EASEE®

DER ERSTE MINIMALINVASIVE GEHIRNSCHRITTMACHER FÜR FOKALE EPILEPSIEN IST AUF DEM MARKT

Aus gegebenem Anlass der am 4. April 2023 erschienenen Publikation in JAMA Neurology informieren wir Sie über den innovativen Gehirnschrittmacher EASEE®.

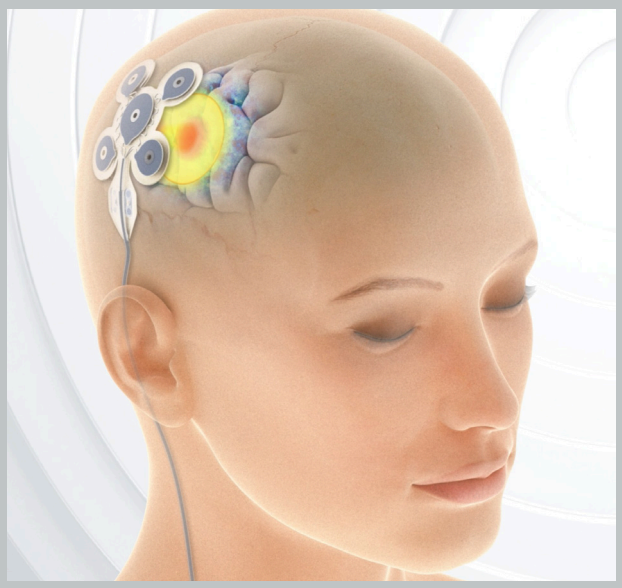
Nachdem einige spezialisierte Epilepsiezentren mit EASEE® im Rahmen der Zulassungsstudien bereits Erfahrungen sammeln konnten, dürfen wir nun auch Kolleginnen und Kollegen im niedergelassenen Bereich über die Möglichkeiten der minimalinvasiven Gehirnstimulation bei PatientInnen mit fokalen medikamentenrefraktären Epilepsien auf dem Laufenden halten.

Im Überblick:

- **53% Responderrate** nach sechs Monaten aktiver Stimulation
- Überzeugendes Nutzen-Risiko-Profil
- Registerstudie zur Evaluierung von Langzeit-effekten wird von Frau Prof. Schmitz in Berlin geführt

OBJECTIVE

Two prospective non-randomized, single-arm trials included 33 adults to show if long-term treatment using epicranial electrical focal cortex stimulation with a novel implantable device (EASEE®) reduces seizure frequency in patients with drug-refractory focal epilepsy.



ENROLLMENT

Patients with drug-refractory focal epilepsy were recruited at **7 European epilepsy centers** from January 2019 to January 2020.

They were implanted with the EASEE® System and were evaluated after 6 months of active stimulation.

The treatment with EASEE® was an adjunctive treatment for adult patients with drug-refractory focal epilepsy.

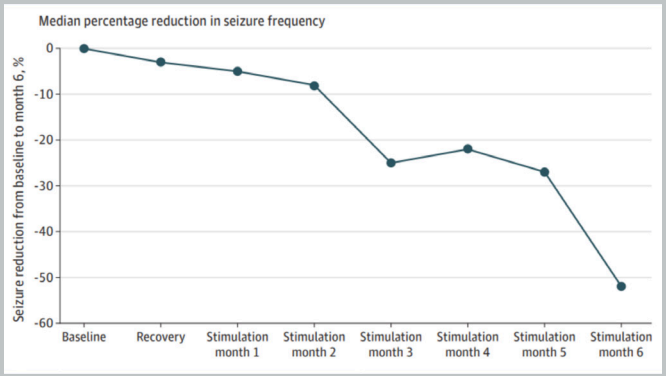
33 adult participants with uncontrolled focal epilepsy were implanted subcutaneously with a pulse generator and an electrode array placed above the individual focus region.

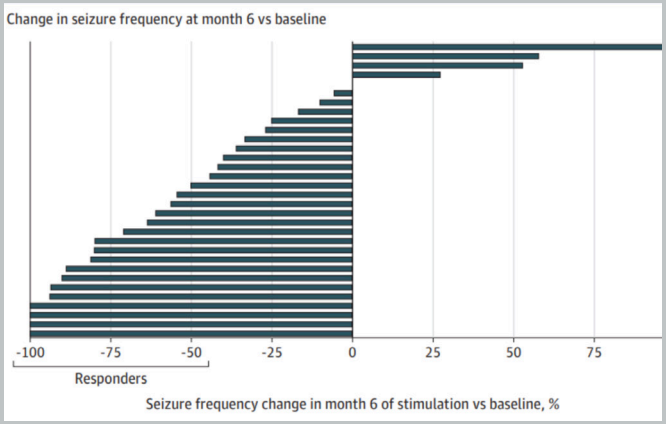
ENDPOINTS

Endpoints were defined as safety and efficacy measures.

The safety was analysed by the incidence of device or procedure related serious adverse events that occurred as of the implant procedure and up to the following 4 months.

The primary efficacy endpoint was the responder rate (defined as at least 50% reduction in seizure rate from baseline) after 6 months of active stimulation.





RESULTS

- The mean implantation procedure duration was 1:21 hours.
- **Safety: no device or procedure related serious adverse events** were reported in 33 patients.
- **Efficacy was shown with a responder rate of 53% at 6 months** in 32 out of 33 patients who received neurostimulation and were analyzed.

CONCLUSION

Results indicate that focal cortex stimulation with an epicranial electrode array can be a **safe and effective new treatment option** for patients with drug-refractory focal epilepsy.

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