Medical Technology – from the Stethoscope to the Robot

Dr. Sudesh Sivarasu | 23/08/2017 | 12h00
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South African Health Care System

- South Africa has a bi-modal system of healthcare
- The private and public health systems are disparate and function as stand-alone enterprises in terms of the target patient profiles
- Dual Burden of Communicable (HIV & TB) and non-communicable diseases under one roof
- Health spending is around 8.3% of GDP way higher than WHO recommended 5%
- Inspite of higher spending, health outcomes are poor compared to other middle income countries
South African Medical Device Industry

Allan Cormack, Physicist
1979 Nobel Prize
X-ray Computed Tomography.

Christiaan Barnard, Surgeon
Performed the world’s first successful human-to-human heart transplant.

This trade deficit can be reduced if medical devices are locally made.

S.A. Medical Device Industry
- Import: 95%
- Export: 5%
Solution to this problem?

- Local Production of Medical Devices
- Creating Affordable and appropriate medical technologies
- Frugal medical innovations
Stanford Biodesign
Frugal Biodesign™

- Clinician Interaction Platform
- Public Awareness
- Medical Device Innovation Process
- Reimbursement & Regulatory Strategy
- IP Management
- Commercialization Strategy

Frugal Biodesign™

Health Professions Council of South Africa (HPCSA)
Medical Device Innovation Process

Solution through a Medical Device Think Tank

Needs Identification & Screening

Concept Generation and Screening

Strategy Development

Prototype

Testing & Verification

Recommendation
Phased Medical Device Innovation Process

- Invent
  - Clinical Need
  - FBP
  - IP
- Verify
  - MVP
  - PCT
- Commercialize
  - L & C
Change of Focus Facilitates Innovation

Patient Centric Innovation

Clinician Centric Innovation

Identify your client

Clinician Interaction Platform

Commercialization strategy

IP Management

Remuneration & Regulatory Strategy

Public Awareness

Frugal Biodesign Process

Clinician Interaction Platform

Commercialization strategy

IP Management

Remuneration & Regulatory Strategy

Public Awareness

Frugal Biodesign Process

Identify your client
Case 1:

Case 1: Paediatric metered dosage inhaler (pMDI) sleeve
Paediatric Metered Dosage Inhaler (pMDI) Sleeve Attachment

Clinical Problem:
Paediatric and Geriatric asthma patients experience difficulty while activating a standard inhaler and keeping track of the dosage.

Solution:
Attachment of a force reduction system for activating a standard inhaler, incorporating a dosage counter.
South African and Global relevance

- South Africa has the 4th highest asthma death toll rate for patients between the ages of 5 and 35 years.
- 3.9 million people in South Africa suffer from the disease and 1.5% die as a result, annually.
- 235 million people suffer from asthma.
- Asthma is the most common chronic disease amongst children.
- Over 80% of asthma deaths occur in low and lower-middle income countries.
Paediatric Metered Dosage Inhaler (pMDI) Sleeve Attachment

Device assembly

FEATURES

• Force reduction mechanism (39.24N to 12.26N).
• Adjustable to accommodate inhalers of various sizes.
• Aesthetics.
• Adjustable and resettable in-built generic dosage counter.

MANUFACTURING

• 3D printing.
• Milling.
• Injection moulding
Paediatric Metered Dosage Inhaler (pMDI) Sleeve Attachment

Force reduction mechanism

Height adjustment mechanism

Handle
levers

Key teeth

Rack component slots
Paediatric Metered Dosage Inhaler (pMDI) Sleeve Attachment

Dosage Counter Mechanism

Pawl
Ratchet wheel
Counter dial
Control gear
Paediatric Metered Dosage Inhaler (pMDI) Sleeve Attachment

Aesthetics
Paediatric Metered Dosage Inhaler (pMDI) Sleeve Attachment

Attachment to various inhalers

Video
Paediatric Metered Dosage Inhaler (pMDI) Sleeve Attachment

Impact

- Force reduction
- Generic dosage counter – resettable
- Accommodate a variety of inhalers
- Effectively target middle to low income groups

![Chart showing comparative force required between males and females from 5 to 12 years of age.](chart)

- Males' force (in pounds): 8.82 (39.23N)
- Females' force (in pounds): 2.76 (12.26N)
Paediatric Metered Dosage Inhaler (pMDI) Sleeve Attachment

Cost comparisons

- Cost of existing inhalers
  - Advair Diskus: R2165 - R3288
  - Symbicort Turbuhaler: R805
  - Standard MDI: R60 (Asthavent) – R240 (Ventolin)
  - pMDI: R50 – R70 (Total R310 max)
Paediatric Metered Dosage Inhaler (pMDI) Sleeve Attachment

Conclusion

- A cost effective solution to a global problem.
- Assist geriatric and paediatric patients from middle to lower income groups in using their standard MDIs.
- Target companies – Cipla, GSK, AstraZeneca.
- Ethical approval has been granted for a 2017 clinical study.
Case 2: Development of the Laxmeter
Clinical Problem

- Stability of the joint
  - ACL, PCL, MCL and LCL  (Drake, et al., 2014; Gilroy, 2008)

- Causes of compromised joint integrity

- Consequences of compromised joint integrity

- Laxity – elasticity and stiffness of ligaments

- How is laxity measured?

https://www.youtube.com/watch?v=d-VgKfiOjmU
Existing laxity measurement devices

- **KT-1000**
  - Unreliable results
  - Diagnosing clinician
  - Difficulty replicating exact position

- **Telos Stress Device**
  - Not ergonomically sound
  - Unreliable results
  - Radiographic assistant
Laxmeter – stress radiography device

- Improve clinician’s diagnosis of injury
  - Multiple degrees of flexion
- Radiographic assistant
- Improved replication
- Eliminate hip joint position affecting results
Laxity measurement devices comparison (currently)

Functional limitations of laxity measurement devices. X represents inability to carry out the test, ‘✓’ represents ability to carry out the test with complications and ‘✓✓’ represents full ability to carry out the test.

<table>
<thead>
<tr>
<th>Laxity Measurement Devices</th>
<th>Abduction Stress Test (MCL)</th>
<th>Adduction Stress Test (LCL)</th>
<th>Lachman Test (ACL)</th>
<th>Anterior Drawer Test (ACL)</th>
<th>Posterior Drawer Test (PCL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GNRB</td>
<td>X</td>
<td>X</td>
<td>✓✓</td>
<td>✓✓</td>
<td>X</td>
</tr>
<tr>
<td>Telos Stress Device</td>
<td>✓✓</td>
<td>✓✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>KT-1000</td>
<td>X</td>
<td>X</td>
<td>✓</td>
<td>✓✓</td>
<td>✓✓</td>
</tr>
<tr>
<td>Laxmeter</td>
<td>✓✓</td>
<td>✓✓</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
Laxmeter – Load Applicator
Laxmeter – Patient Support
Laxmeter – Stress Radiography Device
Laxmeter – Stress Radiography Device
Laxmeter – Stress Radiography Device
Laxmeter – Resultant images
Laxity measurement devices comparison (final)

Functional limitations of laxity measurement devices. X represents inability to carry out the test, ‘✓’ represents ability to carry out the test with complications and ‘✓✓’ represents full ability to carry out the test.

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<td>✓✓</td>
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<td>Telos Stress Device</td>
<td>✓✓</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>KT-1000</td>
<td>X</td>
<td>X</td>
<td>✓</td>
<td>✓</td>
<td>✓✓</td>
</tr>
<tr>
<td>Laxmeter (1)</td>
<td>✓✓</td>
<td>✓✓</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Laxmeter (2)</td>
<td>✓✓</td>
<td>✓✓</td>
<td>✓✓</td>
<td>✓</td>
<td>✓✓</td>
</tr>
</tbody>
</table>

GNRB: Gastrocnemius Muscle Reflex Barker

X: Inability to carry out the test
✓: Ability to carry out the test with complications
✓✓: Full ability to carry out the test
Impact

- 250,000 ACL injuries annually in the US
- Number of active people and cost of surgery is increasing
- Improve the clinician’s assessment of injury to reduce the risk of misdiagnosis
- Therefore, we aim to detect ligamentous lesions and ruptures more reliably
- Women uncomfortable with skin exposure is addressed
## Cost comparisons

<table>
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<tr>
<th>Device name</th>
<th>Type</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>KT-1000™</td>
<td>Arthrometer</td>
<td>ZAR 57281.10</td>
</tr>
<tr>
<td>KT-2000™</td>
<td>Arthrometer</td>
<td>ZAR 112853.27</td>
</tr>
<tr>
<td>GNRB®</td>
<td>Arthrometer</td>
<td>N/A</td>
</tr>
<tr>
<td>Telos™</td>
<td>Stress radiography device</td>
<td>More than the KT-1000</td>
</tr>
<tr>
<td>Laxmeter</td>
<td>Stress radiography device</td>
<td>ZAR 4500 in 2014</td>
</tr>
<tr>
<td>Laxmeter 2.0</td>
<td>Stress radiography device</td>
<td>ZAR 15000 (approximately)</td>
</tr>
</tbody>
</table>
Patents and Licensing

• Patents
  – US – US20150124942 A1
  – UK – GB1319689.4
  – RSA – 2014/08083
  – India – 113/KOL/2014

• GNRB – licensing options
Case 3: Design of a Reusable Adrenaline Auto Injector
50% of school children worldwide suffer from food allergies…
and 5% of the global population has anaphylaxis!
Anaphylaxis is a severe allergic reaction caused by common allergens such as food, insect bites and pharmaceuticals.
It targets organs such as the skin, lungs, stomach, and heart.
And if not treated immediately, can lead to death.
To prevent the worst, sufferers of anaphylaxis must use an adrenalin auto-injector – otherwise known as an AAI.
An AAI is an injection device, that delivers adrenaline to the deep muscle tissue of the thigh,
slowing down the rate of the reaction...
To allow time for the patient to get to the hospital.
So the problem is solved, right?
Well, not exactly…
ADRENALIN AUTO-INJECTORS

So what's the problem?
The issue lies with the device currently available on the market.
While the production cost per device is only $20 - they are sold for $300 each, and can only be purchased in 2-packs, bringing the cost price up to $600.
But since the adrenaline in the device expires and the pen is not reloadable, the device must be disposed of and replaced every 18 months, regardless of use! Generating large amounts of hazardous waste.
When the device does get used, the instructions on the label are unclear and confusing...
So what should be a simple two-step process,
Is often administered incorrectly,
resulting in an injured and untreated patient.
Finally, even if the device is applied correctly, the injection sometimes lacks penetration depth, meaning the adrenaline would be ineffective.
This is because the force at which the adrenalin is injected is not designed for a wide enough variation in body type and age.
These are serious issues that need a solution…
ZIBI-PEN
have been working tirelessly to develop an elegant solution that solves these issues of cost, safety, effectiveness and waste.
Our solution is the ZiBi Pen – a device engineered for optimal safety, simple application, and adjustable penetration depth...
And above all, reusability, which will not only eliminate the heavy cost of having to repurchase the device every 18 months,
but it will also drastically cut down on medical waste.
Case 4: reScribe – Hand Exoskeleton for Fine Motor Rehabilitation
Clinical Problem
Stroke is the leading cause of adult-onset disability with 70-85% of first stroke’s resulting in hemiplegia. Through intensive physical therapy some patients are able to regain lost motor skills. Fine motor skills such as handwriting are rarely recovered using current rehabilitation methods.

Clinical Relevance
- Reduced improvement in motor function
- Increasing permanent disability
- High incidence of stroke
- Shortage of therapists

Key Outcome
5-DOF actuated hand exoskeleton
- Close coupling to the hand resulting in natural movements
- Ability to replay repetitive handwriting sequences
- Utilizes correct tripod handwriting grip
- Neural remapping achieved through task-orientated training

Results
- Reduced workload on therapists.
- Quicker recovery of motor function.
- Reduced incidence of permanent motor disability.
- Technology Readiness Level (TRL) = 4

http://resribetherapy.com/
reScribe – Stepping Stone
Case 5: Open Source 3D printed Ptosis Crutches for Myasthenia Gravis patients
**CLINICAL PROBLEM**

Blepharoptosis, or ptosis, is an ophthalmic complication prevalent in Myasthenia Gravis patients, particularly those of African genetic ancestry.

- The upper eyelid obstructs the visual field.
- The patient has a drowsy/ tired appearance

**Unilateral ptosis**

**Bilateral ptosis**
The desired outcome was a modular ptosis crutch as a non-surgical solution to elevating the upper eyelid above the visual axis.

**Ptosis crutch requirements**

1. The primary function of the ptosis crutch is to elevate the upper eyelid to clear the visual axis.
2. The device must be capable of accommodating for different degrees of ptosis. Thus, the device must be adjustable along the z axis.
3. The device must accommodate for the inter-individual variability of globe projection. Thus, the ptosis crutch must be adjustable along the y axis.
4. The device must cater for differences in the horizontal position of the eye.
5. The device should allow for some blinking effort to occur.
The Ptosis crutch design outcome

The ptosis crutch is a non-invasive assistive device that is attached to the superior border of the spectacle frame.

**Image:** A CAD model of the ptosis

**Image:** The three modular components of the ptosis crutch

**Image:** Photographs of the ptosis crutch attached to the superior border of the spectacle frame.
Ptosis Crutch design outcome

**FUNCTIONALITY**

10 MG patients have tested the functionality of the ptosis crutch.

**Initial Clinical results**

*Clinical Results*

The mean eyelid elevation provided by the crutch = 1.88 mm ± 1.02

*Patients Feedback*

- 8 Patients = visual field was much better
- 2 Patients = visual field was somewhat better
- All patients indicated that they would like to use the ptosis crutch on a long term basis
SOCIO-ECONOMIC IMPACT

- The association of treatment resistant and ocular muscle complication in MG patients of African ancestry emphasizes the need for a local, low cost solution to elevate the eyelid.
- Although this study is focussed on designing a ptosis crutch for MG patients. The application of the ptosis crutch could be of use to individuals with ptosis of other aetiologies.
- The ptosis crutch design is undergoing the process of being launched on an open source innovation platform. This will ensure that the design is easily accessible to ptosis patients or interested institutions.

Image: Photograph of a MG patient wearing the ptosis crutch to elevate the left eyelid above the visual axis

In Conclusion

• MedTech growth within SA must be improved
• Home grown solutions needs more support for further growth
• SA has some of the best innovation that can change the health care space
• Dedicated funding channels for MedTech innovation must be opened up
• BME must be recognized as a Critical Skill in SA
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