Research and Studies
Scientific summary

Pilot Testing of 3D Printing Technology for Transtibial Prosthesis in Complex Contexts (Togo, Madagascar and Syria)

Operations and Technical Resources Division
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PROTEOR prosfit University of Strathclyde Glasgow HANDICAP INTERNATIONAL

Authors
Jérôme CANICAVE (Consultant – 3D projects)
Danielle TAN (Handicap International, Studies and Research Coordinator)

Contributors
Anna BOISGILLOT(Handicap International, Health economist, Technical Rehabilitation Unit)
Roy BOWERS (University of Strathclyde, National Centre for Prosthetics and Orthotics, Department of Biomedical Engineering)
Alan HUTCHISON (ProsFit Technologies, CEO)
Krasimir NIKOLOV (ProsFit Technologies, Research & Development Engineer)

Editor
Handicap International / Operations and Technical Resources Division

Layout
Stéphanie DEYGAS / Handicap International / Innovation and Knowledge Management Unit

The other organisations involved in the study:

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1. Study context

Innovation in physical rehabilitation within complex contexts: Togo, Madagascar, and Syria

The development of new technologies such as Computer-Aided Design/ Computer-Aided Manufacturing (CAD/CAM) System, 3D printing in biosciences, Information and Communication Technologies (ICT), and telemedicine, has opened ground-breaking approaches for providing health services. However, those new technologies are not accessible to low-income countries or in war and emergency contexts. According to the World Health Organization (WHO), "In many low-income and middle-income countries, **only 5%-15% of people who require assistive devices and technologies have access to them.** Production is low and often of limited quality. There is a scarcity of personnel trained to manage the provision of such devices and technologies, especially at provincial and district levels. In many settings where access might be possible, costs are prohibitive" [1].

Innovation is part of Handicap International's 10-year strategy (2016-2025).

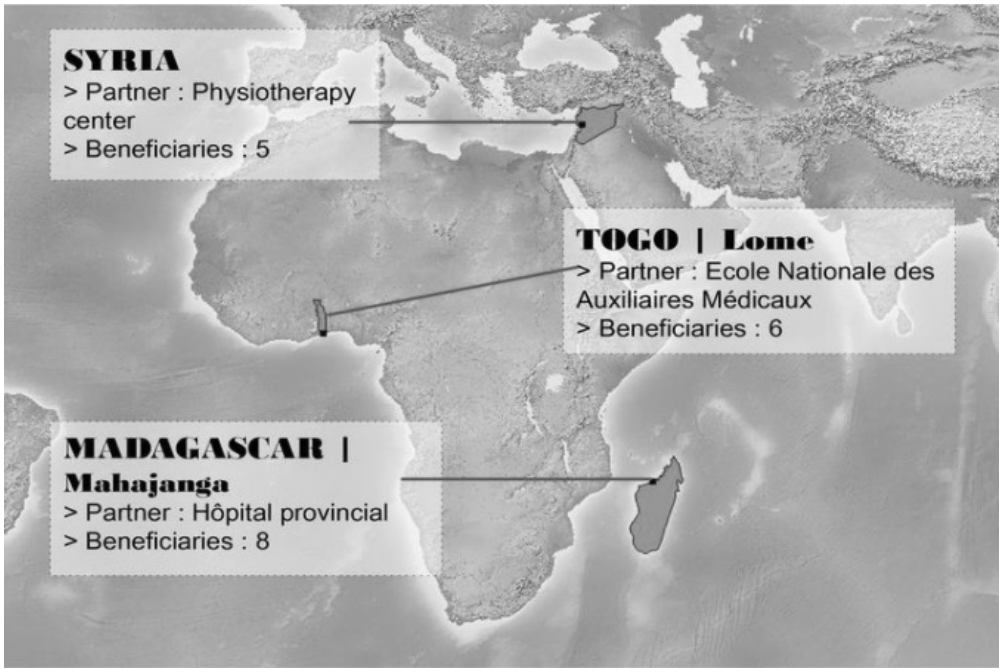
The organisation is involved in physical rehabilitation within complex contexts. In January-October 2016, Handicap International carried out **a pilot testing of 3D printing technology for transtibial prosthesis in Togo, Madagascar and Syria.** In war-torn Syria, the security situation prevents Handicap International from carrying out operations in situ. Prostheses are therefore delivered from neighbouring countries. Local partners have to deal with rudimentary and temporary facilities due to the volatile situation, complicated logistics, as well as a lack of qualified human resources to provide a full range of rehabilitation services. While in Togo and Madagascar, these developing countries lack decentralised services and qualified human resources to meet the need for physical rehabilitation, but they also face challenges in having access to appropriate technologies.

The hypothesis is that the new processes introduced by 3D printing technology should allow:

- The **delocalisation of competencies** outside the zones of conflict or the zones which are hardly accessible.
- The **delocalisation of orthopaedic devices production infrastructures** outside the difficult areas.
- The **simplification in logistics processes** by sending manufactured items instead of raw materials.

[1] World Health Organization. Assistive devices/technologies: What WHO is doing?

Figure 1 - Countries of intervention



2. Objectives of the study

2.1. Overall objective of the study

The aim of the study is to explore and test how physical rehabilitation services can be more accessible to people living in complex contexts via innovative technologies (such as 3D printing, treatment processes that use Internet technology and tools) and decentralised services by bringing them closer to the patients.

2.2 Specific objectives of the study

- To establish new intervention methods in the field of physical rehabilitation
- To evaluate the benefits and the limits of using innovative 3D printing technology for transtibial prostheses by looking at clinical, technological and organisational aspects of the rehabilitation, and in two different contexts: in low-income countries (Togo and Madagascar) and in situation of armed conflict (Syria).

3. Methodology

3.1. Design of the study

Partners

The project brought together a full team of experts, including rehabilitation clinicians, academics and industrials. In partnership with the University of Strathclyde and two industrial companies – ProsFit Technologies and Proteor SAS – Handicap International conducted a study which aimed at establishing new intervention methods in the field of physical rehabilitation by using 3D technology printing:

- ProsFit Technologies JSC[2], an international company based in Bulgaria, was in charge of the technical aspects for the entire socket design and 3D printing process, from measurement to manufacturing;
- Proteor SAS, a French company, was in charge of the provision of the necessary components;
- University of Strathclyde (Scotland, UK), via its Biomechanical Engineering Department, was responsible for the methodological oversight of the study.

Human resources involved in the project

- A Prosthetist from Handicap International's Technical Resources Division – Rehabilitation Unit, Project Manager;
- A research team from the University of Strathclyde;
- A Prosthetics and Orthotics (P&O) expert contracted by the University of Strathclyde;
- A technical team from ProsFit Technologies;
- A clinical team at the three study sites.

3D printing technology

A 3D printed object is produced by creating an additive process (successive layers of material until the object is created). The process starts with a virtual design of the object to be created.

[2] Cf. www.prosfit.com

The design is created by using a 3D scanner that makes a 3D digital copy of an object and creates a CAD (Computer-Aided Design) file.

Then, modelling software can be used to make changes or adaptations to the object in the CAD file. Once the 3D model is corrected, the next step is to prepare it to be 3D printable. It can be done via a USB cable, an SD card, or Internet network. The printing will depend on the type of the 3D printer being used. Once a file is uploaded to the 3D printer, the object is ready to be 3D printed, layer by layer: it is called additive technology. The 3D printer reads every slice (2D image) and creates a three dimensional object.

Equipment/Infrastructure

- A 3D scanner and ProsFit's PandoFit rectification software;
- A 3D printer;
- Components for 24 transtibial prostheses;
- A functional rehabilitation service at the three study sites.

Clinical testing

The study was conducted in several stages over a ten-month period (January-October 2016):

- Identification and social and clinical evaluation of patients already equipped with transtibial prosthetics: eight patients at each of the three study sites;
- Measurement/scan of the residual limb and rectification of the positive;
- Manufacture and assembly of prosthetics components;
- Onsite fitting and delivery.

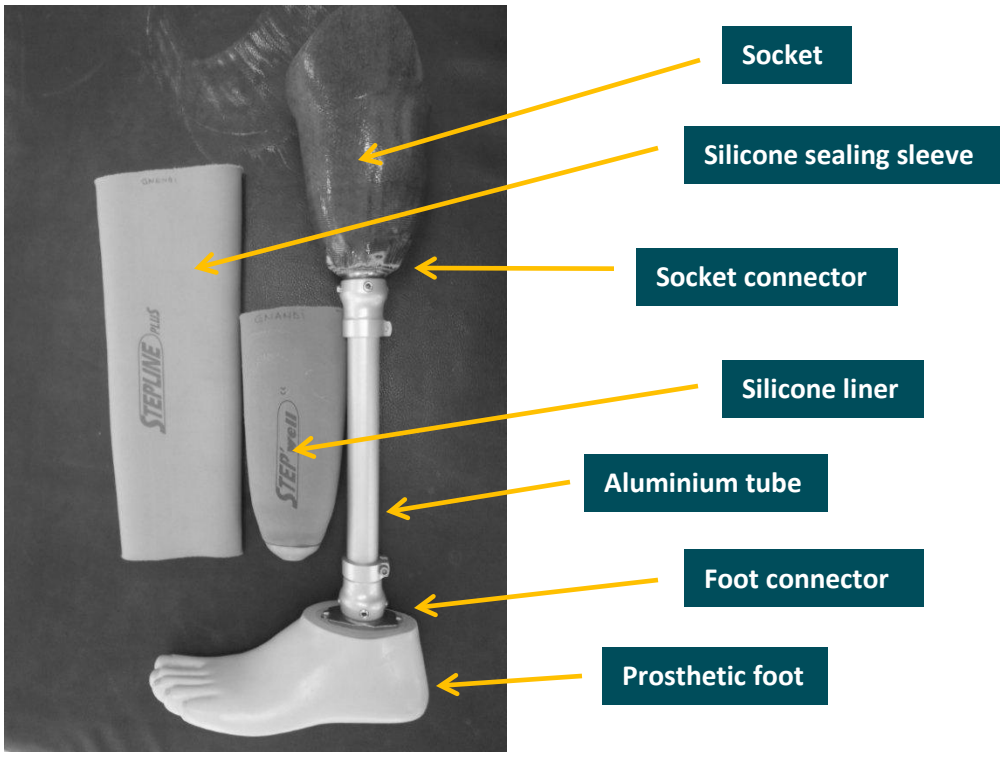
The study protocol entailed comparing the fitting of patients with conventional vs. 3D printed transtibial prostheses.

Clinical testing was done on 19 transtibial amputation patients in three different countries (Togo, Madagascar, and Syria). The patients were randomly assigned to one of two groups:

- Test group: patients receiving a 3D printed socket;
- Control group: patients receiving a socket manufactured by the local partner.

Both the test and the control groups were fitted with a silicone liner.

Figure 2 - Description of a transtibial prosthesis



Three components were evaluated

1. **Technological:** 3D socket compatibility with the mechanical and adaptability requirements (ISO tests)
2. **Clinical:** New process in conformity with the rules of clinical protocols; improvement of performance, adaptability, durability, and comfort; standardized tests (TUG[3], SCS[4])
3. **Organisational:** Benefits in terms of adequacy with patients' expectations and needs, costs, logistics, infrastructures and equipment.

Assessing these three aspects is essential to developing future projects, so that we can improve on any weaknesses in the process and expand it to other pathologies, devices and participants.

[3] Cf. Appendix 5: Timed Up & Go.

[4] Hanspal RS, Fisher K, and Nieveen R. Prosthetic socket fit comfort score, in Disabil Rehabil, 2003, 25(22): 1278-80.

3.2. Location

Key rehabilitation actors at the three study sites

1. **A school for rehabilitation professionals (Ecole Nationale des Auxiliaires Médicaux – ENAM) in Lomé, capital city of Togo**

ENAM is a national institution established more than 40 years ago that offers several educational programmes for allied health professionals, including P&O. The school is located next to the national centre for physical rehabilitation (CNAO), which provides practical and clinical internships for the students. The school teaches all types of technologies for almost all pathologies.

At the CNAO, they use conventional, plastic and modular components. The school's lecturers and the CNAO professionals are well-versed in the subject of lower limb prostheses. Its infrastructure and equipment allow provision of transtibial prostheses using lamination and thermoforming processes.

A comprehensive protocol for fitting these devices is available; there is a clinical evaluation room, a casting/measurement room, a workshop for rectifying the positive and assembling the prosthesis, and a fitting and gait training area.

The human resources involved in the project include five P&O lecturers from the school and a CNAO physiotherapist. The centre, which is located in the capital, is accessible and well known to users. The devices are affordable for most of the population; the technology used is adapted to the patients' overall situation.

This partner was considered experienced and capable of working with all types of technologies for all of the pathologies for which orthopaedic devices are needed.

Figure 3 - Presentation of the new 3D printing process to the patients and P&O professionals in Lomé

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2. A decentralised physical rehabilitation service (Service d'Appareillage et de Rééducation – SAR) in Mahajanga Provincial Hospital, Madagascar

The city of Mahajanga (Mahajanga I) is the capital of the Boeny region in the north western part of the country and the second largest sea port in Madagascar. It is about ten hours by car from the capital, Antananarivo.

Medical centres, dispensaries and hospitals are found throughout the island, although they are concentrated in urban areas and particularly in Antananarivo. Access to medical care remains beyond the reach of many Malagasy, especially in the rural areas, and many of them have recourse to traditional healers.

A 2003 Ministry of Health census estimated the percentage of people with disabilities at 7.8% of the total population, and one in five people is in need of an orthopaedic device. In the Boeny region in particular, there are 23,094 people living with a functional disability and 4,116 people who need an orthopaedic device.

The SAR is located in Mahajanga Provincial Hospital. The SAR is a government rehabilitation centre, established in 1990 with Handicap International support. It provides physiotherapy and prosthetics and orthotics. A PM&R (Physical Medical and Rehabilitation) physician is in charge of the centre, and there are four physiotherapists (PTs) and two P&O technicians.

The physiotherapy department mainly provides treatment for people with fracture sequel, low back pain, etc. P&O activities are almost non-existent due to the lack of equipment and materials. They use conventional technology with metal, wood and leather. The P&O technicians have three years of training from an institute in the capital. They have little experience due to the shortcomings of their education. The human resources involved in the project are the PM&R physician, one physiotherapist and the two P&O technicians.

The infrastructure and equipment are not conducive to production of lower limb prostheses. Almost all devices are provided by the national centre in Antananarivo. The centre is located in a provincial city, and the access is poor. The prices for the devices are too high for most of the population. This partner is considered weak when it comes to providing orthopaedic devices.

Figure 4 -Tests for the fitting of prosthesis

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3. A physiotherapy centre in a conflict zone in Syria (location undisclosed due to security concerns)

An estimated 13.5 million individuals have been affected by the current crisis in Syria: about 250,000 lives lost and almost 1.2 million persons injured since March 2011. There were about 25,000 trauma cases per month nationwide in 2015. Around 1.5 million of persons with disabilities are in need of assistance. Unfortunately, these figures will likely increase if the conflict continues[5]. The World Report on Disability[6] estimates that 15.3% of the world's population is living with disability and that this proportion is likely to increase to 18-20% for

[5] World Health Organization. Syrian Arab Republic: Annual Report 2015. WHO: 2015.

[6] World Health Organization & the World Bank. The World Report on Disability. WHO: 2011.

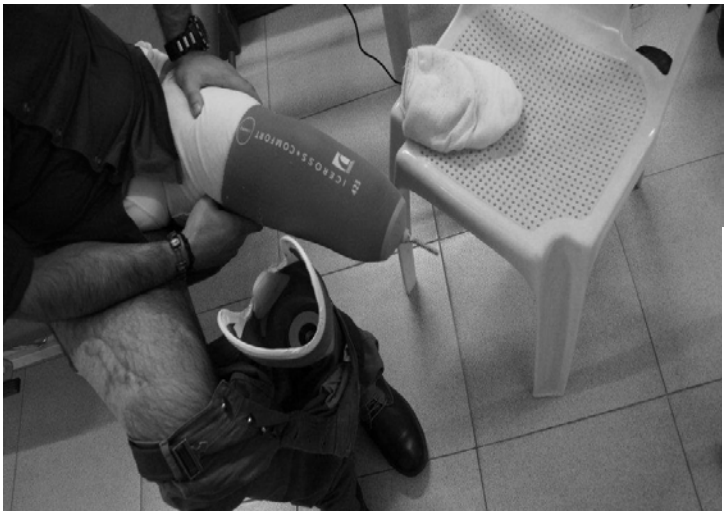
conflict-affected populations. In comparison, among the surveyed refugees, 22% are affected by an impairment, 6% by a severe impairment, and one in five people with an impairment has more than one impairment. The Syrian crisis is leaving an increasing number of people with disability, with a large number of amputations and a higher proportion of spinal cord injuries than in other crises. Persons who have been injured either directly or indirectly as a result of the conflict have seen treatable injuries turn into permanent impairments needing long term rehabilitation and care due to a lack of functional and/or accessible health services, medication, and treatment as well as shortages of physiotherapy and rehabilitation services. Persons with new impairments are also unable to access longer-term rehabilitation. Indeed, one particular concern is the limited availability of physical rehabilitation support.

The physiotherapy centre is located in a provincial city. The centre has been in existence since the start of the crisis, and has to relocate frequently for security reasons. The centre provides physiotherapy services for all types of impairments/disabilities. It also conducts outreach activities at patients' homes.

One experienced physiotherapist is in charge of the service, supported by twelve new graduates. They don't provide any orthopaedic devices; they work with centres in the city or the capital. The technology offered by the P&O centres is modern, and is provided free of charge by the public services. The equipment needed for clinical evaluation, fitting and gait training for people with orthopaedic appliances is available. The physiotherapist in charge of the centre participates in the testing.

The centre, which is located in a dangerous city, is not well known to the population and difficult to access. However, treatment is provided free of charge to everyone. While security issues complicate the situation, this centre is an important partner. The need for prostheses in the country is very high.

Figure 5 - Clinical evaluation of a patient in Syria



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4. Study sample

19 volunteers (6 in Togo, 8 in Madagascar, 5 in Syria) were selected by the local partners according to the following criteria:

- Healthy adult volunteers with a transtibial amputation,
- A stabilised residual limb,
- And a prosthesis that was fitted at least within the past two years.

However, due to local constraints, it was impossible to find four patients for the control group in Togo. While in Syria, security issues made it very complicated for patients to come to the centre. As a result, only five patients were selected for the test group. Finally, only three patients were able to have a printed prosthesis fitted.

Table 1 - Study sample

	Togo	Madagascar	Syria	Total
Total enrolled	6	8	5 (3 completed)	19 (17 completed)
No. of control subjects	2	4	0	6
No. of test subjects	4	4	5 (3 completed)	13 (11 completed)

Ethics

As it is considered clinical research, national ethics committee approvals were needed for the study[7]. Because the ethics committee in Syria is no longer functional, we were unable to obtain such approval. At the first meeting, the process was explained to the participants. They were then given a document to sign detailing the process, their role, and the assurance of confidentiality. That same document also explained that each participant could withdraw from the study at any time[8]. In Togo and Madagascar a folder of the study was proposed to the Ethical Committees for validation[9].

[7] Brus A. Studies and research at Handicap International: Promoting ethical data management. Handicap International: September 2015.

[8] Cf. Appendix 2: Participant Information Sheet (or Appendix 2bis for French version).

[9] Cf. Appendix 4:Comité éthique Togo ; Appendix 5: Comité éthique Madagascar (both in French).

5. Technological findings

The first component of the testing was to technically validate that the 3D printed socket complies with existing standards for conventional devices. The tests were done in a variety of university laboratories and prosthetics clinics, and supervised by ProsFit Technologies JSC.

Founded in 2013, ProsFit is one of the world's top companies to offer a fully-integrated CAD/CAM-based solution that automates the process from scanning to designing and manufacturing customised prosthetic sockets for below-knee amputees. The process uses 3D scanning, proprietary software and 3D printing technology for printing definitive sockets. ProsFit is currently manufacturing the sockets in the UK using commercially-available Fused Deposition Modelling (FDM) equipment with unit costs of approximately EUR150-200K. In order to move towards regional and local manufacturing, ProsFit is also designing and building an affordable proprietary 3D printer that will be able to 3D print robust prosthetic sockets efficiently[10].

Proteor SAS was also involved in the technological aspects. The French company was responsible for supplying the components for transtibial prostheses. Proteor SAS, an independent family-owned group based in France is one of the European leaders in the orthopaedic appliances market with more than 60 workshops all over the French territory. Proteor also operates workshops in Czech Republic and Luxemburg. Set up more than 100 years ago, Proteor employs 830 people in France and in its international subsidiaries in Europe, USA, China, Canada and Morocco. Proteor sells a complete range of Prosthetic and Orthotic products as well as materials, which cater to the specific needs of its customers, namely CPOs, fitting centres, rehabilitation centres, hospitals, NGO. Proteor R&D Department collaborates with university hospital centres, engineering schools and partners worldwide to develop and implement a wide range of technologies for orthopaedic devices. The company has established itself as a major manufacturer and supplier of P&O components all around the world.

The tests compared a laminated socket from a P&O workshop with a socket printed using ProsFit technology. Data was collected on the structural performance of the socket, patient comfort, and patient performance. The tests concerned only the sockets, as the other components of Proteor transtibial prostheses are already CE 1998 compliant.

[10] The 3D printer is expected to be tested and available by the end of 2017, and at a cost that could make it deployable in developing markets.

The key study findings show that:

- 3D printing is a viable technology for manufacturing prosthetic sockets
- ProsFit's sockets meet the industry benchmarks for structural performance.

The pre-failure performance of ProsFit's sockets is comparable to that of traditionally-manufactured sockets, though it should be noted that the failure is brittle in nature, whereas for traditional sockets it is ductile.

Pre-clinical trials were conducted under clinical conditions with five volunteer patients at Salford University's UNIPOD (United National Institute for Prosthetics & Orthotics Development) in July 2014. Based on the same rectified scan, the patients were fitted with two sockets, one manufactured using a traditional method (draping over a positive created on a carver), and the other using 3D printing.

The volunteers gave their feedback on the relative comfort of the two sockets, as well as on their experience with the two processes. All the patients judged the ProsFit 3D printed socket more comfortable, and all the patients were more positive about the ProsFit process[11].

With the need for fewer visits to the clinic, the limb wearer experiences faster "Time to Comfort" (T2C) and greater convenience. If there are any fit issues, ProsFit's 3D printed socket can easily be adjusted with heat.

Using the scan-to-print gives the prosthetist greater productivity and resource flexibility, and hence more time to focus on patient care and other critical activities. This type of approach makes it easier to produce multiple sockets for the same patient, and reduces materials usage and space requirements. The technical architecture of ProsFit's solution allows a prosthetist in the field to get support and coaching from an expert in a remote location.

This increased productivity will be seen in the health system in general, with the ability to accommodate greater numbers of amputees, and better leveraging of limited prosthetist

[11] However, we have to note that one of the sockets cracked while being worn by a K3 user during the study. The rectification had been done in accordance with the usual practice, and could be considered standard. In addition, the alignment appears to have been set within normal parameters. This failure was unusual to see with a K3 user, and a technical investigation found that it was most likely caused by excessive pressure on the wing at the trim line (cf. Appendix 1: Failure Report Madagascar). This was consistent with the fact that the user was jumping over a gulley, and that the crack occurred on landing, where it was exposed to forces exceeding the design specification. It is possible that, if the socket had not failed, those forces could have injured the wearer.

resources. As there is no wet or dirty process involved, there is an opportunity to fit amputees in their community. This can reduce capital costs for new prosthetic centres.

Finally, this approach offers an opportunity for improved dialogue and collaboration between the limb wearer and the prosthetist in the design of the socket. Giving the users the ability to express their needs and participation in the process could increase adoption and use rates.

6. Clinical findings

The second component of the testing was to evaluate how the new 3D process is in conformity with the rules of clinical protocols, in terms of performance, adaptability, durability, and comfort[12].

A prosthetist supervised by Strathclyde University – in collaboration with the service partners – was responsible for the entire process: clinical evaluation, measurement, rectification of the positive, fitting and delivery of the transtibial prosthesis.

The clinical tests compared the process used in the treatment protocol for each technology – i.e. conventional and 3D printing.

The project team conducted two missions in Togo and Madagascar: the first one for measurement, scanning, and rectification of the positive; the second one for fitting and delivery. During those missions, the prosthetist trained the partners in the use of 3D technology.

The agenda in Syria was different: the prosthetist conducted a first mission for measurement, scanning, and rectification of the positive. Training was done on scanning and on prosthesis fitting and delivery. The prostheses were sent to the physiotherapy centre and the fitting was done by the physiotherapist while the prosthetist provided remote assistance via online video conference.

A total of six participants were recruited for the control group (traditional laminated socket prosthesis with silicone liner). The average age of the control group was 40.3 years old (range:

[12] Cf. Appendix 7: Test results.

30 – 56 years old). Three participants had left-side amputations and three had right-side amputations.

A total of thirteen participants were recruited for the test group (transtibial prosthesis made using the ProsFit 3D printed socket with silicone liner). Complete data were available for only eleven of those participants. The average age of the test group was 39.6 years old (range: 14 – 62 years old). Five participants in the test group had left-side amputations and eight had right-side amputations.

Limitations of the study:

- The small size of the sample as well as the small number of completed trials does not allow determination of statistical significance with regard to the study goals.
- The data collected suggest that the SCS (Socket Comfort Score) and the TUG (Timed Up and Go) assessments were not conducted in a consistent manner across the three centres. Only two TUG tests were conducted for each subject (pre- and post-fitting), rather than taking an average of several trials. Pre-fitting SCS scores vary considerably by country, suggesting a lack of uniformity in the standard of pre-trial prostheses. While all prostheses provided in the trial had the same components and SACH foot, these were not the same as the components and foot used in the pre-fitting prosthesis. Therefore, the control group cannot be regarded as truly representative of the existing situation in each country.
- Moreover, the introduction of the silicone liner – which was not previously available to most subjects – means that the control group cannot be regarded as truly representative of the existing situation in each country.
- The patients had very different prostheses at the start of the trial, some of which were very old and in a poor state of repair. This may have affected the outcomes.
- Prostheses in the trial were fit by different personnel, meaning that the interventions were not standardised. Post-fitting tests were done on the day of prosthesis fitting, so there is no information on the longer-term effects of either intervention.
- The baseline data is highly variable, i.e. each participant in the pilot study had a different presentation, a different duration of prosthetic use and a different original prosthesis. Those inconsistencies were not factored into the study or the data collection.
- In all cases, the ProsFit socket was tested with a silicone liner, which in itself presents a confounding variable that affects the results.
- The SCS measurement in at least one of the testing centres appears not to conform to the published methods.

In brief, the tests showed that the new protocol respects clinical rules. Patients' participation has been improved during the process. Remote treatment is now available. Yet, the number of test subjects is insufficient to be conclusive. Moreover, the above limitations seriously limited the potential for reliable and valid statistical analysis. The results may have been affected by hidden factors such as the deteriorating condition of the original prostheses worn by some of the subjects; hence the results or even the trends from the collected data may not be directly attributable to the ProsFit technology. The use of a liner in both prostheses may in itself account for some of the observed improvement in comfort in both the control and the test groups.

Finally, due to the small sample size and non-uniform baseline, we can only infer that the new prosthesis appears to be more comfortable than the old prosthesis for most participants. The new prosthesis also seems to have improved the TUG among most participants, but no statistical significance can be inferred.

Recommendations for future study:

- A well thought-out experimental protocol that takes into account all confounding factors and hidden parameters should be designed and implemented.
- A more rigorous and quantitative assessment method should be implemented.
- Procedures for data validation, verification and repeatability assessment are needed to ensure data quality.
- Assessment should be done blind, and conflict of interest statements should be provided.

7. Organisational findings

The third component of the testing was to evaluate the implementation process in terms of professional practices, cost, time, logistical resources, and technical infrastructure and equipment.

Three different processes for producing transtibial prostheses were compared:

- Production of a locally-made transtibial prosthesis, which is part of the control group. It uses the same components as the 3D printed prosthesis; except the socket is manufactured locally using resin lamination;

- Production of a 3D transtibial prosthesis, which is the test group. It uses the same components as the locally-produced transtibial prosthesis, except the socket is 3D printed;
- Production of a conventional transtibial prosthesis – that matches the appliance currently offered at the partner centre.

This comparison was used to evaluate the various parameters involved by introducing a transtibial prosthesis: the human resources, infrastructure, equipment, materials and components, as well as the logistical constraints and implications for the patient in terms of the number of visits to the centre and the time spent.

Data collection was done remotely by distributing specific questionnaires[13] to each rehabilitation service involved in the pilot project. The questionnaire was designed based on the data needed to calculate the costs for rehabilitation service, and had four parts (human resources, annual production, infrastructure and equipment) with eleven questions. The questionnaires were administered by email and sent directly to the managers of the rehabilitation services. The email data collection took place between July and September 2016.

Human resources

We estimated the hourly pay of each member of the rehabilitation staff needed to make prosthesis, and then scaled that to the average fabrication time for the technology type used. For comparison purposes, we used the average fabrication time for fabricating transtibial prosthesis – reported by an experienced prosthetist (the head of this pilot project) – as a reference.

In addition, when creating its tool for calculating the cost of an orthopaedic fitting service, the ISPO[14] defined a reasonable average work time for fabricating transtibial prosthesis as 620 minutes, plus or minus 60 minutes. Each interlocutor reported their actual production time. In Togo, the process takes 1,430 minutes, which is more than 2 times longer than the time used in developed countries. In Madagascar, it takes 700 minutes to produce a transtibial prosthesis, roughly equivalent to the time used in the calculations. This difference in fabrication time may be explained by steps 4 (prosthesis fabrication), 6 (corrections), and 7 (fitting the prosthesis), where more time is significantly spent in Togo than in Madagascar or than the standard times used.

[13] Cf. Appendix 8: Questionnaire Data (or Appendix 8bis for French version).

[14] ISPO & USAID. Tool for calculating the costs of a prosthetics and orthotics service. USAID: 2005.

Table 2 - Average time required to perform each step of the transtibial prosthesis manufacturing process using the local technology[15]

	1. Social and clinical assessment of people already wearing a prosthesis	2. Casting/ measure-ment	3. Rectifica-tion	4. Prosthesis fabrica-tion	5. Fitting	6. Correction Finishing	7. Prosthesis fitting and delivery	Total average time
P&O technician/ collaborator*	15 minutes	60 minutes	90 minutes	255 minutes	60 minutes	120 minutes	30 minutes	630 minutes

* For step 1, the collaborator was the rehabilitation physician, and for step 7, it was a physiotherapist.

Table 3 - Average time required to perform each step of a transtibial prosthesis manufacturing process using 3D technology[16]

	1. Social and clinical assessment of people already wearing a prosthesis	2. Measurement/ scanning	3. Digital rectification of the residual limb scan on the CAD/CAM software	4. Socket printing	5. Assembly of prosthesis components	6. Onsite fitting and delivery	Average time
Local P&O technician	15 minutes	30 minutes	30 minutes	0	60 minutes	30 minutes	165 minutes
Person in charge of 3D printing	0	0	0	30 minutes	0	0	30 minutes
						Total average produc-tion time	195 minutes + 480 minutes = 675 min.

[15] Source: Jerome Canicave, based on the data collected, 2016

[16] Ibid.

Producing a transtibial prosthesis using 3D technology took 195 minutes of direct labour plus 480 minutes to print the socket, for a total production time of 675 minutes.

In calculating the labour cost for producing a transtibial prosthesis we allowed an additional 45% for all of the periods of inactivity throughout the entire prosthesis production process. That figure was defined by the ISPO and USAID in designing their cost calculation tool, and was established based on the time that technical personnel spend waiting, doing in-house work such as equipment maintenance, working on case files, doing administrative work, and in discussion with colleagues, superiors, members of the multidisciplinary team, etc. In addition, according to the ISPO[17], that 45% allowance represents an average productivity of approximately 69%[18], and should be interpreted as 69% of the available time of technicians with patient access is used for patient-related work. Personnel-related expenditures represent at most 10% of the total cost of orthopaedic fitting in developing countries. Hence the direct labour costs are not a significant factor affecting the price of the prosthesis, and variations in the former (or in productivity) will not have a big impact on its price. While low productivity does tend to increase costs and high productivity to lower them, the impact on the final price is negligible.

In our study, we considered the cost of training a health professional in the new technologies negligible. Indeed, we considered the cost minute, given that the training is assumed to be valid for life, and that the technology does not change fast enough compared with the need for updated knowledge. The time it takes to train rehabilitation personnel to take measurements using the scanner and perform rectification on the CAD/CAM software is an estimated five days, which in Madagascar or Togo represents a cost of approximately €200 per day, or about €1,000 for the entire training.

Infrastructure

The study looked at the cost of the infrastructure used to produce a transtibial prosthesis. We included the cost of the building area used by the orthopaedic fitting service, and we depreciated this cost. Operating costs (cost of technical services, electricity, heating and air conditioning if not electric, water, waste collection, and subcontracted work and services) and all other related costs are also included, and the total cost is broken down to a unit cost per prosthesis produced. In addition, in the case of 3D technology, we estimated the percentage of the building area needed to produce that prosthesis, which was 77.36% of the area of a

[17] ISPO & USAID. *Tool for calculating the costs of a prosthetics and orthotics service*. USAID: 2005
[18] X*1.45=100, X=68.96%

conventional rehabilitation service[19]. That percentage was then applied to the rehabilitation service in each country.

Delivery charges

The shipping costs considered in this study use the estimated cost for a standard 4kg-shipment via DHL, which is €58.42. Also included were the cost of shipping the socket from the 3D printing site to the local rehabilitation centre, and of shipping the components and silicone liner from the manufacturer to the local rehabilitation centre. Shipping these items takes an average of four days for Togo and five days for Madagascar.

Equipment

The following equipment was used to produce the transtibial prostheses:

- In Togo, a carver, an electric oven, an oscillating saw, a vacuum pump, and a soldering iron;
- In Madagascar, an electric oven, an electric drill, a standing vice, a workbench, a complete set of tools, an anvil, a grindstone and a vacuum cleaner.

Production of the 3D transtibial prostheses required a computer, a scanner and CAD/CAM software at the local rehabilitation centre, a computer, CAD/CAM software and a 3D printer at the location where the prosthesis is printed.

Consumables

The consumables used to make transtibial prostheses in developing countries vary from one country to another, and a complete list of such consumables is rarely possible. We assumed that consumables would represent 10% of the overall cost of producing a prosthesis using the local technology. The consumables used for 3D printing are already included in the cost of the printed socket.

[19] Rios JM. Programming guide for the setting up of a rehabilitation centre. Handicap International: 2001 - cf. Appendix 11: Estimation of space.

Cost analysis

- **Togo**

Prices vary depending on the type of technology used. The transtibial prosthesis made using 3D printing has the highest production cost ($2563.60), followed by the local transtibial prosthesis and the one made with conventional technology – the technology currently being used in Togo.

Table 4 - Cost of producing a transtibial prosthesis depending on the technology used in Togo, in USD[20]

Cost category	Local prosthesis (control group)	3D prosthesis	Conventional prosthesis
	USD	USD	USD
Human resources	$ 38.75	$ 5.07	$ 38.75
Infrastructure	$ 906.93	$ 701.62	$ 906.93
Equipment	$51.94	$1.94	$51.94
Delivery costs	$ 0	$130.03	$ 0
Materials	$39.96	$1,068.41	$ 44.84
Components	$480.90	$ 656.52	$348.23
Consumables	$151.85	$0	$ 157.11
Total cost per unit	**$1,670.32**	**$2,563.60**	**$1,547.80**

“Infrastructure” is the largest part of the total production cost for the conventional and control prostheses. However, infrastructure represents a smaller portion of the total production cost when using the additive technology than when using the other types of technology. This is due to the fact that a smaller work area is needed for producing 3D prostheses than for a P&O workshop; the estimated area needed to produce a 3D prosthesis is approximately 77% of the production area for prostheses requiring a workshop.

Components add substantially to the total cost of producing 3D prostheses, since the printed socket is included in that category for the 3D prosthesis while the socket is made from materials for the two other types of prosthesis.

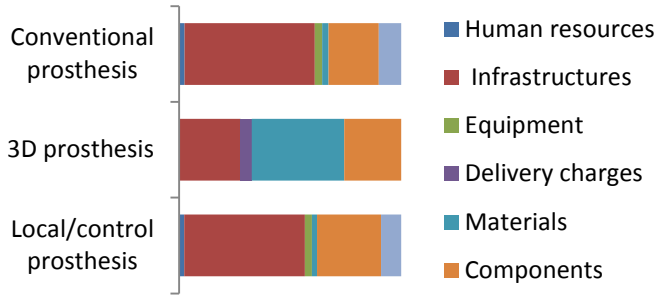
[20] Source: Jerome Canicave, based on the data collected, 2016

Human resource costs are also reduced significantly with 3D printing. Indeed, while it requires an average of 630 minutes of prosthetist time to produce a conventional transtibial prosthesis, additive technology requires only 195 minutes on average of prosthetist time, after which the printer takes care of printing the socket unattended (approximately 480 minutes).

Materials, like consumables, represent only a small portion of the total cost of producing transtibial prostheses using local or conventional technology. Those costs are far lower for the prosthesis made using 3D technology.

The delivery costs currently included in the total production cost for the 3D prosthesis are not representative, since they are estimated based on a printer located in a different country (UK) than where the potential beneficiaries of a 3D prosthesis live. Lastly, those costs do not apply to the other two types of prosthesis.

Figure 6 - Breakdown of cost categories depending on the type of technology used in Togo[21]



- **Madagascar**

The transtibial prosthesis with the highest production cost is the one made using 3D printing technology ($1880.95), followed by the local prosthesis and the prosthesis produced using the conventional technology – which is the technology currently being used at the Mahajanga SAR.

[21] Source: Jerome Canicave, based on the data collected, 2016

Table 5 - Cost of producing a transtibial prosthesis as a function of the technology used in Mahajanga, in USD[22]

Cost category	Local prosthesis (control group)	3D prosthesis	Conventional prosthesis
	USD	USD	USD
Human resources	$ 16,69	$ 0.53	$ 16,69
Infrastructure	$ 16.55	$ 12.81	$ 16.55
Equipment	$ 57.36	$ 1.94	$ 57.36
Delivery costs		$ 130.79	
Materials	$ 49.34	$ 1,074.58	$ 49.34
Components	$ 628.44	$ 660.31	
Consumables	$ 38.49	$ 0	$ 38.49
Total cost per unit	**$806.88**	**$1,880.95**	**$178.44**

The “human resources", “equipment”, and “consumables” costs are far lower for the 3D prosthesis than for the other two fabrication types, as was seen in Togo.

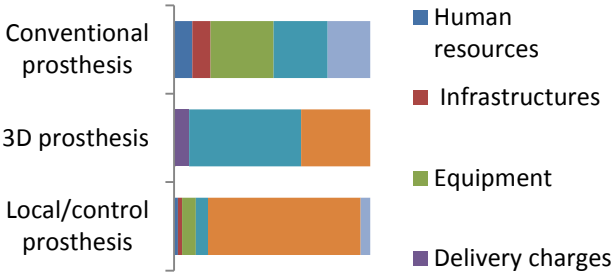
Materials, like consumables, account for only a small portion of the total cost of producing transtibial prostheses using local or conventional technology. Those costs are much lower than for the prosthesis made using 3D technology.

We can see that the production cost for a 3D transtibial prosthesis is about ten times higher than for current conventional production in Mahajanga. The use of local materials to fabricate components is an essential factor in those low costs. One thing we need to think about is the quality of the orthopaedic devices produced in Mahajanga, which was not evaluated in this study.

Finally, the selling price of a conventional prosthesis is much lower than the production cost – $72.17 vs. $178.44 (less than half). Because it is a government service, it does not take into account the necessary human resources, infrastructure, and equipment-related costs. The selling price is even less than the total cost of the components, materials and consumables used ($72.17 vs. $87.83).

[22] Source: Jerome Canicave, based on the data collected, 2016

Figure 7 - Breakdown of cost categories depending on the type of technology used in Madagascar[23]



- **Syria**

The cost of producing a 3D transtibial prosthesis is higher than that for a prosthesis currently produced with conventional technology in Syria.

Table 6 - Cost of producing a transtibial prosthesis according to the technology used in Syria, in USD[24]

Cost category	Local prosthesis (control group)	3D prosthesis	Conventional prosthesis
	USD	USD	USD
Human resources			
Infrastructure			
Equipment		$ 1.94	
Delivery costs		$ 130.03	
Materials		$ 1,068.41	
Components		$ 656.52	
Consumables		$0	
Total cost per unit	**$1,000**	**$1,856.90**	**$1,000**

[23] Source: Jerome Canicave, based on the data collected, 2016
[24] Source: Jerome Canicave, based on the data collected, 2016

That difference is due primarily to the cost of the printed socket, which is $880, and the cost of shipping the socket.

In conclusion, the process reaches patients in remote areas or conflict zones. It reduces the infrastructures, equipment and human resources needed. However, direct costs of 3D printing technology are still too expensive for low-income African countries. In Togo, the cost of a conventional transtibial prosthesis is 60% lower than that of a 3D printed prosthesis; in Madagascar, the cost of the conventional prosthesis is 0.10% of the price of the printed prosthesis. In Syria, the cost of a local prosthesis is 50% that of a printed prosthesis.

In the two African countries, the direct and indirect costs (human resources, infrastructure and equipment) are not included in the selling price. In fact, the selling price is less than the costs of inputs (materials, components and consumables). Those selling prices do not therefore reflect the financial reality of running a P&O service.

The technology used in Syria is basically the same as that in Europe. Hence, there are smaller cost differences in terms of the components, i.e. the silicone liners, the connectors and the foot. However, the 3D printed socket represents a significant additional cost.

8. Conclusion

First, concerning the technological aspects, the study confirmed that the 3D printed sockets meet the structural and mechanical requirements for such orthopaedic devices and seem appropriate for use in transtibial prostheses process.

Regarding the equipment itself, it is interesting to note that an off-the-shelf scanner can be used for the process. Even though the scanner used during the study was brought by ProsFit, a simple scanner from the market is appropriate for this process.

The rectification software provided by ProsFit showed its performance for a transtibial prosthesis. It allows necessary orthopaedic rectification of the scanned stump. It is comparable as the one used for a CAD-CAM system. The printer, however, has to be specifically dedicated to this activity. It fits with the necessary requirements in term of quality of printing (endurance and resistance awaited). At this stage, equipment represents a large portion of the total cost of the fitting process.

Second, concerning the clinical aspects, due to the variety of contexts, it was impossible to apply a strict methodology for fitting the transtibial prostheses. In addition, the sample size was too small and the baseline non-uniform to gather significant and reliable evidence. Yet, the tests showed that the new prosthesis appears to be more comfortable than the old prosthesis for most participants.

Third, in terms of organisational aspects, the study findings show that the 3D process is not economically feasible for Togo and extremely remote from the practices in Madagascar, given the population's difficulty in acquiring even a conventional transtibial prosthesis. In Syria, in the current situation, national and international humanitarian aid projects pay for all of the orthopaedic fitting-related parameters, and can thus cover the real costs of these products.

Because the cost of printed prostheses is too high, it is essential to find some solutions for:

- The cost of the components, and particularly the silicone liners: further research is needed to develop standard liners that can be used with the 3D process and that cost no more than €50 (they currently cost about €300).
- The cost of printing the sockets: the printer has to meet the technical constraints of a transtibial socket. We need to find equipment that is simpler to use but meets the same requirements in term of quality.

Nevertheless, the study highlighted that the 3D process had positive impacts for the patient. Indeed, 3D technology requires much less time working directly with the patient at the service; taking measurements with a scanner is much faster than casting. It is also less invasive and less traumatising, especially for children. Thus, patients are better involved in the process. They can participate directly as the socket is being rectified on the computer. They can share their experience regarding pain, tightening, support/counter support, relief areas, etc.

We have found that the number of patient trips is the same regardless of the technology used. Hence, the 3D process does not impact the cost of accessing the service, and is not an additional cost for the patient. Moreover, because the infrastructure and equipment needed for the 3D technology is minimal and portable, the service can be geographically close to the population, and thus reducing the distance they have to travel.

Despite the limitations of the study methodology due to the field constraints, this pilot project was considered a success as it opens up some promising developments. The decision to test transtibial prostheses was a risky one, given that these are the most orthopedically and technologically complex devices.

In conclusion, there is a need to develop new projects aiming to:

- Improve the research protocol (integrate a cost-effectiveness and a cost-benefit analysis)
- Scale-up the number of trials to scientifically validate the clinical test
- Reduce the costs of soft liners, components, printers through further industrial research
- Test other contexts of intervention (for example, emerging market countries such as India)
- Expand the range of orthopaedic devices: orthoses, upper limb prostheses, etc.

As this pilot study proposes new intervention paradigms, it is essential to continue the research by involving additional clinical and industrial actors in both developed and developing countries.

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Appendices list

These appendices are available on **SkillWeb** (password required).

If necessary, please, contact Jérôme Canicave (**contact@jerome-canicave.org**).

Appendix 1 - Failure report “Madagascar socket”

Appendix 2 - Participant Information Sheet
Appendix 2 bis - Fiche d’information pour les participants

Appendix 3 - Comité éthique (Togo)

Appendix 4 - Comité éthique (Madagascar)

Appendix 5 - Timed Up & Go Test (TUG)

Appendix 6 - Prosthetic socket fit comfort score

Appendix 7 - Test results

Appendix 8 - Questionnaire 3DProject - SYRIA
Appendix 8 bis - Questionnaire Projet 3D - TOGO

Appendix 9 - Estimation of the proportion of the area occupied by a prosthetics and orthotics service with a 3D printer **/** Detailed calculations of Togo & Madagascar’s test

Appendix 10 - Cost analysis

Pilot Testing of 3D Printing Technology for Transtibial Prosthesis in Complex Contexts (Togo, Madagascar and Syria)

In January-October 2016, Handicap International carried out a pilot testing of 3D printing technology for transtibial prosthesis in Togo, Madagascar and Syria.

The aim of the study was to explore and test how physical rehabilitation services can be more accessible to people living in complex contexts via innovative technologies (such as 3D printing, treatment processes that use Internet technology and tools) and decentralised services by bringing them closer to the patients.

This scientific summary provides the context, the objectives, the methodology, the results of the study, and perspectives for the futur.

HANDICAP INTERNATIONAL FEDERATION
138 avenue des Frères Lumière
69371 Lyon cedex 08
T. +33 (0) 4 78 69 79 79
F. +33 (0) 4 78 69 79 94
publications@handicap-international.org

HANDICAP INTERNATIONAL