Safety of Non-invasive Brain Stimulation in Patients with Implants: A Computational Study

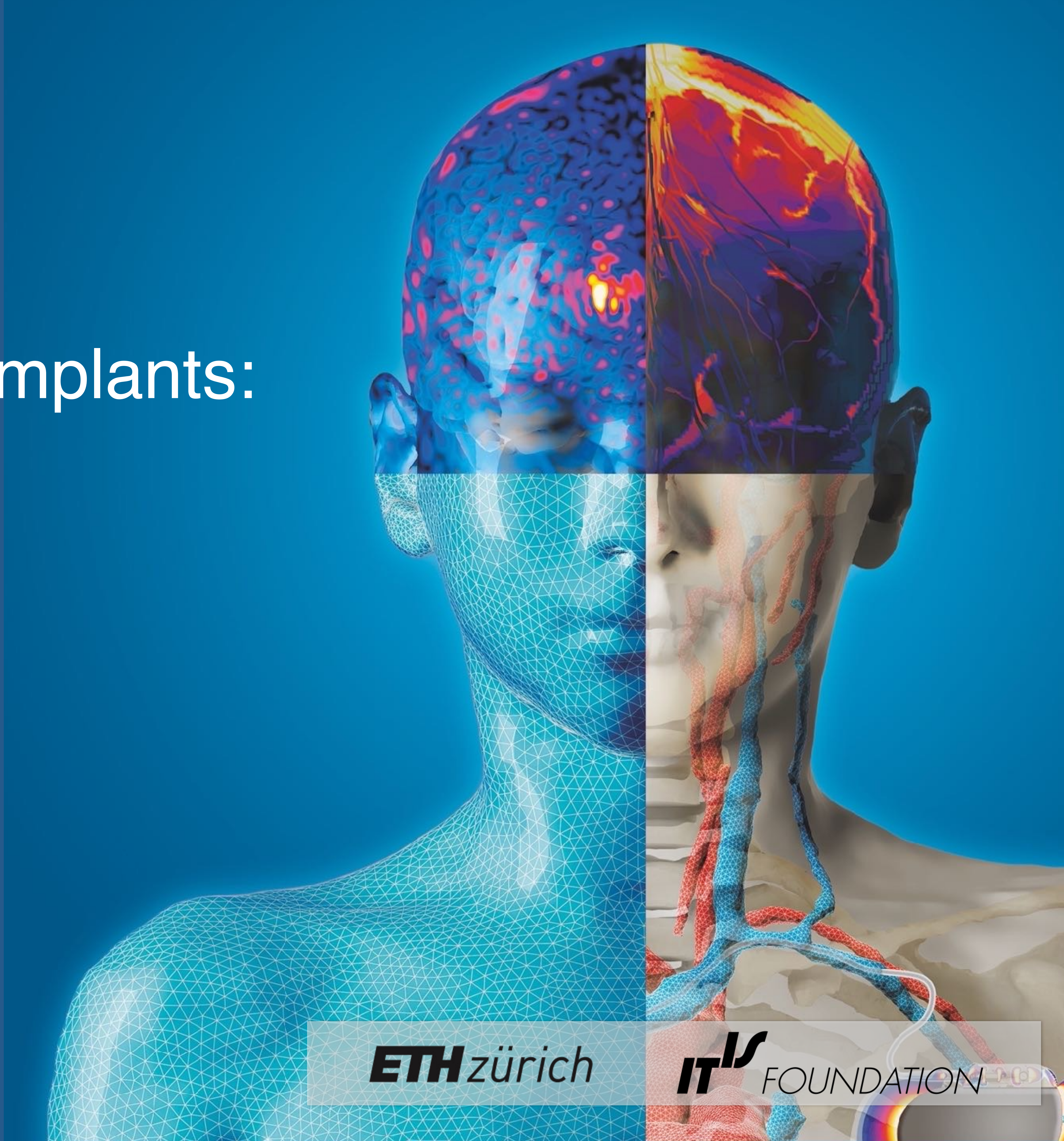
Fariba Karimi, ETH Zurich and IT’IS Foundation

Antonino M. Cassara, IT’IS Foundation

Myles Capstick, IT’IS Foundation

Niels Kuster, ETH Zurich and IT’IS Foundation

Esra Neufeld, IT’IS Foundation



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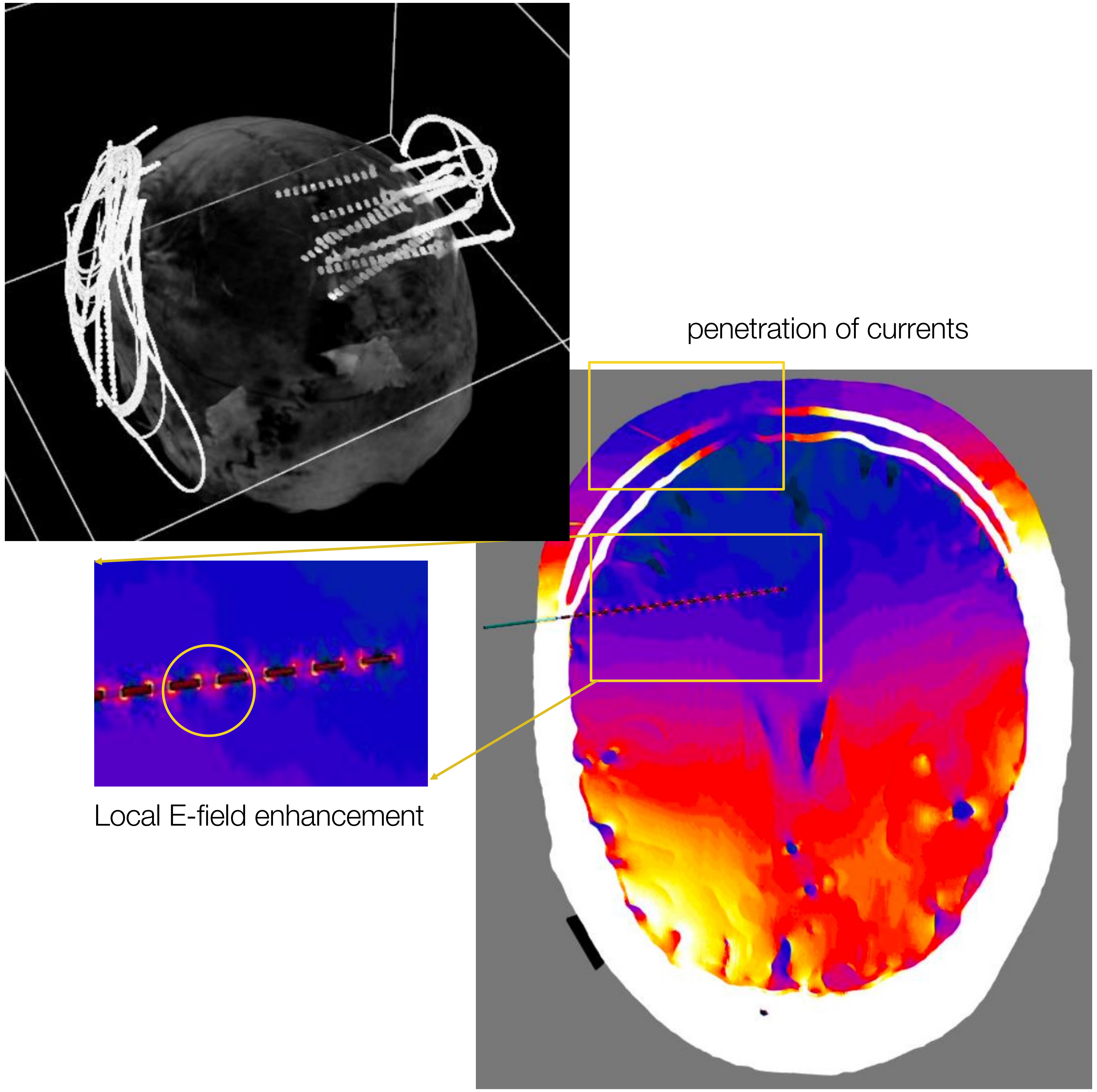
Contents

Introduction & Motivation

- increasing concurrent use of noninvasive brain stimulation in patients with implanted electrodes
  - SEEG electrode
  - DBS electrodes
- potential issues
  - **thermal heating and unwanted stimulation** due to local field enhancement
  - **alternative electric current paths changing exposure** (e.g. low-impedance path between electrodes through burr holes, low-impedance path between electrodes)
- need for systematic safety assessment to
  - identify relevant metrics for safety
  - identify worst case scenario (WCS) facilitating assessments
  - provide guidance about safety assessment during treatment planning (including standardization)



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Considered Safety Concerns

- local field enhancement near metallic contacts
- low impedance pathways between contacts (capacitive coupling)
- capacitive coupling into external / subcutaneous leads
- reduced skull impedance related to drilling

Exposure QoIs

- $E_{IEEE,n}$: peak of the line-averaged vectorial E-field normalized to the incident field in the absence of the implant
  - averaging follows the IEEE 2005 procedure with a straight 0.1 mm line
- $psSAR_{0.1g,n}$: peak spatial-average specific absorption rate (SAR) normalized to the background SAR in the absence of the implant
  - averaging follows the IEEE 1528 standard procedure with a 0.1 g cube
- $G = max(|Eigv(H(x,y,z))|)$: spatial peak of the maximal absolute Eigenvalue of the electric potential Hessian $H(x,y,z)$ near the implant
  - 3D equivalent of the Activating Function (AF) [4], a predictor of neurostimulation for axon fibers
- $\Delta T_{max,n}$: peak temperature increase normalized to the background temperature in the absence of the implant
- the above mentioned concerns were addressed by
  - determination of QoI enhancements factors near highly conductive structures in a homogeneous simulation setup, using 2-3 orthogonal incident E-fields

Simplified Setup

- generic implant
  - diameter (d): 0.8-1.4 mm
  - contact length (L_c): 0.5-3 mm
  - spacer length (L_i): 0.5-4 mm
  - angle of incidence (θ): 0-90
- segmented/dotted
  - (e) Abbott/St. Jude director 6172 DBS lead
  - (f) Boston Scientific Cartesia DBS lead
  - (g) Medtronic SureStim DBS lead
- elongated implant
  - d: 1-5 mm
  - L: 5-50 mm
- scar tissue
  - thickness: 25-300 µm
  - conductivity: 0.019 and 0.05 S/m
- anisotropy:
  - varying principal axis orientation

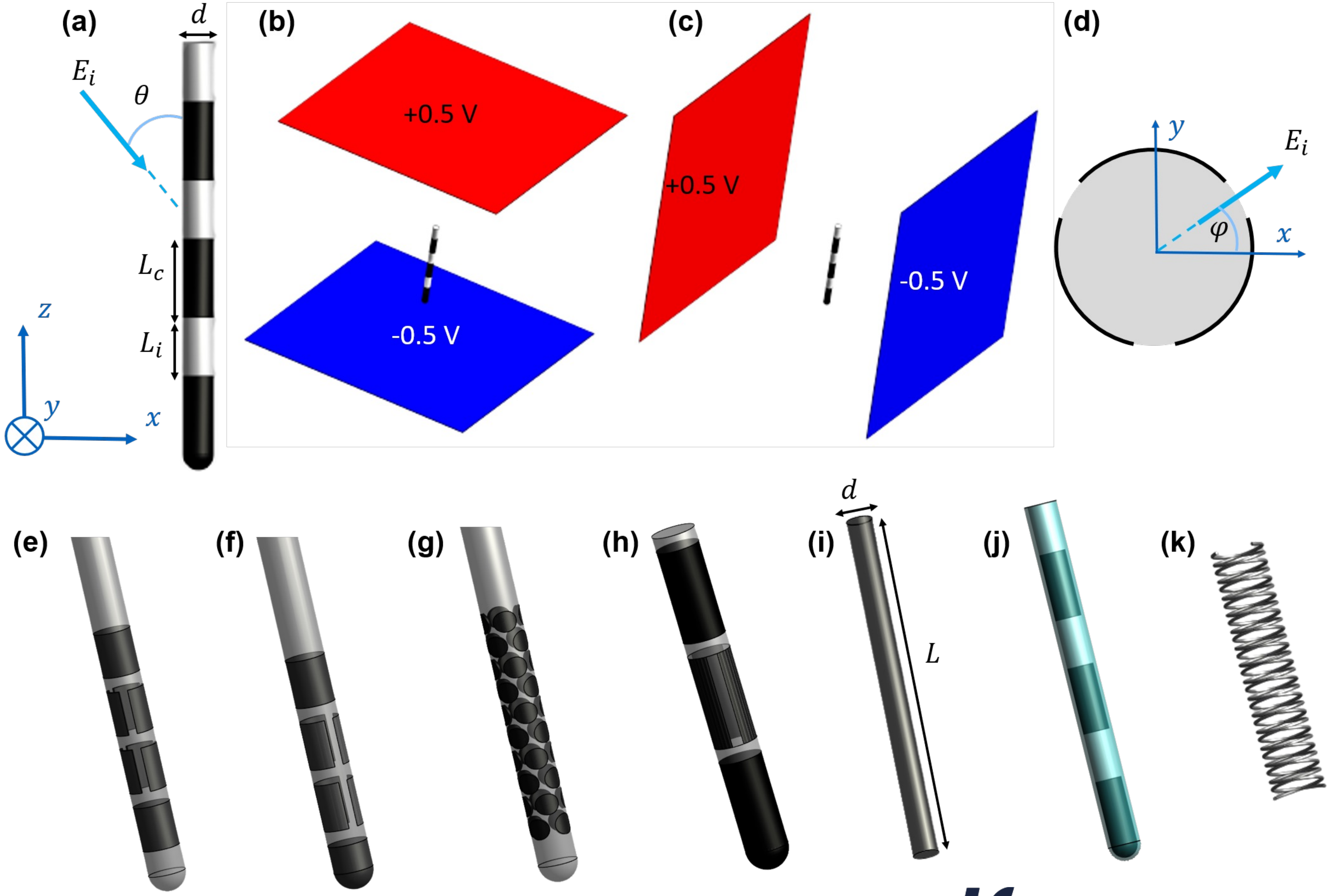

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Illustration of QoIs for d = 0.8 mm implant

Maximum QoIs

- worst case:
  - L_c = 3.0 mm
  - L_i = 0.5 mm
- $E_{IEEE,n}$ and $E_{ICNIRP,n}$ are similar
- scar tissue effects
- segmented and dot electrode effects
- anisotropy effect

Implant diameter	$E_{ICNIRP,n}$	$E_{IEEE,n}$	$psSAR_{0.1,n}$	$\Delta T_{max,n}$
0.8 mm	9.1	9.4	1.39	0.1
1.3 mm	9.1	9.4	1.59	0.12
1.4 mm	9.1	9.6	1.64	0.13

	$E_{IEEE,n}$
generic implant	9.4
with scar tissue (excluding scar exposure)	8.8
segmented and dot electrode	10.5
anisotropy	10.0

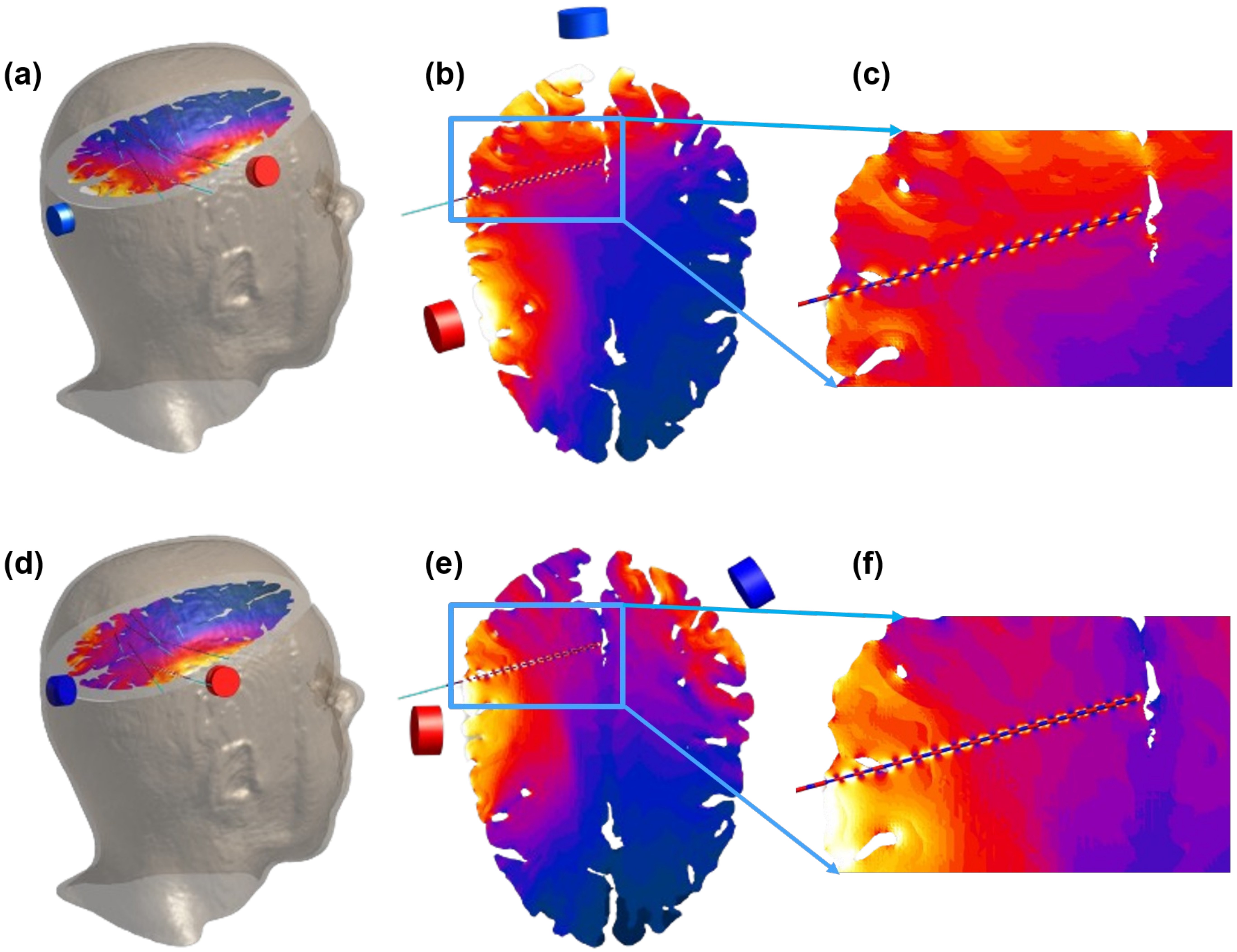
Elongated Cylindrical Implant

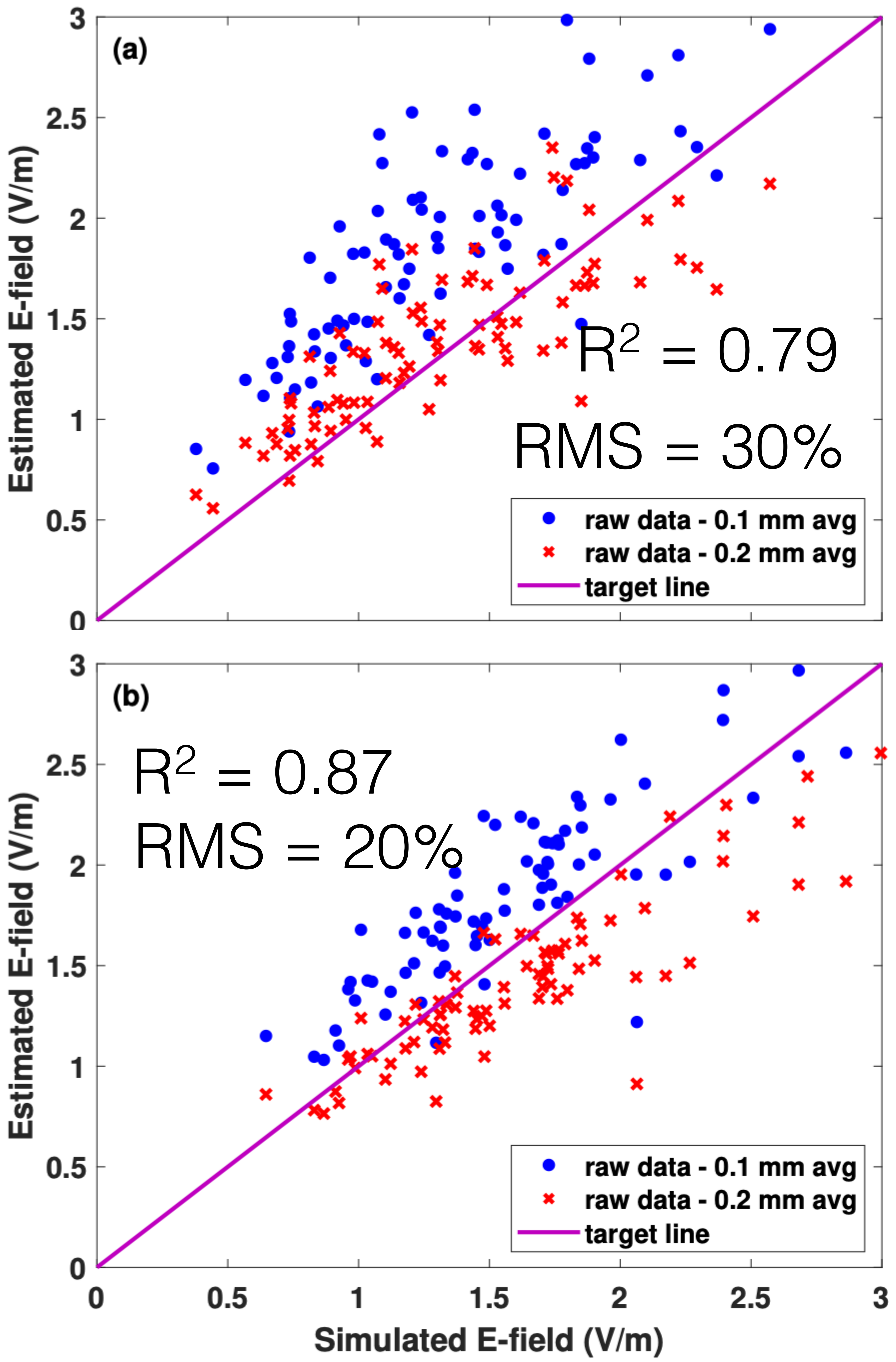
$E_{IEEE,n} \approx 0.8mm^{-1}L + 3.7$

$E_{IEEE,n} \approx 44mm^{0.41}d^{-0.41}$

$E_{IEEE,n}$

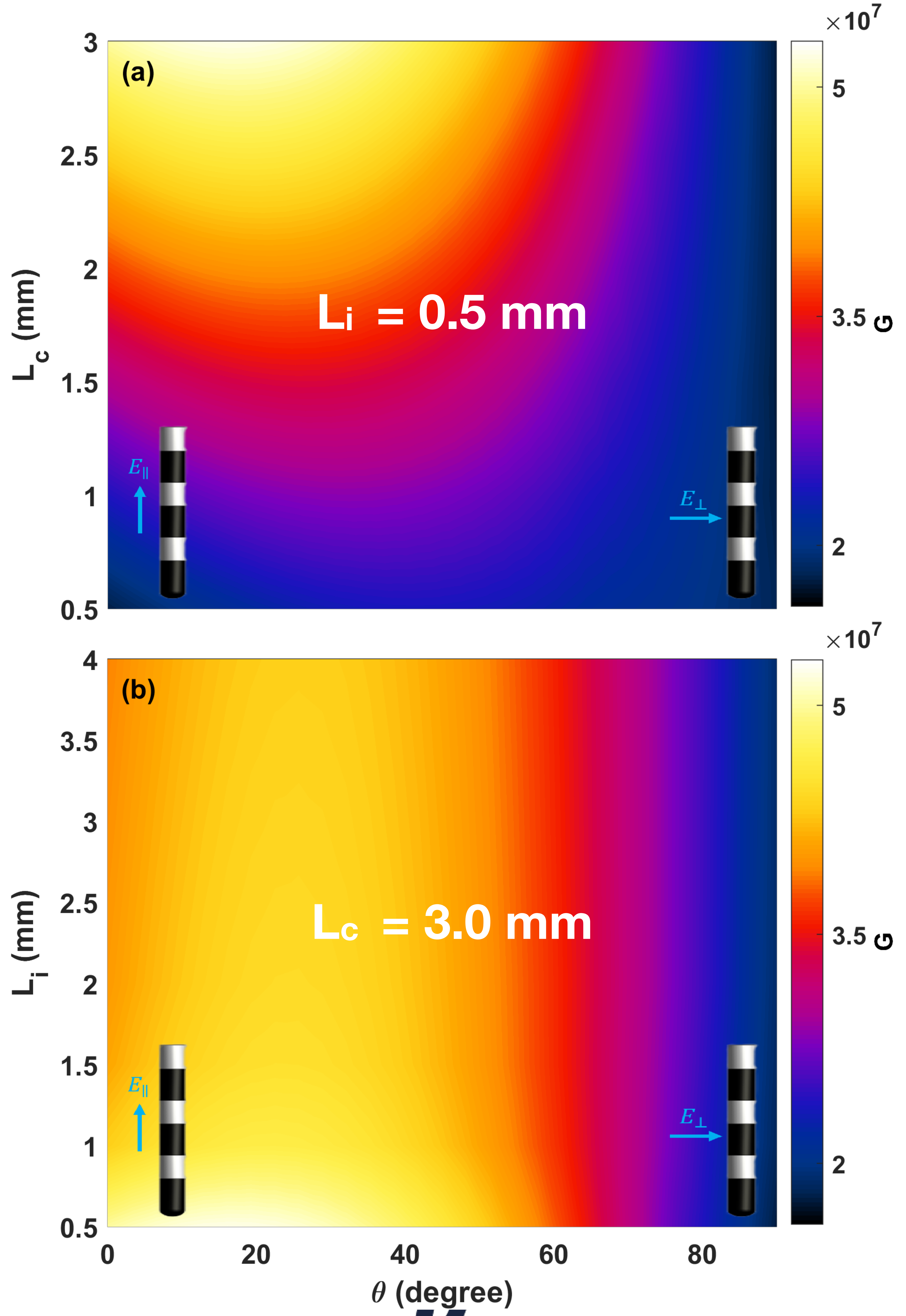
Verification of Enhancement Factor





Neurostimulation

- the stimulation potential of local E-field enhancement near implants: G
- maximum consistent with EM exposure:
  - L_C = 3.0 mm
  - L_i = 0.5 mm



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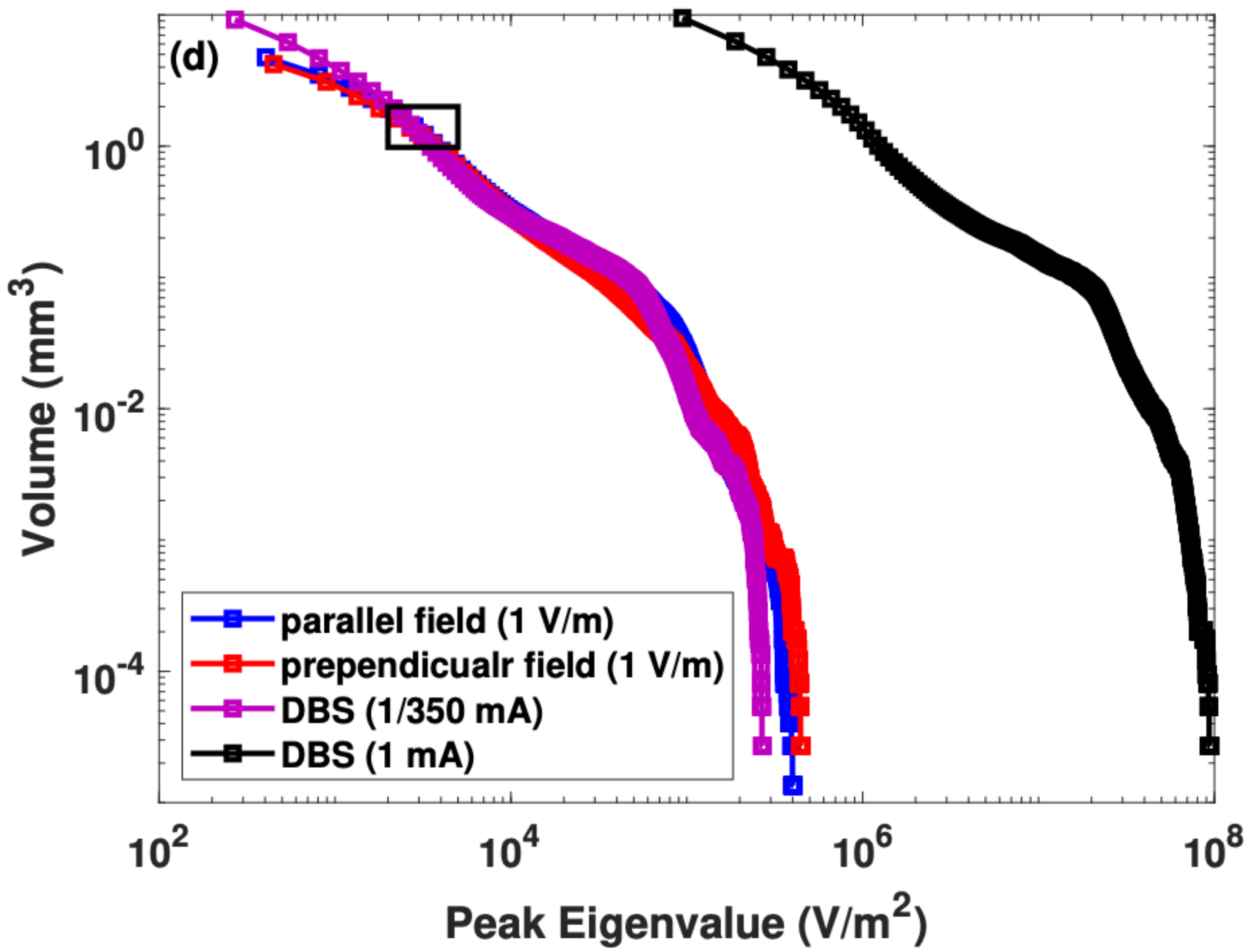
Neurostimulation - Comparison with DBS activation

- DBS: monopolar cathodic stimulation with 1 mA
- passive: 1V/m incident field
- 1 mA DBS current has a comparable effectiveness as field enhancement from passive exposure to an incident E-field magnitude of around 350 V/m (VTA of 1 mm^3)



d=0.8 mm, Lc = 0.5mm. Li=0.5 mm

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Impedance Measurements

- in frequencies of interest: ohmic pathway is >> capacitive coupling between contacts
- capacitive coupling: 3 orders of magnitude less than DBS at 100Hz

quantity	method	AD-Tech	Medtronic
inter-electrode capacitance	measurement	16-20 pF	50-80 pF
wire-tissue capactance	measurement	1 pF/cm	3 pF/cm
ohmic tissue resistance	simulation	500 Ω	1300 Ω

Conclusions

- research related to TIS requires careful, investigation-specific safety assessment
- *in silico* investigations facilitate systematic exploration of diverse exposure conditions & provides guidance for experimental work and stimulation planning
- investigated
  - threshold currents for the safe delivery of TES and TIS
  - assessment of TES and TIS safety in presence of conductive implants
- resulted in proposal for frequency-dependent current threshold & guidance on exposure of subject with implants
- in agreement with history of safe use of TES and TIS
- experimental confirmation necessary, especially for TIS using high frequencies (>10kHz), where assessment relies on biophysically motivated extrapolation