Case series of Sooma Depression Treatment

Summary

- **Open-label data from 57 patients treated with Sooma Depression Treatment either as add-on treatment or monotherapy.**
- **82% of patients achieved treatment response. 35% achieved complete remission. Two patient experienced worsening of symptoms and six patients dropped out.**
- **Mean depression improvement was 61% after two or three weeks of treatment. The treatment was well tolerated and no serious adverse events occurred during over 700 treatment sessions.**

Introduction

Sooma Depression Treatment utilizes transcranial direct current stimulation (tDCS) to modulate brain activity of the dorsolateral prefrontal cortex (DLPFC). It is an effective and well-tolerated treatment option for patients with depression. Sooma Depression Treatment can be prescribed as a monotherapy, or it can be added to pharmaceutical or psychosocial treatment options.

Nine clinics have provided Sooma Depression Treatment outcome data from a total of 57 patients with an ongoing depressive episode. The outcome data reflect how the treatment is applied in clinical practice today and what can be realistically expected as a treatment outcome. None of the clinicians reporting these data have received compensation by Sooma.

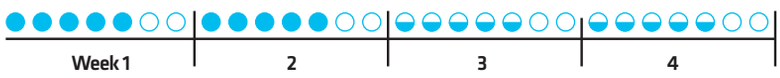
Figure 1. Sooma Depression Treatment. The Sooma tDCS™ medical device consists of a small, battery-powered stimulator, electrodes with saline-soaked sponges and a headcap with pockets for correct electrode positioning. Each session delivers a constant current of 2 mA for 30 minutes, which is repeated each weekday for 2 to 3 weeks. After the acute treatment phase, the sessions can be continued once a week up to 6 months.

Sooma tDCS™ session:

2mA direct current for 30 minutes

● standard protocol ◒ as required

Acute phase: 1 session per day, 5 days a week for 2 to 4 weeks



Maintenance phase: 1 session fortnightly for 4 weeks.
Patients with high risk of relapse: 1 session per week for up to 6 months or as required.

Methods

Outcome data from a total of 57 patients (27 females) with an ongoing depressive episode was provided. The patients were aged from 21 to 80. Nineteen patients received the treatment as monotherapy while 38 received concomitant pharmaceutical treatment that was not modified during the treatment period.

The data was collected from nine clinics worldwide. 37 patients were assessed with various Hamilton Depression Ratings Scales, eleven with BDI, five with MADRS, and four were assessed with MDI. Response was defined as a 50% decrease in depression score across all scales. Remission was defined based on grading guidelines for each scale. Table 1 shows scores used to define remission and severity ratings.

Table 1. Remission and severity criteria used across different rating scales for outcome data.

Scale	Remission	Mild	Moderate	Severe
HDRS-17	8 or less	9 - 13	14 - 19	19 or more
HDRS-21	8 or less	9 - 16	17 - 25	25 or more
HDRS-24	10 or less	11 - 19	20 - 29	30 or more
BDI-21	13 or less	13 - 19	20 - 28	29 or more
MADRS	7 or less	8 - 19	20 - 34	35 or more
MDI	20 or less	21 - 25	26 - 30	31 or more

All patients were treated using the protocol described in Figure 1. Each patient received stimulation sessions with Sooma tDCS™: 2 mA current amplitude, 30-minute session duration, electrode size 35 cm^2, and bifrontal stimulation (anode and cathode on F3 and F4, respectively). Clinicians could adjust the number of treatment sessions performed based on patient needs. The demographic data of patients who completed the treatment is summarized in Table 2. There was no control group in this case series.

Results

The treatment course was completed by 51 patients (89% of all patients). Four patients discontinued treatment due to lack of significant mood improvement. One patient started ECT during the treatment course and one patient was unable to visit the clinic for all sessions. Daily sessions for three weeks was completed by 24 patients while 27 patients completed two weeks of daily treatments. Planned two-week treatments were extended for an additional week for two patients to improve response. On average, patients received 13.5 treatment sessions. Patients with severe depression at baseline were more likely to receive longer treatment (average sessions 13.9 and 12.3, respectively).

The majority of patients experienced a marked improvement as a result of Sooma Depression Treatment. There was a significant difference in pre-treatment (Mean = 28.6 ± Standard deviation = 7.0) and post-treatment scores (12.0 ± 6.8); p<0.001. In total, 18 patients achieved complete remission. Treatment outcomes are summarized in Figure 2.

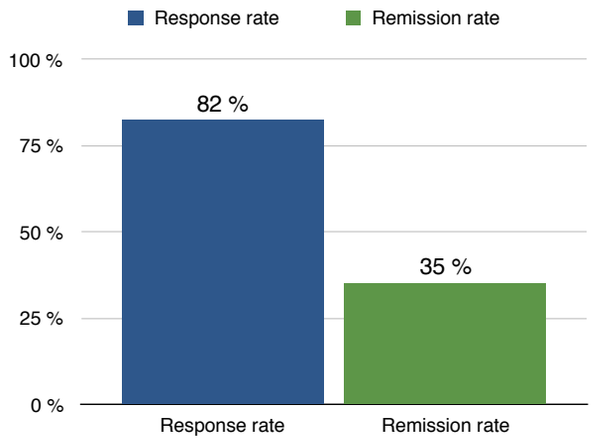


Figure 2. Treatment outcomes of 51 patients after Sooma Depression Treatment.

In addition, statistical significance was found for the monotherapy group (N=19) between pre-treatment (30.2 ± 7.0) and post-treatment (9.5 ± 4.4) scores; p<0.001. As this group received no concomitant treatments, the results indicate efficacy for Sooma Depression Treatment alone.

The mean improvement in depression score was 61%. Eight patients improved by more than 75%, whereas the score increased for two patients, and the improvement was below 20% for two patients. For the majority of patients, depression score improvement was between 50% and 70% as shown in Figure 3.

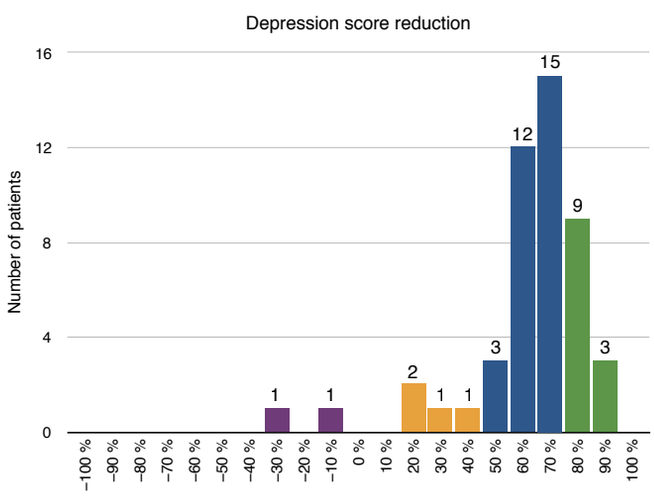


Figure 3. Depression score change after Sooma Depression Treatment.

Pre-treatment severity for most patients was severe (78%) while after two or three week treatment most patients had either mild depression (55%) or were in remission (35%). Besides mood improvement, some of the behavioral and functional changes reported by clinicians were: Increased activity, improved sleep quality, normalized sleep and eating patterns, reduced anxiety and positive effect on sensations of pain. Figure 4 shows the change in depression severity pre- to post-treatment.

Table 2. Patient demographics, treatment sessions and concomitant medication, and pre- and post-treatment depression scores.

Patient no.	Gender	Age	Treatments	Scale	Pre-treatment score	Post-treatment score	Change	Medication
1	F	32	15	HDRS-21	38	9	76 %	None
2	M	42	15	HDRS-21	28	6	79 %	None
3	M	33	15	HDRS-21	34	12	65 %	None
4	M	24	15	HDRS-21	31	7	77 %	Citalopram
5	F	21	15	HDRS-21	28	4	86 %	None
6	M	27	15	HDRS-21	25	7	72 %	None
7	M	46	15	HDRS-21	42	11	74 %	None
8	M	21	15	HDRS-21	26	6	77 %	None
9	M	22	15	HDRS-21	21	7	67 %	None
10	F	33	15	HDRS-21	29	9	69 %	None
11	F	22	12	MADRS	27	13	52 %	Efexor depot
12	F	55	10	MDI	41	36	12 %	Sertraline
13	M	44	10	MDI	36	41	–14 %	Brintellix, Ketipinor, Azona
14	F	55	10	MDI	15	11	27 %	Escitalopram, Olanzapine, Xanor depot
15	M	30	10	MADRS	18	7	61 %	Mirtazapine, Melatonin, Abilify
16	F	52	17	MADRS	35	14	60 %	Venlafaxine
17	M	48	17	MADRS	26	10	62 %	Escitalopram, Diazepam, Simvastatin, Analgesics. Psycotherapy in conjunction with treatment sessions.
18	F	70	10	HDRS-21	34	5	85 %	Vortioxetine, Valproate, Quetiapine, Diazepam and Zopiclone (used occassionally)
19	F	35	10	HDRS-17	25	11	56 %	Escitalopram, Xanax
20	M	40	10	HDRS-17	26	12	54 %	Lorazepam
21	M	31	10	BDI-21	34	8	76 %	None
22	M	25	13	BDI-21	28	9	68 %	None
23	M	19	14	BDI-21	44	6	86 %	None
24	M	37	16	BDI-21	36	12	67 %	Sertraline
25	F	27	13	BDI-21	34	11	68 %	None
26	M	24	13	BDI-21	28	9	68 %	None
27	F	52	10	HDRS-24	31	19	39 %	Bupropione, Mirtazapine, Zopiclone
28	M	44	10	HDRS-24	26	7	73 %	Escitalopram
29	M	38	10	HDRS-24	31	16	48 %	Venlafaxine, Pregabaline
30	F	80	10	HDRS-17	26	12	54 %	None
31	F	41	20	HDRS-17	26	12	54 %	Xanax, ??
32	M	54	20	HDRS-17	29	25	14 %	None
33	M	55	20	HDRS-17	24	12	50 %	Venlafaxine, Mirtazapine
34	F	46	15	HDRS-17	21	11	48 %	Escitalopram, Trazodone SR
35	F	28	20	HDRS-17	27	12	56 %	Paroxetine, Lamotrigine
36	M	48	20	HDRS-17	28	12	57 %	Milnacipran, Mirtazapine
37	M	46	20	HDRS-17	26	12	54 %	Venlafaxine, Agomelatine
38	F	32	20	HDRS-17	25	12	52 %	Escitalopram, Trazodone
39	F	70	10	BDI-21	30	15	50 %	Zanidip, Losartan, Olanzapin, Melatonin, Seronil, Voxra, Lito, Divisun, Obsidan fe++, Amorion comp
40	F	70	12	BDI-21	36	13	64 %	Cardace, Thyroxin, Oxamin
41	M	48	15	BDI-21	39	22	44 %	Pruxal, Lito, Abilify, Valdoxan
42	M	65	15	BDI-21	13	17	–31 %	Venlafaxin, Mirtazapin, Lorazepam, Risperidon, Truxal, Imovane, Losatrix
43	F	27	6	HDRS-24	17	6	65 %	Escitalopram, Bupropione
44	M	60	12	HDRS-17	15	5	67 %	Zopiclone
45	F	61	12	HDRS-17	27	8	70 %	Trazodone, Melatonine
46	M	28	13	HDRS-17	32	11	66 %	None
47	M	52	15	HDRS-17	41	16	61 %	Venlafaxine
48	M	23	10	HDRS-17	26	12	54 %	None
49	F	34	9	HDRS-17	22	7	68 %	None
50	F	24	10	HDRS-17	28	13	54 %	Cipralex, Xanax
51	M	55	10	HDRS-17	26	12	54 %	Lithium, Venlafaxine

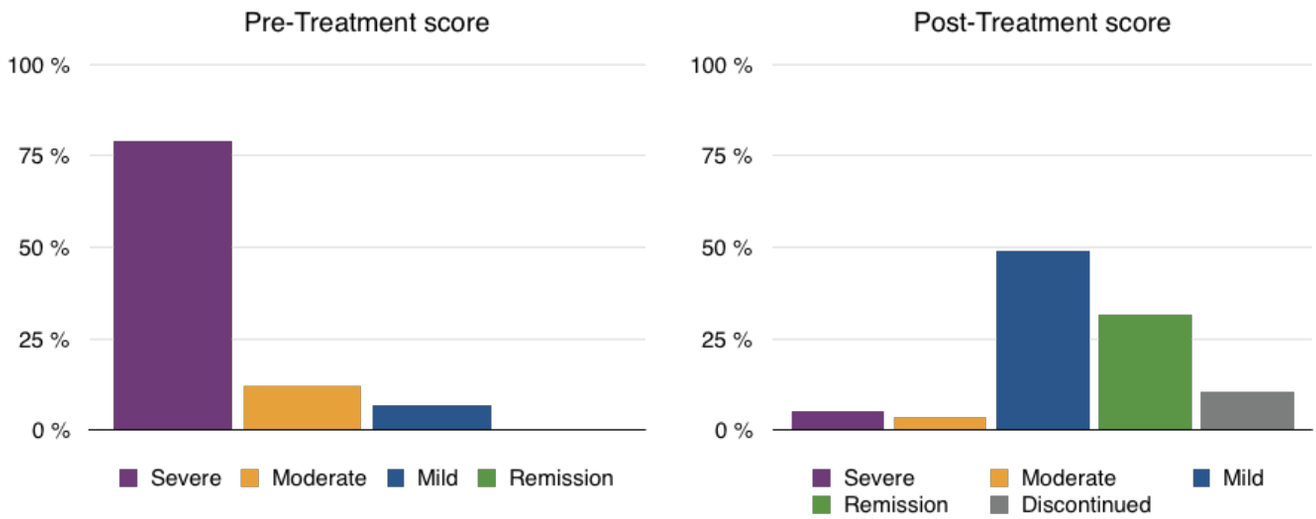


Figure 4. Categorical change in depression severity. On average patients had severe depression when starting the treatment and ended up with mild depression after completion of treatment.

Safety and adverse events

Sooma Depression Treatment was safe and well tolerated by all patients. The dropout rate was 11%. None of the patients described treatment as painful. The 51 patients who completed the treatment received 699 treatment sessions in total, with no reported serious adverse events. The most common side effects were itching or tingling under the electrode during treatment sessions (66% of patients reported at least one itching or tingling occurrence) and transient headache (24%). Two patients dropped out after experiencing increased anxiety.

Conclusions

Based on 57 patients reported by nine different clinics, Sooma Depression Treatment was proven to be a safe and effective treatment method for patients suffering from major depressive disorder. Further, the treatment is well-tolerated and treatment response is consistent across different clinics. Moreover, there were no problems in administering Sooma Depression Treatment in clinical routine use.

How to get started

The treatment system is portable and does not require fixed installation or special facilities. Treatment session can be administered by a trained nurse in a clinic, or by the patient in home environment. Preparations take only a few minutes, and the patient is free to engage in psychotherapy or read a good book during the session. Sooma will train you and your staff in the use of the system and in how to deliver further training to patients. Get in touch at +358 10 328 9811 or info@soomamedical.com to learn more.

About Sooma

Sooma Oy is a Finnish medical device manufacturer, which provides innovative neuromodulation technology for treating depression. Sooma Depression Treatment utilizes Sooma tDCS, a CE-marked medical device, that is affordable, easy to use and easily adaptable to various clinical routines. Sooma Oy holds ISO13485 and ISO9001 certificates.

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