

A photograph of a person sitting on a chair, showing their lower body. They are wearing a grey patterned shirt and blue shorts with a Nike logo. The person has a knee disarticulation prosthesis on their right leg. The background is a plain wall and floor.

Knee Disarticulation Prosthesis

A project focusing on the needs of amputees in landmine-affected countries.

A 6 month exploration

**Designing an Improved Prosthesis for
Knee Disarticulation Amputees**

A collaboration between
The Department of Bioengineering and
The Dyson School of Design Engineering at
Imperial College London. Funded by **Find a Better Way** and
supported by **Exceed Worldwide**.

**Imperial College
London**



Funded by



Executive Summary

Landmines remain a worldwide problem with landmine affected communities in over 60 countries and have been accountable, for example, for thousands of limb amputations across Cambodia since the end of the civil war in 1975. This legacy has produced a generation of survivors with many amputees reliant on basic assistive technologies for mobility.

For the past 30 years, a prosthetics system developed by the International Committee of the Red Cross (ICRC) has been one, and often the only, affordable option available through NGOs in landmine affected countries. Clinical studies reveal that scores, used to evaluate quality of life, are significantly higher for knee disarticulated (through-knee) than transfemoral amputees. Since the ICRC transfemoral device has remained unchanged since its introduction in the 1970s, there is an increasing demand for affordable and functional prosthetic devices specifically for knee disarticulated amputees.

A unique collaboration was established between the Department of Bioengineering and Dyson School of Design Engineering at Imperial to develop low-cost assistive technologies for landmine victims. The team comprised design engineers and bioengineers working alongside amputees, prosthetists and orthotists, physiotherapists, surgeons, and NGOs. This report contains an overview of the initial 6 month exploration phase of the project aiming at understanding the needs of the knee disarticulated amputees and providing them with functional and sustainable prosthetic devices.

Following a review, the most common failure points of the ICRC system included foot, suspension, knee joint, side bar knee configuration and cosmesis. Stability was a feature that all the amputees interviewed claimed to be missing from current solutions. In order to address these needs the team undertook preliminary design work, prototyping and testing for a functional and sustainable prosthetic for knee disarticulated amputees with a focus on stability, knee level asymmetry and suspension.

The prototype knee joint was constructed from 3D printed and machined components and included

inexpensive machine elements used in bicycles, easy to find in Cambodia. Designed as a modular system the prototype accommodates a range of stump sizes and can be fully incorporated into the ICRC lower limb device. The prototype of an external knee joint was developed to:

- reduce the knee level asymmetry,
- reduce the width of external joint such as the ICRC side bar mechanism,
- ensure stability by integrating an improved knee joint locking mechanism and achieving natural force transmission,
- improve functionality by achieving smooth knee rotation,
- increase durability by using components more appropriate to the environmental conditions.

The prototype was successfully tested with an amputee and found to achieve all the objectives set. More specifically, the amputee and the prosthetist highlighted the capability of the prototype to:

- eliminate knee level asymmetry,
- provide stability due to its auto-locking mechanism,
- achieve a direct load transfer from the shank to the socket and
- provide compliance to the limb.

The main outcome of the 6 month exploration is an early stage prototype knee joint for through-knee amputees.

Key areas identified for further investigation include

- **Knee level asymmetry** of through-knee amputees is not only a cosmetic issue, having an impact on perception in society, but also functional.
- **Stability** is critical and heavily determines functionality, especially when the device is used for work related activities.
- **Free swinging knees.** Walking through water, fast or over long distances with free swinging knees can be challenging as the shank does not return fast enough to the extended posture.
- **Keeping the knee in the locked state** is the preferred configuration by amputees who do not feel confident while using their device.
- **The cosmetic** outcome becomes a priority after functionality issues are addressed.

- **Sitting with legs crossed, squatting, and kneeling** are postures constrained by the ICRC knee mechanism.

- **Knee joints for young children** are not provided by the ICRC; adjustable/bespoke ICRC knee components are required.

- **Psychological** support is an essential need for the amputees that can determine the success of the prosthesis.

- **Stigma** is still faced by the amputees especially in the big cities.

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Cross-discipline collaboration

A unique collaboration was established between the Department of Bioengineering and the Dyson School of Design Engineering to develop low-cost assistive technologies for landmine victims.

This report contains an overview of the initial 6 month exploration phase of the project that brought the scientific rigour of the Department of Bioengineering together with the human centred design methodologies and creativity of the Dyson School of Design Engineering to explore and address challenges related to prosthetics in landmine affected countries.

The team is comprised of design engineers and bioengineers working alongside amputees, prosthetists and orthotists, physiotherapists, surgeons, and NGOs addressing related problems.



Bench alignment of a KD prosthesis - CSPO, Cambodia 2016

Project Team



Ian Radcliffe - Mechanical / Bio Engineer

Ian is a Mechanical Engineer with a PhD in Bioengineering, studying at Southampton University investigating bone strain within the resurfaced femoral head. He then went on to work at a leading Cambridge based technology development consultancy. Ian is currently Project Manager on the Sports Innovation Challenge at Imperial College London, a program of curriculum based student projects focused on Disability Sports and Rehabilitation.



Grigoris Grigoriadis - Mechanical / Bio Engineer

Grigoris is a Mechanical Engineer with an MSc in Biomedical Engineering who recently received his PhD in lower limb trauma biomechanics from the department of Bioengineering at Imperial College London. He is currently a Research Associate at the Centre for Blast Injury Studies.



Chris Natt - Design Engineer and Strategist

Chris is a graduate of Imperial College London and the Royal College of Art. He previously worked at the HELIX Centre for Design at St Marys Hospital London, leading commercial projects addressing global healthcare challenges. In 2015 he was selected by the Design Council as one of 50 young designers who represent the future of the UK design industry and was awarded a scholarship from Google to study at Singularity University Global Solutions Program.

Advisory Board



Professor Anthony Bull - Head of the Department of Bioengineering

Anthony is the Head of Department of Bioengineering and the director of the Center for Blast Injury Studies that exists to improve the mitigation of injury, improve and advance treatment, rehabilitation and recovery thus increasing lifelong health and quality of life after blast injury. His research includes the application of joint mechanics knowledge to diagnose and treat pathologies and performance parameters.



Professor Peter Childs - Head of the Dyson School of Design Engineering

Peter is the Head of the Dyson School of Design Engineering and the Professorial Lead in Engineering Design at Imperial College London. His research interests include: creativity; the application of creativity tools; mechanical and product design; robotics; rotating flow, temperature and its measurement, sustainable energy component, concept and system design.



Carson Harte - Chief Executive of Exceed Worldwide (external)

Carson is the Chief Executive of Exceed Worldwide. He trained at the National Centre for Prosthetics and Orthotics at the University of Strathclyde. In the early 1990's Carson and his family moved to Cambodia to help the thousands of people injured by landmines as a result of a civil war. Exceed Worldwide operates across 5 countries in Asia.

Problem Statement

Landmines have been accountable for thousands of limb amputations across Cambodia since the end of the civil war in 1979. This legacy has produced a generation of survivors with many amputees reliant on basic assistive technologies for mobility.

For the past 30 years, a prosthetics system developed by the International Committee of the Red Cross (ICRC) has been one, and commonly the only, affordable option available through NGOs in landmine affected countries such as Cambodia. The system consists of modular polypropylene (PP) parts; its design is a compromise between cost-efficiency and functionality.

The prosthetic device which is preferably offered to knee disarticulated (KD) amputees is the ICRC TF prosthetic, slightly modified to fit a KD socket. Recent clinical findings promote KD over TF amputations in terms of performance outcomes (Penn-Barwell, J. G., 2011). Since the ICRC TF device has remained unchanged since its introduction (1970s) and was designed to address the needs of TF amputees, there is an increasing demand for affordable and functional prosthetic devices specifically for KD amputees.

“The technology available for KD amputees needs to evolve with the surgical advances; the advantages to the amputee are clear but, without the parts for creating purpose built prostheses, many of these advantages are lost.”

- Carson Harte, Exceed Worldwide

Penn-Barwell, J. G. (2011). Outcomes in lower limb amputation following trauma: a systematic review and meta-analysis. Injury, 42(12), 1474-1479.

It is estimated that there have been 63,000 victims in Cambodia from mines and explosives since 1979.

"The key advantage of the KD procedure is stump shape and muscle anchorage it allows for. If done properly you are retaining the vast majority of muscle power."

- Carson Harte, Exceed Worldwide

Amputation of the Lower Limb

The location of a lower-limb amputation can greatly affect the ability of the patient to retain functionality; the more distal the amputation the better the walking independence and functional outcome (Pinzur, et al., 2007). Decision on level of amputation depends on the injury and the quality of the remaining bone and surrounding soft tissues, and the skill and training of the surgeon.

Transfemoral / TF



Knee disarticulation / KD



Transtibial / TT



KD Advantages

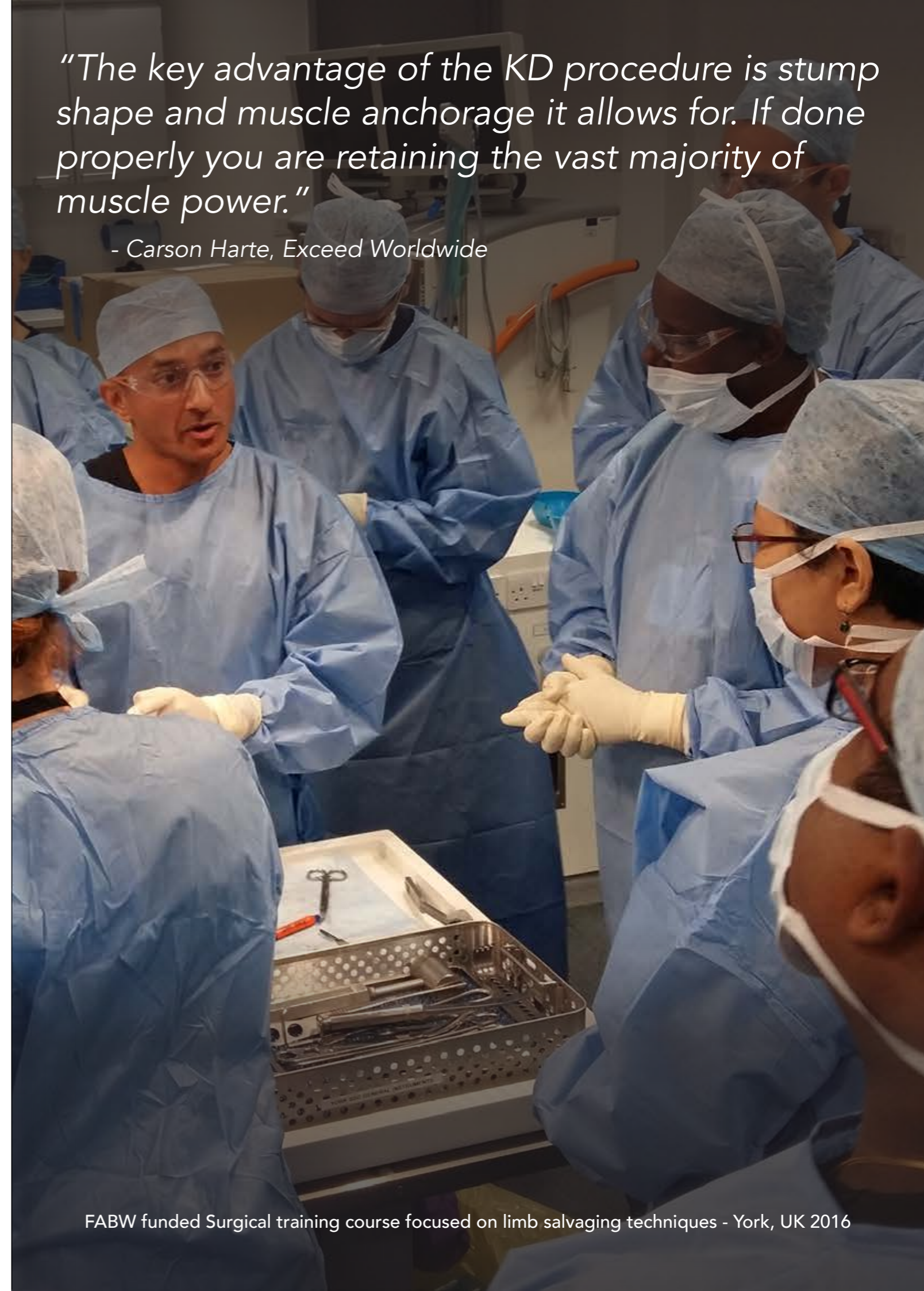
- Simpler surgery
- Retains length, muscle strength, power
- Load bearing distal end
- Self-suspension over bulbous distal end

KD Disadvantages

- Pronounced knee level asymmetry.
- Less sleek / less appealing appearance

Opportunity

Clinical studies reveal that scores used to evaluate the quality of life are significantly higher for KD than TF amputees. However, there is a lack of sustainable, low-cost and functional prosthetic devices specifically focusing on the needs of KD amputees.

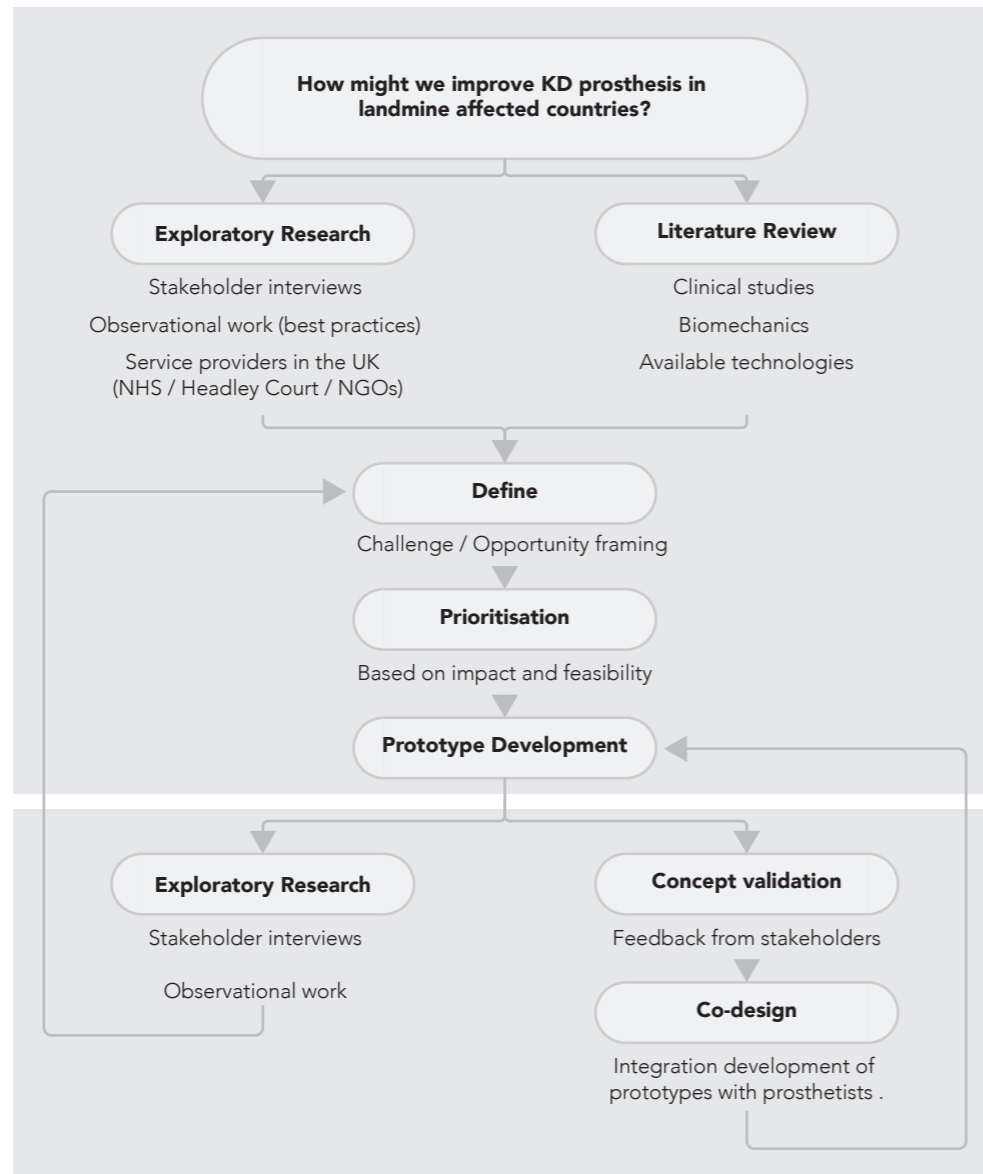


6-month Exploration Strategy

The aim of this project was to understand the needs of the KD amputees and provide them with functional and sustainable prosthetic devices. Over the period of this project, the team were engaged to scope the current situation both in 'modernised' and 'resources restricted' settings before developing novel concepts for KD-focused devices.

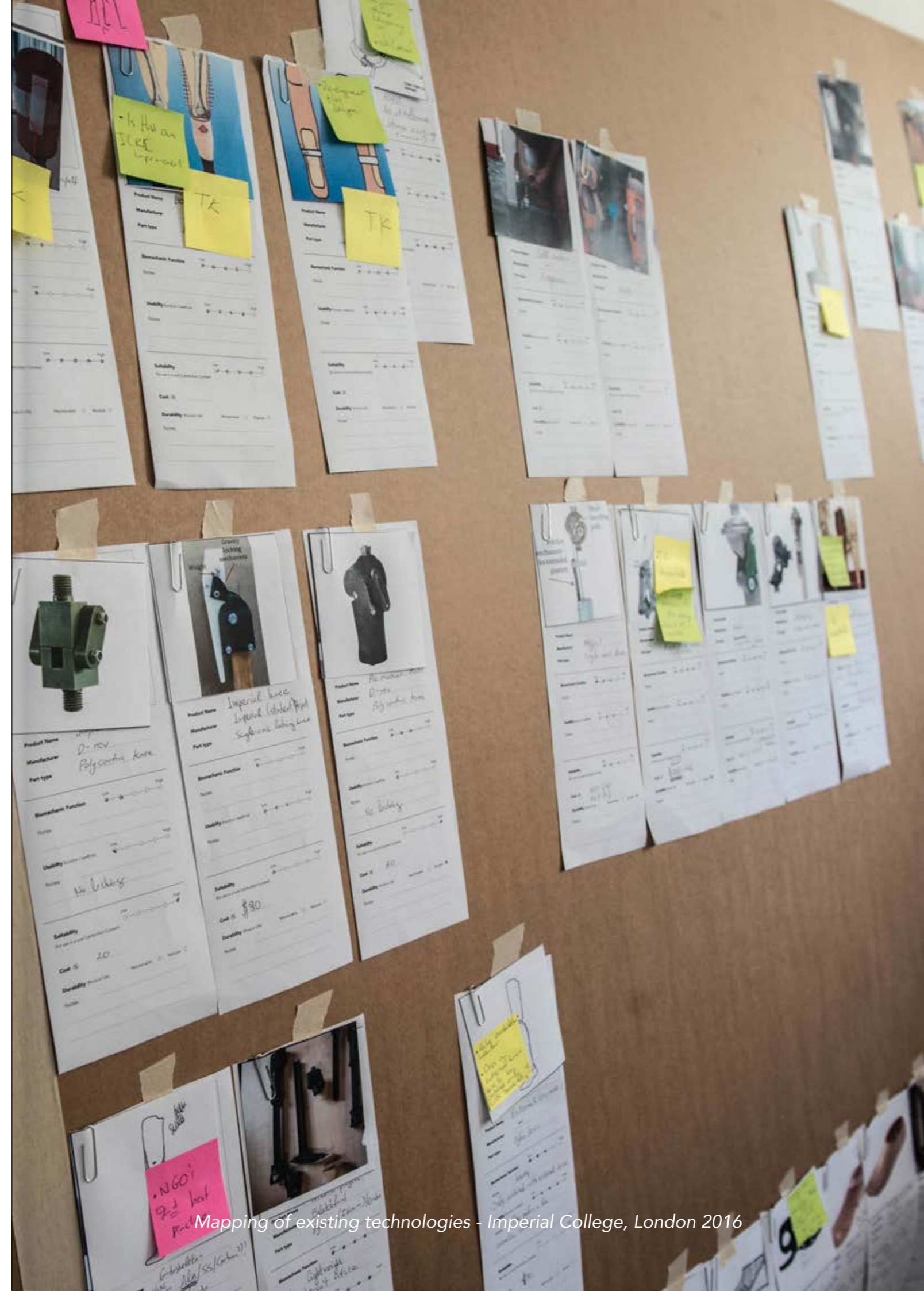
UK

Research and development



Cambodia

Field work



Mapping of existing technologies - Imperial College, London 2016

Exploratory Research

Systemic Analysis

A systemic understanding of the problems surrounding the delivery and use of the prosthesis was developed over the course of the project. Visualised as a map, the collection of research was used to understand individual challenges as part of a larger system. Leverage points, defined as key areas where a change to a process, experience or technology can potentially lead to an improved outcome, were identified and isolated.

From injury to full recovery, the pathway an amputee might follow varies considerably. The various intervening pathways were layered out as a timeline of the patient's recovery based on information from interviews, observational exercises and literature studies.

Touch points with care teams, behavioural patterns, tools and technologies, places and relationships between elements were visualised in the form of flow diagrams, timelines, quotes, objects, costs, and personas.

The map was treated as a living document, updated frequently. All core stakeholders were given an opportunity to contribute to the body of the research including amputees as well as many professionals such as prosthetists and orthotists (P/Os), surgeons, physiotherapists, community workers, psychologists, technicians and NGOs' personnel.



Map of patient pathways - Imperial College, London 2016

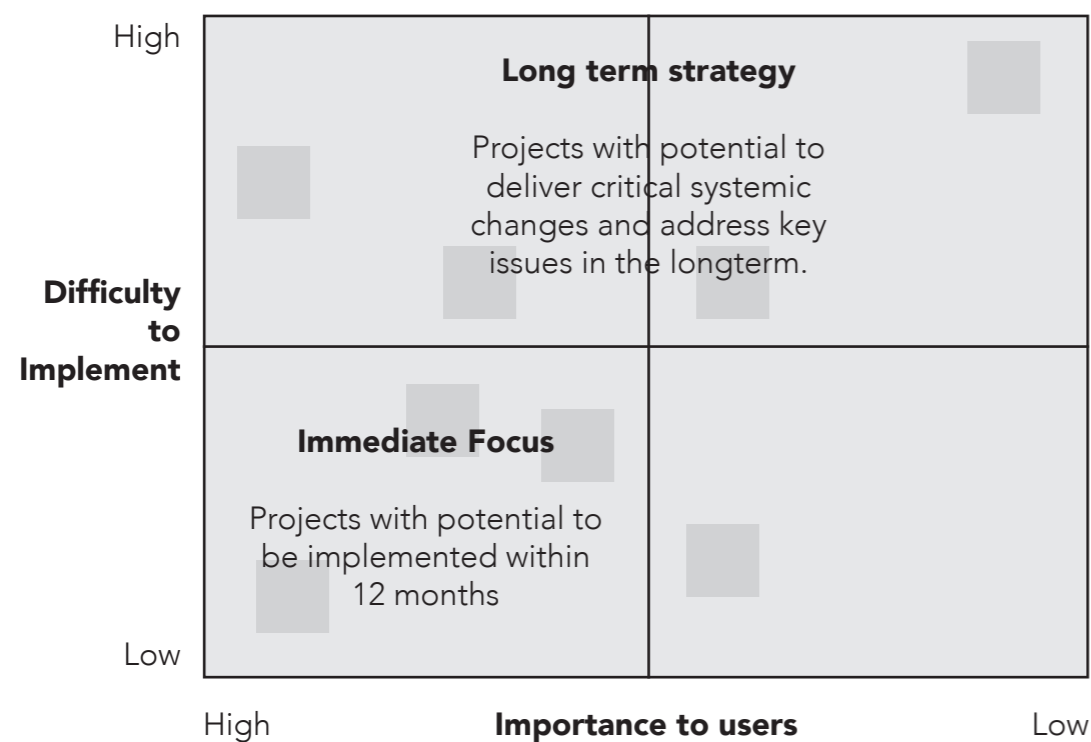
Exploratory Research

Roadmap to impact

Existing solutions and emerging technologies were reported and assessed according to their potential to fulfill the needs of KD amputees. This was performed for each component of the prosthetic device. Cost, appropriateness for the Cambodian context as well as durability were some of the most important assessing criteria.

The parallel analysis of the key findings from the mapping of the systemic pathways and scanning of the available technologies led to the identification of key challenges and relevant opportunities. These potential routes for addressing specific challenges were assessed and prioritised based on their impact to the patient's recovery as well as the difficulty of implementing an intervention.

The exercise was conducted both in the UK and Cambodia. The contextual significance of each opportunity altered their position, sometimes significantly.



Uneven knee symmetry

Challenge
The majority of knee joints on the market cannot be integrated with knee disarticulation prosthesis in a way which maintains good knee level symmetry. The pivot point of the knee has to be positioned lower due to the full length femur, this in turn creates both visual and functional issues for the amputee, sitting in space restricted areas can be problematic as can the short sharp swing though created by the lengthened femur and shortened tibia.

Opportunity
How might we design a low cost knee joint that can provide an even knee level asymmetry for patients with knee disarticulation amputations?

The Cambodian School of Prosthetics and Orthotics

Visit 2016

The Cambodian School of Prosthetics and Orthotics (CSPO), established by Exceed Worldwide, works to deliver high quality, sustainable services that equip, enable and empower persons with disabilities.

Services - Education and Training, Clinical Services, Research Network

Preparation of a positive stump cast - CSPO, Cambodia 2016

Manufacture of the Prosthetic Device

A brief overview of the construction and fitting of the ICRC system for KD amputees

Casting

Three months after surgery amputees can visit CSPO to be measured and cast for the manufacture of their first prosthesis. Prior to this, they should have been instructed by a physiotherapist to perform load bearing and muscle strengthening exercises at home.

Before casting, the P/O takes multiple measurements of the size of both the stump and remaining limb. For KD amputees, casting is performed on a load bearing bench. The P/O applies pressure to the area of the stump above the condyles during casting to ensure good fit and efficient suspension. After setting, the cast is cut vertically and removed.

Rectifying / casting of former

By filling the cast with plaster, the P/O creates a positive mould of the stump. After setting, the outer layer, which is the original cast formed by plaster bandages, is cut and removed. Based on the initial measurements, the P/O refines the positive mould by adding or filing material away.



EVA Foam layer (Suspension)

Suspension and cushioning of the limb within the socket is provided by a layer of EVA foam. The interior shape of the EVA foam is tightly wrapped around the stump while the outer shape is modified to resemble that of a cone or a cylinder to ensure easy donning of the stump with the EVA foam cover into the PP socket.

The EVA foam is stored as flat sheets which are cut to size and glued to a cylindrical form before being heated up and wrapped over the mould of the stump with the aid of elastic bandages.



Polypropylene socket

The PP socket is a subject-specific component which connects the stump to the prosthetic device.

The PP socket is manufactured to tightly fit around the EVA foam layer. The mould, still covered with the EVA foam, is fixed on a vacuum pump which acts as the suction device. After covering the EVA foam with cling film and talcum powder, a 5 mm thick PP sheet is preheated to 350 °C and laid over while it is warm and deformable. The seam of the cast is placed and pinched together towards the posterior side of the socket. While the PP is warm and easy to process, excess material is removed. Talcum powder is added on top to protect the socket from humidity.



Modification of components

The knee joint component of the ICRC prosthesis of KD amputees often requires modification prior to fitting to reduce knee level assymetry; this is described in detail in the following section. The pylon of the device is cut to length based on the measurements taken and a foot is bolted to the distal end.



Bench alignment

Alignment is necessary to ensure the functionality of the final assembly which includes the foot, alignment plates, pylon, knee joint and socket.

Based on feedback from P/Os working at the CSPO, correct bench alignment may count up for up to 80% of the total alignment. The jig suggested to use by the ICRC for bench alignment should replicate the conditions occurring during the casting process and it does when an experienced P/Os and technicians use it.

Experienced P/Os were observed to be able to spot alignment issues quite early, even from the stage of bench alignment and fix them using simple tools, such as plumb lines, for guidance.

Fitting / Dynamic alignment

The amputees are given their new prosthesis to try it while walking with parallel side bars. During this exercise both the amputee as well as the P/O observe, report and discuss issues.

Finishing

The final stage of the construction of the prosthesis involves welding of the ICRC parts and addition of the cosmetic cover. The cosmetic covers are parts made in advance using generic moulds from thin layers of PP or EVA foam, depending on the daily activities of the amputee.



The role of new technologies

The success of the process depends on the training, skills and experience of the P/Os and technicians that work together to deliver a device that will put people up on their feet again. The remarkable raw skills, efficacy and ability of the technicians to accurately align, rectify, and fix the prosthetic devices is at the core of the manufacturing procedure.

Thus, the role of new technologies in addressing challenges in low resource settings should be re-orientated. The focus should not be on de-skilling a complex procedure but **enhancing the abilities of the people who are involved.**



3D scanning of limb - CSPO, Cambodia 2016

Knee joints for KD amputees

The main knee joint mechanisms provided by the ICRC and offered for KD amputees in the CSPO are either the side bar configuration or the TF knee joint, usually shortened.

Both these designs :

- require improvised modifications,
- are time consuming to manufacture,
- lack in functionality, and
- are not KD amputee-centred designs.

Side bar Knee

Side bars are mainly used for knee orthotic devices. When used for KD amputees, they are connected to a heavy and difficult to make exoskeleton (external pylon), while bending of the bars to fit to a bespoke shape is a difficult and time consuming procedure.

Shortened ICRC Knee

The knee joint provided with the ICRC TF kit is commonly used for KD amputees. However, in order to reduce the length of the stump, the knee joint is often shortened (not only for KD but also for TF with long stumps) and the locking mechanism is removed. This modification is both time consuming and removes the ability for the amputee to lock their prosthesis in the stance position.



Side bar setup



Shortened ICRC knee
(No manual lock)

Failure points of the ICRC system

Following discussions with the P/Os and technicians at the CSPO, the most common failure points of the ICRC system were highlighted:

Foot

The rubber on the plantar surface breaks across the central area. This is the most common failure but the component is cheap and easy to replace.

Suspension (TF amputees - not usually incorporated into KD devices)

Pelvic belts used to support and suspend the socket can fail or cause pain / discomfort.

Knee joint (ICRC Single Axis)

The bolt connecting the socket to the knee joint becomes loose and requires tightening. The rubber stops, that decelerate the pylon at the end of the swing phase, wear down and require replacing.

Side bar knee configuration

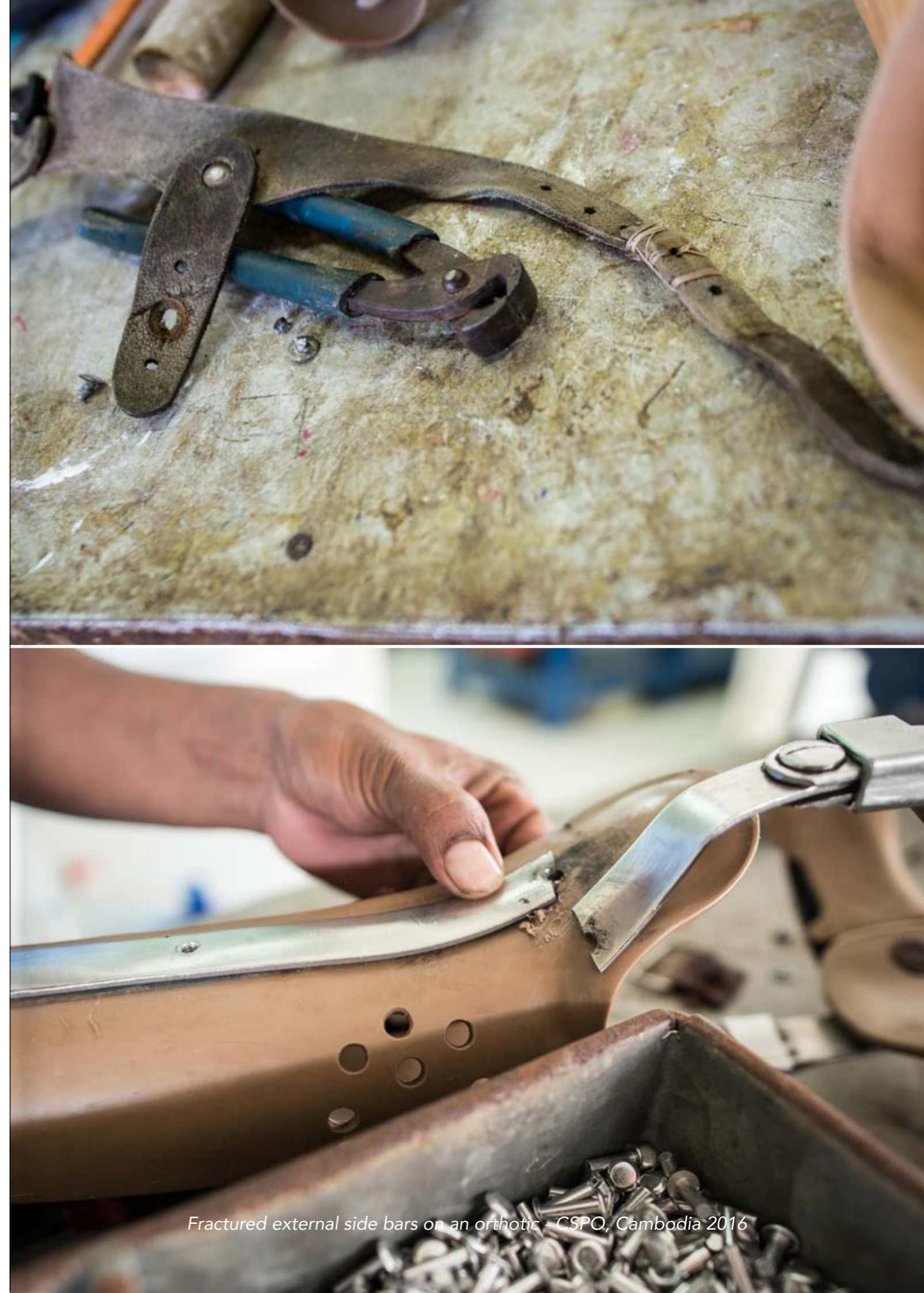
The medial bars fail either at the hinge mechanism or the mounting areas.

Cosmesis

The component can split along the welded seam although this is a rare occurrence.

“There are only two reason why parts do not wear, the component was very well designed for its use or it is not being worn”

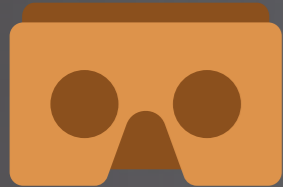
- Carson Harte, Exceed Worldwide



Fractured external side bars on an orthotic - CSPO, Cambodia 2016

Cambodian Context

Community Visits
Key Insights / Challenges



360 image for viewing in virtual reality

Community visits in Phnom Penh and Kampong Chhnang



Cambodia

Our visit to Cambodia was conducted in September 2016 during the wet season which lasts from May to October. For the month of September, the average rainfall in Phnom Penh, the capital of Cambodia, is 250 mm. During the wet season, CSPO expects to receive up to 3 times more amputees due to road traffic accidents.

Approximately 20% of the population lives in an urban environment; this figure is expected to double by 2030.

97% of the population are Buddhists and 1.9% Muslims.

Physicians and hospital bed density are estimated to be less than 0.2 and 1 per 1000 inhabitants, respectively.

Challenge Areas

Determined through discussions with P/Os and amputees.

- Stability of Knee joint
- Pain
- Prosthesis for Children
- Mental Health / Psychological support
- Knee flexibility



Travel during the wet season - Phnom Penh , Cambodia 2016

Stability of Knee joint

"I don't feel confident to go to the rice paddies without the knee being locked. When it is locked I can carry weights up to 20 kg"

- Vatey

Challenge

Stability is a feature that all the amputees we interviewed claimed to be missing from the solutions currently provided. Lack of stability determines the functionality of the device, especially when used for work-related activities. Stability issues are mainly observed when amputees:

- walk in a fast pace,
- walk on uneven ground,
- walk through mud or water,
- squat, or
- carry heavy objects.

Current state

Amputees compensate for the lack of stability by locking the knee joint in the extended position or removing the prosthesis when attempting to do the activities listed above. This is not achievable for KD amputees using adapted ICRC components where the locking function has been removed.



Vatey - 46

Farmer in Kampong
Chhnang

Injured by a landmine while
farming 26 years ago

TF amputee

Stability is the most critical feature of the prosthetic device for Vatey; the knee of her current ICRC device does not feel stable, especially when carrying harvests or walking through water in the rice paddies. Thus, she keeps the knee locked all the time.

Vatey switches between two devices based on the colour of the prosthetic foot. The old-dated device, although less stable and comfortable than the latest, was the device of choice when it comes to attending social events due to the more natural cosmesis.

Knee flexibility

"I don't attend ceremonies as my device does not allow me to sit respectfully. This makes it hard to socialise."

- Kou

Challenge

The seated posture of Cambodians in case of religious or social events is specific for males and females and reflects their respect. This is mainly the cross-legged sitting pose for males and a sitting posture with both knees flexed and set aside for females,. Both postures require the internal/external rotation of the upper part of the lower limb. Amputees fitted with the ICRC prosthetic devices:

- cannot reach a respectful seated posture,
- cannot visit pagodas,
- avoid attending other religious and social events because of their fear that their body stature will be miss-understood as impolite, and
- become isolated.

Knee flexibility is also essential for kneeling and squatting. Amputees working as mechanics currently are not able to kneel on and be supported by the ICRC prosthetic knee.

Current state

In cases where it is not possible to adjust their surrounding environment to perform any of the above tasks (i.e. mount bikes higher for repairing), the amputees remove the prosthetic limb. Another way they currently deal with the limited flexibility of the provided prosthetic knees is to minimise the amount of social or religious ceremonies they attend and therefore become more isolated.



Kou - 57

Bike mechanic and farmer from Kampong Chhnang

Injured by a landmine in a demining operation 32 years ago

TF amputee

One of the major alterations Kou would like to see in a new prosthesis is the ability of the knee joint to fold or bend to the side and allow him to sit with his legs on the side.

Kou faces great difficulty squatting and walking up stairs. He lives with his family in a raised house on stilts but most nights he sleeps on a makeshift bed outside due to the challenge of climbing stairs.

Prostheses for Children

“Children would look down on him. But since he was fitted with the prosthesis they come and play.”

- Mother of child amputee

Challenge

The current ICRC prosthetic devices are not able to fit in sockets of small sizes such as that of the limb of a less than 5-year old amputee. Although there is a smaller size of the ICRC TF knee joint available, it is not small enough to be fitted in all cases of child amputees. In cases where the knee joint cannot be fitted, a rigid, non-articulating limb is manufactured. However, such a solution has negative or questionable effect on the:

- daily activities,
- rehabilitation, physiotherapy and clinical recovery, and
- psychological recovery of the amputee.

Another important aspect for young amputees is their engagement with the prosthesis. A different cosmesis could heavily affect the sentimental connection of child amputees with their prosthesis.

Current state

A rigid limb without a knee component is fitted to kids until the shape of the stump is big enough to fit the small ICRC prosthetic knee component.



Vannak - 5

Pupil in
Kampong Chhnang

Injured in a road traffic
accident 1 year ago

KD amputee

Vannak has worn a rigid, straight prosthesis since his amputation. His mother feels he needs to be fitted with a knee so that he can play and socialise more easily with other children.

Vannak's mother also discussed the challenges of caring for a child amputee, a demanding responsibility that has replaced her full-time job.

Mental Health / Psychological support

“Before the surgery I asked the surgeon not to let me wake up.”

- Keo

Challenge

Psychological recovery is essential in retaining functionality as it heavily affects the determination of the amputees to practice and succeed in using their prosthetic devices.

The main fears the amputees face and can lead to their psychological breakdown are:

- the opinion of other people about them and how they will treat them (stigma),
- how will they be able to support themselves and provide for their family,
- becoming a burden for their family, or
- losing their ability to support themselves as they grow up.

It was highlighted by many amputees that a difficult but critical part of their journey to recovery was the stage of realisation that by practicing and learning how to use the prosthesis they can retrieve functionality. For this purpose, the amputees should be shown successful cases of other amputees who are able to support themselves, return to their jobs, and provide for their families.

Current state

Amputees are mainly psychologically supported by their family and some limited community-based services provided usually by NGOs.



Keo 26

Bike mechanic in
Phnom Penh

Injured in a road traffic
accident 2 years ago

TF amputee

Keo experienced feelings of hopelessness in the early stages of his treatment. He feared for the impact the loss of a limb would have on his life and the burden he would put on his family. By exercising extensively with his new device he managed to regain functionality and start his own bike repair business. Keo believes exposure to stories of amputees who managed to succeed in finding a job and providing for their families would be beneficial for his wellbeing and recovery.

Pain

“I can spend up to two hours cutting grass in the fields to then feed my cows. But cannot walk long distances if I am carrying something.”

- Kou

Challenge

Pain and discomfort have been voiced as the major challenges faced by UK amputees in their daily life. Prior to conducting field work in Cambodia, this was prioritised as an emerging area that requires immediate improvement.

Amputees in Cambodia did not report issues of pain and discomfort on a similar scale. They occasionally experience pain, often after carrying heavy items and due to prolonged periods of standing or walking.

Although in the UK pain and discomfort are mainly associated with limb volume fluctuation and heat, respectively, in Cambodia pain is related to ineffective suspension systems, especially for TF amputees and the pelvic belts provided for them by the ICRC prosthesis. In another occasion, barefoot walking was also reported as painful due to the high stiffness of the solid ankle cushion heel (SACH) foot and its inability to absorb shock.

Current state

Amputees commonly use talcum powder to prevent skin abrasion. Pains caused by physical activity are dealt with by removing the prosthetic device for a period of time.



Kosal - 53

Tuk Tuk driver in
Kampong Chhnang

Injured by a landmine in a
demining operation 20
years ago

Knee Disarticulation
Amputee (KD)

The first time Kosal came to the CSPO and received his prosthetic he didn't want to use it due to pain. A year later he revisited to get a second one. He is currently very confident with his device which seems to be a very successful prosthesis. He mentioned that this wasn't the case at all in the past; he wasn't using his device until he realised the potential behind making the prosthesis functional. A lot of practice was needed to reach that point. Kosal's latest device has a modified ICRC knee, fitted directly under the socket. The locking mechanism was removed but he doesn't mind; he prefers to walk freely.

Summary

Key areas for further investigation

Knee level asymmetry of KD amputees is not only a cosmetic issue, having an impact on perception in society, but also functional.

Stability is critical and heavily determines functionality, especially when the the device is used for work related activities.

Free swinging knees. Walking through water, fast or over long distances with free swinging knees can be challenging as the shank does not return fast enough to the extended posture.

Keeping the knee in the locked state is the preferred configuration by amputees who do not feel confident while using their device.

The cosmetic outcome becomes a priority after functionality issues are addressed.

Sitting with legs crossed, squatting, and kneeling are postures constrained by the ICRC knee mechanism.

Knee joints for young children are not provided by the ICRC; adjustable/bespoke ICRC knee components are required.

Psychological support is an essential need for the amputees that can determine the success of the prosthesis.

Stigma is still faced by the amputees especially in the big cities.

“The ICRC system is often all that is available, normally free. It’s a first hit, a crisis limb”

- John Ross, Blatchford



Soc - 26

Farmer in Phnom Penh

Leg amputee due to a developmental problem 21 years ago

KD Amputee

Soc lives in a village with his family. Uneven paths and flooding through the village cause stability issues while walking; he has fallen whilst carrying heavy objects. When the village is flooded he locks his knee otherwise the water pushes back the shank of the device making walking difficult.

Soc finds climbing up stairs hard, but even harder without his prosthesis. The size of the socket is long making it difficult for him to ride a bicycle or kneel when praying.

A man in a light blue button-down shirt is working in a workshop. He is leaning over a prosthetic limb, which is mounted on a wooden form. He is using a yellow tape measure to measure the limb. He is also holding a metal tool, possibly a caliper or a similar measuring device, against the limb. The background shows a workshop environment with various tools and equipment.

On site Prototyping*

Focus

- Stability
- Knee Level Asymmetry
- Suspension

* Patent pending

External knee joint*

Technology to address knee level asymmetry

***Patent pending**

A prototype of an external knee joint was developed to:

- reduce the knee level asymmetry introduced by single axis joint such as the ICRC TF knee joint,
- reduce the width of external joint such as the ICRC side bar mechanism,
- ensure stability by integrating an improved knee joint locking mechanism and achieving natural force transmission,
- improve functionality by achieving smooth knee rotation,
- increase durability by using components more appropriate to the environmental conditions.

The prototype knee joint was constructed from 3D printed and machined metal components and included inexpensive machine elements used in bicycles, easy to find in Cambodia. Designed as a modular system the prototype rig accommodates a range of stump sizes and can be fully incorporated into the ICRC lower limb device.



Comparison of knee level symmetry - Phnom Penh, Cambodia 2016

External knee joint Integration to the PP socket and single trial

The prototype was successfully tested on an amputee and was found to achieve all the objectives set above. More specifically, the amputee and the prosthetist commented on the capability of the prototype to :

- eliminate knee level asymmetry,
- provide stability due to its auto-locking mechanism,
- achieve a direct load transfer from the shank to the socket (potentially reduced wear on the bearings,
- provide compliance to the limb that is missing due to the increased rigidity of the prosthetic foot commonly used.

The integration and alignment of the prototype to the socket was achieved in collaboration with the technicians and the P/Os of the CSPO. Based on their feedback, the prototype was found to be easy to align and connect to the PP socket.

As this was were a prototype, future improvements regard finalising the design and incorporating other features highlighted as necessary by P/Os and amputees. The design will undergo further iterations improving its strength by mechanical testing structural analysis and finally selecting the appropriate materials for the knee joint.



Feedback / testing - Phnom Penh, Cambodia 2016

Knee Rails

Technology to address knee level asymmetry

Potential

Integration of sliding components and guiding rails is another method to reduce knee level asymmetry between limbs of KD amputees. Knee rail prototypes were developed but not to the required level to trial them with amputees or to get detailed feedback. Such a design has the potential to combine all the advantages of an external knee design with the additional benefit of a compact mediolateral width, an essential feature for facilitating getting dressed. However, such a mechanism is more complicated and bulky than a device mounted externally.

Considerations for future development

- High complexity of the mechanism
- Bulky mechanism

Based on the above limitations and preliminary feedback we collected, further development should be considered in case that the compact mediolateral width is an essential need not covered by externally mounted devices.



Prototype rail knee joint intergration - Phnom Penh, Cambodia 2016

Woven Suspension

Technology to provide better suspension

Potential

Braided tubes have the ability to apply high radial pressure when pulled in the direction of their long axis. Braided fabrics incorporated to the socket of a prosthesis can ensure distribution of the pressure over the stump and thus, efficient and painless suspension.

Considerations for future development

- Effect on health of the skin due to shear forces and nature of the fabrics
- Complexity in applying a tensile force along the long axis of the braided tube
- Challenging to integrate with other materials or add features

Based on the above limitations, the potential of such a design concept can be assessed if a braided structure in the form of a liner that can be easily pulled is produced and tested on an amputee. The benefits of this design seem promising for TF amputees who face great difficulties with suspending their prosthetic device.



Split Socket

Technology to provide better suspension

Potential

The idea of optimising the socket design by removing excess material and retaining only the areas that are necessary for supporting the stump is the current direction of high-end technologies in the field. Such a 'socket-less' design incorporates elements of rigidity and flexibility to the socket and therefore provides stability and functionality and so at the same time it can address challenges as discomfort due to heat build up and limb volume fluctuation.

Considerations for future development

Whilst limb volume fluctuation as well as discomfort due to heat were prioritised as top challenges faced by UK amputees, this is not the case in the Cambodian context. The feedback we collected indicates that these problems are acknowledged but not by many amputees and was not prioritised first as there are more essential needs not covered by the devices currently provided. Other considerations include:

- complexity of implementing features that allow the mounting of separate parts to the PP socket,
- limited blood circulation and, therefore, non-healthy stump as amputees tend to tighten up the parts of the socket more than needed for security and confidence,
- increased cost of implementing sophisticated parts to address the above limitations.



Sketch modelling - Imperial College, London 2016

Local manufacturing

CSPO sources most of its components and materials locally. The sustainable setup offers better value for money than importing, good communication between the factory and clinic and the adaptability to quickly adjust supply to meet demand. The cooperation between consumers and providers also permits the adjustment of several products to the needs of the end users; over the past years a couple of innovative ideas were developed and reached the stage of prototyping in collaboration with both factories.

Using the infrastructure which already exists in the country is essential for developing and providing new technologies; apart from the reasons mentioned above, the high motivation of the locals to contribute to their society also promotes sustainability.

ICRC factory

The ICRC components used by the CSPO are provided by the local ICRC factory which has the capability to produce all parts and materials needed for any ICRC prosthetic and orthotic device. Recently the factory attempted to develop a basic free swinging knee joint that fits directly under the socket to reduce the time needed for shortening the TF ICRC knee joint for KD amputees.

SACH foot factory

The prosthetic feet used by the CSPO are manufactured in a local factory which has managed to get a good reputation over the years due to the durability of its products. Therefore, the feet produced by the factory are also exported to other countries.



ICRC factory - Phnom Penh, Cambodia 2016



SACH foot factory - Phnom Penh, Cambodia 2016

Roadmap and Vision

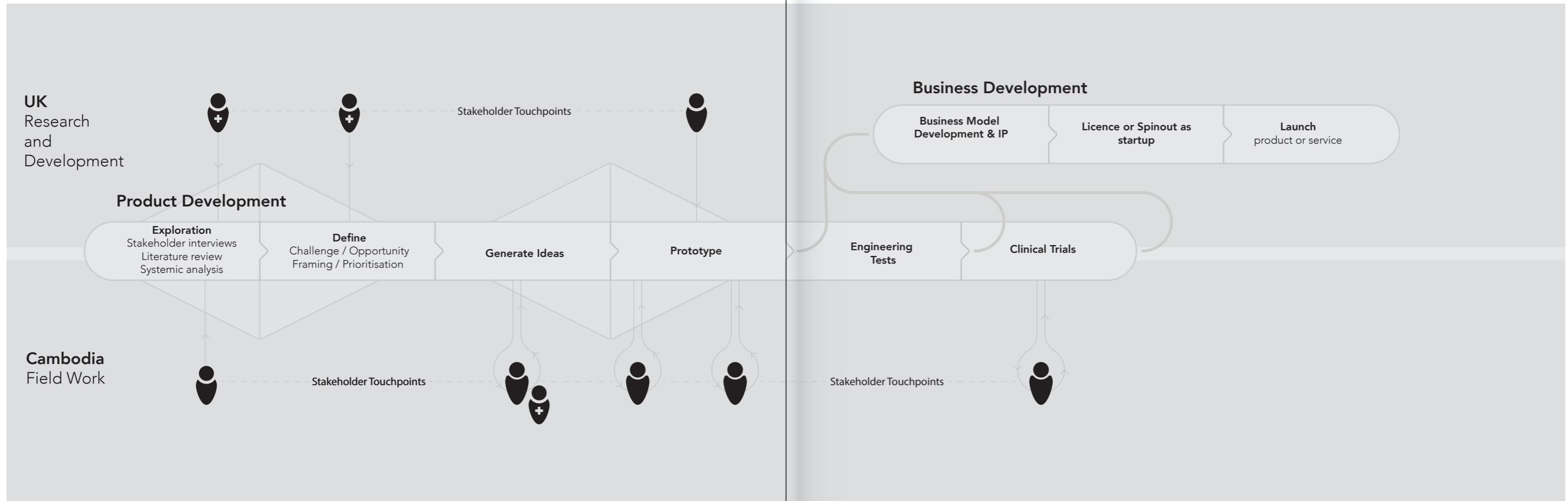
Route to market and additional areas of focus.



Project Road

The main outcome of the 6 month exploration is an early stage prototype knee joint for KD amputees. In addition, a number of opportunities were identified during field work which would improve the quality of life of the amputee. The various projects fit in different stages of the road map below and cover different aspects of our long term strategy.

Long term strategy / Project pipeline



Opportunities for idea generation

Swing Control

Mechanism returning the knee joint to the extended posture at manually adjustable rates.

Knee Flexibility

Ability of the knee joint to bend sideways and adopt a cross-legged posture.

Knee Stability

Better suspension for TF amputees and improved locking mechanisms.

Prototypes in development

External knee joint

'Proof of concept' prototype with improved stability, auto-locking mechanism and eliminated knee level asymmetry.

Longterm Outcome

Modular components

Various modular components compatible with the existing solutions provided by ICRC and other conventional prosthetics.

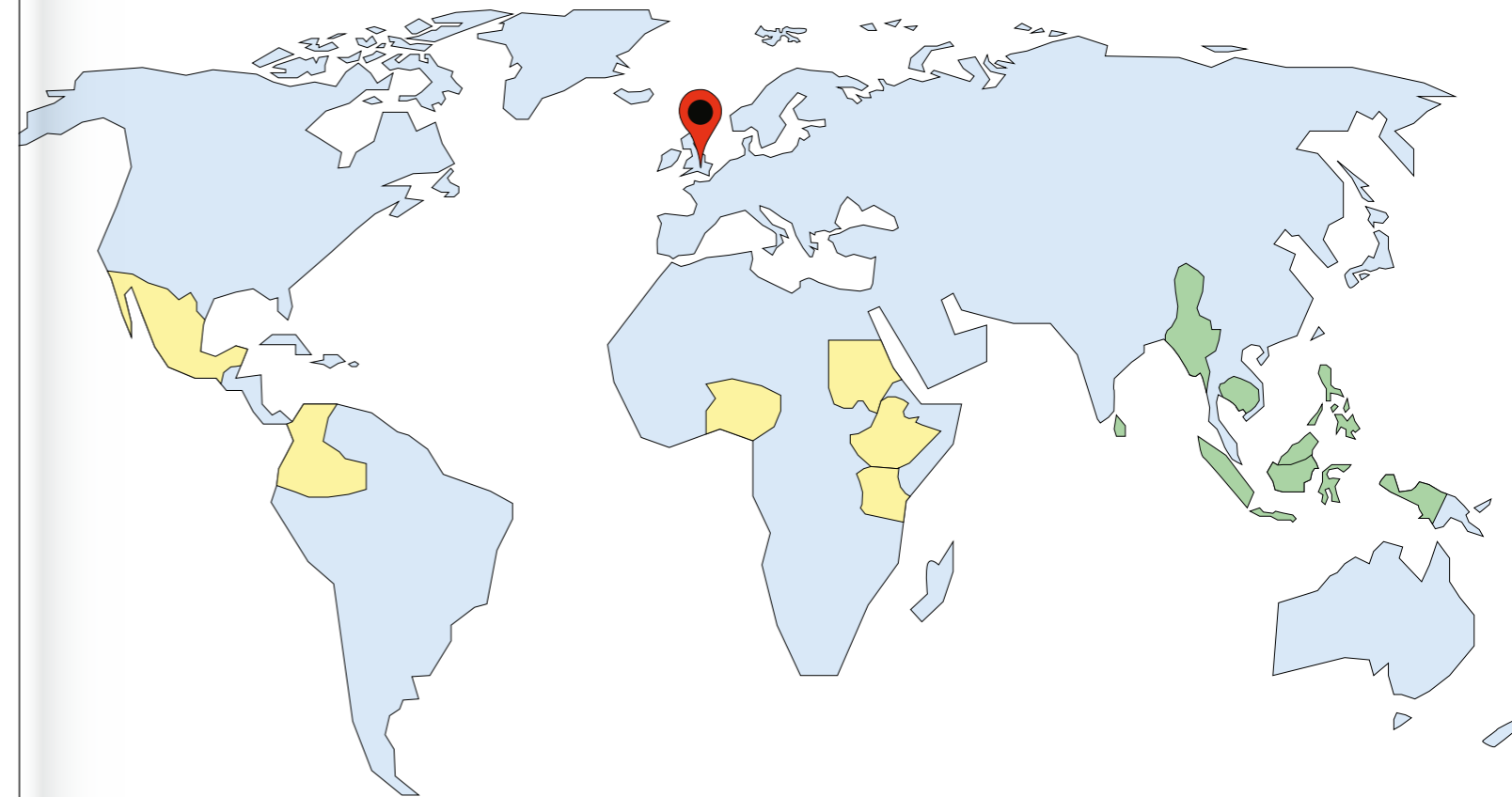
Exploration of challenges in different contexts

Working alongside amputees and care teams in Cambodia put us in a position to understand the criticality of the challenges and prioritise the needs that should be addressed. While the major challenges faced by amputees in Cambodia, as presented in this report, are mainly focused on functionality, the top challenges faced by UK amputees regard discomfort issues caused predominantly due to heat build up and limb volume fluctuation. A possible explanation of the above discrepancy would be that functionality is the essential criterion for the performance of a prosthesis. Once this is successfully addressed, other issues will come up as top priorities, including discomfort.

These observations would have been impossible without working and researching in the field. Climate, cultural norms, roles in the working environment and stigma are amongst the factors which may change the way technologies are applied in different settings. A product developed without spending time in the field where it is targeted for distribution might lead to the production of a prosthetic device addressing needs that are irrelevant to the end users.

Preliminary research of the Myanmar context based on interviews with some CSPO employees who have worked there shows a greater proportion of KD amputees than in Cambodia who face different challenges due to dissimilarities in patient demographics, causes of amputation, material supplies and socio-political environment.

The effect of the field work on the success of this project highly suggests that further field work should be conducted in other warfare affected countries such as Myanmar, Sudan, and Colombia to expose the different needs and address the challenges in a global perspective.



Imperial College London



Exceed Worldwide



ICRC Surgeons

Attendees of the surgical course focusing on new limb-salvage techniques

Wider relevance of work

Developing solutions in and for resource restricted contexts draws on creativity to find solutions to tackle real problems.

Reverse innovation

Reverse innovation might be defined as the potential of solutions developed in a resource restricted context to offer cost, durability or efficiency savings in multiple other markets.

Technology produced for the Cambodian context can be translational for other less constrained settings. Solutions developed in resource restricted areas can offer value in multiple markets and therefore be incorporated into business strategies to help scale the uptake of the product or service. Taking into consideration the current need of healthcare systems of many developed societies to reduce costs and become sustainable without limiting the quality of the services offered, projects similar to this one can offer a great insight and identify pathways for future research and development.



Positive limb casts / plaster moulds - Charing Cross Hospital, London 2016

Acronyms

CSPO / The Cambodian School of Prosthetics and orthotics

EVA / Ethylene-vinyl acetate foam

ICRC / International Committee of the Red Cross

KD / Knee disarticulation

NGO / Non government organisation

NHS / National Health Service

P/O / Prosthetist Orthotist

PP / Polypropylene

SACH / Solid Ankle Cushion Heel

TF / Transfemoral

TT / Transtibial



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