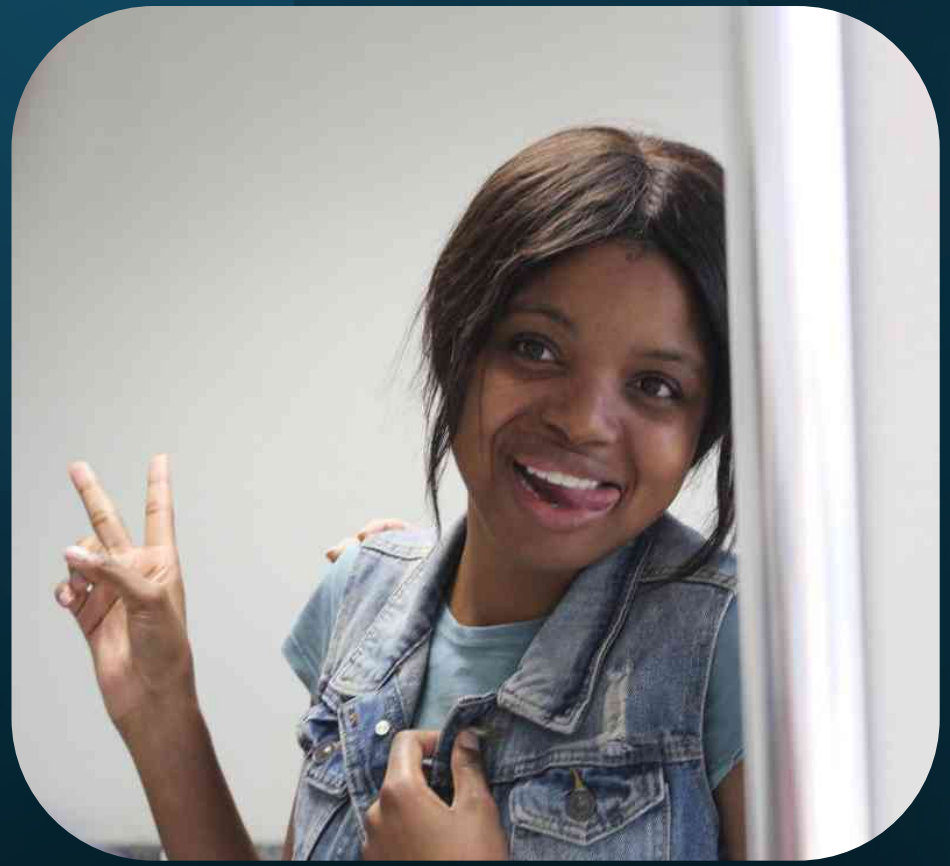
From Research Capability to Societal Impact

Changing Faces, Changing Lives



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Central University of Technology, Free State

DISCLAIMER

- **Some of the slides may contain sensitive clinical photos that may upset sensitive viewers**
- **This is unfortunately the reality that we are facing daily, in order to improve the quality of lives of SA patients**

ACKNOWLEDGEMENTS

- CUT Executive Management
- CRPM Staff
- The Carl & Emily Fuchs Foundation
- EOS
- Department of Science, Technology and Innovation
  - MedAdd Project
  - National Research Foundation (SARChi Chair)
- Charities Aid Foundation of America (CAF)
- Wohlers Incorporate
- Technology Innovation Agency (TIA)
- Technological Higher Education Network South Africa
- EUREKA
- The Free State Office of the Premier
- Industry collaborators
- University collaborators

THE NEWLY ESTABLISHED DSI & CUT FUNDED:

KEY MILESTONES THAT TURNED INTO ENABLERS/MULTIPLIERS

1997: CRPM – First academic 3D Printing unit established to provide research and industry support

2007: CRPM – First Titanium 3D printer installed in Africa

2012: CRPM – Start working towards ISO 13485 certification

2013: CRPM – First South African designed and manufactured 3D-printed mandible implanted in SA

2015: CUT - Awarded a Research Chair in Medical Product Development under the NRF South African Research Chairs Initiative (SARChI)

2016: CRPM – Awarded Carl and Emily Fuchs Foundation R2.25mil (2016 to 2020) "Changing Faces Changing Lives" project was born

2016: CRPM – First institution to receive ISO 13485 for 3D printed medical products in Africa

2019: CUT receives grant from the National Department of Science, Technology and Innovation (DSTI) to the value of R72 mil to establish a Medical Device Additive Manufacturing (MedAdd) Technology Demonstrator. CUT co-funded more than R15mil

CUT TAKING THE LEAD IN SOUTH AFRICA

2016: CRPM – First institution to receive ISO 13485 for 3D printed medical implants in South Africa



CERTIFICATE

dqs

This is to certify that

CRPM

Centre for Rapid Protyping and Manufacturing, Central University of Technology, Free State

20 President Brand Street
Bloemfontein, 9300
Free State
South Africa

has implemented and maintains a **Quality Management System.**

Scope:
The design, development, and production of non-active implantable devices for corrective surgery, and the contract manufacture of non-active implantable and non-implantable 3D printed medical devices.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016

Certificate registration no.	40605054 mp2016
Valid from	2025-09-01
Valid until	2028-08-31
Date of certification	2025-09-01

DQS German Association for Certification of Management Systems (Pty) Ltd.

Debbie Becker
Operations Director

Accredited Body: DQS German Association for Certification of Management Systems (Pty) Ltd., P.O.Box 672, Randburg 2125, South Africa
The validity of the certification can only be verified by the QR-code.



SAHPRA

Page 1 of 4

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

Licence number: 00003743MD

LICENCE TO MANUFACTURE MEDICAL DEVICES

In terms of section 22C(1)(b) of the Medicines and Related Substances Act, 1965
To act as a Manufacturer, Importer and Exporter

This licence is granted to:

Licence Holder

Central University of Technology, Free State
(Centre for Rapid Prototyping and Manufacturing)
20 President Brand Street
Bloemfontein
9301

On the following terms and conditions:

The licence holder and the persons described and named in Annexure 1 shall at all times ensure that all medical devices distributed, irrespective of its registration status, comply with all the provisions of the Medicines and Related Substances Act, 1965, as amended and in particular with sections 14, 18, 18A, 18B, 18C, 19, 20, 22A, 22C, 22H, 23, 26, 28, 33 and the Regulations relating to Medical Devices 2, 3, 4, 5, 6, 13, 14, 17, 18, 19, 20, 21, 22, 23, 24, 25, 27, 28 and all relevant South African Health Products Regulatory Authority Guidelines.

This licence consists of 4 pages.

This facility is authorised to perform the manufacturing activities listed in Annexure 1 to this licence.

CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 21 June 2024

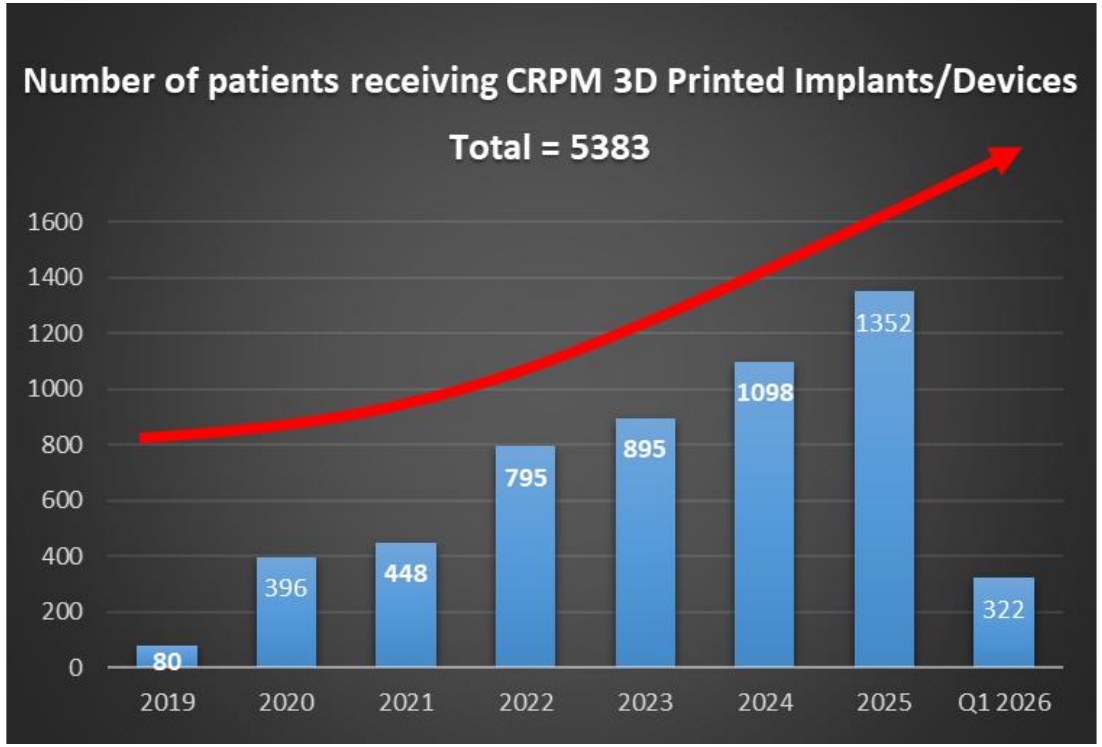
EXPIRY DATE: 21 June 2029

AMENDMENT DATE: N/A

This licence remains the property of the South African Health Products Regulatory Authority. Upon amendment, voluntary withdrawal, recall, suspension or revocation of the licence, the original licence must be returned to the Office of the Chief Executive Officer.

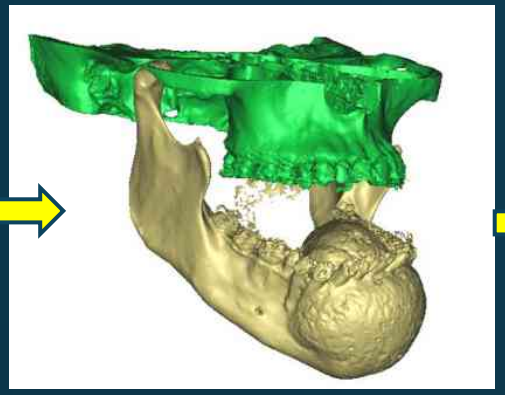
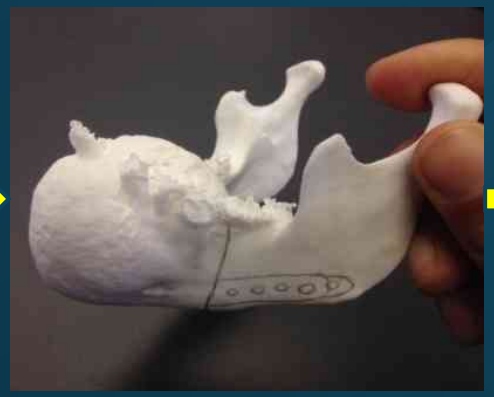
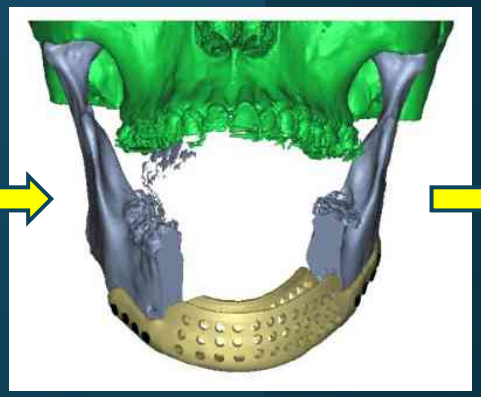
NUMBER OF PATIENTS RECEIVING CUSTOM-DESIGNED 3D-PRINTED IMPLANTS/DEVICES

- To improve patients' lives using cutting-edge technology.
- Continuous and generous support from practitioners, partners, and donors has enabled CRPM to assist **more than 300 patients pro bono** with life-changing reconstructions.
- More than **5,383 patients across the public and private healthcare** sectors have received CRPM 3D-printed implants or devices.

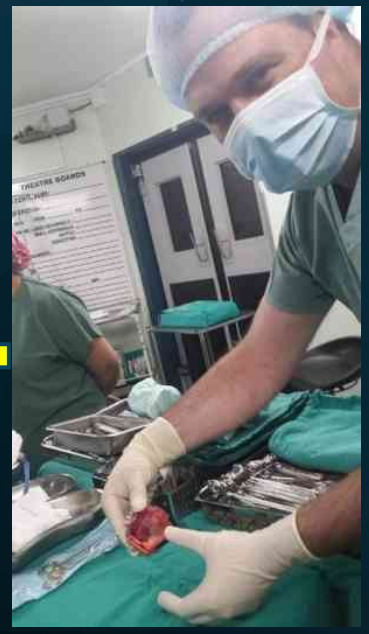


Acknowledgements:

Where it all started in 2016 – Industry pull


The team produced a custom-made laser sintered titanium implant for a 32-year-old female patient with ossifying fibroma, a slow-growing tumour causing the expansion of her lower jaw. The surgeons resected the tumour and restored the function and appearance of the mouth and jaw. The operation was made possible through a partnership with Belgian software company Materialise.






Acknowledgements
Dr Kobus Hoek
Dr Riaan Liebenberg
Dr Philip Jonsson

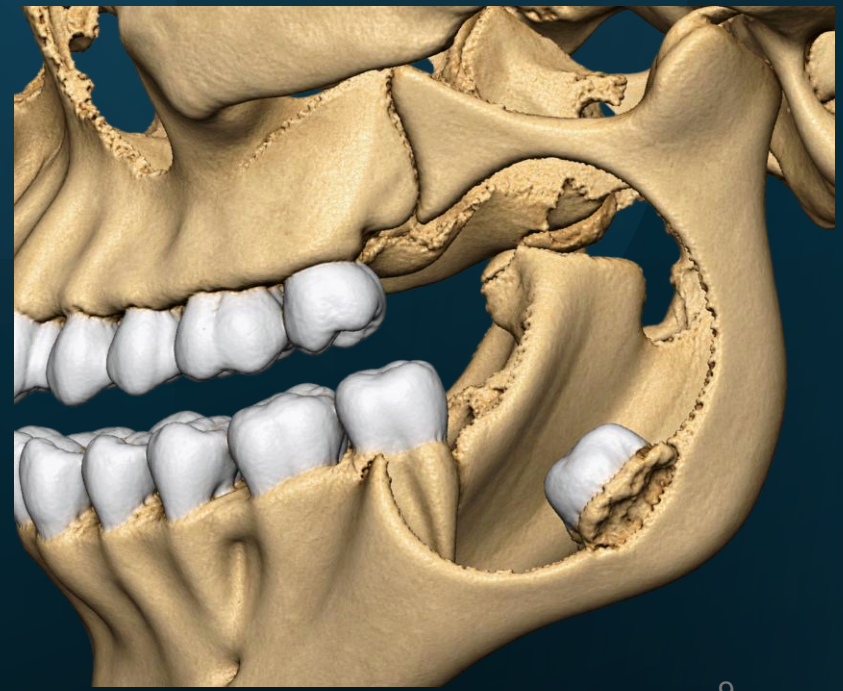
Materialise



ONE PROJECT - MULTIPLE LEVELS OF IMPACT

Impact at different levels

Level	Impact
Individual	Function, appearance, confidence, participation
Family	Reduced burden and improved quality of life
Clinical	Patient-specific solutions for complex cases
University	Research, skills, infrastructure and innovation
Healthcare system	New locally developed treatment capability
Society	Inclusion, dignity and reduced disability



Impact means enabling people to live



Matthew Booth, a 15-year-old talented athlete who lives with a permanent trachea tube due to bilateral vocal cord paralysis. Matthew's active, sports-focused lifestyle presents unique challenges.
Matthew required a trachea tube with a larger diameter to allow for better airflow.

Customised high-performance trachea tube

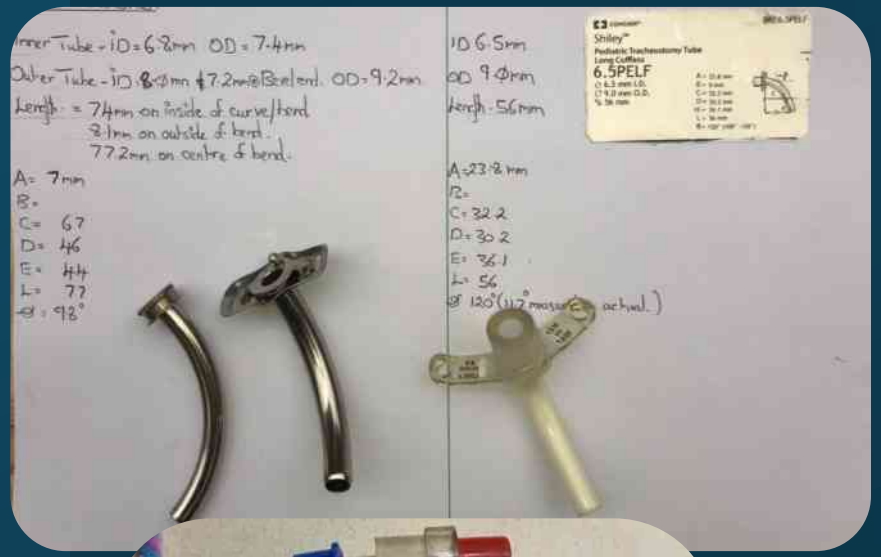
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Improved airflow

↓

Mountain biking + cross-country

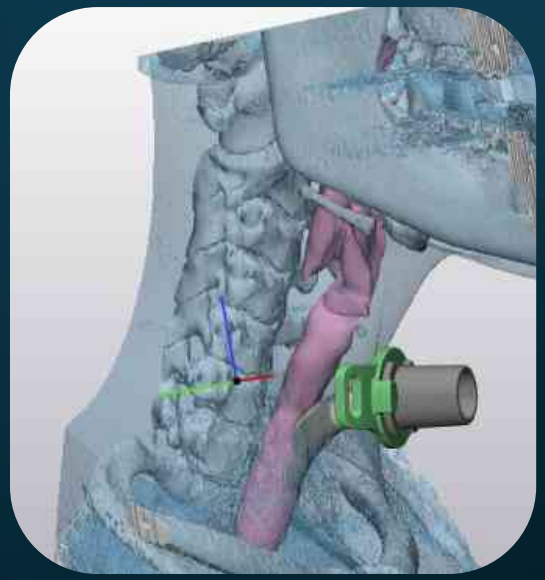
DESIGN INPUT





PATIENT-SPECIFIC DESIGN FROM CT SCAN DATA





FINAL TITANIUM 3D PRINTED TRACHEA





Damian (Matthew's dad) quoted:
"Beyond the physical improvements, the trachi has made a profound impact on Matthew's confidence and overall well-being. He's now able to express a great deal more of his athletic potential, both in cycling and running.

Matthew has become one of the fastest long-distance runners at his high school. At just 15 years old, he's earning tremendous respect from his peers, not only for his athletic ability but for his resilience and determination".

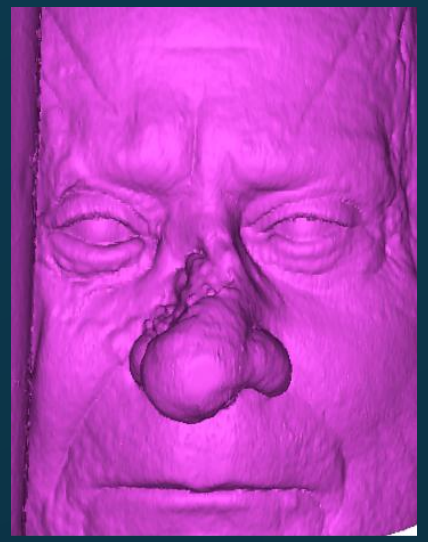


"Thank you again for your time and expertise in the development and manufacture of Matts titanium trachi. You've made an enormous difference in Matthew's life, physically, emotionally, and socially.

We are all deeply grateful".

Basal cell carcinoma

Before CFCL engagement - The patient underwent a rhinectomy procedure at Tygerberg Hospital **without any reconstruction.**

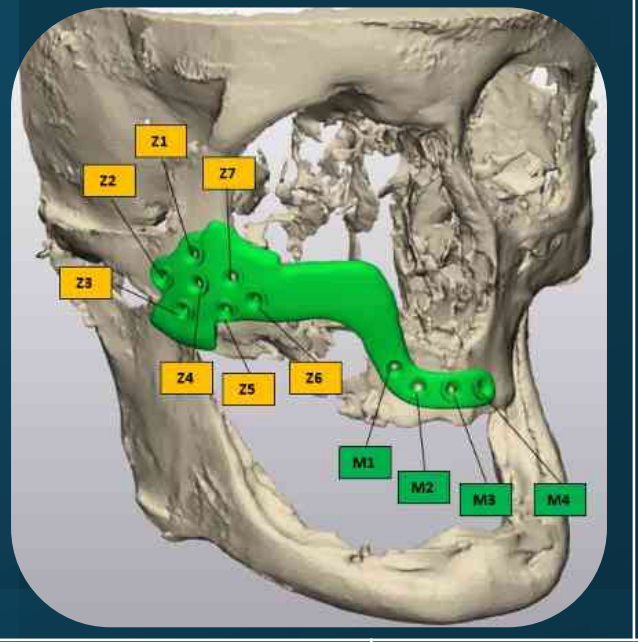


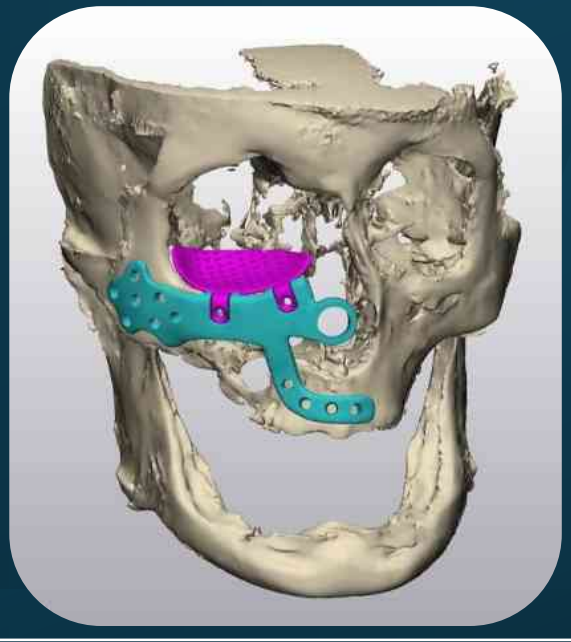



Diagnosis	Patient gender and age: • Male patient The patient was diagnosed with basal cell carcinoma, which necessitated the resection of the nose.
Patient Location	• Villiersdorp, Western Cape

Basal cell carcinoma

CFCL Intervention – Cancer spread to orbital floor and right cheek









Treatment	Resection of the orbital floor and right cheek. Design of patient-specific titanium frame with a separate orbital floor, all manufactured by Additive Manufacturing (LPBF) Patient is currently healing Will receive custom facial prosthesis in November 2026
Patient Location	• Villiersdorp, Western Cape

From Community Challenges to Student Solutions



Department of Mechanical and Mechatronic Engineering

ADVANCED MANUFACTURING (MADM428)

Assignment 2a — **Due date: August 2020**

Lecturer: Dr. J. Combrinck — **Total marks: 100**

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1. Background

A learner from a Special Needs School uses his foot to operate a computer to complete class activities and write, relying on an electronic input device connected to a computer. At present, a makeshift foot support and electronic input device, as shown in Figure 1 below, are being used. However, these devices are not ergonomically suited for the learner, and their movement across the classroom floor during usage makes it difficult to use. As a result, the learner struggles to operate them effectively, and prolonged use becomes tiring.



Figure 1: Learner using a makeshift foot support and electronic input device to write and participate in class activities

2. Assignment

2.1 Designing a device that combines an electronic input component with ergonomic foot support

- Design a cost-effective, ergonomic foot support that integrates readily available off-the-shelf electronic input devices and accessories.
- The design must be adjustable and suitable for use by a variety of learners.
- At least two components of the design assembly must be manufactured using the injection moulding process and designed in accordance with the design rules for injection moulded components.
- Indicate the applicable standards that need be taken into account and implemented throughout the design of the device.
- Any assumptions made during the design of the device must be clearly stated and justified.



Universities quite rightly protect intellectual property, research outputs and institutional interests. Those mechanisms are important.

But there are situations where I believe the societal challenge should come first.

Changing Faces, Changing Lives is one of those situations.

If one university has the clinical expertise, another has the engineering capability, another has the patient population, and a funder is willing to support the intervention,
I don't think the first question should be: who owns the IP?

"The first question should be: how do we help the patient?“

Upcoming cases

Reconstruction - Female paediatric patient





3D printed scull model for implant placement planning



3D model of proposed nasal and lip prosthesis

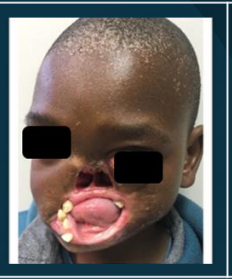


Diagnosis	Patient gender and age: • 10y old female patient At the age of **10 months**, the patient suffered a traumatic amputation of the nose and upper lip when her nose was bitten off by rats. **Almost no treatment has been provided in the past ten years**
Clinical/Implant requirements	• Removal of fibrotic tissue in the upper lip and nasal area • Placement of implants in the maxilla with a custom-made for a custom-made implant to retain nasal and upper lip prosthesis
Patient Location	• Limpopo • **Estimated Treatment Costs = R120k**

Reconstruction - Male patient









A **6-year-old** malnourished HIV-seropositive boy, referred to Polokwane Hospital in Limpopo with a destructive mid-facial lesion

Diagnosis	Patient gender and age: • Male **19-year-old patient** (2026) The patient presented with a large facial defect and gross scarring following radical ablative surgery 2 years prior, for the treatment of Cancrum Oris – Noma (Gangrene emanating from gum infection due to malnutrition, poverty and poor hygiene)
Clinical/Implant requirements	• Removal of fibrotic tissue in the upper lip and nasal area • Custom-made implant to retain new nasal and upper lip prosthesis
Patient Location	• Limpopo

Closing remarks

“Changing Faces, Changing Lives demonstrates that the ultimate value of university research is not only what we know, what we publish or what we patent.

It is, what becomes possible in society because that knowledge exists.

In this case, research became technology. Technology became clinical solutions. And those solutions became changed lives.

That, for us at CUT, is what societal impact means.”

IMPACT ON PATIENTS LIVES THROUGH CRPM @ CUT INTERVENTIONS

	The following are brief excerpts about how patients' lives were fundamentally changed as a result of the projects funded by the Carl and Emily Fuchs Foundation and Wohlers Inc
	Refilwe Stander's (9) mother abandoned her as a baby. Her guardian, Seipati Makhoahle, said this happened because Refilwe was born with a cleft palate. "We are grateful and thankful because before the treatment she was struggling to speak. After the prosthesis she gained a lot of confidence. She can now eat and talk and she is much better," said Seipati.
	A little girl who survived a shack fire will not teased by other children anymore. Selloane Modise (13) was given a prosthetic ear that matches the scars and skin texture of her face. "Her life will now be better. I thank God for the doctors who gave her an ear," said her mother, Masabata.
	Francois Jordaan (82) was diagnosed with basal cell carcinoma in 2009. Two operations and 34 radiation sessions later, his nose and large sections of facial tissue had to be removed as the cancer spread rapidly. When asked what he would have done without a facial prosthesis, he said: "It would have resulted in the unimaginable! Without a prosthesis I would not be able to appear in public. If I were to go out in public without anything, people would ask 'what kind of monster walks around like that?'" "The prosthesis definitely bettered my life," he concluded.

Central University of Technology, Free State

IT IS ALL ABOUT THE TEAM



ACKNOWLEDGEMENTS

- CUT Executive Management
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