ePORE®
therapy

ON THE PULSE OF
PRECISION CANCER TREATMENT

ePORE® & ENDOVE®,
PRECISION INTERVENTIONAL ENDOSCOPY TREATMENT
FOR GASTROINTESTINAL CANCER

MIRAI MEDICAL
Precision Cancer Therapy

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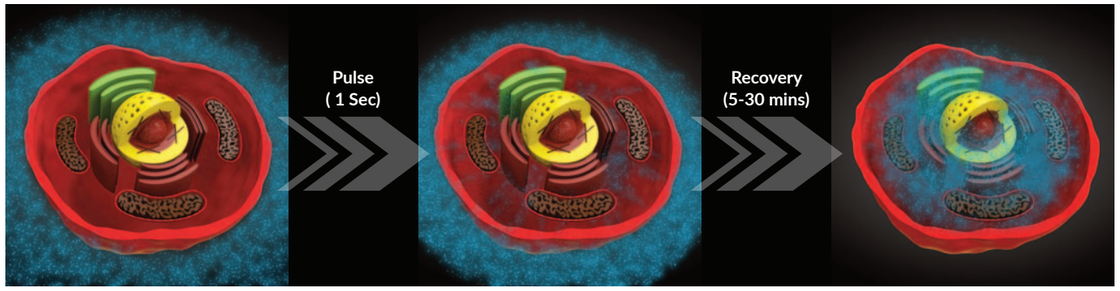
MIRAI MEDICAL has developed an endoscopic approach to target gastrointestinal cancers by utilizing an energy-based technology called electroporation. This treatment approach essentially causes tumour tissue to become extremely porous for several minutes allowing for greater absorption of specific chemotherapy drugs.

Critically, due to the greater conductivity of tumour tissue, the surrounding healthy tissue structures are not damaged in the process. The effectiveness of electroporation in tumour ablation clinically has been reported by a growing number of clinicians in the US and Europe with excellent quality of life and tumour reduction reported for both cutaneous and intraluminal applications.

HOW ELECTROPORATION WORKS?



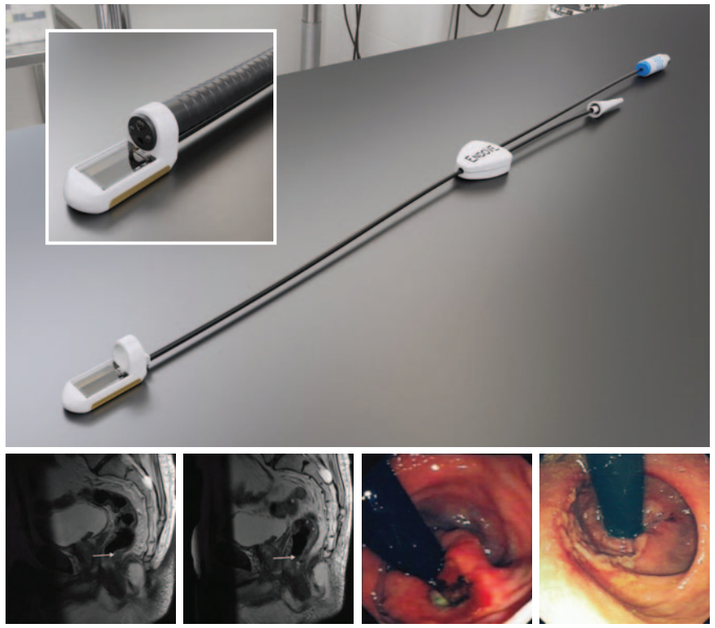
Cell membrane before pulse

Cell membrane during pulse

Cell membrane after pulse (cell returned to original state)

The EndoVE® is the first device to allow for the endoscopic treatment of gastrointestinal tumours. The treatment is conducted under sedation in less than 20 minutes on an outpatient basis. Muscular contractions from the pulses have been eliminated with the new ePORE® generator.

We have conducted a multicenter clinical study to validate the approach, which utilizes a fraction of the normal dose of chemotherapy. Side effects to treatment have been minimized as a result and our outpatient solution is financially attractive in terms of treatment and after-care costs.



ENDOVE® CLINICAL STUDIES

The EndoVE® system has been assessed in clinical trials for patients with inoperable colorectal and oesophageal cancer. The clinical evidence to date with electroporation has demonstrated its excellent efficacy in tumour treatment even in cases where tumours were previously unresponsive to chemotherapy or radiotherapy. No evidence of perforation or other adverse events have been observed to date. The EndoVE® device has demonstrated excellent utility in resolving large circumferential tumours, which typically require two endoscopic sessions for treatment. Smaller earlier stage disease (including Barrett's oesophagus) can be managed in a single session.

HOW IS THE TREATMENT PERFORMED?

The procedure is similar to a standard endoscopy and is performed under sedation. A single low dose of the chemotherapy drug (bleomycin or cisplatin) is provided via intratumoural injection. Calcium has also now been demonstrated to be as effective when injected intratumourally and can be used to replace the chemotherapy drug.The EndoVE® system delivers electroporation pulses directly to the tumour tissue via the ePORE® generator with the process repeated several times until the entire tumour surface area and surrounding margins have been treated. Typically the total procedure takes 20 minutes. Once recovered, the patient will be monitored for several hours before being released on the same day.

DRUG DOSAGES

As the tumour is more porous after electroporation, the required concentration of chemotherapy is a fraction of conventional requirements. For cisplatin intratumoural injection the dosage is 0.5mg per cm3 of tumour, with bleomycin the dosage is 0.6mg / cm3.

WHO IS APPROPRIATE FOR INCLUSION IN THE STUDY?

The EndoVE® can be used to facilitate the management of patients with gastrointestinal cancer. In addition patients with Barrett's oesophagus or early stage disease may benefit from electroporation ablation of their dysplasia.

WHAT ARE THE SIDE EFFECTS?

The side effects when chemotherapy drugs are used in combination are largely eliminated due to the low dosage. Calcium is now available for use as an intratumoural injection in combination with electroporation as an alternative to the chemo option. Pain from the electroporation pulses is limited to temporary muscular contractions during the procedure, which is conducted under sedation. The new ePORE® has also a new higher frequency option to overcome the discomfort associated with the pulses.

POTENTIAL BENEFITS

The EndoVe® is provided as an outpatient procedure that has excellent tumour ablative capabilities, and can reduce the risk of obstruction without the side effects associated with other ablative technologies such as radiotherapy or RFA. Healthy tissue structures remain preserved and reduced bleeding has been reported post electroporation. An elevated presence of Antigen Presenting Cells within the tumour has been reported clinically post electroporation and may play an important role in facilitating a systemic immune response. Early stage dysplasia e.g. Barrett's oesophagus can also benefit from the technology.

If you would like to refer a patient for the colorectal EndoVE® treatment or are interested in performing the procedure yourself, please email **info@mirai-medical.com**

MIRAI MEDICAL
Innovative Cancer Solutions

THE FUTURE OF ePORE® AND ELECTROPORATION

The combination of electroporation and calcium is also an extremely promising area for use with electroporation. *Falk et al* [1] found in a double blinded randomised phase II study in patients with cutaneous metastases that calcium combined with electroporation is safe and has a similar response rate to bleomycin.

The combination of high frequency electroporation performed under local anaesthetic in an out patient setting opens the door to the use of electroporation earlier in the patients disease state, including patients with premalignant disease and those with benign lesions e.g. keloid scars and vulva intraepithelial neoplasia (VIN).

PIONEER registry

Mirai Medical has developed a multi-centre observational medical device registry called PIONEER. The aim of this registry is to assess real-world long-term disease outcomes for patients treated using pulsed electrical fields, in particular tumour response rates, overall efficacy and procedure times.

PIONEER will collect anonymized data from patients treated across multiple cancer hospitals across the world to provide real world evidence on the benefits and value of ePORE® therapy.

To find out more information, please visit our website at **www.eporetherapy.com**

[1] Acta Oncologica. Falk, H., et al., Calcium electroporation for treatment of cutaneous metastases; a randomized double-blinded phase II study, comparing the effect of calcium electroporation with electrochemotherapy. 2018. 57(3): p. 311-319.

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