Estimation of TASER Current Flow and Effects on Human Body

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Background

- PhD thesis topic: pacemakers and defibrillators
- 15+ years of work experience in:
  - Cardiac mapping devices
  - Cardiac ablation devices
  - Intracardiac imaging
  - Implantable pacemakers
  - Implantable defibrillators
- Significant exposure to US (FDA), EU (CE), Japan (MHLW), Canadian (CSA), Australian medical-device regulations
- Developed or contributed to the development of over 10 medical devices that received FDA or CE approvals and were successfully introduced in US or International markets
- Over 130 US patents issued by the US PTO
- Several tens of patents issued in countries other than the US
- Over 100 medical-field publications
- Chair of the IEEE Engineering in Medicine and Biology Therapeutic Systems and Technologies Technical Committee
- Fellow of the American Institute for Medical and Biological Engineering (AIMBE)

TASER CEWs Electrical Output:

How does it compare to that of FDA-approved cardiac medical equipment?

Specifications for M26, X26, External Defibrillators, Pacemakers, RF cardiac ablation generators

Specification	**M26**	**X26**	**ED***	**EP***	**RFG***	**ICD***
Open-circuit peak voltage [kV]	50	50	5	0.1	0.5	1
Peak output voltage in typical load [kV]	5	1.2	5	0.1	0.5	1
Peak output current in typical load [A]	15	3.5	31	0.15	2.5	20-30
Pulse duration [µs]	40	100	10,000	10,000	Sinewave	5,000
Energy delivered in typical load [J/pulse]	0.5	0.07	200	0.04	12,000	40
Power delivered in typical load [W]	10	1.3	n/a	7	150	n/a
Charge in the main phase [µC]	85	100	100000	1500	n/a	50000
Pulse rate [pulse/s]	20 ± 25%	19	single	3	500 kHz	single
Total delivery duration [s]	5	5	0.01	Cont.	120	0.005
On-demand delivery termination	Yes	Yes	No	Yes	Yes	No

* External Defibrillator/Pacemaker – Zoll Medical; RF generator – Boston Scientific; ICD – St Jude Medical

Conclusion: TASER CEW output vs. FDA approved cardiac devices

- TASER CEW loaded peak *voltage* is *equivalent* to that of external defibrillators
- TASER CEW loaded peak *current* is *less than* that of external or implantable defibrillators
- TASER CEW loaded *energy per pulse* is *many orders of magnitude lower* than that of defibrillators or RF generators and equivalent to that of external pacemakers
- TASER CEW loaded *power* is *15-100 times lower* than that of RF cardiac ablation generators
- TASER CEW loaded output *charge per pulse* is *15 – 1000 lower* than that of defibrillators or pacemakers
- TASER CEW output *duration* is *24 times lower* than that approved for RF cardiac ablation.
- These medical device may induce VF. The US FDA, when accepting test data for these devices, accepts a probability of VF induction of 0.002, or 1 in 500.

TASER CEWs Electrical Output:

Does any electrical safety standard provide information of thresholds and probabilities for VF?

How does it compare to electrical safety standard International Electrotechnical Commission (IEC) 479-2?

IEC 479-2: Effects of currents passing through the human body, 2nd Edition, IEC, Geneva, Switzerland, 1987

- No standards of electrical safety address TASER CEW pulse waveforms directly
- Although not directly applicable, IEC 479-2. Section 4.4 describes the thresholds of ventricular fibrillation for impulses of short duration
- It states that “for 50% probability of fibrillation, Fq is of the order of 0.005 As.”
- 0.005 As is equal to 5000 µC
- TASER CEW X26 charge 100 µC
- TASER CEW M26 charge 85 µC
- Worst-case charge/pulse is *50 times less* than the 50% probability level above
- Assuming a standard normal distribution of VF thresholds and normalized standard deviation of approx 25% (as per spread of VF chronaxie and rheobase reported by Ideker et al.), the 50 times lower level implies a theoretical *probability of VF of less than 1 in 2,000,000*

TASER CEWs Electrical Output:

Numerical estimates of current density and electric field strength

Finite Element Modeling

- Finite element analysis (FEA) is a mathematical technique of approximating the solution to Laplace electric field equations
- The technique is well accepted in the field of medical devices and their applications
- The CSA, FDA, CE or MHLW all accept FEAs as scientific justification for presenting the effects of various devices such as RF ablation electrodes, implantable defibrillators, MRI, CT, etc.

Finite Element Modeling

- The presentation analyzes current and electric field distributions and effects based on two FEM:

  - First model looks at distributions skin, fat, skeletal muscle and deep body tissues

  - Second model is a whole body model and looks at distribution inside the heart

Finite Element Modeling

Regions

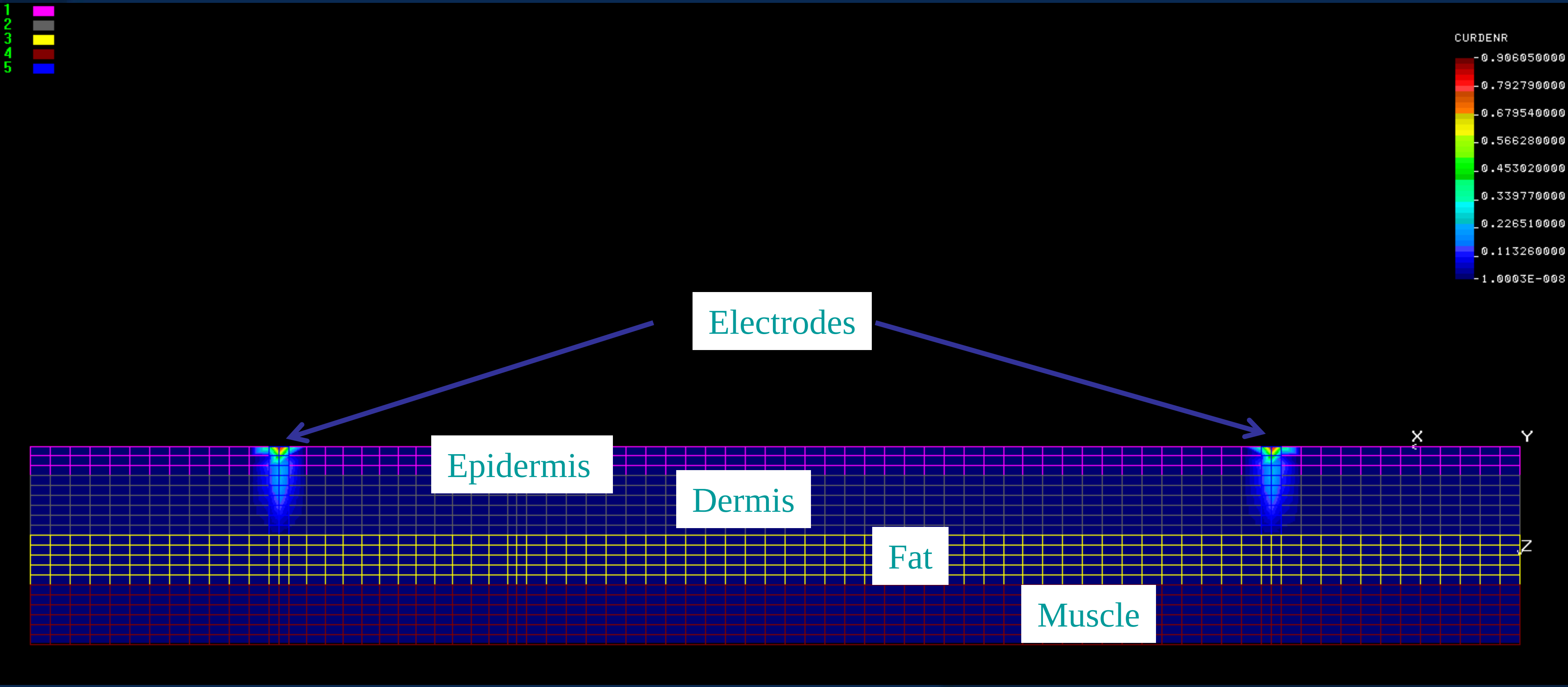
- Epidermis – 3 mm
- Dermis – 6 mm
- Fat – 5 mm (worst case scenario, typical human fat layer thickness is 20-30 mm)
- Muscle – 6 mm
- Electrodes – 9-mm long, 2-mm diameter (fully penetrated standard probe)

- Nodes: 45360
- Elements: 41080 hexahedral elements
- Model: 15-cm long, 5-cm wide, 2-cm deep
- Electrodes: 10 cm apart
- Boundary conditions: 1000 V (X26 peak voltage)
- Steady-state solution

Finite Element Modeling

- Material properties (electrical resistivity)
  - Epidermis – 1 MΩ·cm
  - Dermis – 500 Ω·cm
  - Fat – 2200 Ω·cm
  - Muscle – anisotropic layer
    - $\rho x = \rho y = 200$ Ω·cm (longitudinal)
    - $\rho z = 1000$ Ω·cm (transversal)
  - Electrodes – 0.001 Ω·cm

Finite Element Modeling



Electrodes

Epidermis

Dermis

Fat

Muscle

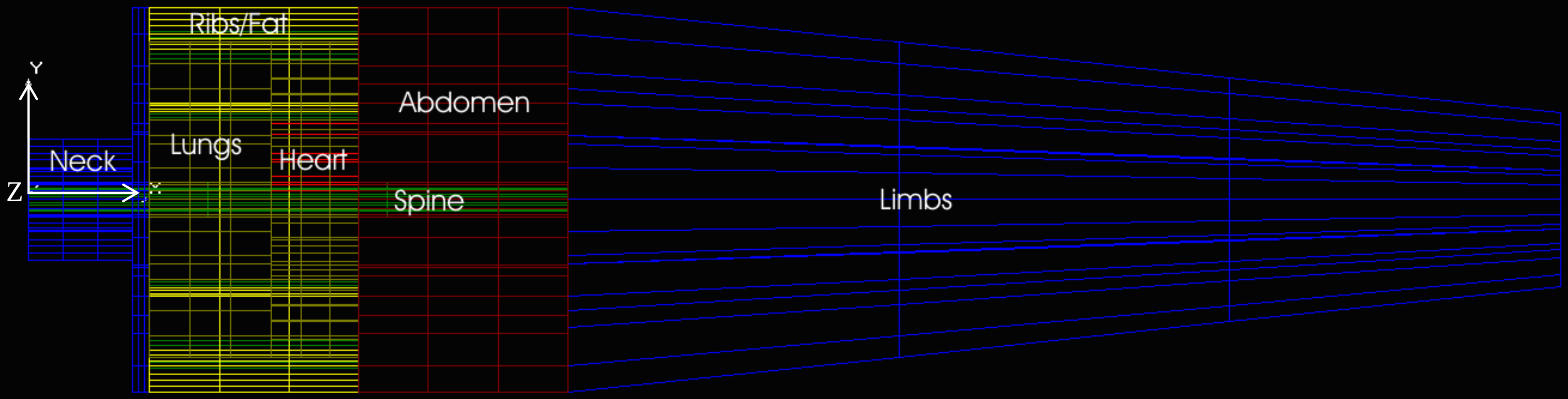
Finite Element Modeling

- Regions
  - Muscle (neck, shoulder, limbs)
  - Heart
  - Bone (spine, ribcage)
  - Lungs
  - Skin/Fat (~ 20-30 mm thick)
  - Abdomen
- Elements: 8640 hexahedral elements
- Model: human body, about 170-cm long
- Electrodes: various placements
- Applied voltage: 1000 V (X26 peak voltage)

Finite Element Modeling

- Material properties (electrical resistivity)
  - Muscle – 300 Ω·cm
  - Heart – 450 Ω·cm
  - Bone – 5000 Ω·cm
  - Lungs – 1100 Ω·cm
  - Skin/Fat – 2200 Ω·cm
  - Abdomen – 200 Ω·cm
  - Electrodes – 0.001 Ω·cm

Finite Element Modeling

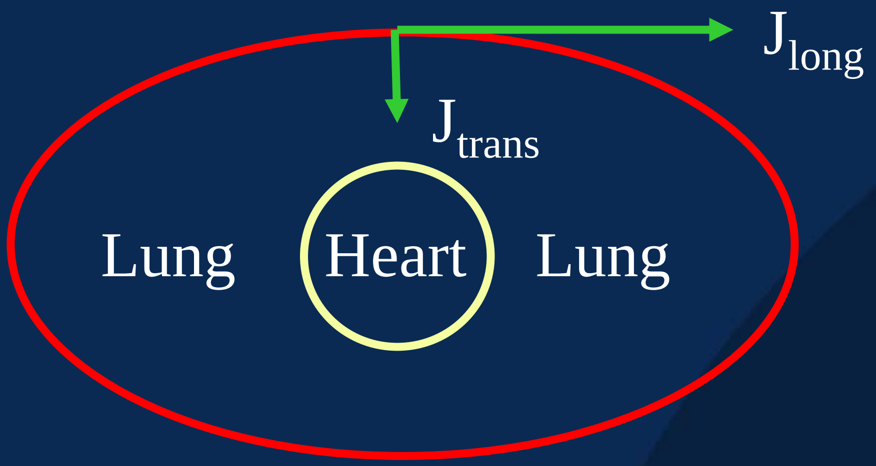


Finite Element Modeling - Results

- Current attenuating effects of skeletal muscle anisotropy
- Current attenuating effects of fat
- Skin-heart distances vs VF thresholds
- VF safety margins
- Cardiac capture safety margins
- Discussion

Anisotropy - background

- Current density (J) more likely to travel around the chest (longitudinally) than ‘into’ the chest (transversally)

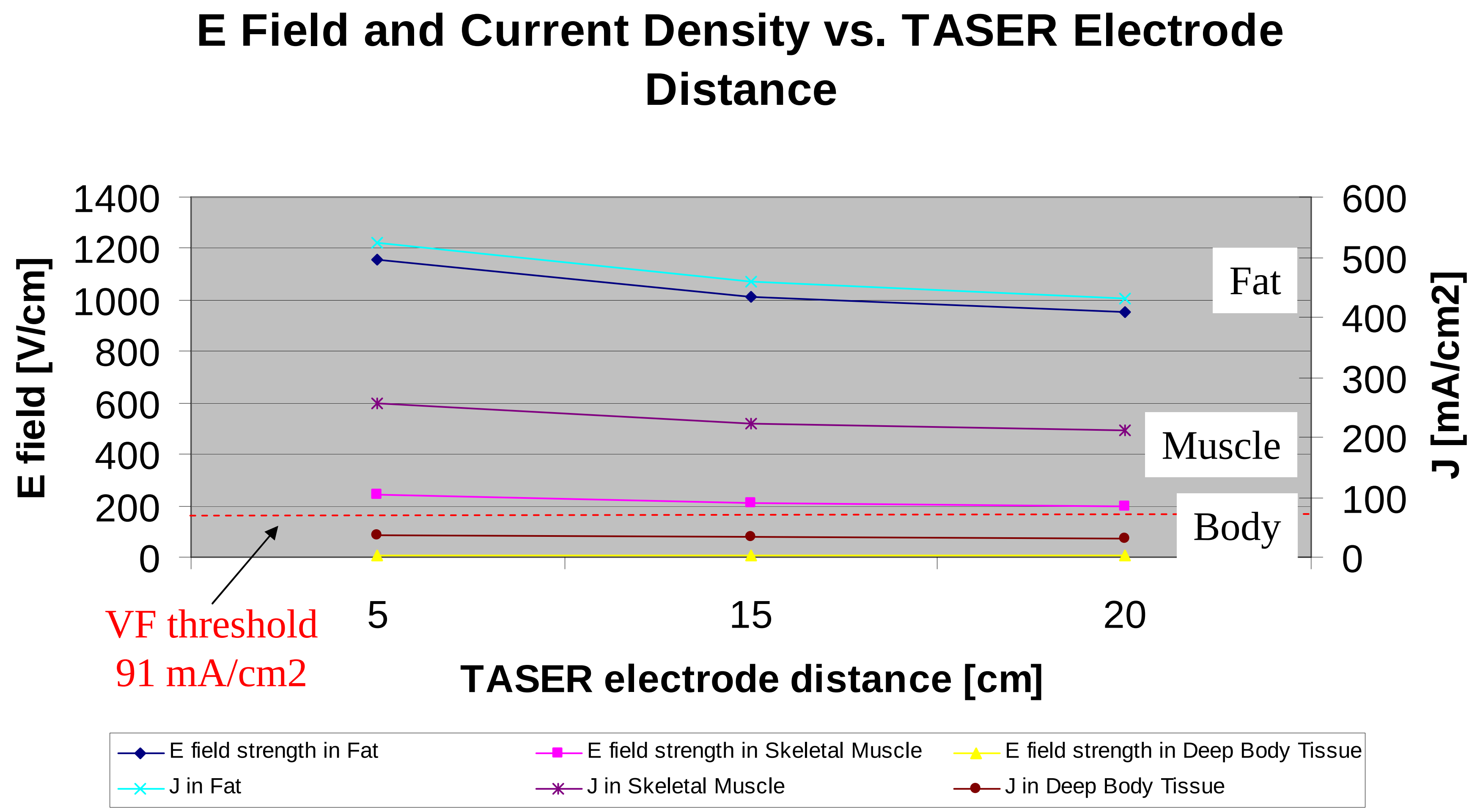


- $J_{long} >> J_{trans}$

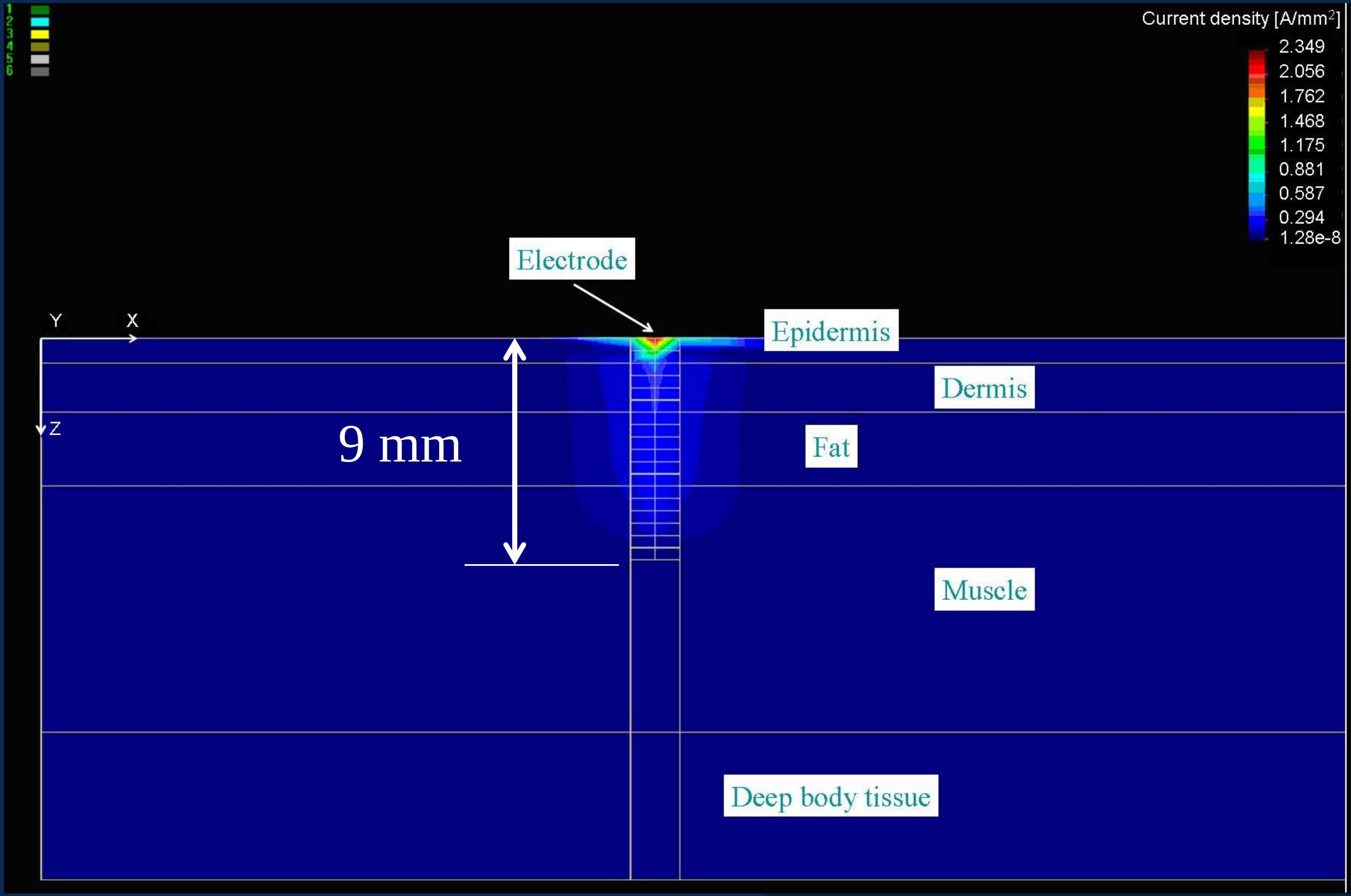
Electrical Shell Effect of Fat and Skeletal Muscle

Condition	J_{trans} [mA/cm^2]	J_{long}/J_{trans}	Comments
Thin body with 5-mm fat and anisotropic muscle layers	15.63	8	Current is diverted away from deeper tissue layers by fat and longitudinal muscle electrical conduction
Muscle anisotropy removed	20.81	5	Removing muscle anisotropy increases current into deeper tissue layers by 30%
Fat and muscle anisotropy removed	45.49	2.9	Removing fat increases current into deeper tissue layers by 200%

Results – E & J vs. Electrode Distance



Results – Skin-heart distance vs VF thresholds



Results – Skin-heart distance vs VF thresholds

- With the TASER CEW probe fully embedded, *J* dropped below 91 mA/cm^2 at *14.7 mm* from the skin surface
- Webster *et al.* indicated that skin-to-heart distances of *14.8 to 26 mm* were required to induce VF in anesthetized pigs (see slide 28)
- The *removal of fat and the replacement of the anisotropy of the skeletal muscle* with an isotropic conductive gel might explain differences with respect to our results above
- For a BMI of 30 kg/m^2, the average BMI in individuals restrained for excited delirium (Stratton), Tchou *et al.* reported a *minimum skin-heart distance of about 35 mm*
- 35 mm skin-heart distance, more than two-fold the 14.7 mm skin-heart VF distance threshold
- Given that current density drops rapidly with distance, the two-fold distance difference provides ***additional margin of safety against VF***

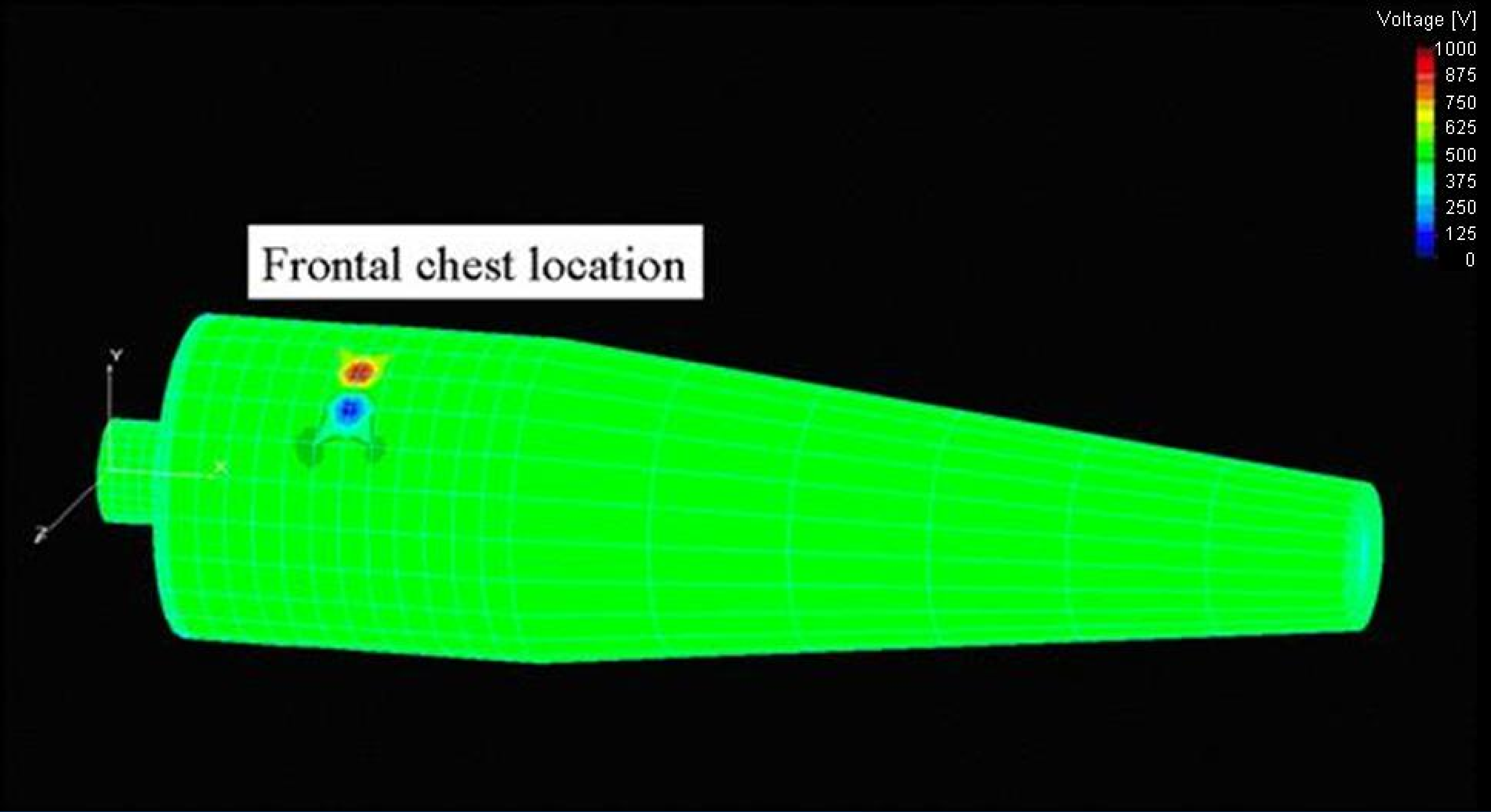
Maximum heart current density and safety margins vs. TASER CEW electrode locations

Electrode separation and position	Maximum current density in the heart	Safety margin with respect to VF threshold (X26 CEW**)	Safety margin with respect to capture threshold* (X26 CEW**)
8” – over dorsal area	0.064 mA/cm^2	1421 times	69 times
8” – left nipple to left thigh	0.24 mA/cm^2	379 times	18 times
3” – frontal chest, straight over heart	2.7 mA/cm^2	33 times	1.7 times

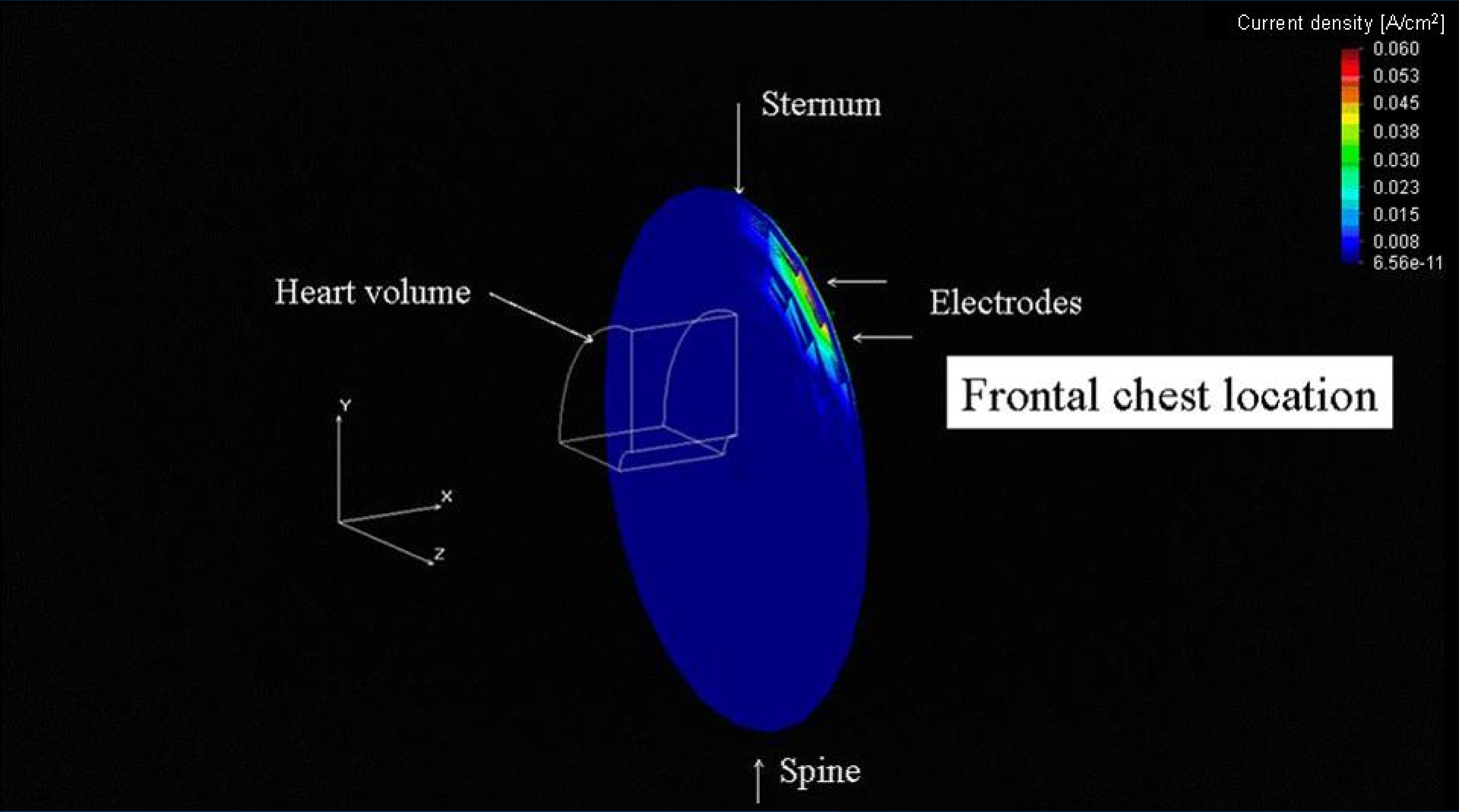
* Multiply current density by 0.45 kΩ·cm to compute E field strength

** TASER CEW M26 margins are wider due to shorter duration of 40 μs

FEM – Voltage distribution [V]



FEM – Heart current density distribution [A/cm^2]



Conclusions

- Current decreases rapidly with distance from electrode
- The fat and skeletal muscle layers have an electric shell effect on currents that reach into deeper tissue layers (such as the heart):
  - The fat layer attenuates the electric field by at least 25 times, even under worst-case minimal thickness assumptions
  - Skeletal muscle preferred longitudinal (with the grain) electrical conduction diverts about 88% of the current away from deeper tissue layers
- In the muscle layer:
  - the transverse current density is less than 15 mA/cm^2
  - the equivalent field strength is in the 15-30 V/cm range:
    - > greater than 2.25 V/cm – threshold to capture motor neurons
    - > but much low lower than levels required for irreversible electroporation (1600 V/cm – Gehl et al. 1999)

Conclusions

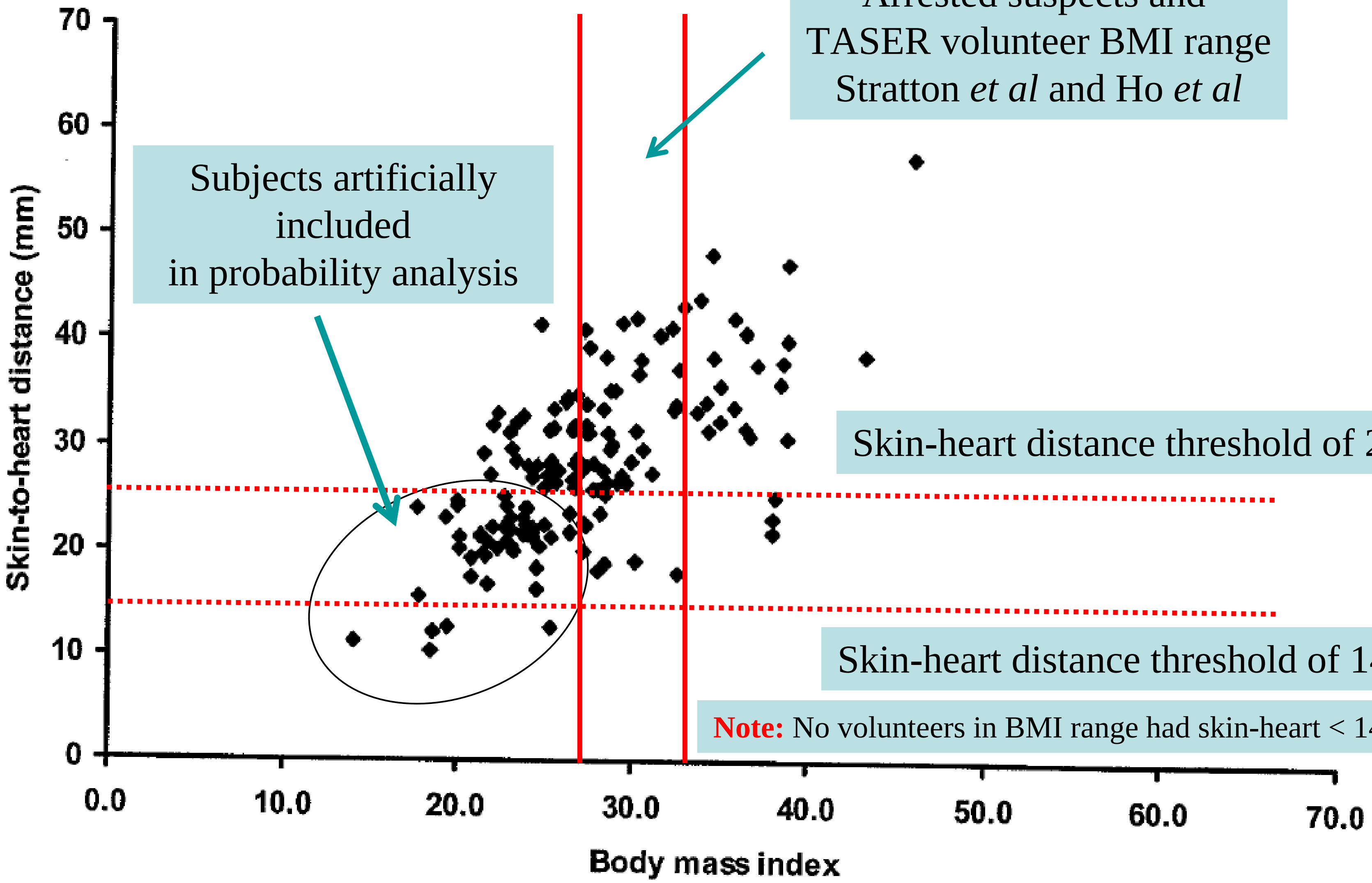
- The fat and skeletal muscle layers significantly reduces the current that reaches deeper into the body
- The skin-heart minimal distance for typical in-custody suspects is at least two times greater than the maximum distance estimated by theoretical models as being necessary to induce VF
- TASER CEW currents are much lower than levels required to trigger ventricular fibrillation (by at least 33 times margin for X26, higher margin for M26)
- TASER CEW currents are not likely to capture the heart, although the capture margin can vary with the TASER CEW application vector
- These numerical models estimate that TASER CEW devices are effective and safe, within a reasonable degree of scientific probability

Comments on VF animal models

- Webster model (University of Wisconsin group):
  - Skin-heart distance for VF = 26 mm with fat and skeletal muscle removed
  - Skin-heart distance for VF drops to 14.8 mm if fat and skeletal muscle NOT removed
  - Typical ICD suspect skin-heart distance = 35 mm (Tchou *et al*.)

- Limitations of Webster model:
  - ✓ Effects of fat neglected
  - ✓ Effects of skeletal muscle anisotropy neglected
  - ✓ Isoflurane is proarrhythmic
  - ✓ Inappropriate suspect population distribution assumptions
  - ✓ Effects of probe penetration angle ignored

- If Webster model considered the skin-heart distribution as per BMI reported for ICD suspects (Stratton, Tchou) then estimated <u>*VF probability would have been zero, rather than 0.0000061*</u>.



Arrested suspects and
TASER volunteer BMI range
Stratton *et al* and Ho *et al*

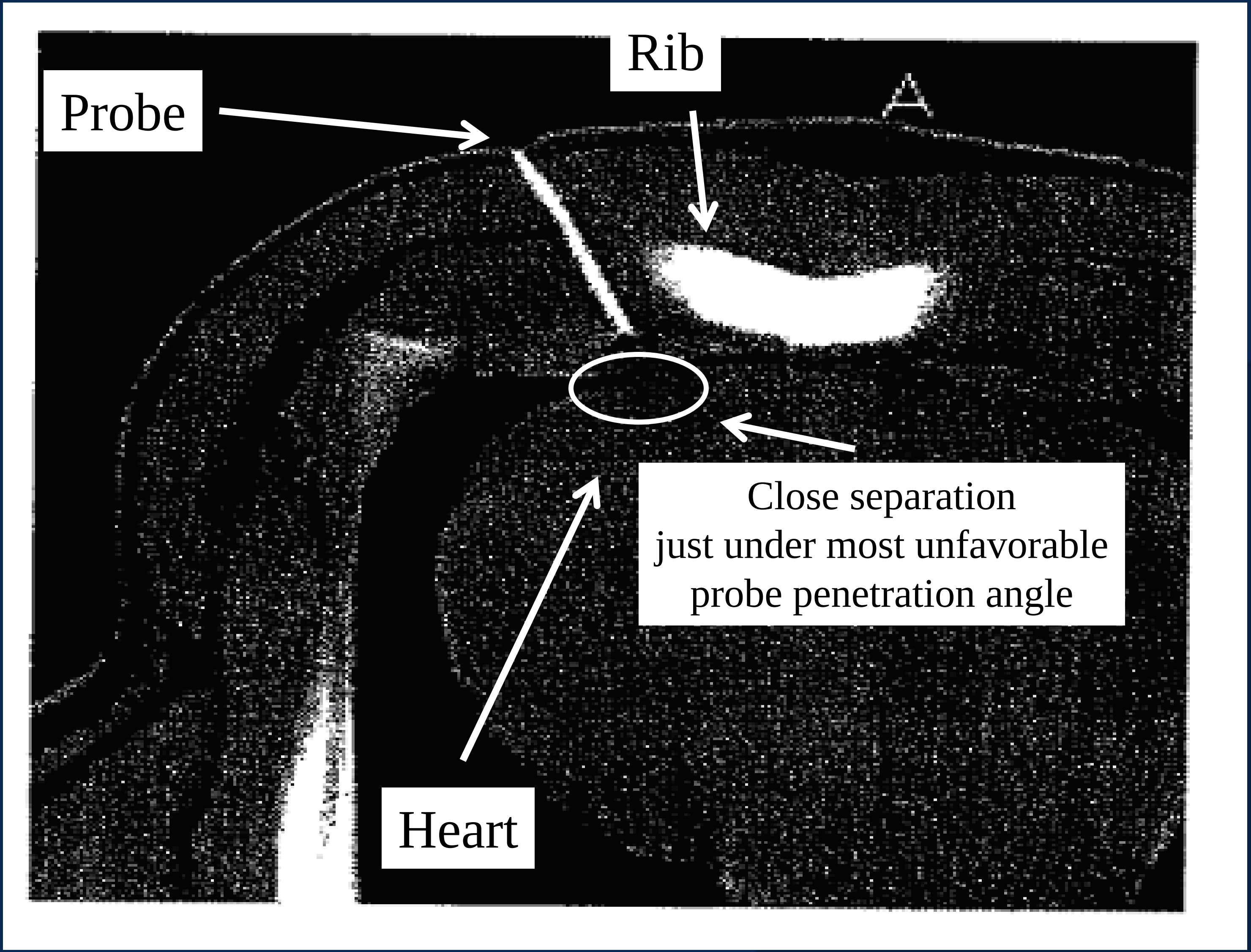
Subjects artificially
included
in probability analysis

Skin-heart distance threshold of 26 mm

Skin-heart distance threshold of 14.8 mm

Note: No volunteers in BMI range had skin-heart < 14.8 mm

Probe penetration angle assumptions



Probe

Rib

Close separation just under most unfavorable probe penetration angle

Heart

Comments on VF animal models

- Limitations of swine models (Webster *et al.*, Dennis *et al.*, Nanthakumar *et al.*):
  - Isofluorane increases significantly susceptibility to mechanical and electrical endocardial irritation
    - In reference below*, we reported that a significant number of swine experienced lethal VF rhythms in absence of any electrical currents
    - VF was triggered either in response to anesthetic or by mechanical irritation of the right ventricular endocardium
  - Swine have a Purkinje fiber system that penetrates deeper into ventricular structures. As a consequence, swine ventricular tissue is significantly more excitable than human ventricular tissue. VT/VF can be easier induced in swine than in humans.
  - Animal size: studies above were conducted on small-size animals. As such, results may be difficult to extrapolate to typical ICD suspects that, on average, weight 91 kg.

- A. J. Greenspon, R. P. Borge, D. Panescu, T. Nguyen, M. Ormont, M. Wadhwa, S. Fertels and D. Dupree, "Validation of a new nonfluoroscopic system for simultaneous multisite mapping and discrete three dimensional localization," *PACE,* Proc. 19th Ann. Sci. Sess. *NASPE*, San Diego, CA, USA, vol. 21, no. 4(2), pp. 965, 1998.

Comments on possible instrumentation errors

- Instrumentation limitations Nanthakumar *et al.*:
  - On page 802, the authors stated that significant differences were found in the intracardiac voltage measured for NID1 (TASER CEW X26) vs. NID2 (TASER CEW M26), 195 ± 64 mV vs. 77 ± 18 mV, respectively.
  - This result may be incorrect.
  - The instrumentation used by the authors attenuated the NID2 voltages 2.5 times more than the NID1 voltages.
  - Consequently, the authors incorrectly reported that there are significant differences in intracardiac voltages between the two systems.
  - The authors should have pointed out that these results were an error of their instrumentation setup, not real difference between the performance of the two devices.
- It is unknown whether this instrumentation error had any significant effects on the conclusion of the study. However, the fact it was overlooked may question the authors' overall methodology.

Comments on possible instrumentation errors

- Instrumentation limitations Cao *et al.*:
  - In Fig. 1, the authors should have stated the VVI or VOO rate.
  - The pacemaker entered noise reversion.
  - In such mode, pacemakers typically pace at an asynchronous rate.
  - Not knowing the rate, it is difficult to understand whether any of the rhythms alleged by the authors were solely due to the TASER device or bore the effects of VVI or VOO pacing.
  - Also, the filtering and sampling capabilities of the pacemaker, as they relate to stored EGMs, were not listed. The reader is left to wonder whether or not any of the results might have been caused by filter settings or by undersampling.
  - Similarly, during TASER CEW pulses, the pacemaker's protection network should have been activated. However, there is no discussion regarding the possible interference between the protection network and the sensed signals. How would the reader know whether or not there is any potential saturation or recovery time for the front-end electronics of the pacemaker?
- It is unknown whether this incomplete information about instrumentation had any significant effects on the conclusion of the study. However, the fact it was overlooked may question the authors' overall methodology.

Are we addressing the right rhythm?

- Above work shows that direct VF induction by TASER CEW devices is very unlikely
- This statement was corroborated even by the Webster *et al.* model.
- Stratton et al., Robison et al., Di Maio etc. all point out that most frequently encountered rhtyhm in ICD cases is asystole or PEA
- It is well known that electricity, such as TASER CEW current, cannot directly induce asystole or PEA.
- Their statistics show that hog-ties, plastic tie-wraps, OC, handcuffs, or physical restraint are much more likely of being associated with sudden ICD.
- Can plastic tie-wraps induce VF?

Are we addressing the right rhythm?

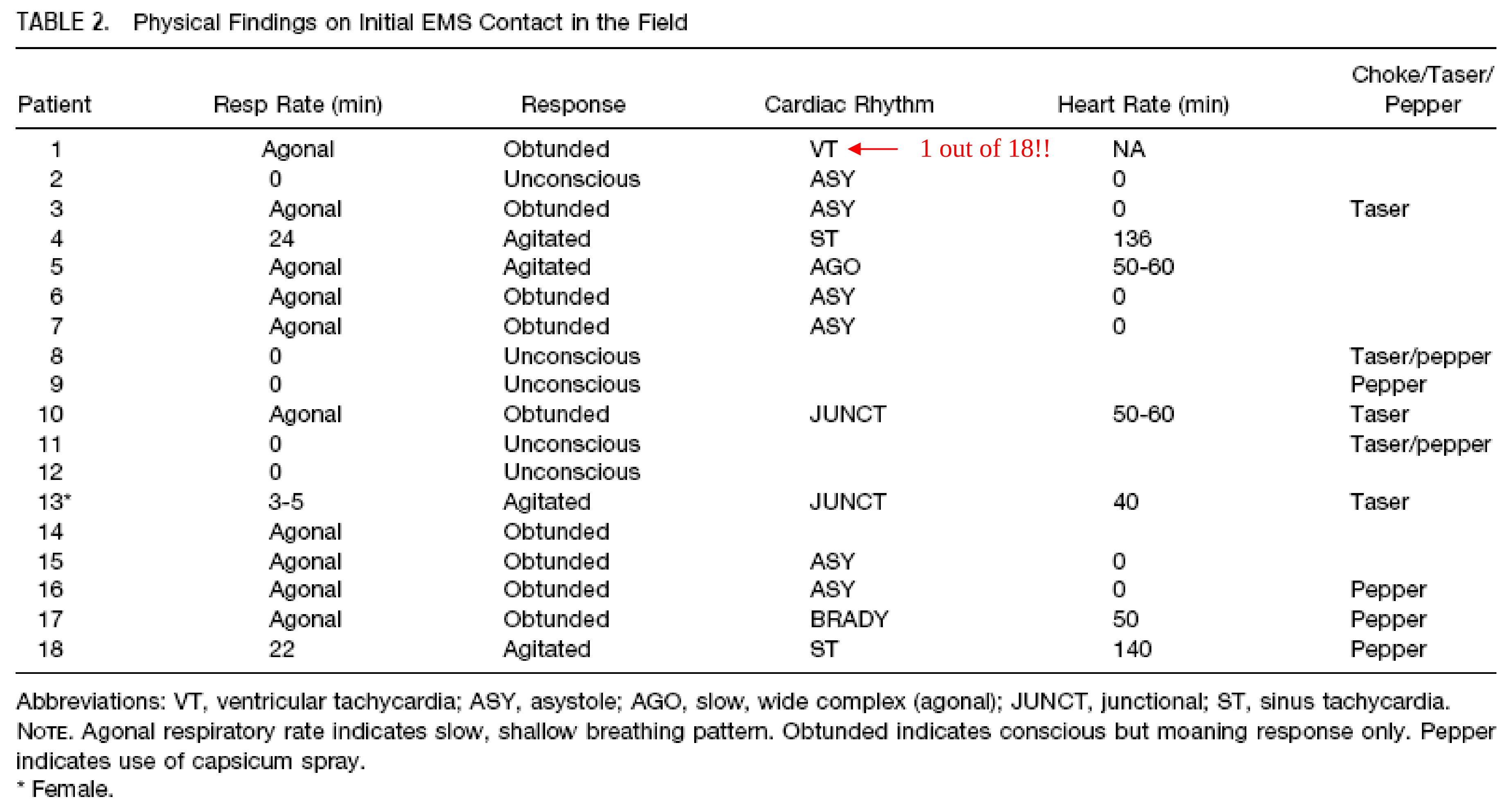


TABLE 2. Physical Findings on Initial EMS Contact in the Field

Patient	Resp Rate (min)	Response	Cardiac Rhythm	Heart Rate (min)	Choke/Taser/ Pepper
1	Agonal	Obtunded	VT ← 1 out of 18!!	NA	
2	0	Unconscious	ASY	0	
3	Agonal	Obtunded	ASY	0	Taser
4	24	Agitated	ST	136	
5	Agonal	Agitated	AGO	50-60	
6	Agonal	Obtunded	ASY	0	
7	Agonal	Obtunded	ASY	0	
8	0	Unconscious			Taser/pepper
9	0	Unconscious			Pepper
10	Agonal	Obtunded	JUNCT	50-60	Taser
11	0	Unconscious			Taser/pepper
12	0	Unconscious			
13*	3-5	Agitated	JUNCT	40	Taser
14	Agonal	Obtunded			
15	Agonal	Obtunded	ASY	0	
16	Agonal	Obtunded	ASY	0	Pepper
17	Agonal	Obtunded	BRADY	50	Pepper
18	22	Agitated	ST	140	Pepper

Abbreviations: VT, ventricular tachycardia; ASY, asystole; AGO, slow, wide complex (agonal); JUNCT, junctional; ST, sinus tachycardia.
NOTE. Agonal respiratory rate indicates slow, shallow breathing pattern. Obtunded indicates conscious but moaning response only. Pepper indicates use of capsicum spray.
* Female.

From: S. J. Stratton, C. Rogers, K. Brickett and G. Gruzinski, "Factors associated with sudden death of individuals requiring restraint from excited delirium," *Am. J. Emerg. Med.*, vol. 19, pp. 187-191, 2001.

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