HemaShock® for Saving Lives in Severe Shock

Oneg HaKarmel Ltd.

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Characteristics of Mass Casualty Situation

- Many injured
- Few skilled healthcare personnel
- Long(er) evacuation times
- No blood available for transfusion

Result:

(too) Many patients die from hemorrhagic shock

HemaShock™ – Auto-Transfusion Tourniquet

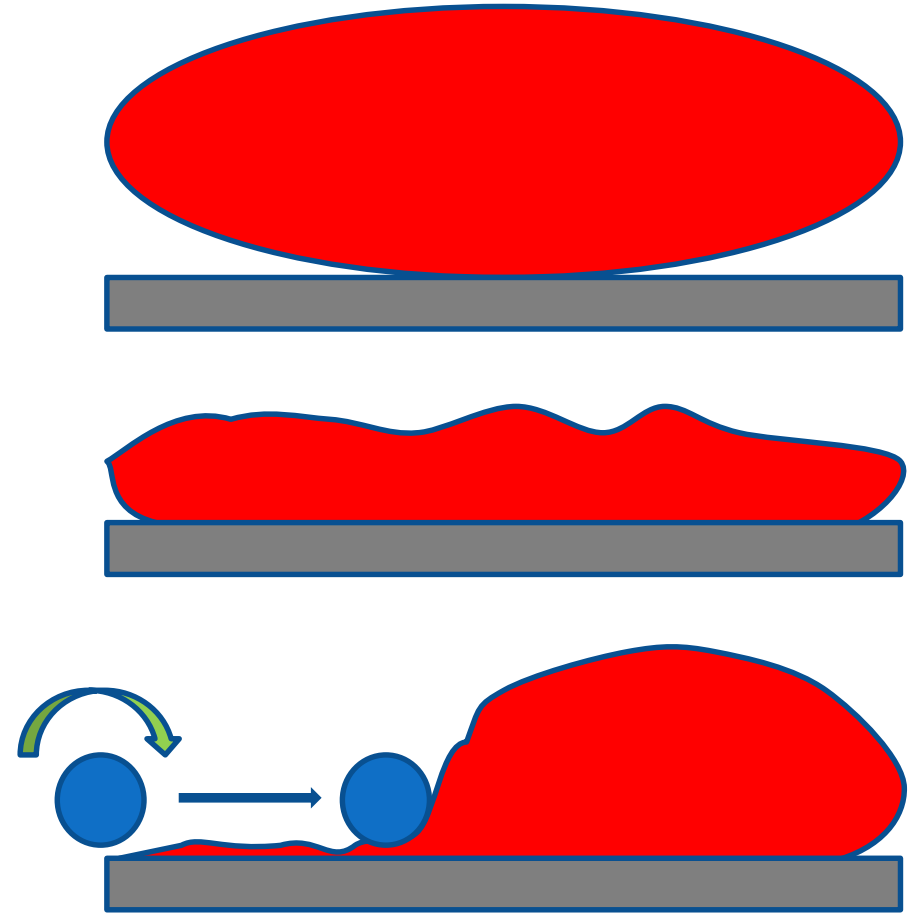
Indicated for patients with **SEVERE HYPOTENSION** ($<80_{mmHg}$) such as in Shock and Cardiac Arrest

Physiological Principles of Auto-transfusion

1. **Normal blood volume**, vascular volume and blood pressure

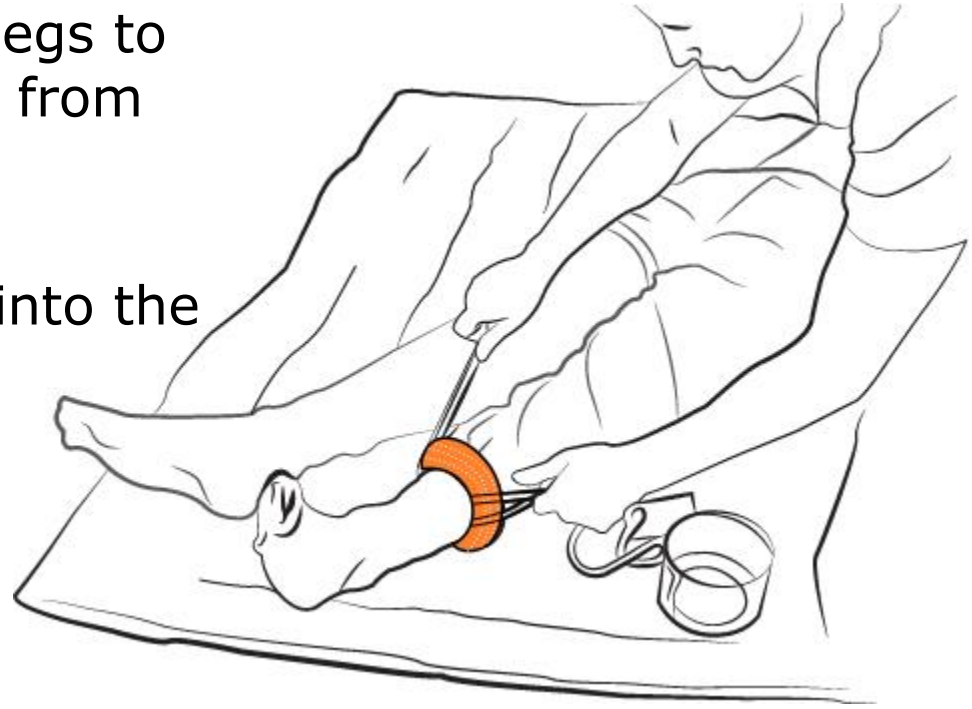
2. **Reduced blood volume** relative to vascular volume → reduced pressure; large "unstressed" volume

3. Applying **external force** on the non-essential part of the body **shifts blood to the central circulation,** restores blood flow and pressure to the essential organs



HemaShock™ – Mechanism of Action

- Displacing blood from legs to core; >500 cc of blood from each leg
- Blocking flow of blood into the legs



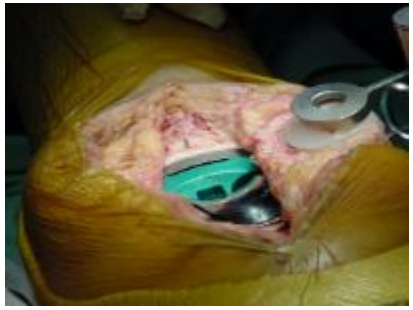
As such, the HemaShock acts as a **mechanical vasoconstrictor**

The HemaShock in Use

Hemorrhagic shock

CPR

Extensively Tested Technology



- The **HemaShock™** shares technology with **HemaClear®** - facilitating **BLOODLESS SURGERY** in orthopedic surgery of the limbs
- **HemaClear®** is clinically practiced for over 10 years
  - Has been used in over 1.2 million operations in >40 countries
  - Holds an impeccable safety track record during OR use

Timing of HemaShock use in Severe Hemorrhagic Shock

Also,

- Act quickly,
- Prevent further deterioration,
- Restore vital signs

Stop bleeding

Volume expansion

Vaso-active drugs

Start IV, O_2 ventilate

Rapid evacuation

Specific treatment - OR

Training

Teaching medics when and how to apply HemaShock should take 45-60 minutes. Removal is only done in hospital after patient's vital signs are stabilized

Thank you!

Pig Pox

It works…

Study in hemorrhagic shock pig model

Protocol

- 8 pigs 35-37 kg; 5 with HS; 3 without HS
- Initial bleeding – controlled at 1.2% /min
- Continued until mean Blood Pressure (BP) was 30 mm Hg
- At this point HemaShock was applied to 4 limbs of HS animals
- All pigs continued to bleed at free flow until no QRS complexes on EKG (cardiac arrest)
- We measured: **volume of blood shed per minute, BP, PETCO2, HR, CVP,**

HS on Hind legs

- Note the HS is brought up above the knee (arrows) and the 4 straps of each HS are tied in a rhomboid fashion to the surgical table.

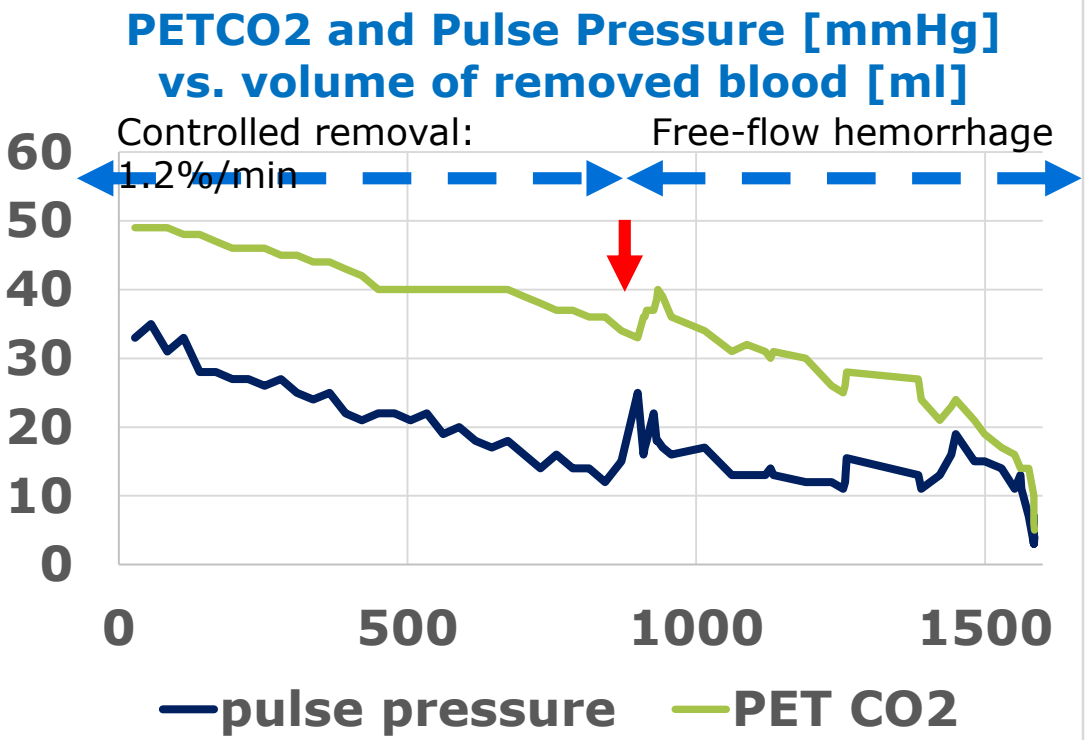
No blood in limb with HemaShock

Blood withdrawal measured by weight and by volume

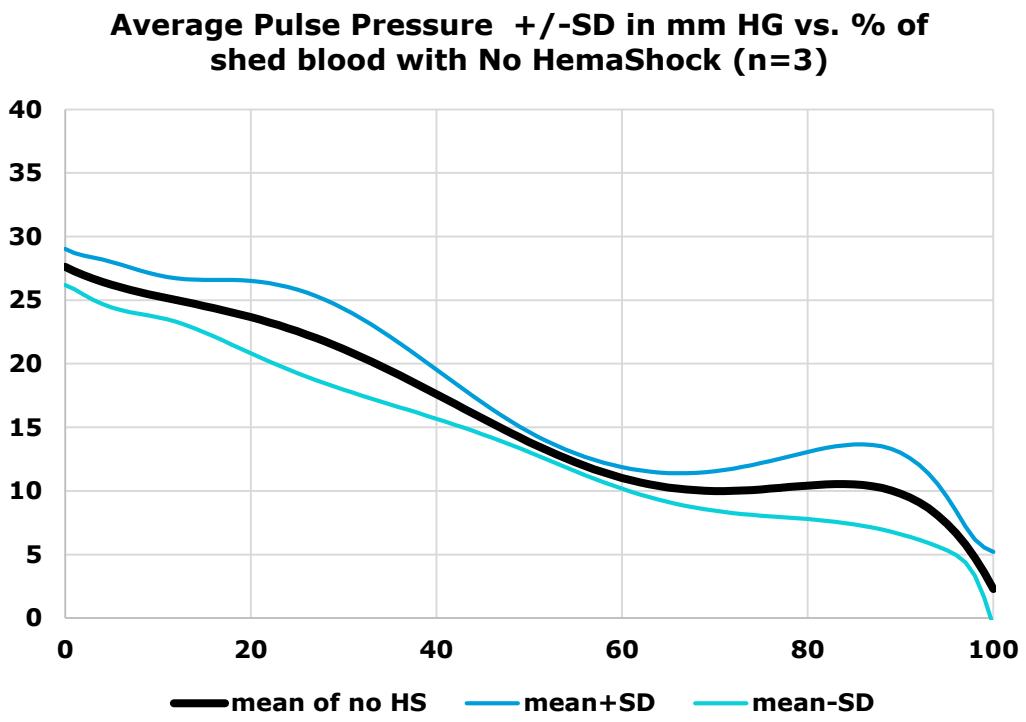
HS on 4 limbs

Protocol with HS

- End-Tidal CO2 and Pulse Pressure as function of bleeding volume.
- Red Arrow: placement of HemaShock



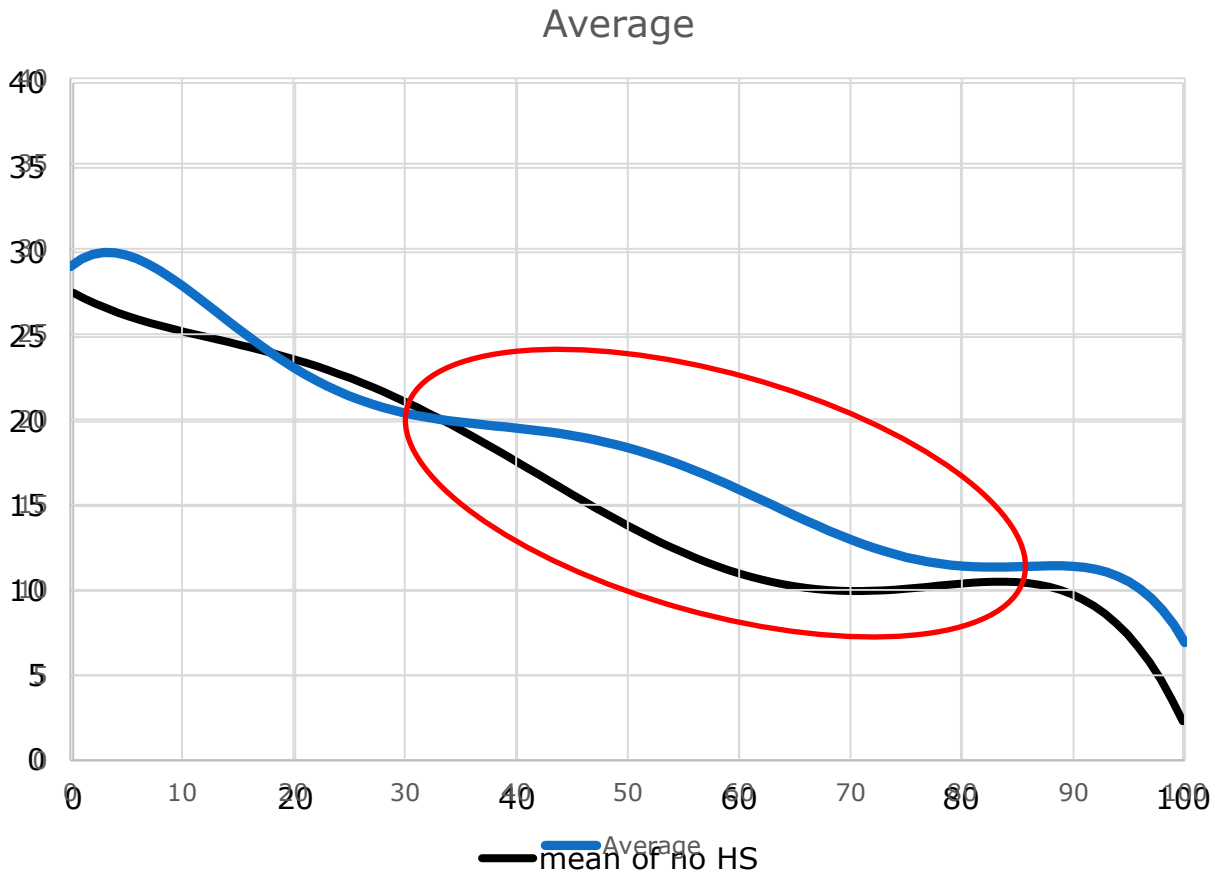
Average Pulse Pressure no HS



Average Pulse Pressure in mm HG vs. % of shed blood with and without HemaShock

With HS (blue line); Without HS (Black line)

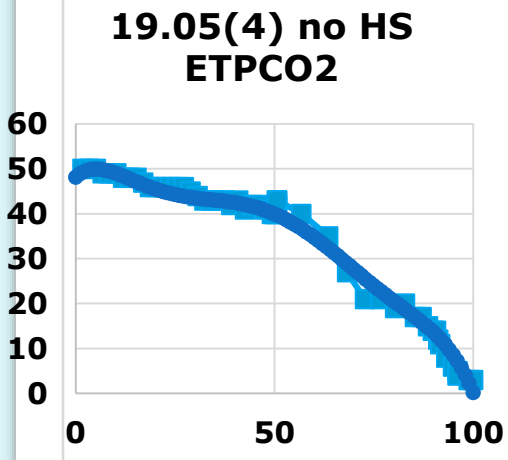
Note the difference after HS was placed

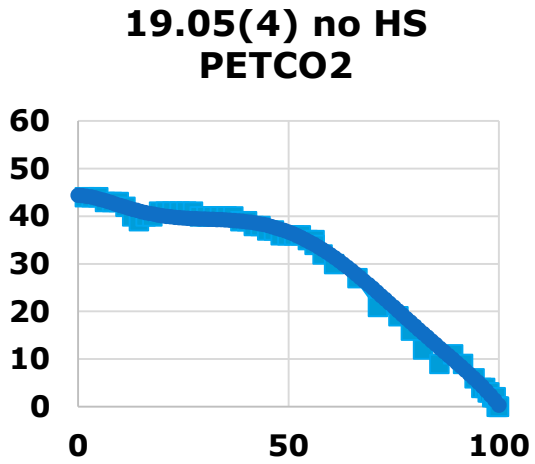


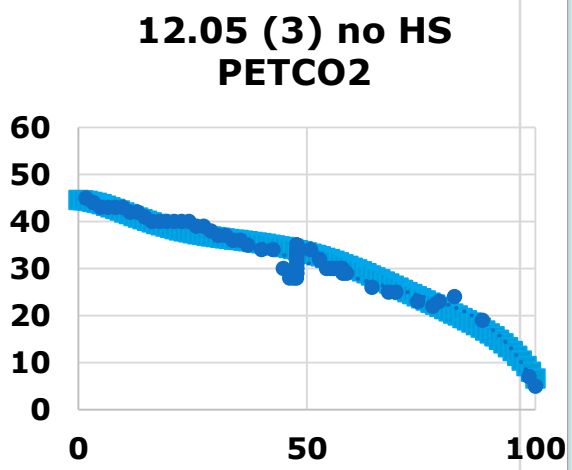
PETCO2 vs. blood loss as % of total bleeding

Without HemaShock

- Data from 3 hemorrhagic shock experiments with controlled blood withdrawal (1.2% of blood volume) until mean BP fell to 30 mmHg, followed by free-flow bleeding. Data plotted vs. bloodloss expressed as % of total bloodloss. 6th order polynomial regression curve fit is shown.

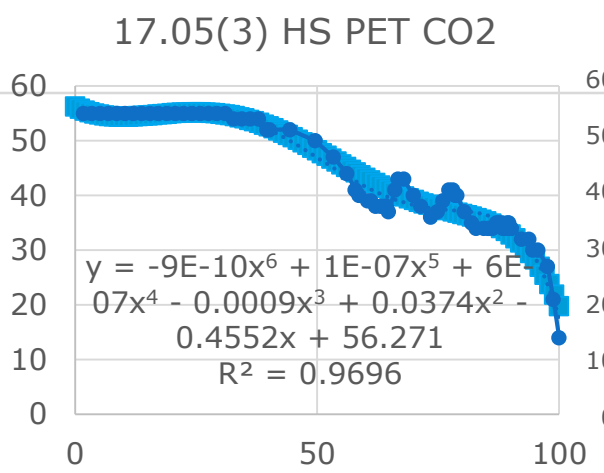


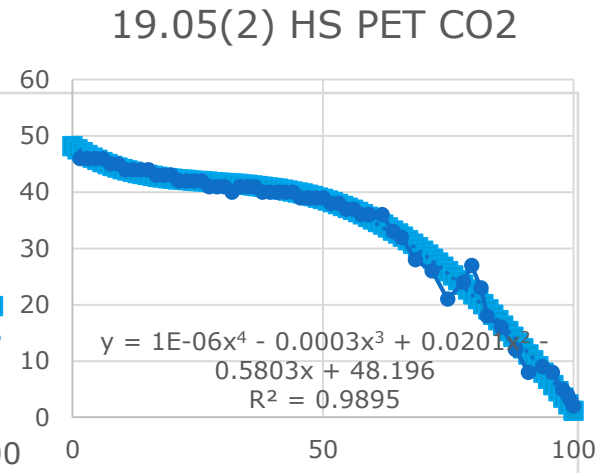


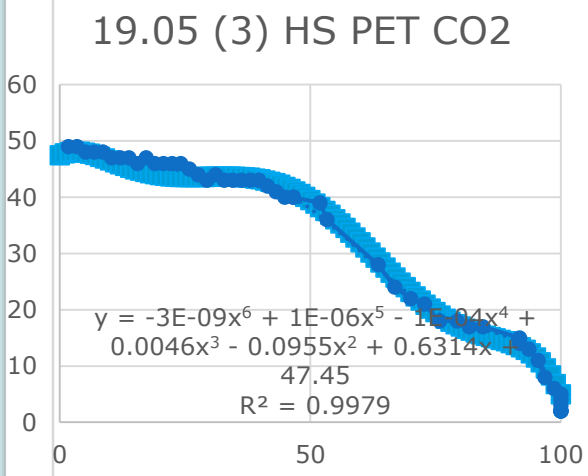


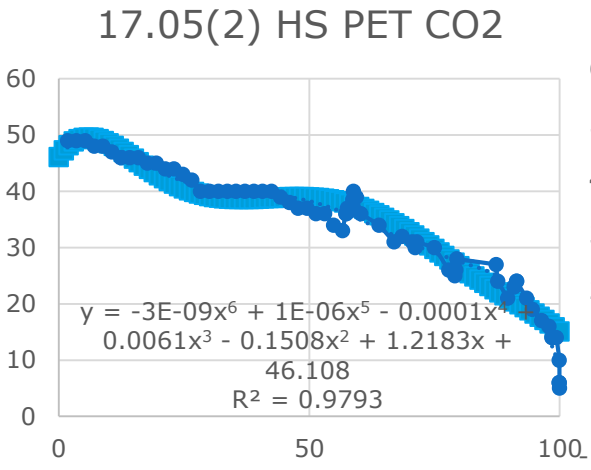
PETCO2 with HS

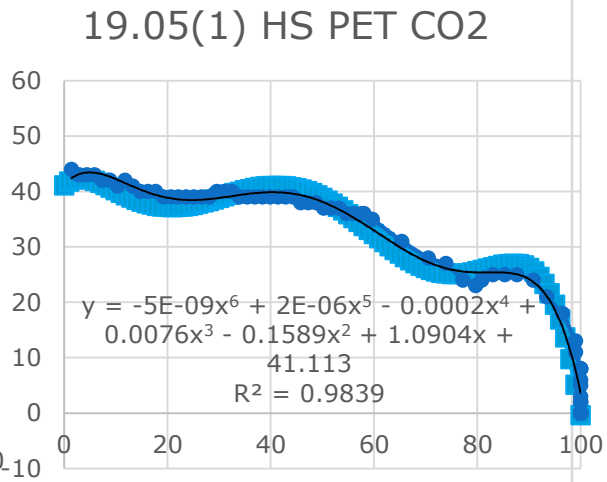
- PETCO2 [mmHg] vs. percent of blood shed with order 6 polynomial fit



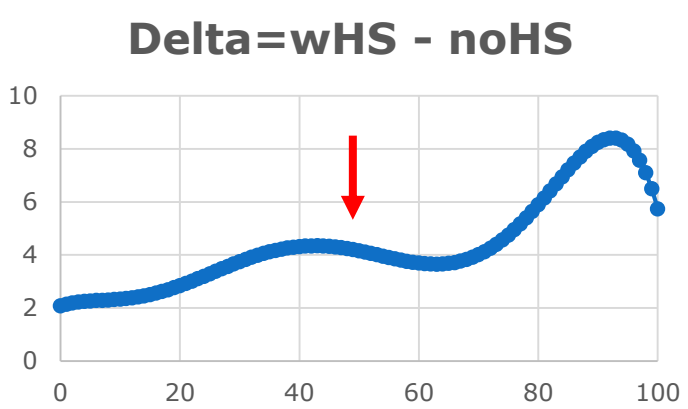


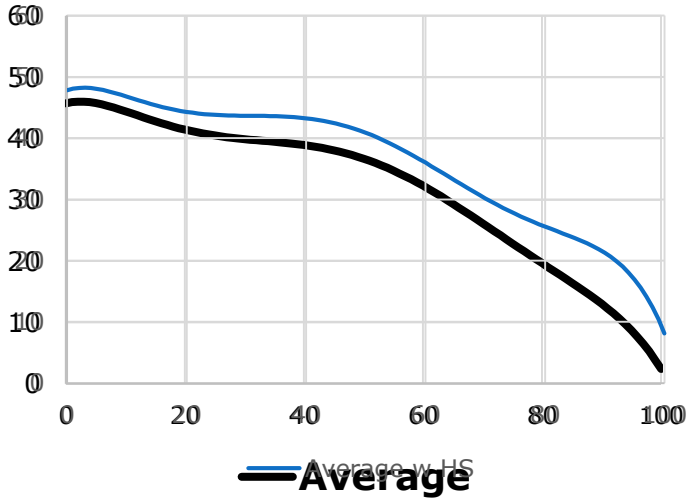






PETCO2 with (blue) and without (black) HS





HS/NoHS percent

		Pulse Pressure [mm Hg]			PETCO2 [mm Hg]		
#		Sum	Average	Minutes	Sum	Average	Minutes
HS/noHS%		151.7032	114.7735	128.3544	149.5489	115.2405	120

- The averages of pulse pressure and PETCO2 are 15% greater with HS than with no HS.
- Survival after onset of free bleeding is 128% and 120% longer.
- Conclusion: we can extend pigs' lives…

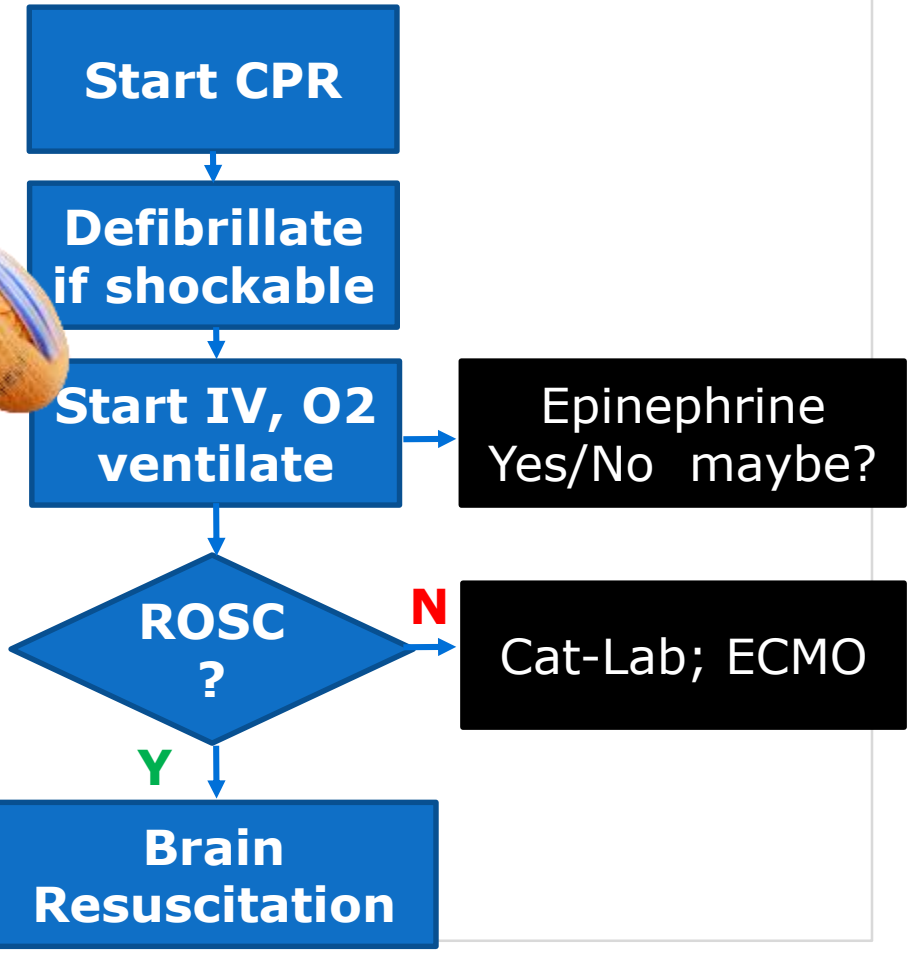
Summary

- Use of HS on 4 limbs of pig (16% of body) is less than 2 legs (24% of body).
- Never the less:
- Applying HemaShock when shock was severe (mean blood pressure 30 mm Hg) increased:
  - **Survival time 20-28%**
  - **Blood pressure**
  - **Pulse pressure 15%**
  - **End-tidal CO2 15%**
  - **Integrated Pulse Pressure-time and PETCO2-time 150%**

Thank you!

The recommended timing of HemaShock® in CPR

Abbreviated AHA protocol



Esmarch Exsanguination Tourniquets – Porcine Study Published in J. Resuscitation

- HemaShock equivalent increased Blood Pressure, Coronary Perfusion Pressure (CPP), Cerebral Blood Flow, and CO_2 Output ($ETCO_2$) during CPR

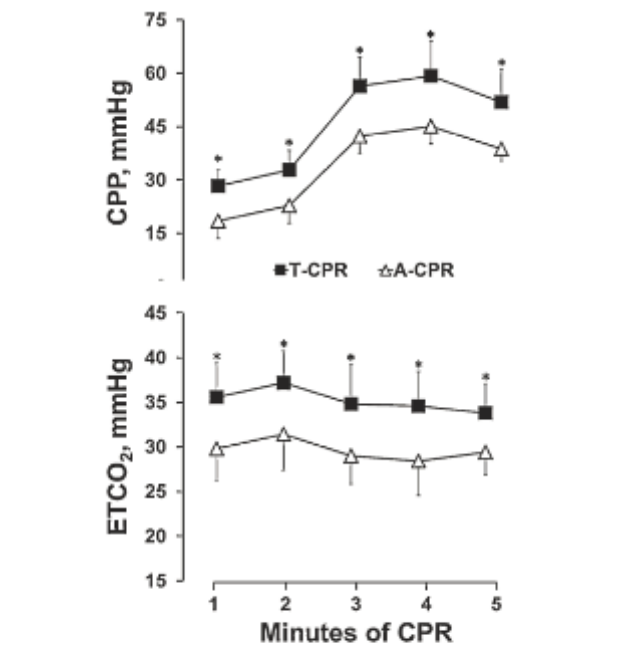
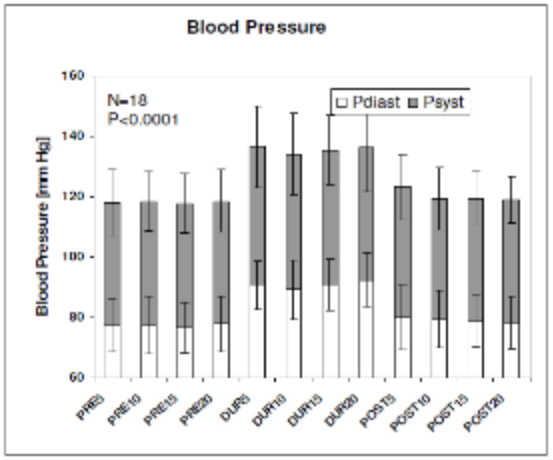


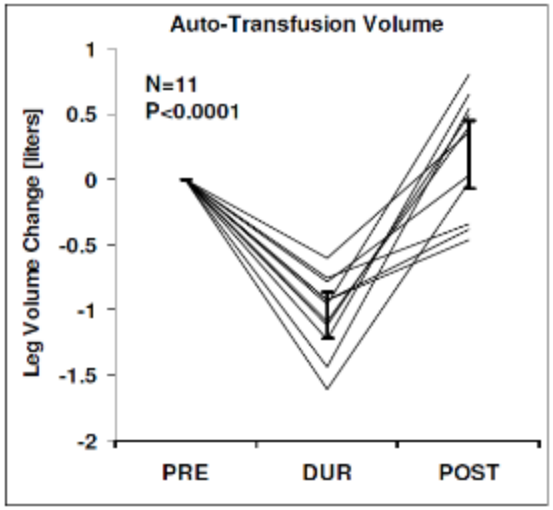
Fig. 3. The coronary perfusion pressure and the end-tidal carbon dioxide during cardiopulmonary resuscitation (CPR). CPP, coronary perfusion pressure; $ETCO_2$, end-tidal carbon dioxide; T-CPR, tourniquet assisted CPR group; A-CPR, CPR alone group. *$p < .05$ vs. the A-CPR group.

Clinical Validation – Healthy Subjects

- **HemaShock™** was applied on both legs for 20 minutes
- Physiological, biochemical and respiratory parameters were measured
- Blood volume shifts were measured

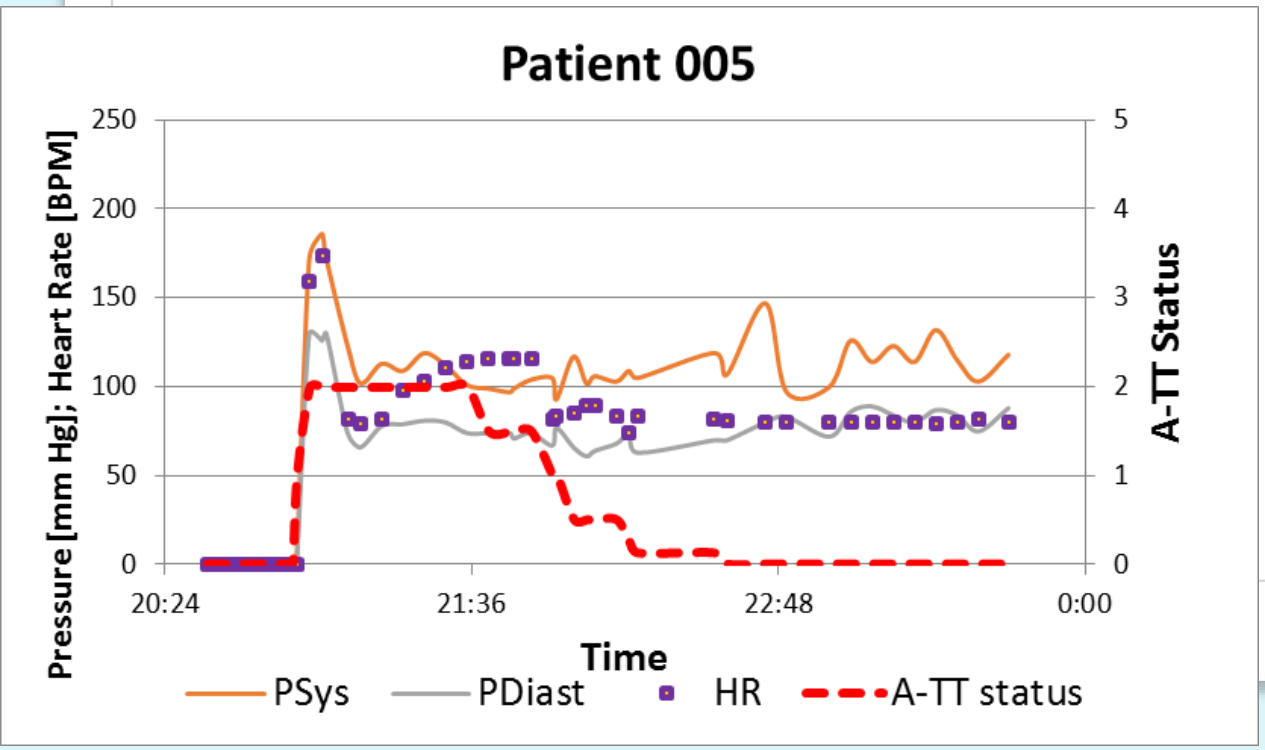
- >1000 ml of blood shifted from legs to core circulation
- Systolic and Diastolic BP were increased
- No Biochemical adverse effects were seen
- No respiratory or cardiovascular adverse effects were observed

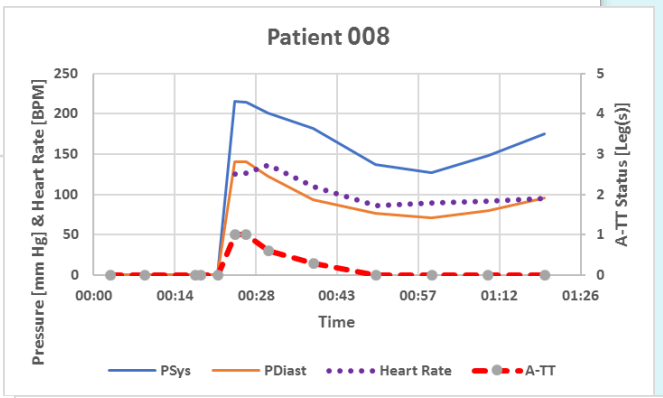


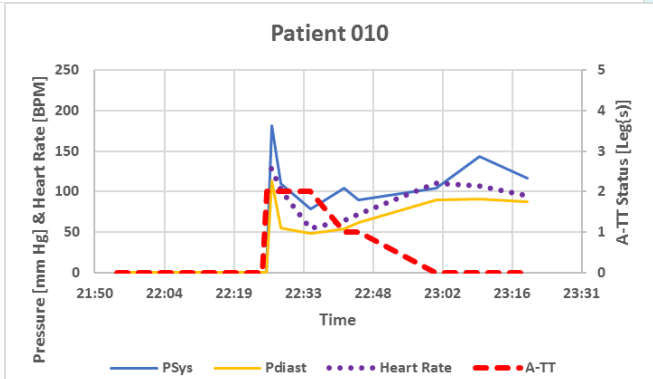


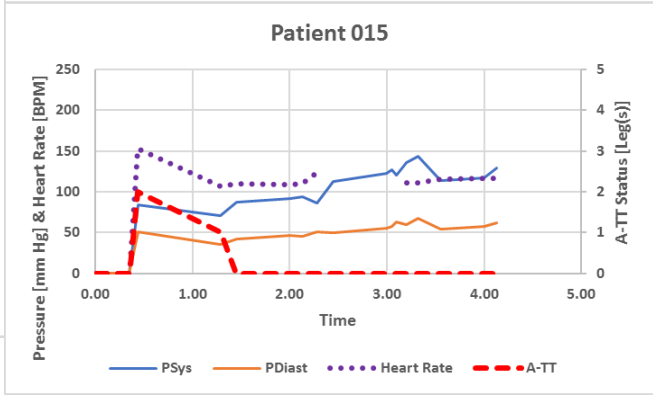
Patients who converted to ROSC once HemaShock was placed

- Witnessed cardiac arrest patients brought to ER during CPR in terminal condition (dilated pupils) >30 min after collapse. Examples of HS-induced ROSC.





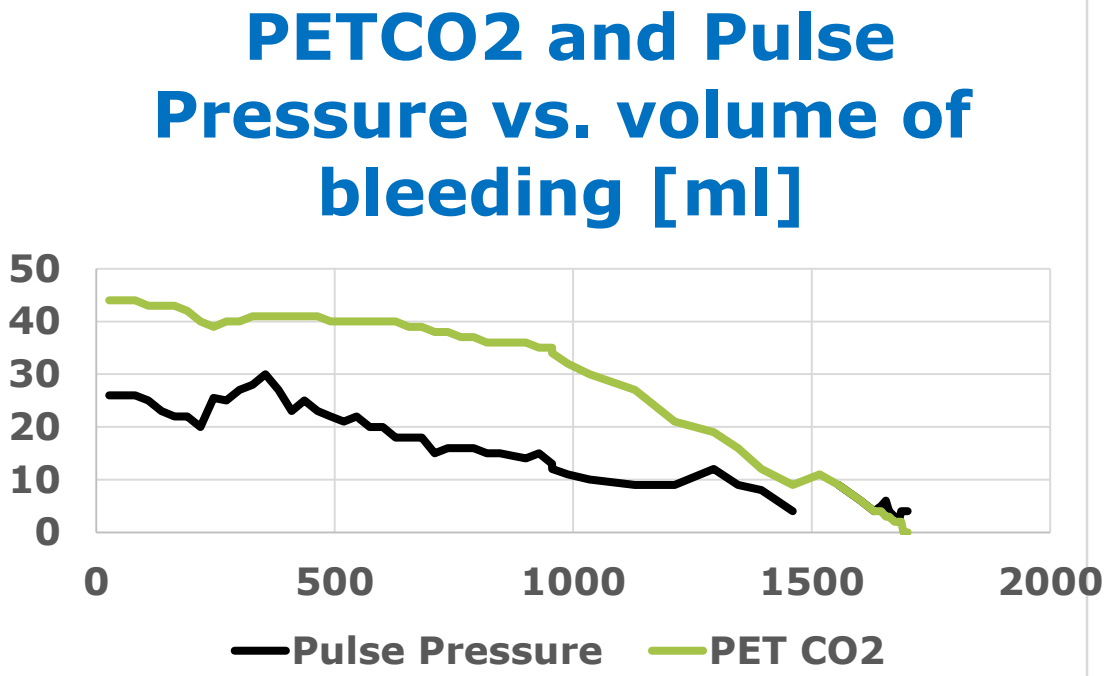




About Us

- Oneg HaKarmel Ltd. was founded by Prof. Noam Gavriely, a physiologist, emergency physician and entrepreneur. The Company first brought to market the HemaClear® (www.HemaClear.com) Which is becoming standard of care in orthopedic limb surgery. Gavriely also founded KarmelSonix Ltd. for acoustic asthma monitoring, now traded on the Australian Securities Exchange as Respiri (https://respiri.co/) and ETView for continuous intra-airway visualization now marketed by Ambu (https://www.ambu.com/products/airway-management/double-lumen-tube-with-integrated-camera). Gavriely holds MD and PhD degrees from the Technion in Israel and did his post-doctoral training at the Harvard School of Public Health. He is the CEO and CMO of the Company
- Leonardo Schwartz is a seasoned operations expert with strong background in quality, manufacturing, and project management in the medical devices arena. Schwartz is in charge of the day-to-day operations of the Company as its COO. Contact: Leonardo@HemaClear.com
- **Oneg HaKarmel Ltd. is located in Tirat Carmel, Israel.**

No HS


PETCO2 and Pulse Pressure vs. volume of bleeding [ml]
50
40
30
20
10
0
0
500
1000
1500
2000
Pulse Pressure
PET CO2

No HemaShock. Sum is the integral from onset of free flow till the end.

	No HS						
		Pulse Pressure [mm Hg]			PETCO2 [mm Hg]		
#		Sum	Average	Minutes	Sum	Average	Minutes
3(1)	12/05/2022	372	12.8	29	745	26.6	28
1	17/05/2022	256	9.5	27	605	22.4	27
4	19/05/2022	147	6.4	23	246	10.25	24
	Average	258.3	9.6	26.3	532.0	19.8	26.3
	SD	112.5	3.2	3.1	257.4	8.5	2.1

With HS

		HS					
		Pulse Pressure [mm Hg]			PETCO2 [mm Hg]		
#		Sum	Average	Minutes	Sum	Average	Minutes
2	17/05/2022	481	13.4	36	908	25.2	36
3	17/05/2022	754	15.1	50	1854	36.9	50
1	19/05/2022	290	8.8	33	442	17	26
2	19/05/2022	201.5	9.6	21	407	19.4	21
3	19/05/2022	233	8	29	367	15.3	25
	Average	391.9	10.98	33.8	795.6	22.76	31.6
	SD	229.6411	3.097095	10.66302	630.9884	8.746599	11.67476