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Transitioning an Open Hardware Project to Distributed Medical Device Production

Julian Stirling

Open Hardware Summit @Home
9th April 2021

- Our experience: The OpenFlexure Project
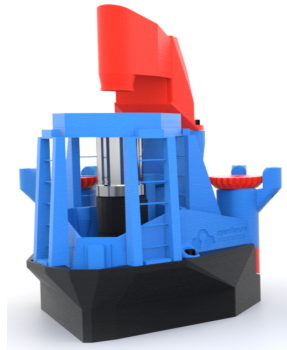- Specific challenges of medical device design
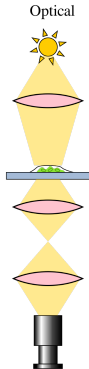- Next steps

openflexure
microscope

3D printing allows unique structure

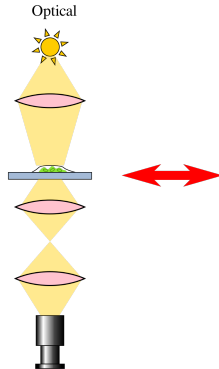Design optimised for plastic (not a cheap imitation)

Anyone can reproduce the design

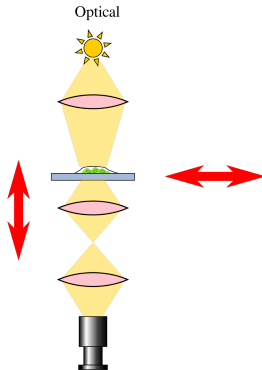Optical

Optical

Optical

Traditional microscopes use
dovetails
Requires precision machining

Traditional microscopes use dovetails
Requires precision machining

We use 3D printed flexures

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How does it work

Purchase cost ~£30,000

Maintenance: Parts cost + engineer travel

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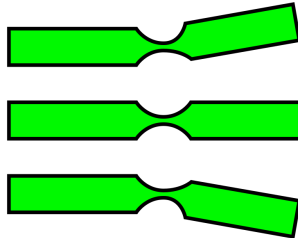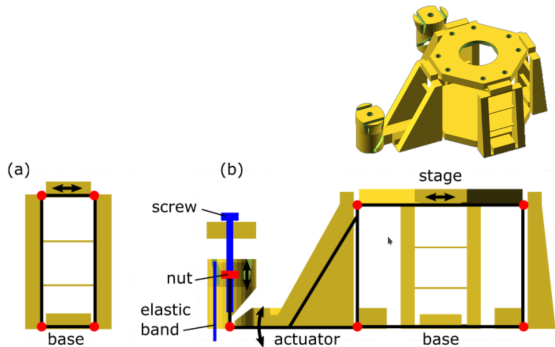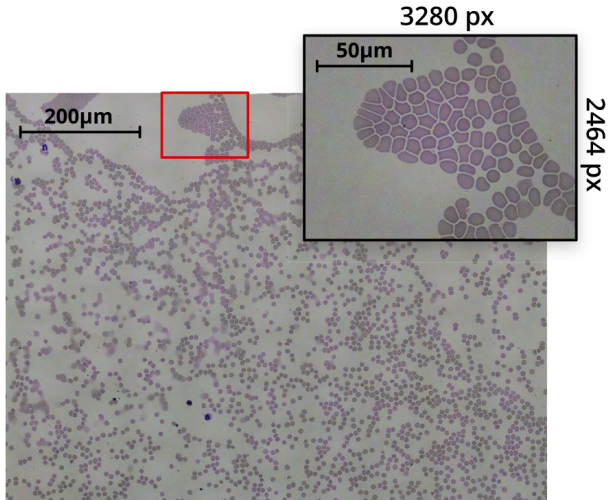
What does a microscope really cost?

Purchase cost ~£30,000

Maintenance: Parts cost + **engineer travel**

Build locally $\rightarrow$ repair locally

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Medical manufacturing

- It works!
- We can build it!
- How much more is needed?

Regulators require evidence of Quality Management for:

- Design - Why is it built this way?
- Procurement - Why do you trust that supplier?
- Production - How do you ensure it is built properly?
- Support - How do you keep the device functioning for its lifetime?

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Regulatory requirements

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Quality managed design

ISO-13485 requires you to:

- Have a Quality Manual - Easier if the standard was open!
- Documented design procedures
- Records of planning and review meetings
- Records of validation and verification
- Control of design and development changes

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Quality managed design

ISO-13485 requires you to:

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- Documented design procedures

- Records of planning and review meetings

- Records of validation and verification

- **Control of design and development changes** - Openly designed projects can do this well

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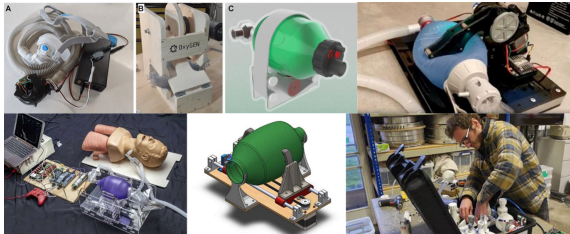
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Manufacturer is responsible

- Manufacturer takes responsibility by producing device.
- Must ensure design was quality managed
- If only the final design is open it is useless for production

Building an air pump is easy

Ensuring a ventilator is safe is hard

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How can an open medical design work?

Prototyping

- Design openly
- Move the conversation online
- Use version control
- Document decisions and mistakes

Design

- Formalise roles
- Formalise reviews
- Formalise discussions
- Formalise documentation
- Formalise planning

DevOps platforms - Version control, roles, reviews, automation

Automated documentation - We are writing our own

Open communication and transparent governance

Need platforms to guide teams through establishing quality managed design

IFAKARA HEALTH INSTITUTE
research | training | services
Clinical evidence

Locally-manufactured
certified medical
device

TMDA

Training and
accreditation

Locally-built
working
microscope

Quality control
& ISO 13485

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Failure mode analysis
Design for manufacture

- Designing a prototype is just the first step
- We all need to work together on working together

OpenFlexure team

Grace Qingxin (Ed) Richard Paul Valerian Julian Joe Samuel Kaspar Joel

And our growing community.