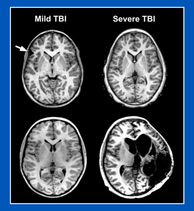

“GALENO”, medical device for neurosurgery
A multidisciplinary approach to complexity

Claudia Piscitelli, medical student, “La Sapienza”, University of Rome
claudiapiscitelli@icloud.com | (+39)3319023168
P.zza Dante n.1 Anagni (FR), 03012, italy

ABSTRACT

BACKGROUND:
Neurological disorders affect billions of people worldwide, making the discovery of effective treatments a major challenge.
“Galeno”, is a theoretical medical device that I designed for patients with severe stroke and brain hernia.
Brain herniation, also known as acquired intracranial herniation, refers to the displacement of brain tissue from its normal position, into an adjacent space due to mass effect.
It is a life-threatening condition that requires early diagnosis.
OBJECTIVE:
“Galeno" has the shape of a helmet, 3D printed.
The goal is to contain swelling, reduce edema and optimize brain homeostasis.
The design of this device combines: neurosurgery, neurotechnology, direct drug delivery into the brain, and modern knowledge of biomedical engineering and computer science.
The aim is to provide optimal and precise control of the conditions in which the patient’s brain is involved, giving the possibility to intervene in any area/zone.
METHODS:
The normal intracranial physiological process can be altered as a result of severe traumatic brain injury, resulting in refractory intracranial hypertension, decreased cerebral perfusion pressure, and cerebral blood flow disorders.
Starting from the main notions of neurophysiology and the mechanisms of cerebral plasticity I imagined and designed this helmet for cerebral herniation that has the shape of a lattice, articulated in horizontal and vertical lines and, like a kind of fishing net, “traps” and protects the brain, without sending it into fatigue.
RESULTS:
“Galeno” theoretically monitors and contains swelling, reduces inflammation, detects changes in the parameters of ICP (cerebral intracranial pressure), blood pressure, brain metabolism, etc.
All this is made possible thanks to the physical-mechanical specialties of the materials with which the helmet is made. The combination of materials makes it possible to create a medical device that can mimic the physiological environment of neural tissue without damaging nerve structures.
Through the sensors, placed in the interface between the device and the brain parenchyma, there is continuous monitoring of the parameters of cerebral perfusion pressure, temperature, cerebral blood flow, partial pressure of O2, etc. "Galeno" can (theoretically) monitor the electrographic and biochemical function of the brain and provide a mechanism to intervene directly through the use of drugs (nanoparticles).

OBJECTIVES

- The intent is to make surgery with “Galeno” the first choice of intervention, facilitating the neurosurgeon's work and the recovery of the patient(s).
- Understanding the functioning of the brain is essential to governing brain processes with the goal of managing pathological dysfunctions.

SUMMARY|CONCLUSION

“Galeno” device and helmet has a reticular structure to support the injured brain - ischemic and/or suffering from TBI. Every year, about 70 million people worldwide suffer from TBI.
The device and helmet are 3D printed (with biocompatible polymers: ceramic and hydrogel) and integrated with other components: brain-computer interface, neuromonitoring, sensors, fluorescence, wireless system, subdural and fluid drainage, etc. Each component chosen has, theoretically, suitable properties to facilitate neural regeneration and repair, following damage.
The innovative network structure, equipped with sensors and fluorescence, makes it possible to map and identify any area of the brain, even the anatomically “difficult” ones. It can function as an anatomical and brain activity scanning device to allow the neurosurgeon a complete acquisition of biochemical-anatomical information.
Swelling, inflammation, ICP, blood pressure, metabolism, etc. will be constantly monitored and treated.
The drugs (nanoparticles) are delivered directly into the brain by a cross-system capable of precisely identifying where action is needed.
The patent application was filed in Italy in October 2022 and in October 2023 I applied to extend it to the United States

RESULTS

“Galeno” represents a Phase 0 (POC) project for subsequent animal and human testing (Phase I).
I’m looking for financiers and partners to take the project to the next phase.

Normal intracranial physiological process may be altered following TBI, resulting in refractory intracranial hypertension, decreased cerebral perfusion pressure, and cerebral blood flow disturbances. Malignant intracranial hypertension is the leading cause of death in patients with TBI.
Therefore, targeted control and treatment of increased intracranial pressure (ICP) is the key issue in the management of severe TBI.

APPLICATION IN RESEARCH

- **MILITARY:**

TBI is a serious threat to the readiness of soldiers and currently appears to lack approved and effective treatment options.
“Galeno” aims to be created and developed as an innovative solution to manage and counter TBI at the time of injury, reducing morbidity and mortality. Through its sophisticated technology, Its purpose is to provide a better understanding of brain functioning, appropriate treatment of brain lesions, and visualization and decoding of brain activity.

FIGURE 1

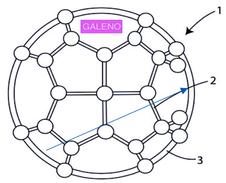

Fig. 1

point of intersection of canals (horizontal and vertical lines) where drugs are released directly into the brain (via nanoparticles)

Surgical device (Fig. 1) for cerebral herniation applied to the brain after decompressive craniectomy.
The device (the helmet) has along the perimeter an outflow system comprising at least one drainage catheter and means of connection to an aspiration system, said outflow system being positioned along the perimeter of said structure and being adapted to convey waste liquids or blood outside.
Surgical device characterised in that said plurality of sensors comprises fluorescent biosensors, said sensors being coated with an ultra-bright and stable biocompatible fluorescent coating, for illuminating one or more areas of said surgical device (1), in particular corresponding to areas of the brain wherein said sensors determine the presence of an edema.
The sensors comprise at least one transducer of a neural interface, said transducer being adapted to register the impulses of a neuron.

- **SPACE:**

Human spaceflight is becoming more frequent and longer, inducing widespread changes in brain morphology (ventricular volume, gray matter shifts, CSF changes, etc.). Studies have shown that upon return from Space, the deficits most commonly found in astronauts are caused by pressure changes in the brain and spinal fluid, thus suggesting the need to find a cure and/or minimize neurological risks for long-duration missions (also with a view to future trips to Mars).

FIGURE 2

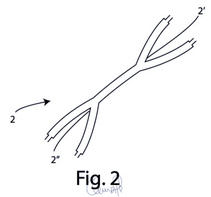

Fig. 2

Tubular canals including an inlet extremity (2’) of one or more drugs and an outlet extremity (2”) for the release of said one or more drugs into the cerebral tissue.

FIGURE 3/4

Detail of canals

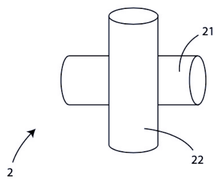

Fig. 3

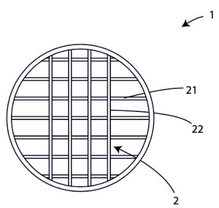

Fig. 4

A plurality of tubular canals (Fig. 4) divided into horizontal and vertical lines covering the entire surface of the helmet.Surgical device characterised in that said structure comprises a first and second level of tubular administration canals, said first level comprising a first plurality of canals (21) parallel to each other and said second level comprising a second plurality of canals (22) parallel to each other and perpendicular to said first plurality of canals (21).

- **SURGERY:**

“Galeno” is theoretically suitable for use in both routine and emergency surgical procedures. By modifying the choice of drugs, it could also enable treatment of brain tumors currently considered “inoperable”

- **NEUROSCIENCE:**

Analyzing the full potential of “Galeno -m.d.”, in the future it could be considered to deepen and improve complex and still little understood neurophysiological knowledge. The innovative structure of the helmet aims specifically to facilitate the study of the brain, mapping its connections and its biochemical, electrical and metabolic changes.

DISCUSSION

“Galeno” was born with the intent to combine medicine-surgery and technology. Modern times require innovative solutions that using the support of technology, help doctors and patients. The project also explores the possibility of using “Galeno” in different areas of medical research.

Despite continuous improvements in emergency care (stroke units, trauma centers, etc.), it’s still difficult to identify/treat brain injury and intracranial hypertension. The lack of understanding of their consequences also hinders patients' reintegration into society, underscoring the importance of research in this area.
Therefore, it is necessary to monitor brain tissue and implement neuroprotective strategies in a timely manner. The goal is to overcome the limitations that have hitherto prevented full knowledge of all the critical details of neural circuits and to close the gaps in knowledge between brain cells, circuits, and the information processing system.

CONCLUSIONS

- Lorem ipsum dolor sit amet, consectetur adipiscing elit. Duis eu sapien metus. Duis vestibulum tincidunt felis, at euismod dolor aliquam sit amet.
- Lorem ipsum dolor sit amet, consectetur adipiscing elit. Duis eu sapien metus. Duis vestibulum tincidunt felis, at euismod dolor aliquam sit amet. Aliquam et erat ac ligula vehicula lacinia. Nam eget porta.
- Lorem ipsum dolor sit amet, consectetur adipiscing elit. Duis eu sapien metus. Duis vestibulum tincidunt felis, at euismod dolor

REFERENCES

1. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7260895/
2. https://link.springer.com/article/10.1007/s00415-019-09541-4
3. https://apps.dtic.mil/sti/pdfs/AD1027329.pdf
4. JAMA Neurology
5. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9454297/
6. https://pubmed.ncbi.nlm.nih.gov/29421552/
7. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6786932/
8. https://www.mdpi.com/1424-8220/23/13/6001
9. https://pubmed.ncbi.nlm.nih.gov/32871471/
10. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9032478/
11. https://pubmed.ncbi.nlm.nih.gov/35011559/