

# Appropriate Prosthetic and Orthotic Technologies in Low Income Countries (2000-2010)

A report of the activities under the Agreement provided by the United States Agency for International Development (USAID) to the International Society for Prosthetics and Orthotics

“ISPO Appropriate Prosthetic and Orthotic Technologies in Low Income Countries”

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Child with a disability, Tanzania. Image JS Jensen

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# Contents:

Page	Contents
2	Foreword
4	Executive summary
<b>SECTION 1: Rehabilitation Technology</b>	
8	Mechanical testing of prosthetic feet utilized in low-income countries according to ISO-10328
9	Clinical field testing of prosthetics in tropical low-income countries
16	Clinical field testing of trans-femoral prosthetic technology
20	Amputation stump casting technology
22	Impact on end-use, or consumer compliance follow-up
24	ISPO Consensus Conference on appropriate orthopaedic technology for low-income countries
25	ISPO Consensus Conference on wheelchairs for developing countries
27	ISPO Consensus Conference on appropriate lower limb orthotics for developing countries
<b>SECTION 2: Education</b>	
29	Scholarships
31	Training the trainers
32	Evaluator training and support
33	Teaching and learning resources
35	Performance indicators and outcome measures
36	ISPO Workshop on Prosthetics and Orthotic Training Institutes in Non-Industrial Countries
<b>SECTION 3: Community Based Rehabilitation</b>	
37	Clinical field follow up by Community Rehabilitation Workers
38	The relationship between prosthetics and orthotics services and Community Based Rehabilitation
<b>SECTION 4: Appendices</b>	
40	Bibliography
41	Ethical considerations
41	Acknowledgements

# Appropriate Prosthetics and Orthotic Technologies in Low Income Countries

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## Foreword

The International Society for Prosthetics and Orthotics (ISPO) has had the great privilege of being the implementing partner for the grant described and reported within this document.

Since 1995, ISPO has been supported by United States Agency for International Development (USAID) through the Leahy War Victims Fund (LWVF). The relationship began at that time with a grant for a conference on appropriate prosthetic technology. The conference brought together more than 100 rehabilitation experts who were charged with the task of deciding how best to use resources and measure effectiveness for Prosthetic and Orthotic services in developing country programs. The conclusions and recommendations reached at that conference set standards used around the world today.

Considering the roles and strengths of ISPO and the mandate of the USAID through the Leahy War Victims Fund, it is not surprising that this relationship developed and continued to evolve and manifest itself over the years. ISPO itself has over 3000 members worldwide from over 90 countries and is an interdisciplinary organization that works to improve the quality of life for persons who may benefit from prosthetic, orthotic, mobility and assistive devices.

From an overall perspective, the outcome of this grant period from 2000-2010 is as follows:

- Prosthetics and orthotics teaching programs have been strengthened by the provision of scholarships to those who are trained in various schools globally to internationally recognized standards. We were able also to support the upgrading of teachers and teaching material;
- We tested several major prosthetic component designs and published the results. We found several flaws in prosthetic foot design that led to prosthetic limbs malfunctioning and breaking and so have made recommendations for improvement;
- We designed and field-tested a monitoring and evaluation program and tool to enable local and international organisations to better manage and measure the impact of rehabilitation programs;
- We encouraged follow-up of graduates and their patients in the field.

The impact of this work for some of the world's most disadvantaged communities is that:

- More people with mobility disabilities have been able to access safe and effective care from trained clinicians;
- Scholarships were awarded to students who then became trained professionals. Now, most graduates have secure livelihoods and are able to support themselves and their families;

- We expect that the recommendations derived from the prosthetic foot testing work will have a direct impact on designers and manufacturers of prosthetic feet so that failures of these essential parts will become less frequent.

We have learned that there is still much to be done to improve the availability of appropriate prosthetic and orthotic technologies in low income countries and that our work will continue in this regard. We have also learned that in order to maintain and develop postgraduate clinical and technical skills, these new professionals will need to further support and continued mentorship at various levels to help facilitate their continued development professionally.

Throughout my tenure with ISPO, it has been a great pleasure and honor to have worked with the many collaborators of this initiative. The personal commitment and exemplary work with their results oriented approach is acknowledged. ISPO wholeheartedly thanks these individuals for their significant contributions. In addition, a very special thank you must be bestowed upon Dr. J.S. Jensen, for his many years of committed and dedicated hard work as the Project Manager, for all the USAID/LWVF grants that ISPO has received until today.



Dan Blocka, B.Sc., C.O.(c), F.C.B.C.,  
 Immediate Past President, ISPO  
 Chair, USAID-ISPO Steering Committee



Our work continues with the support of another collaborative agreement with USAID 2008-2013. These images show an ISPO field visit team evaluating scholarship graduate work in Vietnam in October 2010. *Images Mel Stills*

**Appropriate technology** is a system providing proper fit and alignment based on sound biomechanical principles which suits the needs of the individual and can be sustained by the country at the most economical and affordable price.

*Definition endorsed at the ISPO Consensus Conference  
Appropriate Orthopedic Technology for Low-income Countries,  
Moshi, Tanzania, September 2000*

## Executive Summary

### The need:



Prosthetic limb user, Cambodia. Image JS Jensen

25.5 million people in the world are estimated to need prosthetic and orthotic devices. The majority of these people cannot exercise their human rights: *the right to a standard of living adequate for the health and well-being of individuals and their family, including food, housing and medical care and necessary social services*. Appropriate prosthetic and orthotic devices for persons with impairments or loss of limbs or malfunction of the spine are important to assist these persons to participate in domestic, social and employment activities. These technologies are best provided by clinicians trained to deliver safe and effective prosthetic and orthotic services. Devices should be designed to withstand everyday use over many years and often in the extreme environments of high ambient heat and humidity that can exist in low income countries.

### Outcomes:

This grant, provided by the Leahy War Victims Fund of the United States Agency for International Development, helped to improve prosthetics-orthotics service delivery and achieved the following outcomes:

**Consensus conferences:** Consensus conferences allowed international agreement to be reached about appropriate technologies for people with mobility difficulties in the light of

limited scientific evidence on this important rehabilitation topic. An early outcome of this project was the successful delivery of an ISPO Consensus Conference entitled *Appropriate Orthopaedic Technology for Low-income Countries* held in Moshi, Tanzania, in September 2000. Two further ISPO Consensus events were delivered under the project: *Appropriate Lower Limb Orthotics for Developing Countries*, Vietnam, April 2006; and *Wheelchairs for Developing Countries*, India, November 2006.

**Prosthetic limb components:** Numerous designs of prosthetic limb components exist. Of these, prosthetic feet are an important consideration in the prescription of prosthetic limbs and only a small range

of prosthetic feet are available and affordable in low income countries. Firstly we mechanically tested different kinds of prosthetic feet in a test laboratory. We then followed up a number of users of trans-tibial prosthetic limbs in their own locale to investigate how their prosthetic feet survived the rigors of daily life. We were interested in determining the durability of the prosthetic feet in the laboratory and in the field and our findings were disappointing in that the materials the feet are made from tend to fail relatively quickly under cyclic testing or regular use under the normal in-country conditions of rough terrain or high humidity and ambient temperatures. We found that when tested, prosthetic feet made from rubber were statistically superior to polyurethane feet.

We also followed up a number of persons with trans-femoral prosthetic limbs in the field and found that prosthetic knee components prescribed for use in low income countries often had knee joints mechanisms that loosened, making them less useful.

We found that when prosthetic components begin to wear and fatigue, they do not then function properly making walking more difficult. In the worst cases, when the component part has critical failure, the entire prosthetic limb cannot be worn.

**Scholarships:** 109 Scholarships were awarded to educate and train prosthetists/orthotists and orthopaedic technologists primarily from post-conflict areas. In the last two years, scholarship agreements included a commitment from the home country employer or government and the scholar that the scholar would return to their home country to work for at least 3 years post-graduation with a guaranteed position.

**Training the Trainers:** Training the trainer short courses upgraded the skills of teachers for programs in prosthetics and orthotics in Cambodia and Tanzania. The objective of this upgrading training was to improve the effectiveness of teaching and learning in the institutions where scholars were educated.

**Evaluator Training:** We received support to train ISPO evaluators whose work includes recognition of training programs in prosthetics and orthotics who meet internationally agreed standards. Minimum standards of patient care were promoted through this work.

**Educational resources:** Teaching and learning resources were developed and delivered.

**Performance Indicators:** We developed performance indicators and outcome measures to monitor and assess the quality of educational provision and prosthetics and orthotics clinical services.

## Impact:

The impact of the work done under the agreement *ISPO Appropriate Prosthetic and Orthotic Technologies in Low Income Countries* is multifactorial because of the different activities undertaken, but we believe that all outcomes will have a significant impact on the end user of prosthetic and orthotic devices living in low income countries.

- ✓ We have succeeded in building the pool of trained clinical staff working in lower income countries so that more persons with disabilities can be assured of access to prosthetic and orthotic technology services provided by personnel with an acceptable portfolio of clinical and technical skills.
- ✓ We have promoted safe standards of practice education for prosthetists/orthotists and orthopaedic technologists. The USAID grant has helped to support increased interest and activity in the international standards of education for prosthetists/orthotists and orthopaedic technologists. This has certainly been a key ingredient to promoting safe standards of patient care for persons needing to access prosthetic/orthotic services.
- ✓ We have strengthened the learning environment for student prosthetists/orthotists and student orthopaedic technologists in lower income countries by training their teachers in pedagogical techniques and by provision of more learning resources.
- ✓ Through use of outcome measures and analysis and dissemination of audit study results, we have augmented quality improvement cycles in both education and clinical services.
- ✓ When reviewing the long term use of prosthetic components of people with disabilities in their usual environment we were able to promote the importance of disability rights to the device users and their communities.
- ✓ Showing interest in the personal outcomes of persons with disabilities also made a positive impact upon promotion of the work of their rehabilitation service provider.
- ✓ We have a better understanding of the usefulness of prosthetic technology to users in lower income countries. We published the results of the prosthetic review follow up studies and these results can be used to help with prescribing decisions.
- ✓ Although we are not aware of specific improvements in device design as a direct result of this work, it underlines the importance of testing new designs before generally launching them on the market. We hope that the device designers will take note of our results to design more durable devices that will better assist people with limb absence to be able to fully participate in society.

## Lessons learned:

Our activity under this program *ISPO Appropriate Prosthetic and Orthotic Technologies in Low Income Countries* is an important element of the portfolio of work done by ISPO over the first decade of the new millennium. We are privileged to have been a part of global efforts to provide rehabilitation services to some of the world's most disadvantaged communities. There is still much work to do to improve rehabilitation technology services for people with physical disabilities in lower income countries and we have learned that our efforts cannot diminish in this regard – we must continue our efforts to ensure that appropriate prosthetic and orthotic technologies are made more readily available.

As we reflect upon the program of work done over the decade we find a common thread to our work which is about skills development. All aspects of our work have been about nurturing or assessing the clinical and technical skills of prosthetists/orthotists and orthopaedic technologists for the benefit of persons with physical disabilities who need access to rehabilitation technology for their mobility.

Our work has naturally focused on supporting scholars and enhancing their learning environment. Looking back on the successes and challenges of this approach gives us the benefit of hindsight. We are now aware of a likely drop in skills level where clinicians work in isolation after graduation in countries where peer communities and support is limited and this can lead to a reduction in quality of patient care. It is becoming clear that as well as supporting professional training through the provision of scholarships we will in future need to refresh our efforts to support the postgraduate community by encouraging mentoring of new graduates. This mentoring could be provided by in country professionals who could encourage and participate in self-sustaining professional communities and clinical interest groups.

To date we have spent a significant amount of time analysing student performance and we need to shift our focus to be more patient centered when measuring outcomes. We also wish to look more closely at the work done by the trained clinician to find out more about how their training has influenced patient care. In considering the circumstances in which rehabilitation services are provided, and the limited resources available in low income countries, we have also come to realise that long term record keeping should be implemented within quality control systems.

We also believe that role development within the wider service team is important. We are particularly interested in finding new and innovative ways to deliver services that are effective and efficient. We are interested in understanding and encouraging role development for all members of the wider clinical team and particularly for community based rehabilitation workers who can be a first point of contact for persons with mobility challenges in their communities.



Community activity, Tanzania. Image JS Jensen



## SECTION 1: Rehabilitation Technology

### Mechanical testing of prosthetic feet utilized in low-income countries according to ISO-10328

Twenty-one different prosthetic foot models supplied by Non-Government Organisations (NGOs) and commonly utilised in the developing world were made by either natural rubber (14), polyurethane (PU, 5) or ethyl-vinyl-acetate (EVA, 2).

The initial Static Proof test, which simulates a single momentary load (2,240 N), was not passed due to permanent forefoot deformation exceeding 5mm. In addition, all tested feet had significant internal failures that were visible when sectioned longitudinally.

Forefoot deformation for non-Jaipur rubber feet came closest to meeting the standard at  $8.3 \pm 3.4$ mm; deformation of the various types of rubber Jaipur feet was the greatest at  $22.5 \pm 5.4$ mm. Forefoot deformation for PU feet was  $13.6 \pm 5.5$ mm. Forefoot deformation of the EVA feet was  $22.8 \pm 5.7$ mm. Breakage of the forefoot was observed with 3 rubber feet (VI Cambodia, HI Mozambique, PHN Cambodia) and 2 PU feet (Alimco India, PFThai).

After the Static Strength test, permanent deformation of the feet increased. The average maximum deformation for rubber SACH forefeet varied from 17 to 30mm, and 11 to 26mm for the heel; rubber Jaipur forefeet 47 to 60mm and heels 13 to 19mm; PU forefeet 20 to 44mm and heels 20 to 33mm; and EVA forefeet 33 to 50mm and heels 16 to 31mm. Breakage of the forefoot was observed with 2 PU feet (Alimco India, PFThai) and 2 EVA feet (Afghan, ASB Ethiopia).

After completion of the Cyclic Test (1,3302 N, 2 million cycles) the prosthetic feet were sawed in half longitudinally and closely examined visually. All feet revealed internal derangements:

1. Deformation of rubber or PU foam under the keel of forefoot and/or heel : HCMC Vietnam, VI Cambodia, EB1 Vietnam, BAVI Vietnam, HI Cambodia, ICRC Myanmar, HI Angola, TATCOT Tanzania (all rubber feet); Kingsley USA (PU foot) and CR-SACH from ICRC Switzerland (PU foot).
2. Delamination from the keel : HI Mozambique, PHN Cambodia (rubber), and CIREC Colombia (PU).
3. Delamination between foam layers : BMVSS, NISHA, MUKTI, and OM (all Indian Jaipur rubber feet).
4. Two environmental factors were tested; UV light 400 hrs at  $55 \pm 3^\circ$  for 20 weeks; or  $38^\circ$  with 98-100% humidity for 20 weeks. The influence was minimal for rubber feet with respect to deformation and inconsistent for the polymer feet; in particular for the forefeet. Creep increased with humidity exposure in some feet of natural rubber. However, creep decreased with UV exposure for these natural rubber feet, as was also the case for EVA feet, whereas the creep increased for two PU feet. Comparison of the effect of humidity and UV exposure generally showed less creep with UV exposure.

Inspection of the internal structures after the laboratory testing revealed failures in all tested feet.

**Conclusion:** None of tested feet passed the standard ISO testing protocol. ISO-10328 testing prior to release of a new foot construction for use by persons with lower limb amputation in developing countries is important to better assure the prescriber and user of the integrity of the prosthetic foot.

## Clinical field testing of prosthetics in tropical low-income countries

**Vulcanised rubber prosthetic feet:** This study of prosthetic feet was completed either at foot failure or follow-up appointment of people with transtibial amputation who had been prescribed a prosthetic foot made from vulcanised rubber in Cambodia or Vietnam. The study was conducted by an ISPO team (an orthopaedic surgeon and a prosthetist).

78 prosthetic feet were delivered in Vietnam from the Vietnamese Training Centre for Orthopaedic Technology (VIETCOT):

- 41 EB-1 feet were delivered with a SACH-foot design developed by Prosthetics Outreach Foundation, Hanoi, Vietnam. The foot consists of a wedge formed wooden keel with a vulcanised textile-rubber sandwich construction for the heel cushion, mid- and forefoot.
- 37 VI-Solid feet were delivered from the Vietnam Veterans of America Foundation (VVAFA), Kien Khleang, Cambodia. The internal construction of the foot is a large tooth shaped polypropylene keel with anchoring holes, tyre-rubber sole and rubber foam heel cushion, and textile reinforcement of heel, mid-foot and dorsum.

108 feet were delivered from the Cambodian School for Prosthetics and Orthotics (CSPO), Cambodia:

- 40 VI cavity heel feet from VVAFA, Cambodia had a cavity formed in the heel cushion to act as a shock absorber.
- 38 PP-rubber feet with SACH rubber-feet from ICRC, Phnom Penh, Cambodia. The polypropylene keel is dog tail shape formed with multiple anchoring holes and wound with rubber bands. The sole is reinforced with tyre rubber.
- 30 HI feet were supplied from Handicap International, Phnom Penh, Cambodia. The big tooth shaped polypropylene keel has anchoring holes and is wound with rubber bands. The heel cushion is of polyurethane.

War ordnance was the cause of amputation in 59% (94/158) of cases. At the time of follow-up 94% were community ambulators and 79% in work. Failure was recorded in 41% (64/158) after 20 months on average. The VI-Solid foot performed best with 18 months survival of 97% and only 6% (2/31) had failed by the end of study at 26 months; wear of the sole being the problem, but only one foot needed exchange. The EB-1 Foot followed the same survival with 97% intact at 18 months, but by the end of the study after 20 (16-22) months 33% (11/33) new feet were needed because of wear of sole or keel. The VI-Cavity Foot was followed for 27 (7-32) months with an 18 months survival of 89%, but by the end of the study new feet were mounted in 40% (14/35) of cases due to wear of the foot sole.

The following table gives detailed information about the rubber foot study.



Rubber feet at review. Image JS Jensen

Vulcanised rubber prosthetic foot study												
Study parameters	Vietnam				Cambodia						TOTAL	
	EB-1 Foot		VI-Solid Foot		VI-Cavity Heel		PP-Rubber Foot		HI-Foot			
Delivered	41		37		40		38		30		186	
Follow-up	33	80%	31	84%	35	88%	29	76%	30	100%	158	85%
Months Follow-up	20	20-22	26	13-27	27	7-32	15	14-29	10	6-17	20	6-32
Age at Amputation	23	4-55	23	4-44	24	11-41	25	16-48	25	7-48	24	4-55
Age now	40	19-66	40	19-57	40	24-53	40	21-60	43	17-55	40	17-66
Skilled Work	8	24%	10	32%	8	23%		0%	7	23%	33	21%
Unskilled Work	17	52%	16	52%	16	46%	22	76%	21	70%	92	58%
Non-limb User	3	9%	6	19%							9	6%
Community Ambulators	30	91%	25	81%	35	100%	29	100%	30	100%	149	94%
Walks > 1 km	28	85%	24	77%	35	100%	26	90%	30	100%	143	91%
Intensive Users	24	73%	20	65%	31	89%	29	100%	30	100%	134	85%
Insufficient craftsmanship	1	3%			2	6%	1	3%	1	3%	5	3%
Failure	14	42%	2	6%	15	43%	24	83%	9	30%	64	41%
- foot cover	1	3%									1	1%
- foot sole worn	4	12%	1	3%	13	37%	20	69%	3	10%	41	26%
- keel worn	8	24%			1	3%	3	10%	4	13%	16	10%
- bolt attachment									1	3%	1	1%
- new foot needed, no.	11	33%	1	3%	14	40%	23	79%	6	20%	55	35%
- foot survival, 18 Months	32	97%	30	97%	31	89%	11	38%			104	66%
- foot survival, 12 Months	33	100%	30	97%	34	97%	27	93%	24	80%	148	94%
- foot survival, 6 Months	33	100%	31	100%	35	100%	29	100%	30	100%	158	100%
Time to Failure, Months	20	16-22	26		27	7-32	15	10-29	10	7-17	20	7-32

The HI-foot was only followed for 10 (7-17) months on average, had 12 months survival of 80% and 20% (6/30) new feet were needed because of worn keel or sole. Eventually the PP Rubber foot from ICRC in Phnom Penh was followed for 15 (10-29) months. It started out well with 12 months survival of 93%, but dropped dramatically to 38% at 18 months and by the closure of the study 79% (23/29) feet had been exchanged because of worn soles.

There is really no explanation of the poor performance of the PP-Rubber Foot other than all the sole failures takes place in front of the keel, where the natural toe-break will take place (see image, right).



Feet were sawn through & examined. Image JS Jensen

**Conclusion:** This study of prosthetic feet used by persons with trans-tibial amputation in Cambodia and Vietnam revealed that the most durable feet made from rubber were from Veterans International, Cambodia, and the EB-1 from the Prosthetics Outreach Foundation in Hanoi. The two feet from Veterans International provide a low cost, durable and locally manufactured prosthetic foot solution for low income countries. The suppliers of the other feet were not aware of the problems because no systematic follow-up is undertaken by the NGO workshops beyond the first year and users hesitate to go back to the workshop for unknown reasons (perhaps financial).

### Polyurethane Prosthetic Feet:

A similar study to the rubber foot study was conducted for polyurethane prosthetic feet in El Salvador, Cambodia and Vietnam.

A total of 82 polyurethane prosthetic feet were delivered by a clinic of the University of Don Bosco. El Salvador: 50 Kingsley-Strider-08 feet were SACH feet consisting of a wooden keel with a textile belt drive forefoot reinforcement encapsulated by molded polyurethane (PU) foam; 32 CIREC feet consisted of a spring-blade foot developed by CIREC, Colombia. They are made of a wedge formed solid PP keel moulded around two PP spring-blades. The core is placed in a metal mould, which is filled with PU foam that is cured to form the heel cushion and encapsulate the entire foot.

In Cambodia, 38 55 SACH feet from CR Instruments, Switzerland and ICRC were tested at CSPO. The dog-tailed, fenestrated PP keel is encapsulated in PU foam.

In Vietnam, 35 Fujian feet from Endolite-Asia, were tested at VIETCOT, Vietnam. The internal construction of the foot is a tooth shaped wooden keel and textile belt forefoot reinforcement encapsulated by PU foam. The following table gives detailed information about the polyurethane foot study.

Polyurethane prosthetic foot study										
Study parameters	El Salvador				Cambodia		Vietnam		TOTAL	
	Kingsley Strider		CIREC		CR-SACH		Fujan			
Delivered	50		32		55		35		172	
Follow-up	33		20		55		28		136	79%
Months Follow-up	17	1-37	13	5-27	18	11-18	11	11-11	11	1-37
Age at Amputation	28	16-50	23	1-72	25	16-59	22	13-44	24	13-72
Age now	35	26-62	36	20-73	42	21-68	44	20-57	41	20-73
Skilled Work	8	24%	5	25%	3	8%	9	32%	25	21%
Unskilled Work	12	36%	5	25%	33	87%	15	54%	65	55%
Non-limb User							3		3	3%
Household Ambulators	4		2						6	5%
Community Ambulators	29	88%	16	80%	38	100%	25	89%	108	91%
Walks > 1 km	26	79%	10	50%	36	95%	22	79%	94	79%
Intensive Users	23	70%	10	50%	37	97%	23	82%	93	78%
Inadequate Craftsmanship	6	18%	5	25%	7	18%	5	18%	23	17%
Failure	29	88%	7	35%	43	78%	13	46%	92	68%
- foot cover					13	24%			13	10%
- foot sole worn	20	61%		0%	23	42%	8	29%	51	38%
- keel worn	9	27%	6	30%	6	11%	5	18%	26	19%
- bolt attachment			1	5%	1	2%			2	1%
- new foot needed, total	26	79%	5	25%	38	69%	13	46%	82	60%
- foot survival, 18 Months	15	45%	16	80%	17	31%			48	35%
- foot survival, 12 Months	24	73%	17	85%	31	56%	12	43%	84	62%
- foot survival, 6 Months	31	94%	20	100%	52	95%	21	75%	124	91%
Time to Failure, Months	15	1-35	16	7-22	10	4-18	11	4-11	11	1-35



PU feet at review. Images JS Jensen

War ordnance was the cause of amputation in 59% (70/119) of cases. At the time of follow-up 91% were community ambulators and 76% in work.

Failure was recorded in 68% (92/136) after 11 months on average. The CIREC foot performed best with 18 months survival of 80%; wear of the keel being the problem leading to exchange of 25% (6/20). The Kingsley foot had the longest follow-up with 12 months survival of 73%; wear of foot sole and keel being problematic and new feet were needed in 79% (26/33) at 15 months.

The worst problems were experienced with only 43% survival at 12 months of the Fujian Foot because of wear of the sole and keel with 46% (13/28) new feet needed, and 31% survival at 18 months of the CR-SACH Foot because of deterioration of the foot cover when exposed to strong sunshine and the sole walking bare-footed. At the end of the study at 11 months 69% (38/55) were exchanged. ICRC and CR Instruments have tried new compositions of PU foam in collaboration with the supplier, but we are unaware of any major break-through.

The best performing foot in this study appeared to be CIREC foot from Bogota, Colombia. All users claimed to be intensive users, but it was noted that craftsmanship and user compliance were on the low side, and the drop-out from follow-up was the highest and so we do not have confidence in the results.

**Conclusion:** polyurethane based prosthetic feet cannot be recommended for tropical areas of the developing world.

### **Vulcanised Jaipur Rubber Feet:**

In the 1970's Dr. P. K. Sethi initiated the development of a prosthetic foot as an alternative to the conventional SACH foot, but which allowed barefoot walking, squatting and cross-legged sitting. The foot was originally designed with a high ankle block of wood facilitating fixation to the aluminium shank of the prosthesis with wooden screws; a block of sponge rubber layers glued together to resemble the mobility of the normal ankle, subtalar and midtarsal joints. Originally the tarsus and metatarsals were replicated by a wooden wedge with plantar reinforcement by cord lining. Each block was enclosed in a shell of hard rubber, covered with natural rubber and vulcanised. In later models the fore-foot was replaced by a hard rubber block or sponge rubber layers. The sponge rubber parts allowed for dorsi-flexion, plantar-flexion, supination, pronation, internal and external rotation and provided a more natural gait closer to the performance of the normal foot.

Two studies of persons with trans-tibial amputation using Jaipur rubber feet produced by two different manufacturers – MUKTI, Chennai and NISHA Foot Centre, Kartarpura, Jaipur, India were conducted. The constructions are in essence identical to the original design of the Jaipur foot with a wedge formed block of sponge rubber layers, separated by a wall of natural rubber from the cubical, compressible heel block of sponge rubber layers, separated from the wooden ankle block. The whole construction is wrapped with natural rubber and vulcanised. The studies were conducted at the ICRC project in Ho Chi Minh City, Vietnam. The prostheses were produced by prosthetic technicians, but check-out carried out by one of two expatriate prosthetists. The participants were seen for follow-up by an ISPO-team at 8-9 months and 15-17 months. Study participants were seen either at failure of their prosthetic foot or at the

latest follow-up. The clinical field testing was conducted in accordance with the system developed by ISPO.

Other ISPO assessment teams visited centers in Honduras, Uganda and India. At all three centers the technology had been introduced through a three week training course provided by trainers from BMVSS. The Teleton project in Honduras was sponsored by Rotary International, the materials supplied by BMVSS with the prescription supported by a physiatrist, and the prosthetics fabrication and fitting undertaken by an occupational therapist and a maintenance man. The projects in Kumi and Baluba, Uganda were coordinated by World Rehabilitation Fund (WRF) and utilised orthopaedic technologists and technicians with several years' on-the-job training. The Indian project in Kerala was administered by the Tropical Health Foundation, sponsored by Rotary Jaipur Limb Project of the United Kingdom, and utilised technicians with more than fifteen years on-the-job training.

Vulcanised Jaipur Rubber Feet studies										
Study Parameters	ICRC, HCMC, Vietnam				Comparative studies					
	MUKTI- Foot		NISHA-Foot		Honduras, 2001		Uganda, 2002		India, 2002	
Delivered	41		42		109		104		107	
Follow-up	41	100%	40	95%	31	28%	70	67%	71	66%
Months Follow-up	16	9-17	15	8-17	31	11-81	36	11-44	37	16-51
Age at Amputation	20	13-28	20	7-48	24	0-72	37	1-70	40	0-82
Age now	51	25-55	51	36-61	33	13-85	58	6-84	46	20-86
Skilled Work	12	29%	7	18%	7	23%	3	4%	13	18%
Unskilled Work	21	51%	24	60%	9	29%	49	70%	18	25%
Non-limb User					4	13%	2	3%	4	6%
Household Ambulators			7	18%	3	10%	7	10%	10	14%
Community Ambulators	41	100%	33	83%	12	39%	63	90%	61	86%
Walks > 1 km	41	100%	40	100%	8	26%	51	73%	23	32%
Intensive Users	37	90%	33	83%	11	35%	33	92%	28	76%
Inadequate Craftsmanship	3	7%	3	8%	16	52%	41	59%	40	56%
Failure	23	56%	19	48%	16	52%	47	67%	34	48%
- foot cover	1	2%					5	7%	1	1%
- foot sole worn	2	5%	3	8%	1	3%	12	17%	3	4%
- keel worn	6	15%	14	35%	15	48%	40	57%	34	48%
- bolt attachment/others	14	34%	2	5%		0%		0%		0%
- new foot needed, total	11	27%	11	28%	13	42%	41	59%	16	23%
- foot survival, 18 Months					20	65%	41	59%	63	89%
- foot survival, 12 Months	27	66%	30	75%	24	77%	49	70%	67	94%
- foot survival, 6 Months	41	100%	39	98%	29	94%	61	87%	69	97%
Time to Failure, Months	16	15-17	9	5-16	17	2-38	17	3-41	30	3-47

There was a high follow-up rate on the prospective studies in Vietnam, but a low follow-up rate in the retrospective studies, which could influence the results. The groups from Honduras and India are less intensive users and fewer had jobs and the craftsmanship is generally poor in the retrospective series.

The 12 months survival exceeded 65%, but was lower than the experiences with both PU feet and in particular rubber feet. The failure rate was around 50-65% both with the feet provided by trained staff and the technicians in Honduras, Uganda and India. The problems were mainly related to the keel and heel block with separation of the sponge layers followed by fracture of the skin. The need of a new foot was less than 30% in Vietnam and India, but 42-59% in Honduras and Uganda.

For the Honduras and Uganda users similar results were seen with around 40% failures after 18 months, whereas the Indian feet have about 20% less failures at 30 months, which is apparently the life-time for Jaipur feet.

Based on confidence interval for estimated proportions it is possible to evaluate the reliability of the results obtained from subpopulations of the original finite population of N=320 (Machin et al., 1997).

If, for instance, the true proportion of e.g. inadequate fit among the cohort of 320 is 78%, a sample size of 70 is required to produce a 95% confidence interval with a width of  $\pm 10$  percentage points around the estimated proportion. Assuming that proportions found among the 172 amputees seen are of similar magnitude to those in the complete population of 320 amputees provided prostheses the sample size of 172 amputees is sufficient for producing confidence intervals with a reasonable width. For misalignment, the observed proportion was 78%, which leads to the confidence interval [0.71-0.85]. This interval includes with 95% probability the true proportion in the total population of N=320.

This analysis was performed for each of the projects involved, but the sampling number for Honduras was low and the requirement for statistical adequacy could not be met.

**Conclusion:** When the studies were pooled together the results allowed us to conclude, with 95% certainty, that the HDPE-Jaipur technology for trans-tibial amputees failed to meet the standards for socket fit, socket wall adequacy, alignment, length, craftsmanship and system related failures (i.e. foot), patient compliance, and occurrence of pain. The same conclusions could be reached with the number of patients seen in the individual projects in Uganda and India.

### The Shape&Roll Foot

The Shape&Roll prosthetic foot mimics the natural walking characteristic of “roll over”. The foot was designed by a team at Northwestern University, USA for use in developing countries. The prosthetic foot core is made by melting pieces of polypropylene-polyethylene plastic in an oven followed by



Jaipur foot failurers. Images JS Jensen



Foot cross section. Image JS Jensen

compression in a lever-molding device and shaped to lengths of 22-25 cm. A flange is left at the heel for shock-absorption, and saw cuts in the forefoot allow for an appropriate shape in dorsi-flexion during walking. A sock of about 6mm polyurethane is made and the core is put on as a shoe with the help of a shoe-horn. No attempt is made to glue the cover to the core, nor is it sealed at the top.

The following table gives details for the study:

Shape-and-Roll Foot Study, Cambodia		
Follow-up	35	
Months Follow-up	9	8-10
Age at Amputation	25	6-44
Age now	45	17-60
Skilled Work	10	29%
Unskilled Work	24	69%
Non-limb User	0	0%
Household Ambulators	1	3%
Community Ambulators	34	97%
Walks > 1 km	30	86%
Intensive Users	21	60%
Inadequate Craftsmanship	7	20%
Failure	30	86%
- foot cover	12	34%
- foot sole worn	25	71%
- keel worn	2	6%
- bolt attachment		0%
- new foot needed, total	30	86%
- foot survival, 18 Months	0	0%
- foot survival, 12 Months	11	31%
- foot survival, 6 Months	19	54%
Time to Failure, Months	5	1-9



35 users were followed up after an average of 9 months use. Severe wear of the sole at the heel was observed in 20/35 (57%) cases in combination with breakage of the cover over the first toe or loss of all the cover and sole distal to the level of the metatarsal heads after 5 (1-9) months on average. Eventually the whole keel was expelled and the foot filled up with water and mud in the many open spaces. New feet were needed in 86% of cases within 9 months.

**Conclusion:** We recommend that further use of this model of the Shape&Roll polyurethane based, non-sealed feet is brought to a halt and for ethical reasons those few feet still functioning should be exchanged.

### The ATLAS Prosthesis for people with trans-tibial amputation

The ATLAS system consists of an integrated I-beam shin and foot-keel blade, designed for fibre reinforced thermoplastic injection moulding, and an injection moulded elastomeric toe-break. The shin-foot component comes with a full-length durafoam cosmetic cover. The height of the prosthesis is adjusted by cutting off the length of the I-beam, which is then fixed to a H-profiled slot in a chassis with two clamp screws, and between that and the prosthetic socket an alignment coupling is interposed to allow linear shift, angulation and rotation at one level. The prosthetic socket is not part of the system, but is individually made in the conventional fashion.

The prostheses were tested in 49 cases in Cambodia and 36 cases in El Salvador. Six were lost to follow-up and 15 were non-users; mostly because of unsatisfactory socket fit (9), but in six cases because of a shrieking noise from the shin-foot piece during walking. Intensive users were 89% (59/66) and 77% (51/66) could walk more than one kilometer. In Cambodia 56% (23/41) had failed after 10 (3-20) months and in El Salvador 72% (18/25) after 18 (3-31) months. The most serious failure was fracture of the shank in 36% (24/66) happening during sports or walking. The foot sole worn out in 14% (9/66), the IH-beam



needed tightening in 17% (11/66) and the cosmetic cover worn out in 8% (5/66). The survival curves for the two countries followed that of the HI-rubber foot from Cambodia tightly. With a failure rate of about 40% after 1½ year the ATLAS system was considered unacceptable and was later withdrawn.

## Clinical field testing of trans-femoral prosthetic technology

This report presents the experiences with people with trans-femoral amputation provided with either a prosthesis of conventional design with resin-laminated socket, wooden blocks, uniaxial knee, and a vulcanised rubber foot of SACH design; or a polypropylene prosthesis based on a tubular, modular system from ICRC (International Committee of the Red Cross) with a polypropylene draped sheet socket, a uniaxial knee joint, and a vulcanised polyurethane-rubber covered SACH design made with polypropylene keel.

The prostheses were supplied by the orthopaedic workshop at the Category-II recognised school, TATCOT (Tanzanian Training Centre for Orthopaedic Technologists) by its' teachers or under their supervision. The TATCOT prosthesis had a knee mechanism from Otto Bock, Germany of uniaxial design; in 5 cases with swing phase control, 8 cases as a freely swinging knee, and in 14 cases as a locked uniaxial knee. The TATCOT vulcanised rubber foot is a SACH design. The components were united with wooden blocks, and static bench alignment performed.

The ICRC prosthesis had a uniaxial knee mechanism from CR Equipments S.A., Switzerland. The shank part is fixed to the proximal housing by a transverse hollow axis, which is fixed with a transverse bolt/nut arrangement with side washers. The rotation of the axis is secured by 2 screws that are tightened into the trough of the axis. In 12 cases the knee locking mechanism was left open for the knee to swing freely, and in 23 cases a locked knee was utilised. Two dynamic alignment discs were placed between the socket and the knee unit, and between the foot and the shank. The CR-foot is a SACH design with polypropylene keels and toe-break with a vulcanised polyurethane-rubber cover.

All 27 TATCOT prostheses provided were seen for clinical and technical follow-up after a median of 20 (8-27) months. Of 42 ICRC prostheses provided 35 were seen for follow-up after 15 (6-26) months, and 7 were lost to follow-up.

Failures associated with wear of the prosthetic foot occurred in 5 cases with TATCOT rubber feet and 4 cases with the CR-foot from ICRC, requiring replacement of the foot in 7 cases. A further 7 patients with CR polyurethane feet needed to have the attachment bolt tightened or a malrotation corrected. Failures associated with the prosthetic foot thus occurred in 19% (5/27) of TATCOT prosthesis and 31% (11/35) of ICRC prostheses ( $p = 0.26$ ). Failures of function and stability of the knee joint occurred in 5 cases (19%) with the TATCOT prostheses, requiring a new prosthesis in 3 cases. The failures were related to the knee brake, the axis and the lock. Equivalent failures were encountered in 7 cases (20%) with the uniaxial knee from ICRC. However, an additional problem was observed in 12 cases after 10 months and a further 2 at the 16-months follow-up, namely wobbling or slackness of the knee axis because of loosening of the bushings and the fixation bolts for the axis. In 8/12 users with a non-locked knee this failure was observed, as compared to 5/23 with locked knees ( $p < 0.008$ ). This involved need of adjustment by an orthopaedic

technologist or technician in 40% (14/35) of cases, but only 3 knees needed to be replaced. At the second follow-up 6 months later the same wobbling had reappeared and required a second adjustment. This problem was, however, not associated with the insecurity of the knee reported by 4 patients (15%, 4/27).

Trans-femoral study				
Study parameters	TATCOT-RW		ICRC-PP	
Delivered	27		42	
Follow-up	27	100%	35	83%
Months Follow-up	20	8-27	15	6-26
Age at Amputation	28	6-51	26	7-57
Age now	38	12-67	36	22-67
Skilled Work	9	33%	11	31%
Unskilled Work	4	15%	13	37%
Non-limb User	1	4%		0%
Household Ambulators		0%	2	6%
Community Ambulators	26	96%	33	94%
Walks > 1 km	24	89%	33	94%
Intensive Users	23	85%	33	94%
Inadequate Craftsmanship	4	15%	14	40%
Failure	13	48%	27	77%
- socket	4	15%	7	20%
- socket change	2	7%	4	11%
- knee unit	4	15%	7	20%
- wobbles	1	4%	14	40%
- knee adjusted		0%	13	37%
- new prosthesis	4	15%	3	9%
- foot cover		0%	2	6%
- foot sole worn	5	19%	2	6%
- keel worn				
- bolt attachment		0%	7	20%
- new foot needed, total	4	15%	3	9%
- survival, 18 Months	85%		23%	
- survival, 12 Months	93%		43%	
- survival, 6 Months	100%		100%	
Time to Failure, Months	19	8-21	10	9-21

the screws aimed at adjusting the swing phase and at fixating the rotation of the knee axis, worked loose, although the side nuts had a built-in nylon bushes intended to lock the nut.

**Conclusion:** Although loose joints are a simple issue that only requires tightening of nuts, or locking them with glue, it is a significant problem that needs to be addressed by the design engineers. The staff used for the fabrication in this study had been through a practical hands-on course, but still did not fully acknowledge the importance of these screw arrangements and might have ignored sufficient tightening in the first place or did not understand that wobbling of the knee was associated with loosening of the nuts. However, as the problem reiterated itself it is unlikely that this is the main cause - the problem is in the design. The repair cannot be expected to be addressed by a non-educated technician in a remote village, but it requires the user to seek help at the orthopaedic workshop, which might be a day travel away.

Poor socket fit requiring new sockets were encountered in 4 cases (15%) with TATCOT prostheses and 7 cases (20%) with ICRC prostheses. An additional 2 limb users had their TATCOT prosthesis replaced because of failure of the knee joint. The failures were considered to be linked to the components in 46% (6/13) of failures in the TATCOT group, but 63% (17/27) in the ICRC group ( $P = 0.33$ ).

The study was conducted at a school for education and training of Category II orthopaedic technologists with the aim of eliminating the educational factor in fabrication of the prosthesis, as the prostheses were all made by Category I prosthetists and their associates. This goal was not achieved in respect of mal-rotation or loosening of the CR-foot, probably because the professionals were not used to the techniques of attaching the foot to a tubular shank with a bolt.

In trans-femoral users a complex knee mechanism has previously shown to be a problem with the ATLAS knee (Jensen and Raab, 2003). A uniaxial knee design was utilised in both components in this study. With the ICRC knee, in particular when used in a free swing fashion, the side nuts and

## Clinical Field Testing of HDPE-Jaipur Trans-Femoral Prosthetic Technology

The assessment team evaluating the Jaipur foot used for trans-tibial prostheses also surveyed 72 trans-femoral users provided with prostheses according to the Jaipur system by the same technician trained for three weeks at the BMVSS in Jaipur, India. The fabrication is rather complex (Jensen et al 2004), but based on usual plaster of Paris technique with a quadrilateral socket and a uni-axial knee-joint.

Clinical Field Testing of HDPE-Jaipur Trans-Femoral Prosthetic Technology						
	Honduras		Uganda		India	
Delivered	80		35		43	
Follow-up	32	40%	12	34%	28	65%
Months Follow-up	29	10-57	38	17-46	36	17-54
Age at Amputation	46	0-77	21	8-46	41	9-66
Age now	55	9-91	27	15-80	48	28-76
Skilled Work	6	19%	3	25%	5	18%
Unskilled Work	11	34%	4	33%	7	25%
Non-limb User	13	41%	3	25%	9	32%
Household Ambulators	7	22%		0%	12	43%
Community Ambulators	12	38%	9	75%	7	25%
Walks > 1 km	9	28%	7	58%	4	14%
Inadequate Craftsmanship	27	84%	12	100%	23	82%
Failure	27	84%	11	92%	23	82%
- poor fit	16	50%	11	92%	18	64%
- inadquate walls	8	25%	11	92%	18	64%
- socket	4	13%	1	8%	8	29%
- socket change	6	19%	3	25%	7	25%
- knee unit	10	31%	6	50%	4	14%
- screws	12	38%	1	8%	4	14%
- misalignment	24	75%	11	92%	21	75%
- new knee	9	28%		0%	4	14%
- new prosthesis	1	3%	3	25%		0%
- foot cover		0%		0%		0%
- foot sole worn	4	13%	5	42%	7	25%
- keel worn		0%		0%		0%
- screw attachment	5	16%	5	42%	7	25%
- new foot needed, total	9	28%	5	42%	7	25%
- survival, 18 Months	72%		100%		86%	
- survival, 12 Months	94%		100%		100%	
- survival, 6 Months	100%		100%		100%	
Time to Failure, Months	15	1-57	22	12-46	29	17-54



A misaligned knee joint, anterior view

**Conclusion:** It is not possible to approve the HDPE-Jaipur technology for trans-femoral users as an appropriate technology with the way the services are provided and some of the components used. The material and components are of high technical standard and could provide a low cost possibility, but improvement is

The patients were followed for a median of 32 months. Fifty percent (36/72) were working and 39% (28/72) community ambulators, whereas 35% (25/72) were non-users. This can in part be associated with 86% (62/72) of the prostheses being assessed as defective craftsmanship. Poor socket fit was encountered in 63% (45/72), inadequate walls in 51% (37/72) and misalignment in 78% (56/72). Among the non-users 32% (8/25) had experienced failures, but the assessors found need for new sockets or poor alignment in 84% (21/25).



Inadequate anterior and lateral socket walls and tuber seat. Images JS Jensen

needed. The utilisation of manpower is unacceptable. The non-trained technicians are unable to adapt a prosthesis to an amputation stump with a functional result even with more sophisticated materials and components. A recognised prosthetics training is required to ensure proper use of materials and correct alignment of the prosthesis.

### **The ATLAS prosthesis for people with trans-femoral amputation**

The ATLAS system includes of an alignment device, which allows movement in any direction. In the knee mechanism a threaded pivot runs in a moulded housing with a transverse split brake. This has a combined function of knee flexion bearing and stabilising brake. A shock cord runs forward across a groove in the brake moulding, acting as an extension assistance spring. There is a manually operated knee lock. The lower knee moulding ends with an H-profiled slot with two clamp screws into which the shin/foot component is fixed. This consists of an integrated I-beam shin and foot keel-blade, designed for fibre-reinforced thermoplastic injection moulding, and an injection moulded elastomeric toe-break.

At UDB, El Salvador 22 TF prostheses were delivered, but 6 users were lost to follow-up 10 (1-18) months later and 3 were non-users and one household ambulator. Eight (8) were in work and 12 could walk > 1km. The prosthetic fit was inadequate in 69% (11/16) and misalignment observed in 62% (8/13). A total of 92% (12/13) failures needed repair or replacement including 12 knee joint failures, 3 alignment problems and 3 socket cracks.

At CSPO, Cambodia 25 prostheses were delivered, but 6 missed the follow-up. 12 people were in work and 14 could walk > 1km. At the first follow-up at 7 (4-11) months 89% (17/19) knees had failed; 7 extension assist and 1 knee lock broken and 8 knees loose. All needed repair, including 9 new prostheses, which led to withdrawal by 3 amputees. At the second follow-up after 17 (6-20) months only one knee was intact for light use at home. The 15 users having totally demolished the knee joint were offered a second generation component, but 6 months (2-18) later this knee had also failed and the study was terminated. There was no likelihood that major design changes in the knee mechanism would be of any help, as the problem would then be transferred to the shin/foot part, which had already demonstrated its inadequacy.

**Conclusion:** It was concluded, that the ATLAS trans-femoral system should be abandoned from use for these patients. This was done.

## Amputation stump casting technology

Inadequate fit of the prosthetic socket is a frequently occurring problem in the developing world with the use of conventional Plaster of Paris casting technique. The sand-casting technology developed by the Center for International Rehabilitation (CIR), Chicago, USA might have been a possible improvement in consistency of prosthetic fit. Sand-casting for shape capture and socket fabrication has not yet resulted in a technical break-through in the developing world and total contact could only be achieved by applying 3 (2-5) one-ply wool stump socks. The new CIR-Wu technology was then introduced. The principal difference was that the original sand-container was replaced by a small light-weight casting-bag containing polystyrene beads, and an air compressor was no longer needed. However, a vacuum pump with a large surge tank was still required.

Twenty-eight younger established limb users were selected for the sand-cast testing and followed for 7 and 11 months. First, the stump was dressed with two terry compression socks and a relief added over pressure sensitive areas. A nylon sock was applied and over that a thin plastic bag. A supra-condylar brim was added and kept in place with tape. The stump was inserted into a container with fluidised silica sand and vacuum applied. A thin plastic bag was pulled over the container to seal it, and the stump removed from within the thin plastic bag leaving the brim as part of the walls of the negative cast. A suction mandrel was placed in the negative model, which was filled up with silica sand and vacuum applied. Vacuum was released from the main container and the positive model removed followed by rectification by gentle pounding. The positive model was vacuum-draped with a thermoplastic polypropylene sheet after a small plastozote disc was added to the distal end to prevent grounding. At the first follow-up a transparent trial socket was made by the sand-casting technique and another (check socket) by plastic draping on a positive Plaster of Paris cast of the initial socket. At both follow-up visits, socket mapping was performed after dressing the stump with 1-4

compression socks. Total contact was achieved in all cases; although in check sockets 5 areas were larger and 3 smaller than expected. One trial sockets was larger.

A pilot-study with 10 persons with trans-tibial amputation was performed with the new CIR casting method by the same Category-I prosthetist who did the original sand-casting method. First the stump was covered with a thin nylon sheet and a thin plastic bag and the casting bag rolled on to a level slightly above the trim line. A second plastic bag with a vacuum connector attached was applied onto the end of the casting bag and then pulled over the casting bag towards the knee. The second plastic bag was held down by a rubber band, and the first bag folded downwards to cover the second bag and secured with another rubber band distally to the former. At this time the vacuum pump was connected and the air evacuated

Stump casting technology study				
	CIR-Wu-Casting		Sand-Casting	
Number	10		28	
Users of Prosthesis	10	100%	25	89%
Intensive	5	50%	23	82%
Walks > 1 km	8	80%	22	79%
No Comfort	2	20%	9	32%
Pain	1	10%	10	36%
Satisfied	8	80%	25	89%
Good Fit	8	80%	19	68%
Wide Fit			5	18%
Tight Fit	2	20%	4	14%
Difference Circumference, CIR-Wu versus Sand-cast				
	Min	Max		
Patella Tendon	1,3	0,1		
Patella Tendon + 4 cm	0,5	-0,2		
Patella Tendon + 8 cm	1,2	0,5		
Patella Tendon + 12 cm	1,5	0,5		

resulting in the casting bag becoming a solid negative mould of the amputation stump. By pulling and

pushing on the socket, comfort was checked. Additionally, weight bearing on a padded auto jack was possible. The negative mould was removed, but the vacuum suction maintained. The negative mould was filled with silica sand, a suction mandrel inserted, and a bottomless plastic cup placed on top of the sand and filled up with sand. The first plastic bag was then pulled over the bottomless cup and taped onto the mandrel to seal the sand inside the cavity of the negative mould. Vacuum was applied to the mandrel to form the solid positive sand model. The vacuum suction was maintained through the mandrel, but released from the casting bag, which was then removed. The positive model was modified and made ready for drape vacuum forming or bubble vacuum forming of the prosthetic socket. Users were followed for 5 months. The circumference of the positive cast was measured at the level of the posterior trim-line, and 4, 8, and 12 cm distally for each method of casting. At follow-up the satisfaction rate between the two groups did not differ, but the sand-cast group used the device more intensively. It is clear that comfort complaints were less with the pilot group (20% versus 32%) and prosthetic fit was better (80% versus 68%) with no wide fits. This was specifically reflected in the measures of circumference that were significantly lower at all levels with the CIR casting system, and also that only one sock was required to obtain total contact as compared to 3 (2-5) with the sand-casting system. Further, 21% (6/28) of the sand-cast sockets were considered failures. However, the need of a well-trained prosthetist is not eliminated by this technology.

**Conclusion:** the CIR casting method is a positive development for casting transtibial amputation stumps.

## Impact on end-user or consumer compliance follow up

A number of publications exist on certain prosthetics or orthotics technologies but little is known about general consumer compliance with orthopaedic devices. Hughes (1996) said at the ISPO/USAID/WHO consensus conference on appropriate prosthetic technology: “while all the agencies are well intentioned...there is an almost complete failure to evaluate the outcome of their efforts”. Most organisations still do not have quality data on the service they provide for their most remote patients. In the extensive ISPO/USAID program on prosthetic foot testing we developed some quality benchmarks for user compliance (Jensen et al 2005; Jensen & Raab 2007):

### ISPO quality benchmarks for user compliance

Patient compliance	95±5%
Non-users	5±5%
Walk > 1km	90±10%
Pain	5±5%
Satisfied	90±5%

### Technical compliance

Good socket fit	60±5%
Malalignment	10±5%
Insufficient craftsmanship	10±5%



Assessment of graduate work. Image M Thorpe

### Patient compliance studies

	TATCOT, Cat-II					VIETCOT, HANOI, VIETNAM					
	Trans-femoral, RW		Trans-femoral, PP		Trans-tibial	VI-Solid		Fujian		EB-1	
Prescribed	27		35			31		28		35	
Patient Compliance	23	85%	35	100%	Patient Compliance	25	81%	25	89%	30	86%
Non-Users	1	4%	0	0%	Non-Users	6	19%	3	11%	3	9%
Walking > 1 km	24	89%	31	89%	Walking > 1 km	25	81%	22	79%	27	77%
Pain	3	11%	7	20%	Pain	6	19%	10	36%	8	23%
Satisfied	25	93%	32	91%	Satisfied	25	81%	25	89%	30	86%

Trans-tibial	CSPO, PHNOM PENH, CAMBODIA									
	CR-SACH		Handic Int		PP, ICRC		VI-Cavity		VI-Multi-ax	
Prescribed	55		30		29		37		56	
Patient Compliance	55	100%	5	17%	29	100%	37	100%	56	100%
Non-Users	0	0%	14	47%	0	0%	0	0%	0	0%
Walking > 1 km	53	96%	16	53%	29	100%	35	95%	55	98%
Pain	0	0%	0	0%	0	0%	2	5%	0	0%
Satisfied	55	100%	28	93%	24	83%	37	100%	54	96%

Trans-tibial	UNIVERSITY DON BOSCO, EL SALVADOR			
	Kingsley		CIREC	
Prescribed	33		20	
Patient Compliance	33	100%	18	90%
Non-Users	0	0%	2	10%
Walking > 1 km	26	79%	10	50%
Pain	8	24%	7	35%
Satisfied	26	79%	14	70%

### Quality of Life Studies

The World Health Organization has developed and promoted Quality-of-Life scales based on self-administrated forms or interviews. Other groups have also worked with such systems like the SF-36, which has been applied frequently to orthopaedic patients in the USA. The most recent development from WHO is the WHO-BREF tool, which is based on 26 questions that can be subdivided into 4 domains:

**I Physical** (Pain Prevention, Medical Treatment, Energy, Getting Around, Sleep, Working Capacity);

**II Psychological** (Enjoy, Meaningful, Concentration, Body Appearance, Self-esteem, Negative Mood);

**III Social** (Relations, Sex, Friend Support);

**IV Environment** (Safe, Environment, Money, Info Needed, Leisure, Living Place, Access, Transport).

We used the questionnaire in the local language and the interview was conducted by a local (secretary, CBR-worker) with the following results, applicable only to individuals over 14 years of age.

There were only sporadic differences between intact and failed prostheses that required repair or replacement; mainly because of poor socket fit or worn prosthetic foot. There were no differences in domain scores in this rather small study. This system has not proved its usefulness with trans-tibial prosthetics, but further studies should be conducted. No significant differences were found in domain scores in identifying prosthetic failures for trans-femoral users.

With the orthotic appliances there were more evidence in failures as they significantly influenced the domain scores in the psychological domain for KAFO orthoses ( $p=0,02$ ). The environmental adoption domain was significantly ( $p=0,02$ ) affected for the AFO orthoses. However, the differences do not lead to any clinical awareness.

**In conclusion**, we did not see any benefits in continued use of this system in the way it was employed because we felt it was not sensitive enough to demonstrate significance in our special population, but the series were very small. Future follow-up studies should consider whether or not to use this outcome measure.



## ISPO Consensus Conference on appropriate orthopaedic technology for low-income countries

The conference was held in Moshi, Tanzania, 18-22 September 2000. 77 participants included government programs and non-government organizations, education programs and resource persons. A full report was published. Consensus was reached about the following points:

1. Appropriate technology is a system providing proper fit and alignment based on sound biomechanical principle which suits the needs of the individual and can be sustained by the country at the most economical and affordable price. That statement from a 1995-conference was endorsed and it was agreed that it applies to the whole field of prosthetics and orthotics.
2. It is the responsibility of NGOs to consider the positive or negative impact of the introduction of new technology on the existing system and service.
3. New technology should be evaluated through pilot testing which would allow other local organisations to become familiar with it.
4. Other in-country organisations should be invited and encouraged to participate in decision making about the introduction of new technology.
5. The need for improved access to and transfer of information was emphasised as also was the need for publication of activities.
6. There is an urgent need for research, development and evaluation activities in relation to appropriate orthopaedic technology.
7. Although more numerous, the orthotics needs in low income countries have been largely neglected. Orthotics services should be given at least equal priority to the prosthetics services.
8. There was general agreement on the factors to be considered in applying quality assurance in prosthetics and orthotics services and its importance was emphasised.
9. It was emphasised that data collection is an essential element of quality assurance to identify problems.
10. Results oriented (simple) and product oriented (complex) types of quality assurance were considered and their relative places in the development of a service identified.

# ISPO Consensus Conference on wheelchairs for developing countries

**Definition of an appropriate wheelchair:** A wheelchair is appropriate when it meets the individual's needs and environmental conditions; provides proper fit and postural support based on sound biomechanical principles; is safe and durable; is available and can be accessed, maintained and sustained in the country at the most economical and affordable price.

This conference was held in India in November 2006 and a full report was published. Consensus was reached on a number of points including:

**Needs assessment:** According to WHO it is estimated that about 10% of the population are people with disabilities. There is no accurate figure for the number of people in developing countries that require a wheelchair. It is estimated that about 1% in any given population, i.e. about 65 million people worldwide require a wheelchair. Anecdotal evidence indicates a very small minority of those in need have access to an appropriate wheelchair.



Wheelchairs can allow participation in sport. Image J Fisk

## Outcome measures

- Reliable record keeping is essential for all phases of wheelchair provision including assessment, prescription, fitting, delivery and follow-up.
- Regular follow-up/evaluation of outcomes of wheelchair provision should be performed.
- User satisfaction surveys should be performed and include measures of the impact of wheelchair provision on the quality of life of the user.

## Services

- Wheelchair services are an integral part of wheelchair provision.
- User participation is an integral part of wheelchair services.
- Wheelchair services should be delivered by trained personnel.
- Government has the primary responsibility for sustainable wheelchair service. Wheelchair services should be an integral part of national strategies.
- The wheelchair services are encouraged to ensure that people with disabilities from all sectors of society are provided with appropriate wheelchairs including those from marginalised and vulnerable groups such as women and children.
- The aim of wheelchair services is to ensure that the person in need of a wheelchair receives it together with the necessary information and support. The wheelchair should meet the individual's needs in terms of mobility, appropriate fit, comfort, safety and ability to carry out activities of daily living and exercise basic human rights.

## Distribution

It is recommended that, irrespective of method of distribution:

- The provider has the capacity to provide the wheelchairs in a reasonable and responsible manner;
- The distribution is based on an assessment of the situation in the country or the region of the country and considers the impact on local wheelchair producers and service providers;
- Procured wheelchairs meet or exceed relevant international standards and be appropriate for the environment of use;
- Wheelchairs are provided following a provision process that meets or exceeds internationally agreed minimum requirements for service provision, including requirements for assessment, fitting, user training and follow-up;
- Distributors coordinate their distribution with national and local governments as well as producers and providers of wheelchairs in the country.

## Training and education

- It is recognised that training and education are key elements for developing, introducing, maintaining and building sustainable wheelchair services.
- All stakeholders need to be trained and/or informed regarding their roles in wheelchair provision.
- In particular the user and assistant must be properly informed and trained.
- An expert group under the umbrella of an internationally recognised organisation should:
  - develop the professional profiles for the training of people involved in wheelchair service provision.
  - specify the content of the various training, education and information modules required.

## Present Status

WHO has in collaboration with stakeholders developed a basic module of 2 weeks duration on establishing a sufficient service provision of wheelchairs in developing countries, which has been tested in India and the Solomon Island. The group is currently working on a 2 weeks intermediary programme and a 3 days course for managers and policy makers to be ready for testing in Romania, Kenya, and the Philippines by February 2011 and to be launched in September 2011.

# ISPO Consensus Conference on appropriate lower limb orthotics for developing countries

This conference was held in Vietnam in April 2006: Conclusions and recommendations included:

## Needs assessment

- Need of orthotics has not been met and orthotics should be given greater attention.
- The greatest area of need is the lower limbs.
- Epidemiological data collection related to orthotics needs is required for policy and service development.
- Standardised tools and methodology need to be developed and implemented for data collection.

## Outcome assessment

- Reliable patient record keeping is essential for all phases of orthotic management including prescription, checkout and follow-up.
- Regular follow-up/evaluation of outcomes of orthotic management should be performed. This should include functional outcomes.
- User involvement including satisfaction surveys must be an integral part of outcome assessment.
- User satisfaction surveys should be performed and include measures of the impact of orthotic management to enhance the quality of life.

## Education

- There remains an overwhelming unmet need for trained persons to work in the orthotics sector in developing countries.
- The meeting endorsed the ISPO standards of education and the WHO/ISPO guidelines for education and training.
- There is a need for upgraded knowledge and understanding of medical and rehabilitation personnel in issues relevant to orthotic management.
- Need for upgraded knowledge and understanding of relevant pathologies for orthotics personnel.
- The conference endorses the use of quality management and outcome systems in P&O educational institutions.
- P&O schools should promote the role of orthotics in rehabilitation, the rehabilitation team and continuing education.
- ISPO should establish a working group to investigate issues related to the provision of orthopaedic footwear in developing countries.



Training in orthotic care. Image J Fisk

## **Technology**

- Need for research, development, production and evaluation of appropriate orthotic components.
- ISPO should explore and implement methods to share and transfer appropriate technology.
- ISPO should promote and encourage the coordination of availability and accessibility to appropriate orthotic technology.

## **Rehabilitation team**

- Establish better links between orthotic service and user groups.
- The user/family must be an equal member of the rehabilitation team.
- There is a great need for exchange of information between different rehabilitation personnel.
- It is recognised that the full clinical team is not always available. However it is recommended that the minimal clinical team should include the user/family and the orthotist.

## **Community based rehabilitation**

- Establish a network between the orthotic service and CBR, PHC and/or other community based programs – an example of a positive relationship between CBR and orthotic services is the implementation of the Ponseti club foot management program in Uganda, amongst other places.
- A close working relationship between CBR programs and the orthotics service providers should facilitate early detection, early intervention and follow-up to promote optimum functional capacity and prevent further impairment.

## **Quality management**

- Schools should promote the knowledge and need of quality orthotic services as a part of their education curriculum.
- Orthotic service providers need to develop and implement quality management procedures.
- The conference endorses the use of quality management and outcome systems in orthotic service delivery.

## **Cost calculation**

- The conference recommends promotion, feedback, evaluation and development of the ISPO/USAID cost calculation tool.
- It is recommended that the individual P&O schools use the ISPO/USAID cost calculation tool in their curriculum.
- Recommend the establishment of a forum through which users of the ISPO/USAID cost calculation tool can communicate.

## **General**

- Orthotic management should address the most common conditions encountered in the field. These include; cerebral palsy, clubfoot, polio, stroke/traumatic brain injury and the insensate foot.
- Orthotic treatment should be based upon individual assessment of the patient's functional deficit.
- General orthotics treatment protocols may be impractical due to the variability of individual patients' presentation.

## SECTION 2: Education

The purpose of the Collaborative agreement in relation to education was to improve prosthetics-orthotics service delivery through:

- Scholarships
- Training the trainers
- Evaluator training and Support
- Teaching and learning resources
- Performance indicators and outcome measures
- ISPO Workshop on Prosthetics and Orthotic Training Institutes in Non-Industrial Countries



Scholars learning anatomy. Image J Fisk

### Scholarships

In total 109 scholarships were awarded to scholars attending 8 educational institutions and 100 of these scholars graduated as professionals. The following summary gives detail of the scholarship allocations and the associated programs the scholars attended:

#### ISPO Category I scholarships:

##### **B.Sc. Prosthetics-Orthotics, Tumaini University, Tanzania**

With support from the USAID grant 18 students were awarded scholarships since 2003. 16 scholars graduated, one is in their last year, and one was terminated in 2004 for poor performance.

##### **B.Sc. (Hons) Prosthetics and Orthotics, University of Strathclyde, Glasgow**

1 student was awarded a scholarship and graduated.

##### **Category I upgrading, University Don Bosco, San Salvador, El Salvador**

4 teachers were upgraded successfully from ISPO Category II to ISPO Category I standard.

#### ISPO Category II scholarships:

##### **Diploma in Prosthetics-Orthotics, TATCOT, Moshi, Tanzania**

9 students were awarded scholarships through the USAID grant; 7 of whom graduated (2 were expelled for poor performance).

##### **Diploma in Prosthetics-Orthotics, CSPO, Phnom Penh, Cambodia**

11 students were awarded scholarships through the USAID grant; 8 graduated

##### **Diploma in Prosthetics-Orthotics, VIETCOT, Hanoi, Vietnam**

12 students were awarded scholarships through the USAID grant; all graduated.

##### **Diploma in Prosthetics-Orthotics, University Don Bosco, San Salvador, El Salvador**

19 students were awarded scholarships through the USAID grant; all but one graduated.

##### **Diploma in Prosthetics-Orthotics, Pakistan Institute of Prosthetics and Orthotics Science (PIPOS), Peshawar, Pakistan**

17 students were awarded scholarships through the USAID grant; all but one graduated.

### **Diploma in wheelchair technology, TATCOT, Moshi, Tanzania**

5 scholarships were awarded and graduated as Wheelchair Technologists.

### **Lower Limb Orthotic and Prosthetic Technologists, TATCOT, Moshi, Tanzania**

9 students were awarded scholarships and graduated.

### **Lower Limb Orthotic and Prosthetic Technologists, Mobility India, India**

4 students were awarded scholarships and graduated.



Kamala Kumari Karki. Image CSPO

### **Graduate profile - Kamala Kumari Karki, Nepal**

Thanks to an ISPO Sponsorship funded by the USAID Scholarship Fund, Kamala followed a 3 year Diploma in Prosthetics and Orthotics course at the Cambodian School of Prosthetics and Orthotics and has now returned to her home country of Nepal to work as an Orthopaedic Technologist. Affected by leprosy herself, Kamala has sensation loss, muscle atrophy, limited range of motion and limited muscle strength in both hands. Despite her disability, Kamala successfully participated in her studies and passed her final examination in September 2010. Thanks to her courage, energy and hard work, Kamala is now in a position to help other persons with a disability to be fully included in society.

### **Scholar performance:**

Extensive analysis (year by year and subject by subject analysis) was conducted around the performance of funded scholars and their classmates attending the seven prosthetic and orthotic programs. A separate report, *Student & Graduate Performance of classes with USAID funded ISPO Scholars: 2003-2010*, was circulated to the program providers to help inform their quality improvement plans.

**Scholarship Graduate Performance:** Graduates of the scholarship program began clinical practice soon after their graduations. Clinical and technical assessment of the devices made by scholars and graduates of TATCOT, CSPO, VIETCOT and UDB was made by a team of external ISPO assessors by following up their patients. Outcome measurements were made of alignment, fit and craftsmanship and in the main outcomes were positive. Some problems of fit and craftsmanship were highlighted. Results are included in the report referred to above.

**Conclusion:** Educating personnel to international standards is key to developing prosthetic and orthotic rehabilitation services in low income countries.



ISPO assessor with patient in Vietnam.

Image M Thorpe

## Training the trainers

Basic educators courses were led by a group of expert Faculty from the medical school in Illinois, USA and delivered to faculty of prosthetics and orthotics programs at the CSPO, Cambodia and TATCOT, Tanzania and were supported by the USAID grant. The Illinois medical school is world renowned for its educational techniques especially surrounding problem based learning. This short course ran over a week and focused on instructional design and delivery. One course in Cambodia was attended by 12 assistant teachers from CSPO, TATCOT, VIETCOT, and PIPOS. An initial course in TATCOT in 2004 was followed up with another course in September 2007 at TATCOT with 2 Ugandans, 2 Kenyans and 5 Tanzanians from schools or clinical placement facilities.

The professional outcomes for course participants were to be able to:

1. design a course/curriculum that focuses on professional performance outcomes, makes use of professional experience, and addresses professional standards and local characteristics, opportunities and constraints;
2. design/deliver a course/curriculum that builds in reasoning and problem solving;
3. design/deliver a course/curriculum that builds in continuing learning;
4. articulate the student performance outcomes they expect of their students;
5. translate professional experience into a form for systematic use in instruction.
6. facilitate an experience-based case session using a defined process;
7. plan instructional sessions around student performance outcomes that specify how students will use the knowledge and skills to be acquired.
8. give a presentation following principles designed to stimulate active learning;
9. outline a procedure for delivering skills acquisition sessions;
10. outline a procedure for using student's clinical experience for instruction;
11. design instruments to assess all aspects of trainee progress toward curricular outcomes, incorporating principles of performance assessment;
12. communicate both formative feedback and performance appraisal to students;
13. design a program evaluation system that gives continuous feedback on the effectiveness of instructional design and delivery;
14. create a comprehensive course syllabus for their course/curriculum that includes a detailed instructional design, detailed descriptions of the delivery methods, a student assessment system and a program evaluation system.

The personal outcomes for course participants were that they worked as a member of a collaborative team to improve instruction and identify sources for continuing learning for themselves and their students.

**Conclusion:** Feedback from the faculty about the training course was very positive. It is difficult to clearly demonstrate how the course has influenced current teaching methods as many different factors would influence this. The prosthetics/orthotics training program offered by CSPO and TATCOT have been maintained and the schools are also training centres for their word regions. A follow-up query among the participants was positive, but the case based learning (CBL) system has only occasionally been used outside of the two schools.



## Evaluator training and Support

Following an original course in August 2006 attended by 10 potential evaluators, the USAID grant funded 11 new evaluators to be trained at a 3 day Evaluator Training Seminar in Toronto, Canada (September 2-4 2010), doubling the pool of experts involved in ISPO evaluations.

The aims of the training seminar were to:

- harmonise the approach taken for ISPO Category consultations, evaluations and examinations.
- clarify and discuss the ISPO Professional Profiles and Learning Objectives as it relates to the evaluation and examination process.
- describe and discuss the ISPO Protocol for Evaluation & Examination.
- describe, discuss and give examples of the implementation of the evaluation process.
- present and discuss scenarios and case studies of the evaluation process.

Over the time of the grant the following schools and pathways of education have been evaluated:

### **ISPO CATEGORY I (prosthetist/orthotist education and training):**

Bundesfachschule für Orthopädie Technik pathway, Germany;

Hong Kong Polytechnic, Hong Kong;

Institut Supérieur Technologique Montplaisir, France;

La Trobe University, Australia;

Mahidol University, Thailand;

National Commission on Prosthetic and Orthotic Education with the American Board for Certification in Orthotics, Prosthetics and Pedorthotics, America;

Tumaini University, Tanzania;

University of Don Bosco, El Salvador;

University of Strathclyde, Scotland

### **ISPO CATEGORY II (orthopaedic technologist education and training):**

Cambodian School of Prosthetics and Orthotics, Cambodia;

Programme de Formation Professionnelle des Ortho-Prothesistes, Togo;

International Committee of the Red Cross Modular Courses (Afghanistan, Sudan, Ethiopia);

Institut de Formationaux Carrières de Santé, Morocco (lapsed);

Mobility India, Single Discipline Courses;

Pakistan Institute of Prosthetic and Orthotic Sciences, Pakistan;

Sri Lanka School of Prosthetics and Orthotics, Sri Lanka;

Tanzania Training Centre for Orthopaedic Technologists, Tanzania;

University of Don Bosco, El Salvador;

Vietnamese Training Centre for Orthopaedic Technologists, Vietnam.

In addition to the 11 people trained 16 others expressed interest and will be offered an online training course in the future based on the Toronto seminar.

**Conclusion:** Activity around consultation and evaluation at Category I and II levels continues to grow as countries strive to meet the needs of their clinical services by training personnel to the minimum standards for appropriate patient care. The expanded pool of trained evaluators means that the work of advising and evaluating schools about prosthetics and orthotics education can continue. It is envisaged that there will be sufficient evaluators to support regional activities in the field.

## Teaching and learning resources

ISPO has for more than 20 years worked together with the World Health Organization on setting international standards for the education of professionals in Prosthetics and Orthotics, and evaluates programs against these standards. The following activities illustrate the commitment of ISPO to supporting program providers in the non-industrial world:

### Donation of Books

ISPO collected or purchased a number of textbooks known for their quality and relevance for the service provision in the industrial world. Two copies were given to the libraries of the recognized schools; in French to ENAM, Togo and FORMA, Morocco; in English to CSPO, VIETCOT, PIPOS, and UDB.

- Atlas of Prosthetics and Limb Deficiencies, American Academy of Orthopaedic Surgeons, 2003 by Smith, Michael, Bowker.
- Atlas of Orthotics and Assistive Devices, American Academy of Orthopaedic Surgeons, 1997 by Goldberg and Hsu.
- Lower-Limb Orthotics. Fishman S. Prosthetic-Orthotic Publications, New York 2002
- Guideline for Orthotic Management of Lower Extremity Disability and Custom Orthotic Seating. Raab W, Kaphingst W, Rechsteiner R. VIETCOT 2001
- Les Ortheses du Membre Inferieur. M Raeme & C Tardif. CCDMD, College de Montmorency, Montreal 1999.
- Le Corps et ses Mouvements. L Hebert & D Camirand. Editions Saint-Martin, Montreal 1996.
- Le Positionnement. RM Letts. CCDMD, College de Montmorency, Montreal 2001.
- Outline of Orthopaedics J Crawford Adams , DL Hamblen, Churchill Livingstone 2001
- Lower limb prosthetic components: Design, function and biomechanical properties. G Fitzlaff, S Heim. Verlag Orthopadie Technik 2002
- Partial Foot Amputations. Söderberg B, Wykman A, Schaarschuch R, Persson BM. SOL, Helsingborg 2001

### Donation of Computers

ISPO received a donation of a larger quantity of computers from banks and business schools in Denmark, when they shifted to newer models with more power in late 2004. We refurbished the computers with new hard-disks; installed Windows-98 and matching Office-97 packages, and tested them all. That work was made possible by donations from Danish industrial funds. It was of great pleasure for ISPO to be able to offer the donation of 20 re-furbished computer sets with keyboards and screens together with a net-work printer to each of the individual schools with the purpose of setting up a computer laboratory to be used for the utilization of distance learning instruction material in Prosthetics and Orthotics. It was our strong belief that this donation will contribute to both upgrading of teacher staff with the newest material and improve the didactic learning process for the students. VIETCOT, Vietnam was not allowed to import used equipment, but UDB, El Salvador received 30 computers; CSPO, PIPOS and TATCOT received 20 computers; and latterly Queen Elizabeth Hospital in Malawi received 5 computers.

## Blended Learning Programs

ISPO has closely followed the development and realisation in Mexico, Colombia, Brazil and Angola of blended learning packages at University Don Bosco, El Salvador as prosthetics-orthotics modules (Lower Limb Prosthetics, Lower Limb Orthotics, Lower and Upper Limb Orthotics, Upper Limb Prosthetics, Spinal Orthotics). The general objective of these educational programs is to facilitate an upgrading of empirically trained technicians with academic education to an acceptable level in the field of orthotic and prosthetic science. Blended learning programs combine internet based modules, including self-testing, with periodical face-to-face practical workshop seminars with tutorial supervision. The Spanish-language program from UDB has received recognition as an ISPO Category-II program.

**EXPERIENCES FROM BRAZIL:** The program provided in Brazil with graduation 2007 was joined by 16 Brazilians and 4 Colombians. The average scores of all 5 modules were above 70.

**EXPERIENCES FROM BOSNIA:** In Bosnia, Module 1, Lower Limb Prosthetics has been provided for 13 students. The Professional Practice Final Score was composed of 20% of the marks for Clinical Contribution and 80% of marks for Case Presentation. As many as 38% (5/13) scored below the 50-pass mark in Clinical Contribution and another 23% (3/13) achieved marginal scores. However, the combined scores were Outstanding or Excellent in 77% (10/13).

Clinical Modules were weighted with 10% for Workshop Application, 40% for TT-prosthetics and 50% for TF-prosthetics. One student failed the module because no TF-prosthesis was presented, but that individual will get another chance of measuring, casting and manufacturing under controlled circumstances to enable continued studies. Again 77% (10/13) were graded Outstanding or Excellent.

**EXPERIENCES FROM TANZANIA:** TATCOT has, with support from inWent, Germany, developed a blended learning module on Spinal Orthotics which contains 7 modules over a 9 months period. The first program was completed in October 2008 with 22 students from 7 countries. The teaching was a combination of remote electronic presentations to their home country and two practical sessions in Tanzania. The students were graduates from TATCOT 1991 through 2008; one was a female the others males. One student – graduate 2006 – failed Professional Practice, 3 students dropped out and 3 students had 1 – 2 marginal scores in Materials Technology and/or Biomechanics. The average score was 79 (66-88) meaning that all but one were graded Excellent.

ISPO has through the USAID grant translated and edited the program into French with the aim of letting ENAM and the Haitian Special Task group make use of it. ISPO is now exploring the possibilities of further translation.

**Conclusion:** blended learning is a useful and established mode of learning in the field of prosthetics and orthotics.

## Performance indicators and outcome measures

In the award it was proposed that ISPO develop a protocol for graduate follow-up. We therefore developed questionnaires for school-leavers and their teachers regarding the theoretical and practical outcome of education and training.

We developed a Student Survey based on previous work by a number of educationalists (Georgia Tech, Northwest University Prosthetics Orthotics Certificate program (NUPOC), National Commission on Orthotic and Prosthetic Education (NCOPE) and TATCOT).

We also attached a Teacher Assessment of Graduate's Clinical skills based on Knowledge Base; Clinical Proficiency; and Behavioral Skills.

We sent the questionnaires to school-leavers from 2005-2009 and received responses from 14 Category I graduates from TUMAINI, Tanzania and 77 from CSPO, UDB, VIETCOT, TATCOT, PIPOS.

We first asked the candidates about theoretical knowledge. This was evaluated higher for topics they had not been in close contact with before. The pattern was the same for all the Category-II programs, but was not as obvious with the Category-I programs, as these students had been exposed to specialist subjects before. We then asked the teachers about their impression of the student's perception of theoretical knowledge. Finally the difference between the self-estimate and the preceptor's assessment was calculated.



Students learn clinical & technical skills. *Image J Fisk*

**Conclusion:** In general teachers assessed students better than the students themselves. The conclusion of this investigation based on a limited number of feedback questionnaires is that the school-leaders should collect this kind of information and compare results from year to year to assist with curriculum revision.

Further to these studies, questionnaires have been developed about performance, skills, patient relations and inter-professional relations, which have been sent to graduates and another to their employer about two years after graduation, but the number of responses is still low.

## ISPO Workshop on Prosthetics and Orthotic Training Institutes in Non-Industrial Countries

The conference was held in El Salvador in March 2002 and was attended by 23 educators, 17 resource-persons, 13 NGO-representatives and 2 USAID-observers.

The outcomes of the meeting were: (✓ means done)

To learn more about the existing accreditation, education systems, teaching practices, exams and other areas of prosthetics and orthotics education. ✓

To develop guidelines on modular training, distance learning, and other methods of upgrade training for sub-Category-II personnel.

➤ ISPO will develop an explanatory document outlining the process for sub-Category-II modular upgrade training ✓ which will only be approved when offered by recognized Category-II and Category-I schools

To develop simple but appropriate upgrade strategies between Category-II and Category-I

➤ There are appropriate but no simple strategies for upgrading. Each will depend on the individual institution and its academic requirements. Existing schools have given examples of upgrading possibilities within their institution. Category-I entry is laid down by the institution and could involve recommendations from ISPO. ✓

To acquire more information on finance and funding of sustainable schools of prosthetics and orthotics

➤ Examples from different schools were given. ✓

To develop an improved data base of Category-I and Category-II programmes including those not yet accredited

➤ ISPO has been working on a data base on schools. It will publish all information on Category-I and Category-II courses on the web site. ✓

To develop a network or forum for resource and information sharing between schools

➤ The web page will be utilized to receive and exchange information. ✓ ISPO will encourage twinning between schools to facilitate exchange of materials.

To develop protocols or guidelines for the training of trainers in prosthetics and orthotics schools

➤ ISPO Education Committee should be asked to consider the development of guidelines for the training of teachers (partly completed). This will include the collection of information from existing sources.

To encourage more schools to follow the ISPO standards in training and seek ISPO accreditation

➤ ISPO will encourage existing schools that have yet not applied for recognition to do so. ✓ Collaboration is encouraged between schools with regard to the process.

To develop approved data base or resource centre for training literature

Schools are invited to submit a list of teaching materials/resources they have to the ISPO Education Committee.

To encourage the spread of prosthetics and orthotics education at Category-II level, at least in an increased number of countries

➤ ISPO should act with WHO to transmit information on professional and training standards to individual nations and to non-governmental organizations. ✓

## SECTION 3: Community Based Rehabilitation

### Clinical field follow up by Community Rehabilitation Workers

Because of the shortage of prosthetics-orthotics personnel in developing countries it is almost customary to send the consumer home with the device without any review appointments for check-up visits. There is also often no instruction given about what to do if anything goes wrong with the device (such as something becoming loose, breaking, or the device not fitting anymore). Veterans International in Cambodia developed a short training program for community rehabilitation workers (CRW) with the idea that with some paramedical training they should also be able to assist with the follow-up of consumers with orthopedic appliances to identify the need for repair or replacement or the need for the device being taken to an orthopaedic workshop.

Some of the major NGO's have, for a number of years, discussed the establishment of a training program, but none have yet transpired. We knew that the CCBRT Hospital in Dar-es-Salam, Tanzania, used community rehabilitation workers to follow children with cerebral palsy. We also knew that Handicap International used CRWs in their programs in Nepal, but none of these two latter groups had any training in prosthetics and orthotics.

We developed an abbreviated interview form translated into the local language and asked the CRWs to use that and conduct a simple assessment of the consumer-device compliance and the need for intervention. We tested the follow-up methodology at CCBRT, Tanzania and in Nepal as well as in a prosthetic foot testing series in Cambodia.

Interviews about user intensity and walking capacity were similar between the local CRWs and the international examiners (orthopedic surgeon + certified prosthetist). However, when it came to pain, comfort and satisfaction there was a conceptual difference.

Technical assessment was difficult for the CRWs regarding socket fit, which reflects the lack of pre-training, whereas it was easier for CRWs to identify a failed knee or foot.

The CRW's missed 4 failures at CCBRT and 3 failures in CAMBODIA.

**Conclusion:** Observing Community Rehabilitation Workers interviewing people with disabilities, we found that they would be more efficient in their referral and advice if they could be trained to understand the basics of prosthetic fitting and stump management. Some more in-depth training could improve the Community Rehabilitation worker's competency in advising people with disabilities. This would enable CRWs to analyse if the problem came from the use of the device or the quality of the device produced. They would also benefit from training about the long term effect of people using defective devices when these are obviously in need of repair or renewal.

# The relationship between prosthetics and orthotics services and Community Based Rehabilitation

*Section by Claudie Ung-Montaufray*

In 1999 a joint statement on “The Relationship between Prosthetics and Orthotics Services and Community-Based Rehabilitation” (CBR) was made by WHO and ISPO and revisited in 2003. It addressed the training needs of prosthetics and orthotics personnel and CBR and, at the same time, CBR Personnel and prosthetics/orthotics. ISPO has retrieved information on education and training of Community Rehabilitation Workers (CRW) in prosthetics and orthotics in programs including CBR/P&O relationships such as Veterans International Cambodia and VIETCOT in Vietnam. In 2007 a more proactive approach began with the intervention of a consultant in FATO (Africa), ISPO and CBR conferences from 2007 to 2009.

The new Strategy for Rehabilitation, Equalization of Opportunities, Poverty Reduction and Social Inclusion of People with Disabilities (ILO, UNESCO, WHO 2004) had been included by some agencies in the implementation and planning of prosthetic and orthotic activities. Most agencies involved in the CBR collaborative approach developed a strategy on training with technical and financial policies and monitoring to ensure that persons with disabilities have access to devices for repair and maintenance. At best this integrated them back into the mainstream of their society. In the cases identified as good practice, some Institution Based Rehabilitation (IBR) had to develop a CBR program and/or the CBR program had to develop a prosthetic/orthotic workshop to respond to this need.

The consultancy has shown that the concept of the multidisciplinary team provides the link between IBR, P&O and CBR and is acknowledged by most rehabilitation professionals. At the rehabilitation team level, we have seen a more integrated approach in treating persons with disability needs.

The main findings of the group discussion in Kigali in May 2007 have been re-iterated by a consultant with different shareholders in Africa and Asia both at the field and the office level. The objectives are:

- A highly independent PWD able to perform his/her activities of daily living
- A socially empowered PWD: de-stigmatised, fully re-integrated
- An economically empowered PWD: accessing schooling or working
- PWD forming specialised groups for advocacy of their rights

It was of concern to note that few schools, apart from Mobility India, have integrated a curriculum where their students are exposed to the rights of disabled people coupled with practice at CBR level. Involvement in training of both CBR and prosthetist/orthotist staff has been effective.

### Next steps regarding Community Based Rehabilitation

- A consortium of agencies/donors working in the sector of prosthetics and orthotics and CBR should be set up at international level
- Common basic policies and implementation guidelines should be reviewed and developed into operational guidelines.
- The consensus of WHO/ISPO will need to be renegotiated with the other international associations of professionals also linked with CBR. This group should look at integrating their policies.
- A consortium of agencies should action practical activities:
  1. To conduct a wider research/conference on the impact of such projects. Consider best practice and clarify the benefit for the user of prosthetics and orthotics services.
  2. This research/conference should aim to develop an operational plan to implement activities related to the provisions of the convention on rights for persons with disabilities (CRPD), especially article 20 and 26 on personal mobility, habilitation and rehabilitation (participation) in projects.
  3. To develop guidelines for enhancement of reporting outcome/impact for beneficiaries of prosthetic/orthotic and CBR programs.
    - Development of a prosthetics and orthotics related training package for CBR workers that could be used as a training course.
    - Develop guidelines for clinicians on the prescription and follow up of assistive devices.
    - Develop guidelines for rehabilitation personnel (e.g. physiotherapists and occupational therapists) on assessing and training of users of assistive devices.
    - Develop guidelines on CBR related training packages for prosthetic/orthotic personnel at school and program level.

WHO should ensure that each country office encourages partnership activities within their National Strategic Development Plan.

**Conclusion:** ISPO should influence actual and future country rehabilitation project links to prosthetics/orthotics programs.

School curriculum should be reviewed to incorporate mandatory curricula in CBR setting and should train their staff in identifying international/national funding channels to develop such a partnership at local level.

Prosthetic & orthotic programs working in isolation should be aware of changes needing to occur to mainstream their activities in the wider rehabilitation sense



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## Ethical considerations

Ethical clearance was assured from the relevant body in all studies. Ethical considerations for studies included participants giving full informed consent, consenting to the collection of information, given the opportunity to withdraw at any time without prejudice to care. Any treatment was of a non-invasive character with no contact to natural orifices, circulation or central nervous system.

For student and graduate studies, ethical issues in the relationship between employer

and employee are considered minimal because the employer has committed to not acting upon the outcome of these studies against the graduate under scrutiny. It is envisaged that this will provide a learning experience.

Recording and analysis of clinical compliance data must still be one of the corner stones in evaluation of the prosthetics and orthotics service provision.



Prosthetic clinic, Vietnam. Image M Thorpe

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