI and EQ5-D.

	Improved Pain Rating ODI	Improved Walking Capability ODI	Improved Standing Capability ODI	Improved ODI Disability %
SCS plus MinuteMan	29.63%	25.93%	18.52%	51.85%
MinuteMan monotherapy	17.24%	27.59%	17.24%	41.38%
P value	0.28	0.89	0.90	0.44

	Improved Pain Rating EQ5D	Improved Mobility EQ5D	Improved Self-care EQ5D	Improved usual Activities EQ5D
SCS plus MinuteMan	29.63%	29.63%	33.33%	40.74%
MinuteMan monotherapy	10.34%	20.69%	13.79%	17.24%
P value	0.07	0.45	0.09	0.05

Table 2: Percentage of subjects who reported improvement in various areas of disability and quality of life as measured by ODI and EQ5-D with P values.

Conclusion

Our data suggests the MinuteMan treatment results in an improvement in walking and standing with or without combined SCS therapy for a typical pain patient population. Concomitant treatment with SCS therapy did lead to self-reported improvements in areas of functional capacity as reported in specific EQ5D categories, with improved usual activities reaching statistical significance between the two groups. EQ5D Improved pain and improved self-care and ODI pain rating, walking capacity, standing capacity, and disability trend towards statistical significance. This data suggests that SCS therapy can augment some of the functional benefits associated with the treatment of neurogenic claudication due to spinal stenosis with the MinuteMan device.

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