Wearable Artificial Organs
The unmet needs…
DISCLOSURES

Patent holder
Stock holder  Warable Artificial Organs Inc
UNMET NEEDS IN WEARABLE ORGANS

Do we have better answers to the following questions:

- What can I expect?
- How long do I have before I’m gone?
- Does it hurt?
- Can I work?
- Do I need help?
- How am I going to pay for this?
WEARABLE ORGANS, THE UNMET NEEDS

WHAT ARE THE GOALS

• Reduce mortality
• Improve quality of life
• Reduce cost
• Improve access
• Simplify care
UNMET NEEDS IN DIALYSIS: To improve quality of life

Pill burden
Doing time on the chair
Cramps
Thirst
Fatigue
Draconian diets
Salt restriction
Depression
Disability
Effective diets
Fear
Fluid restriction
Needle sticks
Hospitalizations
Poor sleep
Sinus Node Disease

Sinus Node Block: The heart rate slows down due to the very slow movement of electrical signals in the sinus node.
We can miniaturize anything and everything……

Why not a dialysis machine!!!?
WHY WE NEED THEM

Wearable Artificial Organs Will Disrupt The Way Medicine is Practiced Time After Time

Billions of Health Expenses Globally
Worldwide there are millions of people with failing organs

Dialysis alone $88,000+ Annual Cost
In the US, average cost per patient is $88,000...
In total $40B in for treatments and growing.

Improving life span and income
Older population, more western diets

Exorbitant Hospital Costs
Expensive technologies and drugs labor intensive, regulations

Need for increased collaboration
Physicians, nurses, engineers and... patients.

We need IT, AI, Nano...
Better technology applications for pediatrics, military, disaster relief, and many other products
The World Cannot Afford ESRD

Eli Friedman M.D.
US CLINICAL TRIAL DATA

Clinical Trial Summary:

- WAK provided continuous solute clearance and volume removal capacity for patients with ESRD
- Acid-base and electrolyte homeostasis were maintained:
  - no restriction on patients' dietary choices,
  - no use of phosphorus-binding medications.
  - Hemodynamic parameters remained stable
  - Ultrafiltration was achieved as intended
- No unexpected adverse treatment effects

The Following 6 Slides Provide Key Data From The Study:

Table 1. Characteristics of the subjects at enrollment

Table 2. Mean plasma concentrations of blood urea nitrogen and β2-macroglobulin
  Figure(A). Blood urea nitrogen (mg/dl).
  Figure (B). Plasma β2-microglobulin (mg/l).

Figure 3. Summary small solute, middle molecule clearance, blood flow, dialysate flow
  (A). Plasma urea, creatinine, phosphorus, β2-microglobulin clearances (ml/min)
  (B). Blood and dialysate flow (ml/min).
The Wearable Artificial Kidney (WAK) Blood Circuit

Color Code
Red: Blood from patient
Blue: Blood to patient
Gray: Electronics
White: Heparin
Night Time Dialysate Circuit

Blood-leak/bubble detector, pump power-up and alarm/shutoff system
WAK pump
Dialysate regenerating system
Battery

Blood-leak-detecting probe
pH detector

Tubing color code:
- Black: Electrolyte supplement
- Yellow: Dialysate to regenerating system
- Brown: Bicarbonate
- Green: Dialysate from regenerating system
- Electronics/cables are shown in gray

Pump/bag color code:
- Black: Electrolyte
- Yellow: Waste (UF)
- Brown: Bicarbonate
Day Time Dialysate Circuit

Tubing color code:
Yellow: Dialysate to regenerating system
Brown: Bicarbonate
Green: Dialysate from regenerating system

Electronics/cables are shown in gray

Pump/bag color code:
Yellow: Waste (UF)

Blood-leak/bubble detector, pump power-up and alarm/shutoff system
WAK pump (carbon)
Battery
Dialysate regenerating system
Dialyzer
Blood-leak-detecting probe

Private and Confidential
The Wearable Artificial Kidney V2.0
US Patent No. 6,960,179 and other patents
UF = 500 to 1000 ml/hr shrinks the intravascular space

UF = 50 to 100 ml/hr
Physiological fluid removal rate
Free serum concentrations of the protein-bound retention solute p-cresol predict mortality in hemodialysis patients

Protein Bound p-cresol is not toxic

Free particles are toxic

Bammens B et al. KI. 2006
## CLINICAL BENEFITS

Continuous (WAK) vs Intermittent (Stationary)

<table>
<thead>
<tr>
<th>Blood Filtration Time</th>
<th>Fluid Removal</th>
<th>Phosphorous Removal</th>
<th>Potassium Levels</th>
<th>Salt Overload</th>
<th>Arterio-Venous Connection</th>
<th>Hospitalizations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CONVENTIONAL HEMODIALYSIS (Intermittent)</strong></td>
<td>9 to 12 hours per week</td>
<td>2 - 3 liters in 3 - 4 hours</td>
<td>Insufficient: Must take many, expensive pills with stringent food restrictions</td>
<td>Fluctuating high &amp; low levels can cause arrhythmia or sudden death.</td>
<td>Removal, requires severely limited intake</td>
<td>Frequent heart attacks, strokes, infections, and hypertension</td>
</tr>
<tr>
<td><strong>WAK HEMODYALYSIS (Continuous)</strong></td>
<td>Continuous 24 / 7 (168 hrs a week)</td>
<td>2 - 3 liters in a 24 hour period</td>
<td>Removes phosphorous similar to a healthy kidney, without pills</td>
<td>Normal levels</td>
<td>Removes like healthy kidney</td>
<td>No fluid overload or salt retention</td>
</tr>
<tr>
<td><strong>WAK ADVANTAGE</strong></td>
<td>Continuously filters at NATURAL physiological rate</td>
<td>Continuous removal at SAME RATE AS KIDNEYS</td>
<td>Does NOT require food restrictions or pills. $4B Savings a Year</td>
<td>LESS RISK OF SUDDEN DEATH from abnormal potassium levels</td>
<td>Little salt. NO HYPERTENSION, HEART DISEASE; Patients eat normally.</td>
<td>Control blood pressure; FEWER HEART ATTACKS AND STROKES</td>
</tr>
</tbody>
</table>
### PATIENT BENEFITS
Continuous (WAK) vs Intermittent (Stationary)

<table>
<thead>
<tr>
<th></th>
<th>Dietary Restrictions</th>
<th>Drinking Restrictions</th>
<th>Transportation Requirements</th>
</tr>
</thead>
</table>
| **CONVENTIONAL HEMODIALYSIS**  
(Intermittent) | Very little or no potatoes, dairy, citrus or juices. | No more than 800 ml/day since no water is excreted; no urine produced between sessions | Require an ambulance or van 3x per week round trip |
| **WAK HEMODYALYSIS**  
(Continuous)    | **NONE**                                                  | **NONE**                                                  | Requires filter change 1x per week (Sterile environment) |
| **WAK ADVANTAGE**     | **NO RESTRICTIONS**                                      | **UNRESTRICTED WATER AND FLUIDS**                         | **MUCH FEWER** trips to doc office, hospitals, clinics |
WAK 6 HOURS TRIAL
First US Human trial in progress
**CLINICAL BENEFITS: WAK VS STATIONARY**

<table>
<thead>
<tr>
<th>CLINICAL CRITERIA</th>
<th>CONVENTIONAL HEMODIALYSIS (HD)</th>
<th>WAK</th>
<th>BENEFITS: WAK vs HD</th>
</tr>
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<td>Blood Filtration Time</td>
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<td>Continuous 24 / 7 (168 hours / week)</td>
<td>Continuously filters at natural physiological rate</td>
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<td>Fluid Removal</td>
<td>2 to 3+ liters in 3 to 4 hours</td>
<td>1.5 - 2.0 liters over 24 hour period</td>
<td>Continuous removal at same rate as healthy kidneys</td>
</tr>
<tr>
<td>Phosphorous Removal</td>
<td>Insufficient; patient must take numerous expensive pills, endure food restrictions</td>
<td>Removes like healthy kidney, no pills</td>
<td>No food restrictions; no pills = $4B Savings / Year</td>
</tr>
<tr>
<td>Potassium Levels</td>
<td>Fluctuating high / low levels can cause arrhythmias, sudden death.</td>
<td>Normal</td>
<td>No food restrictions; no risk of sudden death from abnormal potassium levels</td>
</tr>
<tr>
<td>Salt overload</td>
<td>Removal, requires severely limited intake</td>
<td>Removes like healthy kidney</td>
<td>Patients eat normally, incl. salt; No hypertension, heart disease</td>
</tr>
<tr>
<td>Arterio-venous connection</td>
<td>Shunt: 2 Large-bore needles; Multiple vascular surgeries</td>
<td>Catheter: Tunneled under the skin</td>
<td>No needle sticks or repeated surgeries</td>
</tr>
<tr>
<td>Hospitalizations</td>
<td>Frequent heart attacks, strokes infections, hypertension</td>
<td>No fluid overload or salt retention</td>
<td>Control blood pressure; Fewer heart attacks, strokes</td>
</tr>
<tr>
<td><strong>KEY PATIENT ISSUES</strong></td>
<td></td>
<td></td>
<td></td>
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<td>Restrictions: Dietary</td>
<td>Very little or no potatoes, dairy, citrus or juices</td>
<td>None</td>
<td>No restrictions, incl. salt</td>
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<td>Restrictions: Drinking</td>
<td>No more than 800 ml/day since no water is excreted; patients make no urine in between dialysis sessions</td>
<td>None</td>
<td>Unrestricted salt, water and other fluid intake</td>
</tr>
<tr>
<td>Transportation</td>
<td>Ambulance or van 3x / Wk round trip</td>
<td>Requires 1x / Wk filter change (Sterile environment)</td>
<td>Fewer trips to doc office, hospitals, clinics</td>
</tr>
</tbody>
</table>
LESS MONEY!!!!

- Less CV disease
- Less HTN
- Less Epo iron and blood transfusions
- Less hospital use
- Less hypotension and less iv saline
- No phosphate binders
- More dialysis time
- Less pill burden
- Less staff
- Less hospital use
- Less CV disease
- Less hypotension and less iv saline
- No phosphate binders
- More dialysis time
- Less pill burden
- Less staff
Inventions have long since reached and I see no hope for further developments….

Julius Sextus Frontinus (Roman Engineer 10 AD)

The Americans have need of the telephone but we do not. We have plenty of messenger boys…

Sir William Preece (Chief Engineer, British Post Office. 1878)

I think there is a world market for maybe five computers……

Thomas Watson. (Chairman, IBM. 1943)
The WAO Team
Thanks You!
Blood access via outpatient catheter placement

Cuff

Catheter exits abdomen

Catheter from superior vena cava