



Sooma tDCS™ for treatment of major depressive disorder - two case reports

Transcranial direct current stimulation (tDCS) is an effective and well-tolerated treatment option for depressed patients. Sooma tDCS™ can be used as a monotherapy or as an adjunct to antidepressant medication and psychotherapy. During treatment, a constant current is administered according to the treatment protocol. Here we report two patient cases treated with Sooma tDCS™ for major depressive disorder.

Patient I

A 52-year-old woman was diagnosed with severe treatment-resistant depression in 2005. The patient also suffered from colitis and musculoskeletal disorders. Since 2007, she had been on continuous antidepressant medication with low efficacy and intolerable side effects. As an alternative to antidepressant medication, in 2013 she was treated with electroconvulsive therapy (ECT) and achieved a good clinical response. However, with ECT the patient experienced highly unpleasant side effects that affected her memory, and she felt that the therapy was difficult to complete due to practical and logistical arrangements.

In 2015, the patient was treated with duloxetine and milnacipran. Duloxetine caused increased liver enzyme levels, while milnacipran lacked efficacy and caused perspiration. Sooma tDCS™ treatment was then initiated as an alternative treatment strategy to ECT.

The intervention protocol for Sooma tDCS™ was as follows: 17 sessions with 2mA direct current stimulation for 30 minutes (every weekday for 3 weeks, followed by one session per week for an additional 2 weeks). During the treatment, the patient was treated with venlafaxine (titrated up to 112.5 mg/day), and psychotherapy was included in each of the treatment sessions. Depressive symptoms were assessed using the Montgomery-Åsberg Depression Rating Scale (MADRS), and the Beck Depression Inventory (BDI).

The patient responded well to Sooma tDCS™ treatment as demonstrated by a significant improvement from severe to mild depression during the 5-week treatment period (Figure 1). According to the patient and her psychotherapist, her mood was already improved during the second treatment week, as indicated by better functionality, less anxiety, and

normal appetite and sleep. The patient reported mild side effects, such as feelings of dizziness and headache during the treatment.

For this patient, both Sooma tDCS™ treatment and ECT resulted in good clinical response to severe, treatment-resistant depression. However, compared to ECT, Sooma tDCS™ was better tolerated.

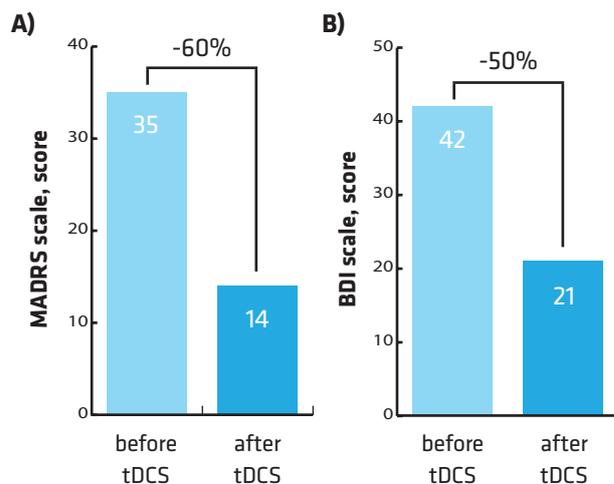


Figure 1. Clinical outcome in patient I after Sooma tDCS™ treatment as measured by A) MADRS or B) BDI depression rating scales. The score was evaluated before the first tDCS treatment session and after the last, 17th tDCS session (5-week treatment).

Patient II

A 48-year-old man was diagnosed with severe treatment-resistant depression in 2013. The patient suffered also from moderate panic disorder, unspecified personality disorder, and sleep apnea. During two years of continuous treatment, the patient received psychotherapy and various antidepressant medications, including bupropion, pregabalin, and venlafaxine. In 2015, he received two separate interventions of Sooma tDCS™ treatment, as previous therapy options did not provide sufficient clinical response or were poorly tolerated.

Both interventions followed the Sooma tDCS™ treatment protocol described in the previous case report. Escitalopram (20mg/day) and quetiapine (25mg, 1–2 doses per day) were administered during the treatment. In addition, the patient continued to use diazepam (10mg, 4–10 doses per day, if needed), simvastatin (10mg/day), and analgesics for migraine. Simultaneous psychotherapeutic sessions were included in the treatment.

During the first intervention, the patient had a good clinical response during the initial 3-week treatment period. However, during the maintenance treatment period, he suffered from panic symptoms while traveling on vacation. The patient administered high doses of diazepam. According to the psychotherapist, the Sooma tDCS™ treatment was effective for the depression symptoms, but did not relieve the symptoms of panic disorder.

Three months later, the patient underwent an additional intervention with Sooma tDCS™. At that time, he had a good clinical response demonstrated by a significant improvement after the 5-week treatment period (Figure 2). According to the patient, his mood was significantly better already during the second treatment week. The psychotherapist stated that the Sooma tDCS™ treatment also positively affected sensations of pain and anxiety. The patient reported mild side effects; he described tingling on the head during treatment, and experienced one uncomfortable mild electric shock.

From the patient's perspective, the Sooma tDCS™ treatment was a good add-on therapy to antidepressant medication and psychotherapy.

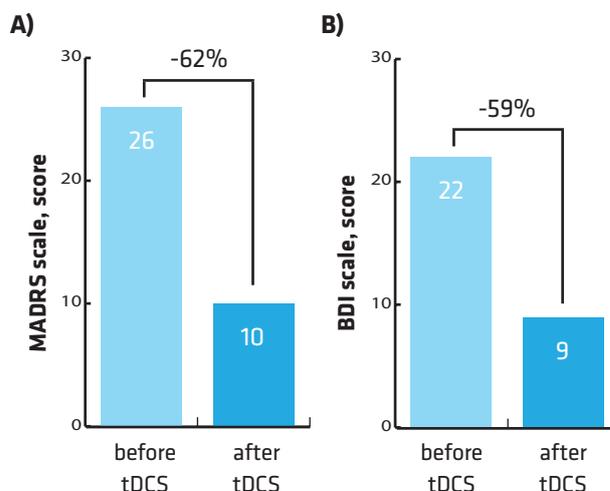


Figure 2. Clinical outcome in patient II after Sooma tDCS™ treatment as measured by A) MADRS or B) BDI depression rating scales. The score was evaluated before the first tDCS treatment session and after the last, 17th tDCS session (5-week treatment).

Sooma tDCS™ session:

2mA direct current for 30 minutes

Initial treatment:

1 session per day,
5 days a week
for 2 to 3 weeks

Maintenance treatment:

1 session per week
up to 6 months
or as required

5-minute preparation + 5-minute after session



About Sooma

Sooma Oy is a Finnish medical device manufacturer, which develops innovative neuromodulation technology for treating depression. Sooma tDCS™ is a CE-marked device that is affordable, easy to use, and easily adaptable to various clinical routines. Sooma Oy holds ISO13485 and ISO9001 Quality Management Systems certificates, and has international patents pending.



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