



Sustainable Orthotic Component Manufacturing in Vietnam
Cooperative Agreement No. 442-A-00-02-00188-00
Final Project Report
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Introduction

Vietnam is faced with a large, growing demand for orthotic services. According to a 1994-1995 MOLISA Disability Survey reported in a disability meta analysis by Thomas Kane in 1999, the estimated number of Vietnamese in need of orthotic care exceeds 260,000 individuals (Kane: 27). Diseases, such as polio, cerebral palsy and clubfoot, and congenital birth defects account for the majority of these cases.

Over the last few years, Vietnam has graduated an increasing number of qualified orthopedic technologists from the Vietnamese Training College for Orthopedic Technologists (VIETCOT), and many of the existing Ministry of Labour, Invalids and Social Affairs (MOLISA) and Ministry of Health (MOH) orthopedic workshops have been upgraded with modern fabrication equipment and are now able to manufacture modern orthotic devices. With improved education and facilities comes a demand for higher quality components by the technologists and their patients. In response to this demand, modern orthotic components have increasingly been imported to Vietnam at great expense. In order to satisfy the ever-increasing demand for higher quality orthotic components with the limited funds available in Vietnam to purchase such components, it was determined that the local manufacturing of quality orthotic components would be the most cost-effective solution. Moreover, by strengthening the capacity for the local fabrication of key orthotic components within the Vietnamese orthopedic rehabilitation sector, the sector would move closer to a sustainable supply of such components, in turn reducing the need for external assistance by non-governmental organizations (NGOs).

The Prosthetics Outreach Foundation (POF) had worked for 10 years with the Orthopedic Technology and Rehabilitation Center (OTRC) in Ba Vi, Ha Tay Province, Vietnam to establish a reliable supply of locally-made quality prosthetic components. Building on this experience and with generous support from the U.S. Agency for International Development, POF partnered once more with OTRC to aid the center in the manufacturing of essential orthotic components.

In the implementation of this project, POF and OTRC worked closely with a number of key NGOs active in Vietnam's rehabilitation community, including VIETCOT and the Vietnam Veterans of America Foundation (VVAFA). In 2002, the group met in Hanoi to determine how best to advance the quality of orthotic care in Vietnam. From this and subsequent meetings a consensus emerged that POF should focus its attention on the achievement of two *primary goals*:

1. Advance the manufacturing and field testing of key orthotic components for both children and adults in Vietnam; and

2. Increase the production and strengthen the quality control in manufacturing of these key orthotic components to insure successful localization of production.

These two overarching goals were then further targeted through the following *project sub-goals*:

1. Ensure that orthotic products made in Vietnam are affordable within the context of the Vietnamese orthopedic rehabilitation market;
2. Establish improved quality control standards during manufacturing and reliable supply of products to customers; and
3. Assist the Orthopedic Technology Rehabilitation Center (OTRC) to become the preferred supplier of orthopedic rehabilitation products for hospitals and workshops in northern and central Vietnam managed not only by the Vietnamese Ministry of Labor, Invalids and Social Affairs (MOLISA), but also by the Vietnamese Ministry of Health (MOH).

In operationalizing these goals POF identified two *main objectives*, one centered on the production of custom-made orthotic knee and ankle joints, the other on prefabricated orthoses. Specifically, the project identified targeted assistance for OTRC with the manufacturing and field-testing of:

Objective 1: Orthotic knee and ankle joints

- Drop-lock knee joints;
- Offset drop-lock knee joints;
- Drop-lock knee joints with adjustable flexion adjustment; and
- Orthotic ankle joints with dorsiflexion-assist.

Objective 2: Prefabricated orthoses

- Lumbar Sacral Orthoses (LSO);
- Wrist-Hand Orthoses (WHO); and
- Cervical Thoracic Orthosis (CTO)

Main Project Outcomes

A. Infrastructure Improvements

With funding provided under this cooperative agreement, POF was able to purchase and upgrade manufacturing equipment at OTRC that had limited production speed and the quality of manufactured orthotic parts. The new equipment has significantly improved OTRC's production capacity and made it possible to introduce new manufacturing techniques, such as vacuum pressure forming. New manufacturing equipment purchased and installed includes:

1. Large oven for heating sheet plastic for the WHO, LSO products;
2. Milling machine for secondary machining of orthotic joints and CTO sub-components;
3. Higher quality milling cutters for CNC and manual machining; and
4. Measurement instruments for quality inspecting of all component parts.

Additionally, OTRC manufactured a large vacuum bag molding machine with high capacity vacuum pump and vacuum tank.

B. Local Manufacturing of Quality Products

All seven product types listed in Objectives 1 and 2 were completed and the following sizes are now available for these products at OTRC:

Product Name	Available Sizes
Drop lock knee joint	1 Adult and 1 Child size
Offset knee joint	1 Adult and 1 Child size
Adjustable angle knee joint	1 Adult size
Ankle joint with spring	1 Adult and 1 Child size
WHO	Adult and Child sizes – A, B, C, D, E, F
LSO	Adult sizes – A,B, C, D
CTO	1 Adult and 1 Child size

Consultation with a team of foreign clinical consultants was critical in the definition of product groups and product features. Members of the INGO clinical team reviewed drawings and prototype samples as the product groups were developed. The team at VIETCOT focused on the joint products, while VVAF staff advised on the preformed WHO, LSO and CTO products. The following are the teams of participating INGO and Vietnamese clinical consultants.

INGO Clinical Consultants	Organizational Affiliation
Wilfred Raab	VIETCOT
Michael Rechsteiner	VIETCOT
Kerry Fisher	VVAF
Jo Nagels	VVAF
Wendell Endley	VVAF

Vietnamese Clinical Consultants	Organizational Affiliation
Tran Cong Duc, Lecturer	VIETCOT
Tien, Orthotist	OTRC

U.S. Clinical Consultants	Organizational Affiliation
Mel Stills, CO	Private Consultant
Garth Shippen, CO	Private Consultant
David Gerecke, CPO	Private Consultant

OTRC assigned Project Engineer Dao Bui Loi to collaborate with POF in the development of all products. Mr. Loi was responsible for a wide range of duties, as well as providing primary communication with Raymond Pye, Project Manager for POF. Mrs. Vu Huong Sen, the POF translator at OTRC, provided invaluable daily communication during most of this 3-year project, translating almost 1,000 documents. Mr. Loi and Mr. Pye used a combination of written e-mail, e-photos, scanned sketches, drawing files, and mpeg videos to communicate during the development of each product. In addition Mr. Pye made 8 trips to OTRC during the project period and worked more than 800 hours on site at OTRC, POC, and MOLISA rehabilitation sites in Vietnam.

During the development of the WHO and LSO devices it became necessary to generate sufficient anatomical measurement data for the Vietnamese population before a range of mold sizes could be made. The clinical advisors assisted with defining the critical dimensions and OTRC staff then proceeded to measure over 200 Vietnamese children and adults. This data was reviewed and a corresponding set of mold dimensions chosen for adults and children.

C. Product Affordability

The first project sub-goal, which is to ensure that the new orthotic products are affordable, is very important for the success of the new orthotic products in Vietnam’s increasingly free marketplace for orthopedic rehabilitation products. As a government-managed facility, OTRC is faced with particular challenges in this regard because it has large institutional overhead costs. On the other hand, as a state-subsidized facility, profits are restricted to approximately 5% of the manufacturing costs which puts a check on product prices.

Keeping the cost of the new orthotic products low was a key consideration in the implementation of this project. Pricing for all products appears reasonable, especially considering the use of higher-quality materials. The competitive pricing and high quality of OTRC’s new orthotic products is reflected in a steadily growing demand for its orthotic products. In 2005, the following orders for the new orthotic products were recorded:

Product	Cost per Pair or Unit (VND)	Cost per Pair or Unit (USD)	NGO Orders	MOLISA Orders
Drop lock knee joint	VND 320,000 / pair	USD 20.13 / pair	706 pairs	120 pairs
Offset knee joint	VND 310,000 / pair	USD 19.50 / pair	70 pairs	30 pairs
Adjustable angle knee joint	VND 350,000 / pair	USD 22.00 / pair	20 pairs	15 pairs
Ankle joint with spring	VND 220,000 / pair	USD 13.84 / pair	40 pairs	10 pairs
WHO	VND 80,000 / unit	USD 5.00 / unit	50 units	120 units
LSO	VND 200,000 / unit	USD 12.58 / unit	80 units	60 units
CTO	VND 250,000 / unit	USD 15.72 / unit	20 units	15 units

Nevertheless, OTRC must compete with lower-quality and hence lower-priced components entering the market.

D. Improvements in Manufacturing Quality Control & Supply Management

OTRC has significantly improved their quality management as a result of this project. The improvement in product quality is a direct result of the changes in the design, manufacturing, documentation and a quality inspection process now implemented at OTRC as well as the use of new manufacturing equipment and tooling.

During the design phase, POF emphasized improving the quality of the drawing documents and used the documents as the undisputed foundation for every design change, manufacturing and inspection discussion. Mr. Loi was responsible for design engineers, mold makers, machinists and inspectors all working with the current version of product drawings. OTRC staff has made excellent progress following the discipline of the product drawing.

Because of the improved drawings, quality inspection of subcomponents and finished products became easier. The inspection process is now accepted by all members of the manufacturing team and it is understood that the drawing alone is the guiding document when a quality inspection decision is challenged. Prior to this project, the inspection of products at OTRC was left to the individual worker and rarely were products rejected unless a mistake was visually obvious.

Now OTRC has a written, management-approved Quality Plan, a dedicated Quality Inspection Room and a dedicated Quality Inspector that measures subcomponents during manufacturing and final assembled products. The Quality Inspector reports directly to Mr. Loi who is independent of the manufacturing workers union. The Quality Inspector has a set of inspection instruments and made duplicate sets of inspection tooling to aid the machinist and speed up the inspection process.

In the past, OTRC struggled with a lack of a consistent and reliable supply of materials used in the manufacturing process. This led to significant fluctuations in the quality of available inputs and hence of the quality of the resulting products, as well as frequent production delays due to an inability to obtain specified materials. Over the last three years, POF has worked diligently with OTRC to develop a network of reliable suppliers that can ensure a consistent supply of quality materials at any time. For example, OTRC now has established relations with a US supplier for the aluminum alloy bar material used in the fabrication of orthotic knee and ankle joint products. Local material suppliers were identified in Hanoi for aluminum sheets, stainless steel sheets, and fasteners for the various orthotic joint products and the CTO. And the plastic sheet material for the WHO and LSO products are now imported from reliable foreign suppliers.

E. Improvement of Customer Relations

POF actively assisted OTRC to engage in Vietnam's emerging free market for orthopedic components to listen to the needs of its customer and to develop its marketing capabilities. For example, OTRC displayed and demonstrated the new orthotic products at three POF-organized annual orthopedic and rehabilitation seminars in Hanoi. OTRC has also strengthened its supplier relations with the Rehabilitation Departments of Bach Mai Hospital, Viet Duc Hospital and the National Hospital of Pediatrics.

A major accomplishment during the process of defining, designing, manufacturing and evaluating the new orthotic products was the much improved communication between OTRC engineering staff and the Vietnamese clinical staff. In the past, OTRC management and engineering staff had a poor record of communication with their clinical customers, especially the technologists that fit their products. After three years of constant prompting to meet face-to-face with MOLISA and MOH technologists, communications between engineers and clinicians has improved significantly. This is important because clinical staff are now able and willing to bring technical problems with OTRC products to the attention of OTRC technical staff, which in turn allows OTRC engineers to find improved product design and manufacturing solutions without delay.

D. Product Evaluation

Evaluation Framework

POF planned an evaluation of all seven product types manufactured under this cooperative agreement in cooperation with MOLISA and with assistance of its INGO clinical partners. The primary goal of the evaluation was to assess the *manufacturing* quality of the new orthotic products measured by the *function, reliability* and *durability* of the device, as opposed to the quality of the fit of the orthotic device which is highly dependent on the clinical skills of the orthopedic technologist who fits the device to the patient. This differentiation is important because the supplier of the products relies on the clinical skills of the personnel fitting the device.

Other important considerations in the design of the evaluation process were the desire to strengthen the local capacity of evaluators in Vietnam and to foster an honest dialogue between patients (users), clinicians (intermediary) and engineers (provider) regarding the quality and function of the products. POF believes this to be of utmost importance in order to develop the abilities of local professionals to perform such evaluations in the future without external assistance.

To realize the goal of enhancing the local evaluation capacity, an evaluation team of Vietnamese professionals with both engineering and clinical training and experience was assembled. The team included the following members:

Team Member	Affiliation
Dr. Tran Quoc Hung	Team Leader (Rehabilitation Section, Finance Dept., MOLISA)
Mr. Phan Dang Minh	Orthopedic Engineer (Retired)
Mr. Tran Duc	Workshop Manager (Orthopedics Institute Hanoi)
Mr. Tran Cong Duc	Teacher (VIETCOT)

This all-Vietnamese team received advice, particularly in the development of an evaluation questionnaire, from POF's INGO clinical partners.

The following rehabilitation facilities were included as evaluation sites:

MOLISA Orthotic Joint Evaluation Sites	MOH Prefabricated Orthoses Evaluations Sites
Haiphong Orthopedic and Rehabilitation Center	Rehabilitation Dept., Bach Mai Hospital
Ba Vi Orthopedics Technical Rehabilitation Center	Rehabilitation Dept., National Hospital of Pediatrics (NHP)
Thai Nguyen Orthopedic Rehabilitation Center	
Thanh Hoa Orthopedic Rehabilitation Center	
Vinh Orthopedic Rehabilitation Center	

POF was particularly pleased with the cooperation of the MOH facilities that arranged for the evaluation of the WHO, LSO and CTO products, as MOH and MOLISA have not always cooperated well in the past. Likewise, POF was encouraged by the stellar performance of Tran Cong Duc, VIETCOT, and Pham Thuy Hong, POF. Mr. Duc in particular proved to be a very

capable professional who played a key role in analyzing the evaluation data. Mrs. Hong was instrumental in making the necessary logistical arrangements for the evaluation team and translating the reports.

Evaluation Schedule

Upon manufacture, inspection and distribution of the orthotic joint products by OTRC to the MOLISA evaluation sites in January 2005, the first of two evaluations took place on August 2-11, 2005. The second MOLISA evaluation took place from November 28- December 15, 2005.

A first evaluation of child-sized prefabricated orthoses occurred in November 2005 at NHP after the prefabricated products had been delivered by OTRC in August 2005. During this review, additional sizes of the WHO and CTO were requested, which were delivered to NHP in January 2006. The final MOH evaluation meetings focused on adult-sized prefabricated orthoses and took place at Bach Mai Hospital in February 2006. In each instance, the meetings served as an opportunity for clinical personnel and the evaluation team to assess the function and overall fit of the prefabricated orthosis. In the case of the MOLISA evaluations, patients were also included in this dialogue.

Evaluation Findings

POF Project Manager Pye traveled with the evaluation team during the second MOLISA evaluation in late 2005. Mr. Pye noted that the team was well organized and, after a group discussion of each case, came to a consensus regarding its observations. Mr. Pye was pleased to observe the detailed discussions between the sites' clinical staff and the evaluation team, although he noted that there are cultural inhibitions to openly criticize the work of others. Nevertheless, by the end of the evaluation the team had identified several product features that needed more refinement. These included:

- The bearing material was not hard and indicated wear;
- The bearing shaft retaining screw had loose threads and needed repeated tightening; and
- The bulky appearance and additional weight of the Dorsi Assist Ankle Joint was not liked by technologists, however, the function was acceptable to the patients.

The new aluminum bar material is difficult to bend without cracking;

During the clinical visits, the evaluation team noticed a significant difference in the level of experience that the orthopedic technologists exhibited at different rehabilitation sites and the negative effect that inexperienced staff were having on the fitting of some of the orthotic products. The team strongly recommends additional training for technologists in bending aluminum side bars. Incorrect bending technique and inappropriate bending tools resulted in cracks or breaks of a common grade of aluminum bar that is being used around the world for this purpose.

Overall, the results of the evaluations are encouraging not only because they identified product features that need to be strengthened, but also because the overwhelming majority of test patients reported high levels of function of the products: 92% of active walking patients reported using their orthotic device for 10 or more hours per day. Likewise, the evaluation found a high level of reliability for the new orthotic products: 95% of visual joint wear after 11 months was considered acceptable.

Ongoing Evaluation Efforts

Due to delays during the development stage of the project, which in turn delayed the start of the product evaluations, and a commitment by POF to complete the evaluations by the end of December 2005, to date, evaluation data is only available for 7 and 11-month periods. However, POF is pleased to report that MOLISA has agreed to continue the evaluation in order to assess the durability and continued function of the orthotic knee and ankle joint products after 24 months.

In the coming months, OTRC will also explore design improvements for the manufacturing of the orthotic knee and ankle joint products. During the evaluation OTRC engineers realized that more testing and design development could improve the durability of current designs and may lead to the discovery of new low-cost solutions that will enable more orthotic fitting at Vietnamese workshops. To start this process, OTRC, with assistance from POF, has begun to build a force-controlled cyclic testing machine that will be used to examine the durability of the ankle joint bushings.

The Challenges Ahead

POF is pleased with the overall progress that was made over the last three-and-a-half-years through this project to help Vietnam develop an indigenous supply of well-functioning, reliable orthotic components for children and adults in an effort to meet the country's increasing demand for higher quality orthotics. POF and OTRC worked hard to address a wide range of manufacturing supply, technology, planning and quality control issues that had prevented OTRC in the past from becoming a preferred supplier of orthopedic rehabilitation products for hospitals and workshop in northern and central Vietnam. Manufacturing equipment was upgraded, material supply secured, production processes streamlined and professional quality inspection standards defined and integrated into the overall manufacturing process. Further, all seven new orthotic products manufactured under this cooperative agreement were field-tested and the feedback from these evaluations is now informing the production process, resulting in improved products with better function and reliability. The success of these efforts is best illustrated by the high level of patient satisfaction with the products and the significant number of new product orders that were placed with OTRC in 2005 by both the Vietnamese government and NGOs. Finally, in addition to bringing about the successful localization of high quality orthotic component production, through this project, POF was able to make an important contribution to improving the communications and cooperation between MOLISA and MOH staff.

Yet, despite these successes, formidable challenges remain. One of the key challenges rests with OTRC. As noted in this report, a free market for orthopedic rehabilitation products in emerging in Vietnam. Due to the considerable capacity that was built through this project, OTRC is in a strong position to do well in this market. However, OTRC is handicapped by high institutional overhead costs and management practices that are rooted in the fact that the center is managed by MOLISA. The former limit the factory's ability to control the price of its products; the latter impede the center's ability to quickly and flexibly respond to market trends and other market signals. To live up to its full potential, POF believes, both issues need to be addressed.

Moreover, OTRC is challenged by new competitors that are entering the emerging orthopedic rehabilitation product market. These competitors have introduced to the market lower-cost/lower-quality alternatives to OTRC products. A yet unanswered question is whether the market is willing to pay a premium for higher quality orthotic products made by OTRC or foreign suppliers, or whether the demand will move toward the lower cost/lower quality products.

In this respect, it would be very helpful if the Vietnamese government were to establish binding minimum quality standards for orthopedic rehabilitation products and only reimburse rehabilitation service providers for products that meet or exceed these minimum standards. Given that the Vietnamese government is by far the biggest purchaser of orthopedic rehabilitation products in Vietnam, such a policy would have a significant positive impact on the market for orthopedic rehabilitation products as far as the quality of these products is concerned.

At a minimum, MOLISA and MOH must approve the products developed under this cooperative agreement for use at their hospitals, orthopedic centers and workshops. MOLISA has done so; a corresponding decision by MOH is still pending. In the future, it would be advisable to negotiate a binding agreement with the Vietnamese government to ensure approval for reimbursement of any new orthopedic products prior to the project start.

Finally, MOLISA and MOH are faced with another key challenge: Vietnam still needs to develop a sustainable funding base for a relatively highly developed orthopedic rehabilitation system. Thanks to the support of funders such as USAID and a number of INGOs, including this project, the country was able to choose an orthotic technology path that is based on the use of modern materials, components and well-educated professional technologist staff. It is unclear what finance system Vietnam plans to introduce that is capable of supporting this orthotic delivery system without ongoing external assistance.



New Milling Machine at OTRC, Purchased with Cooperative Agreement Funds, Used for Secondary Machining of Orthotic Joints



Quality Inspection at OTRC during Assembly of Drop-Lock Knee Joints



*Hand and Forearm Measurements in Preparation for
Wrist-Hand-Orthosis Mold Design*



Wrist-Hand Orthosis Molds



Vacu-Forming a Wrist-Hand Orthosis at OTRC from Polyethylene Material



Mr. Tien Using Vacuum Bag Molding Machine at OTRC to Mold a Lumbar-Sacral Orthosis



Two Evaluation Patients with Knee-Ankle-Foot Orthoses at OTRC



Evaluation Team Inspecting a Knee-Ankle-Foot Orthosis for Durability at Thai Nguyen Center



Dr. Hung, Evaluation Team Leader at Thai Nguyen Center, Interviewing a Patient with a Drop-Lock Knee Joint and Ankle Joint with Dorsiflexion-Assist



*Success – Mother and Daughter in Thai Nguyen – Daughter Has a
Knee-Ankle-Foot Orthosis – Walking Normally Again*