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Clinical Images

Intraoperative Monitoring & Guiding System for Neurosurgery

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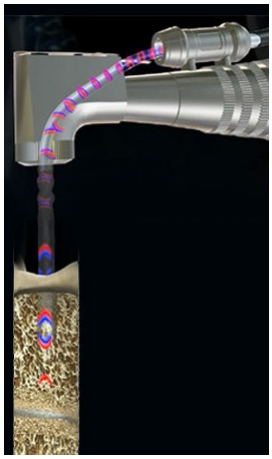
We developed a unique ultrasonic technology for Neurosurgery applications:

1. ***Interactive scull drilling by its monitoring & guiding.***
2. ***Location & size of a tumor in brain***
3. ***Location & size of a tumor in to the spinal cord or close to it.***
4. ***Real-time tumor's residual thickness monitoring during its dissection.***
5. ***More...***



Blind Man's Bluff

The Problem

I. Bone drilling: are inexact and often, blind art.

II. Defining accurately: are inexact in

(a) tumor location and size in brain and

(b) the residual part of a tumor during a dissecting process.

Current Solutions

I. MRI, CT and other X-ray imaging pre-surgery; inaccurate manual gauges; real-time options are expensive.

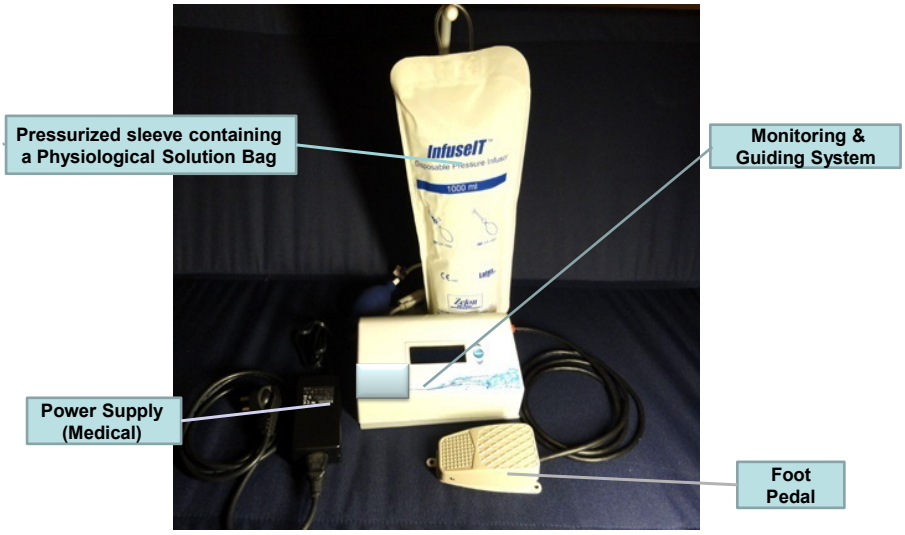
Ultrasonic - intraoperative, large transducer, expensive, long learning curve,

not RT.

Our Solution

Affordable, intraoperative & real-time monitoring with feedback to surgeon

The Developed System



Competitive Advantages

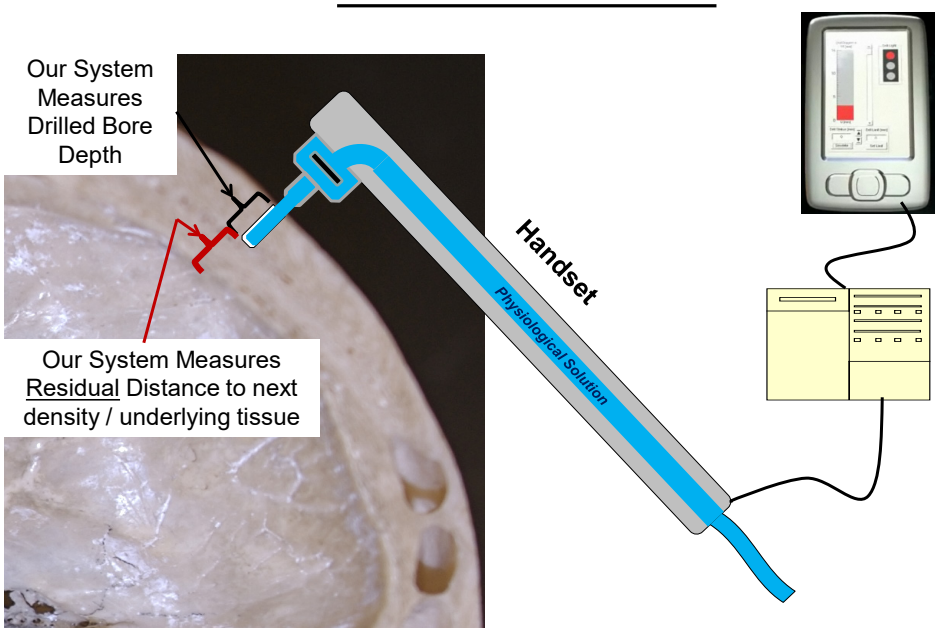
- Accurate (í 0.2mm) and independent of the surgeon
- No changes to surgical technique (Complementary technology)
- Intraoperative and real-time
- Simple to use & short learning curve
- Safe
- Affordable system & disposable handpiece
- Compact & MIS
- Saves time

Clinical Human Trials

Helsinki & Israel Ministry of Health (IMH) approvals obtained, and successful regulatory tests were performed.

Present applications of the system in Neurosurgery:

1. **Neurosurgeries of the skull and the spine (bone applications).**
2. **Location and size of a tumor in brain and spinal cord (pre-surgery) – soft tissue applications.**
3. **Thickness of remaining part of a tumor during its dissection (in brain and spinal cord).**



A disposable Handpiece

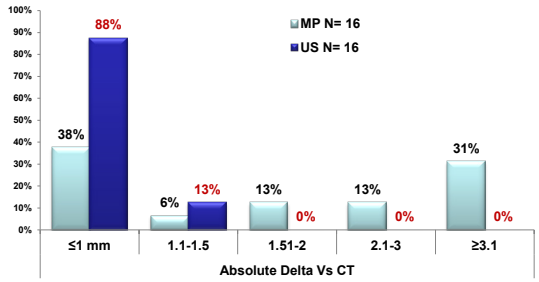
The System Measures *Simultaneously* within less than 1sec

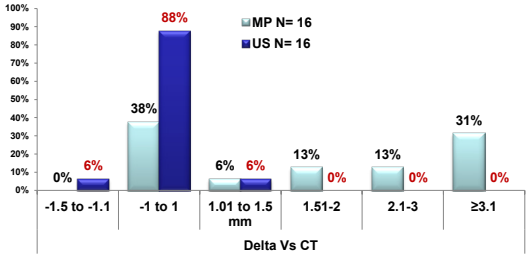
* Drilled depth.
* Residual Distance to the Dura.
* Residual distance to be drilled.
* Directional Information.

The measuring results are displayed Alpha-numerically, Variable Audio Pitch and Flickering Light

Display

Statistical Analysis of Clinical Trials





Statistical Consequences

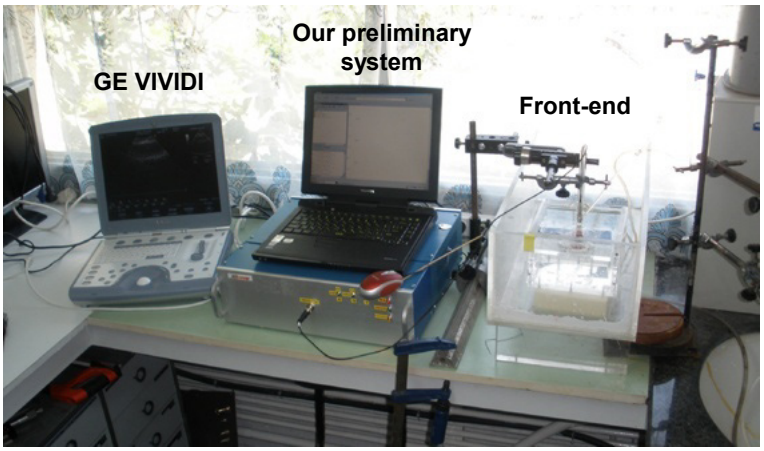
All the differences between CT and our measurements are below or equal to surgeons "safety margin" during drilling for implantation surgery. Thus, our measurements are statistically similar to the CT measurements.

2. We achieved a clinical measuring condition that is almost completely independent of the surgeon.

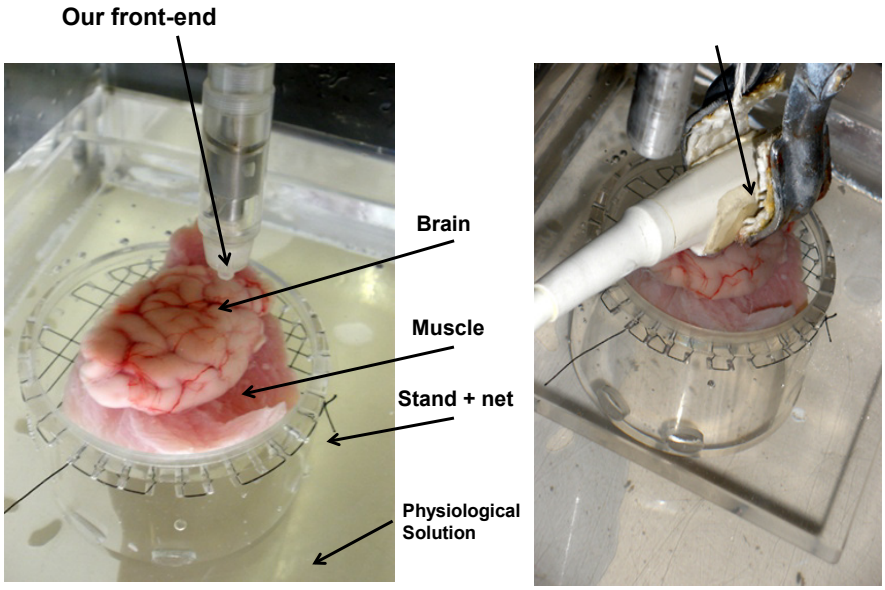
3. It was proved that our system took-out almost all the measuring ambiguities during clinical trials.

Measuring Experimental Systems

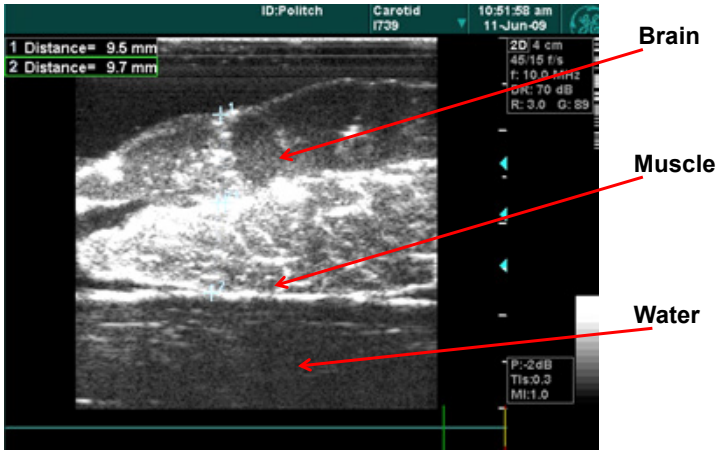
(Ex-Vivo, Soft Tissue)



Laboratory ex-vivo Experiments

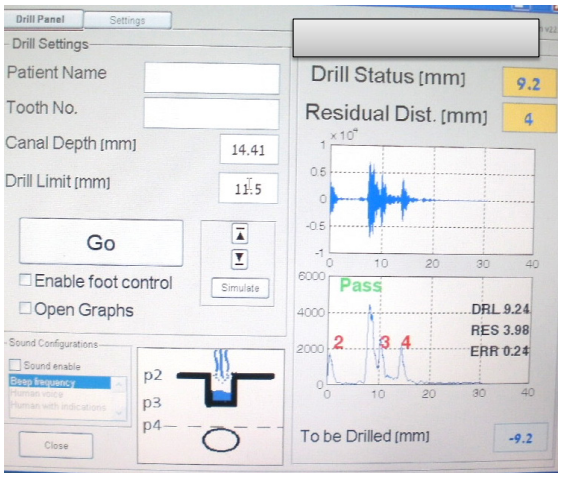


Laboratory Experiments/Cont'



Ultrasonic (US) Image from GE VIVIDI

Our Display



Thickness of muscle slice on/below brain

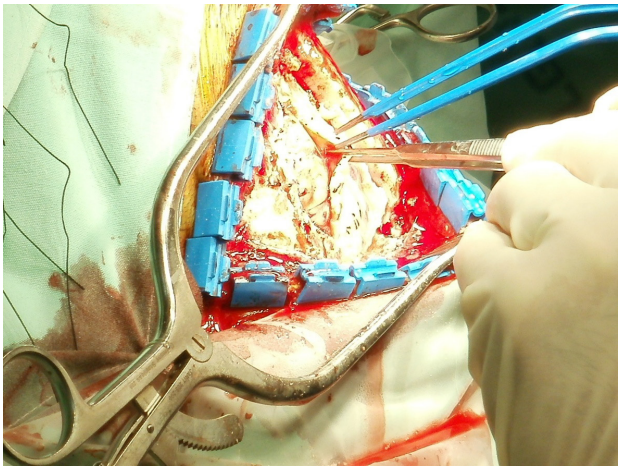
with GE type VIVIDI and our Neuro system

Exp. No.	GE, mod. VIVIDI Average Thickness [mm]		Our Neuro Average Thickness [mm]		Δ [mm]	
	Meat	Brain	Meat	Brain	Meat	Brain
I Meat on brain	6.3	8.2	7.4	7.2	1.1	1
I' Meat on brain	8.7	7.1	7.6	7.2	1.1	0.1
II Meat on brain	10.4	6.5	9.6	5.8	0.8	0.7
III Brain on meat	8.3	8.5	8.1	8.3	0.2	0.2
IV Brain on meat	12.8	12.3	13.8	10.8	1	1.5

The average measurements and the differences Δ between them, as measured by GE type VIVIDI and our Neuro system.

During a human brain neurosurgery
While applying our system

The dissected skull and part of the brain, at the tumor location,
While applying our system



SONOWAND – US instrument in the operating room

Some data: Price >$750,000; Large transducer – large part of skull removal; For measuring, it requires to stop the surgery - not real-time; Measuring accuracy í 1,5mm;

Comparison of Measuring Results - examples
(Sonowand vs our system)

TUMOR DEPTH [mm]				
Sonowand	Our system	Delta (+)	Delta (-)	|Delta|
2	2.3	0.3`		0.3`
7.5	7.3		0.2	0.2
0	0			0
0	0			0
4	3.7		0.3	0.3
3	3.2	0.2		0.2
3	3.2	0.2		0.2
2.3	2.7	0.3		0.3
4	4.2	0.2		0.2

|Delta| = 0- 0.2: 66.7%
|Delta| = 0.21 – 0.3: 33.3%

TUMOR SIZE [mm]				
Sonowand	Our System	Delta (+)	Delta (-)	|Delta|
20	31.1	11.1		11.1
24	27.7	3.7		3.7
25	27.4	2.4		2.4
26	27.5	1.5		1.5
20	18.8		1.2	1.2
20	18.9		1.1	1.1
20	18.5		1.5	1.5
15	16	1		1
23	24	1		1

|Delta| = 1 - 1.5: 66.7%

|Delta| = 1.6 - 3: 11.1%

|Delta| > 3.1: 22.2%

During Dissecting Process

Measurements with our system

Dissection	Measurement	Residual tumor thickness
#	#	mm
1	1	18.6(+0.6; -1)
	2	17.7(+0.8; -1.1)
	3	5.6(+1.1;-0.9)
	4	4.8(+1; -0.9)
2	1	12(+0.4; -0.5)
	2	6.7(+0.3;-0.4)
	3	5.5(+0.2; -0.3)
	4	3.8(+0.2; -0.3)

Achievements

* Technology/Science

•Two operating prototypes, applied intraoperatively in Rambam Medical Center.

* Successful experiments on phantoms and ex-vivo fresh animal brain and muscle.

• Regulatory approvals of all these systems for hospital human trials.

• IRB (Helsinki) and Israel Ministry of Health approvals for human neurosurgical

trials.

Achievements/Cont'

Regulatory

* Helsinki approval

• Israel Ministry of Health approval

• Regulatory approvals for Safety, EMC & Sterilization.

Ex-vivo trials

• Successful ex-vivo brain experiments of a pig brain + muscle.

In-vivo human trials during neurosurgeries

• *in-vivo intraoperative clinical trials at Neurosurgery Dept., Rambam HCC, Haifa, Israel*.

Potential Applications

Soft tissue-tumor *intraoperative*

diagnostics & monitoring

liver, kidneys, pancreas, lungs,

breast, ophthalmology, orthopedic oncology,

and more.