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Original Research Article

The Development and Study of Rehabilitation Education Materials for Persons with Lower Limb Amputation in Developing Nations: A Pilot Investigation

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ABSTRACT

Introduction: Prosthetic rehabilitation education materials for persons with low literacy skills in developing countries do not currently exist. The purpose of this study was to create and test such materials.
Methods: Working in collaboration with a United States based non-profit organization, LIMBS International, researchers created a clinician manual, clinic posters and a patient take-home pamphlet using effective, proven methodologies known to the field. Because of constraints related to the international test population, only the content of the posters was tested. A questionnaire was developed to assess acceptability of the posters using poster ratings, and understandability using object identification and sequence comprehension questions. Four test populations included persons with amputation in the United States, Peru, and Eastern Africa, and students with English as a second language in the United States.
Results: Poster ratings were high (87-96%) among all test groups. Sequence comprehension scores were 89% for United States and 86% for Peruvian patients and 56% for United States students. Sequence comprehension was not tested in Africa due to time constraints. Identification scores were varied among groups (56-72%).
Conclusion: Field testing revealed that the posters were suitable for all test populations and identified which images should be modified to increase understandability. Multi-modal testing is a practical way to identify suitability and understandability of education materials. This study illustrates the methodological process of design of education materials for persons with low health and reading literacy skills.

Key Words: patient education, prosthetics, low literacy.

INTRODUCTION

Approximately 80% of persons with amputation in need of a prosthetic device live in developing countries, with an estimated 25.5 million in need of prosthetics or orthotics in Asia, Latin America, and Africa. [(1)] Moreover, prosthetics training programs do not exist in over 75% of developing countries. [(1)] As a consequence, prosthetic education materials that are literacy-appropriate for this population do not exist. In many developing countries, patients rarely have the opportunity to return to the clinic for any type of follow-up

because of issues with accessibility. Furthermore, prosthetic devices are minimally effective without adequate patient training provided by a qualified clinician.

Health education materials created for persons with low reading and health literacy skills have been developed for patient populations in both the United States (US) and abroad. Reported topics include instruction in medication use, injury prevention, wound care, cardiac health, discharge instructions, stroke, radiation therapy and phototherapy. [2-11] Several barriers exist when attempting to create education materials for these target populations including: gaps between the readability of the materials developed and the literacy level of the patients they are intended for, communication, accessibility of resources, cultural differences, meanings of pictures and symbols and formulation of documents. [12-17] Most health information in the US, while peer-reviewed, is written for a reading level beyond 10^{th} grade comprehension. Since 30-50 percent of the target audience cannot read at this skill level, the intended message is not understood. Prosthetic education materials authored for patients in the US, though peer-reviewed, are too technical and lengthy; the average reading grade level of these materials is tenth, with a range of four to sixteen. [18] There is support in the literature that patient education materials should be authored at less than the eighth grade reading level. [5] It has been documented that audiences with poor reading ability lose interest quickly with content that they are struggling to comprehend. [13] Similarly, many healthcare professionals provide oral instruction that contains medical and technical jargon which impedes patient learning; the result of which leads to noncompliance and subsequent increased healthcare costs. [19] Patients with low literacy levels, suffer the highest rates of morbidity and mortality from chronic diseases and conditions. [13] The fact that they cannot comprehend the information to improve their health either verbally or visually seems to be an important contributing factor. [20]

Very little prosthetic education material exists that is suitable for patients with low literacy skills. The Hesperian Foundation and the World Health Organization have published prosthetic rehabilitation manuals and instructions for health care providers; the text of these documents is lengthy and sophisticated, unsuitable for most patient use. [1] Hesperian health guides provide information related to constructing prostheses, but no specific information about rehabilitation for patients with amputation. [21] The International Committee of the Red Cross is the largest provider of prosthetic devices. Their rehabilitation manual is 72 pages long, consists of stick figures and is designed for clinicians. [22] A set of note cards intended for patient use was created using text and photographs; however, the photographs are not "stand alone" and require the accompanying text to provide clarification. [23] Since patients in developing countries rarely return to the clinic, it is important to also consider providing education materials that are implicit.

LIMBS International (LIMBS) is a non-profit organization that designs, creates, and tests new prosthetic devices in their research laboratories in the US and in clinics throughout the developing world. There are six training centers located in the Dominican Republic, Bolivia, Senegal, India, Kenya and Bangladesh, serving over 23 countries. LIMBS International certifies local practitioners on-site to fabricate and fit trans-femoral and trans-tibial prosthetic devices. [24] LIMBS International recognized the need for physical therapy clinical expertise in the areas of residual limb care, exercise, and walking activities. More specifically, LIMBS sought a relationship with a college/university to provide collaboration on projects involving engineering, prosthetic and physical therapy faculties. A Memo of Understanding was

signed by representatives of the two organizations in 2012.

In a study by Rau et al (2007), it was determined that intense physical therapy improves the functional mobility skills of persons with lower limb amputation in developing countries more effectively than walking alone. [25] The purpose of this pilot study was to address the need for education materials for clinicians and patients associated with LIMBS training centers. Aim one of this study was to use effective, proven strategies to develop high-quality prosthetic rehabilitation education materials suitable for the named population. Aim two of this study was to evaluate the acceptance understandability of a portion of the education materials with local and international test populations.

MATERIALS AND METHODS

The following section describes the development of education material (Phase 1) and the preliminary testing, approvals, collaborations, and field testing (Phase 2). The project timeline provides a visual outline of the process (Figure 1).

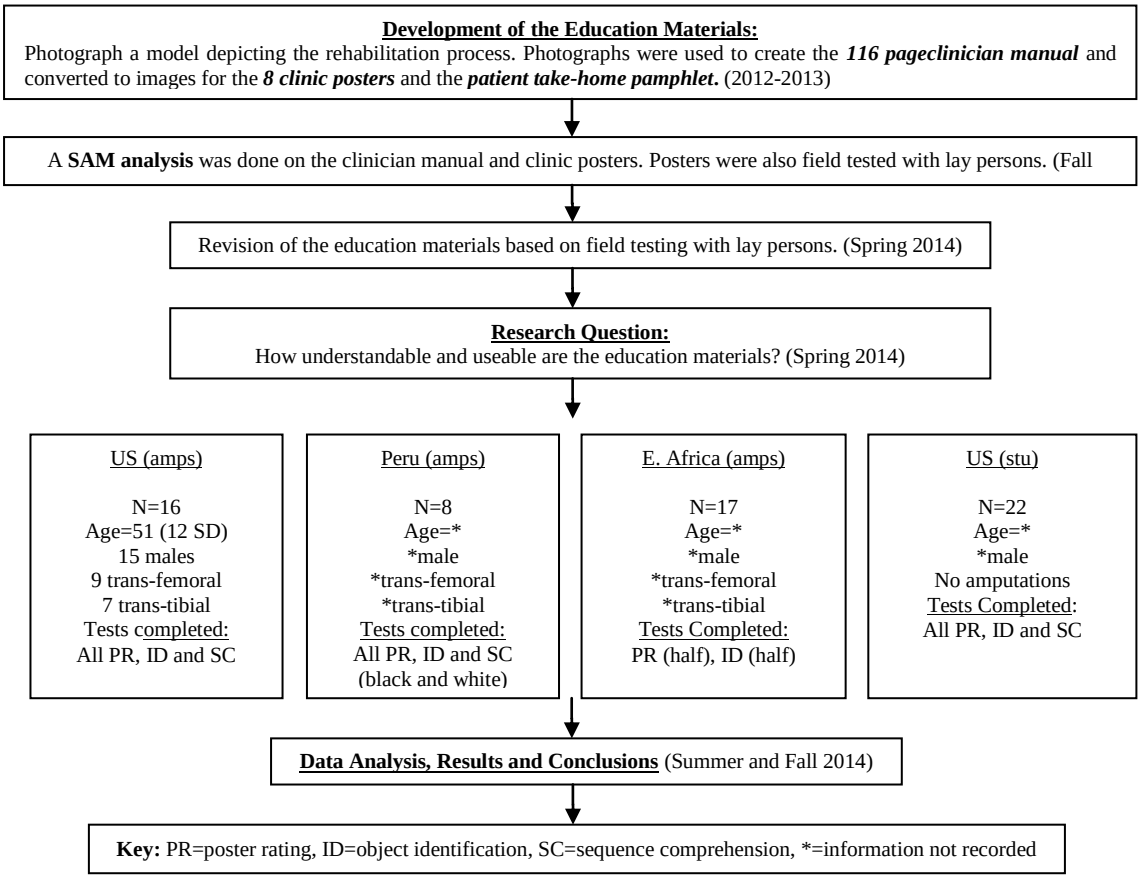

Figure 1: Project Timeline

Phase 1: Development of the education materials

Based on clinical needs, LIMBS International requested that a manual for local clinicians and clinic posters be created. After a review of the literature, researchers decided that a patient take-home pamphlet would improve the education efforts. Content topics for the manual include residual limb care, stretching and strengthening exercises, pre-gait and balance activities, gait on different surfaces with various assistive devices and patient assessments. To illustrate the rehabilitation process, a person with a trans-femoral amputation was photographed performing activities. Enhancement of the photographs was accomplished with software in the

Adobe Illustrator Suite. Collaborating with the University's Visual Communication Design Department yielded professional quality products with superior images and insightful layouts. Researchers followed examples of existing evidence-based approaches to health education for persons with low reading and health literacy skills in both the US and abroad. [2-11] In addition, two texts were utilized: "Teaching Patients with Low Literacy Skills. Second Edition" and "Health Literacy From A to Z: Practical Ways to Communicate Your Health Message." [26,27] The manual provides clinicians with information specific to rehabilitation of persons with lower limb amputation. It is 116 pages, comprehensive, and authored in English. The clinic posters identify key points for patients and illustrate instructions to aid clinicians during their brief in-clinic time together. Social cognitive theory suggests that patient education materials designed to activate patients toward healthier behaviors ought to (1) improve knowledge of the health effects of behavior change, (2) positively influence outcome expectations, (3) emphasize facilitators to behavior change, (4) address impediments to behavior change, and (5) enable the creation and achievement of short-term goals. [28]

Visual aids in the form of pictorial, graphic or verbal symbols are utilized by health educators to communicate instructions to patients, [29] especially those with low literacy skills. Pictorial symbols produced as photographs, illustrations or drawings are recommended for adults with little or no reading ability. [26,29] However, when their use is not carefully considered, a pictorial will confuse rather than educate the audience.[2] Likewise, the pictorial must capture the attention of the audience and look like what it represents. Visual aids should be culturally specific, [30] as culturally-sensitive pictures have been shown to enhance recall, improve attention and comprehension. [3,12,16] Involving the target populations in the process of creating the materials through field testing yields a better product. [26,31] The addition of oral instructions to written materials and pictographs has been shown to also improve comprehension. [3,7,32] The purpose of the clinic posters is to provide clinicians with graphic illustrations of the most important content. The topics include skin care, conditions when to return to the clinic, exercise with and without the prosthetic device, walking on various surfaces with different assistive devices and transfers. The clinic posters are virtually wordless, except for brief titles, as the addition of a few words organizes the images, promoting readability and recall. [15] Images were created in modular form such that skin color, facial characteristics and body type could be easily altered graphically to better reflect each international region's racial characteristics; patient populations prefer education materials that correspond specifically to their race. [31] Lastly, the content of the posters was modified to create a patient take-home pamphlet using the same graphics, since multiple sources of education improve learning [12] and patients rarely have the opportunity to return to the clinic. A summary of the principles used to develop the education materials can be found in Table 1.

Phase II: Preliminary testing, approvals, and collaborations

Prior to testing with the target populations, a Suitability Assessment of Materials (SAM) was performed to confirm that the posters and clinician manual were appropriate for the target population. [23] The SAM consists of six general topics with 24 scored sub-topics. The six topics include content, literacy demand, graphics, layout and typography, learning stimulation/ motivation and cultural appropriateness. The SAM provides a numerical score and percentage rating that falls into one of three categories superior, adequate, or not suitable. Since access to an international population was not possible at this stage of product development, scores were obtained from 19 local persons with no prior knowledge of prosthetics. This preliminary

testing revealed that the clinic posters and clinician manual had an average rating of 36 and 33, respectively, placing them both in the category of superior. Nevertheless, based on the SAM, a few additional changes to the poster images were made to add clarity to the materials prior to field testing.

A second preliminary activity included the development of appropriate approvals and questionnaires to measure the acceptance and understandability of the clinic posters, and identify international collaborators. Approval for both local and international study was obtained from the University's Human Subjects Committee. Subjects were adults ages 18-80 who were independent with their mobility skills and without cognitive impairment. The consent form and questionnaire were authored at a 5th grade level of readability, using the Flesch-Kincaid Grade Level (23), to promote comprehension. [12,15]

Surveys or questionnaires are often used to gather data related to subject characteristics or opinions, as part of descriptive, exploratory or experimental designs. [37] The questionnaire was created using another as a model. [38] The questionnaire obtained subject demographics, and assessed subject acceptance and understandability of the posters. There were ten poster rating (PR) questions measuring subject report of acceptance and understandability. In addition, eight object/concept identification (ID) and six sequence comprehension (SC) activities were included. The ID questions were aimed at measuring subjects' actual ability to identify and understand topics, while the SC activities evaluated comprehension by asking subjects to perform or verbally describe six different physical activities illustrated in various posters. Researchers scored the level of comprehension based on the observed physical performance or verbal recount. Subjects were also given the opportunity to provide comments. No pre-instruction was provided.

It would not have been possible to conduct any research without local and international collaborators. Researchers collaborated with six organizations in four countries. For local testing in Connecticut, there were four Hanger clinics, one university organization, and one New England Prosthetics and Orthotics Systems facility. For testing in Peru, researchers partnered with Dreaming and Working Together, a non-profit organization that makes an annual one-week service trip to Lima, Peru and typically fits 25-40 patients with prosthetic devices. For testing in East Africa, researchers collected data through three clinics with Great Lakes Rehabilitation in Uganda and two facilities with LIMBS International in Kenya.

Field Testing Protocol

All tests were completed in a face-to-face setting, along with an interpreter as necessary. Tests lasted approximately 30-40 minutes. Subjects were given the posters and asked to respond to PR questions, then shown images and asked to identify objects/concepts for ID and respond to SC questions. The posters used for testing in Peru were translated to Peruvian Spanish.

Test populations

Four populations were tested: persons with lower limb amputation in the US, Peru and East Africa, and students in the US with English as their second language (ESL) (Table 2). Although the education materials were developed for persons in developing countries, persons with amputation in the US were tested to determine if the posters could lend any teaching value locally. The ESL students, a sample of convenience, were included to determine the understandability of the pictographs in the posters as their English skills were low to moderate and they had no prior knowledge of prosthetic rehabilitation.

Statistics: When suitable demographic information was available with a population, correlations were calculated between age and PR, age and ID+SC, experience and ID+SC, and education and ID+SC. Descriptive statistics (mean and standard

errors) are presented. Pearson's correlation coefficients and associated p values were calculated using the "corrcoef" function in Matlab software (The Mathworks, Natwick, MA USA 2013).Correlations were used to determine the relationship between demographics and poster acceptance and understandability. In all tests, $p<0.05$ was considered significant.

Table 1: Principles specific for developing patient education materials for persons with low literacy skills

Principle		Rationale	Broad Explanation
Use of Visual Aids[2, 11, 13, 14, 31,33]		The use of visual aids in the form of pictorial symbols, graphic symbols, verbal symbols, and illustrations has been proven for better retention of material.	Pictorial symbols produced as photographs, illustrations, or drawings are utilized by health educators to communicate instructions to patients. Graphic messages are recalled more effectively than a heard, or read one. Pictures can be effective substitutes for words.
	Pictorial Symbols[3, 4,16]	Pictures and related text are easier to comprehend and adhere to than pictures alone.[16] Pictures can sometimes be effective substitutes for words.[4] There is a higher recall with pictures than text alone.[3]	
	Graphic Symbols[10]	Graphics provide short directives geared towards patient behaviors. Simple line drawings are beneficial.[10]	
	Verbal Symbols[2]	Supplement of written information to get a message across, for example, "Return to Clinic" is portrayed through easy identifiable symbols[2]	
	Illustrations[6,8, 15,34]	Used to emphasize key concepts and are not meant to be decorative. Must be kept simple (Seligman). Increases the meaning and retention of subject matter.[8] The use of cartoon illustrations were used to improve comprehension of instructions. Patients were proven to be more compliant with instruction when viewing cartoons.[6]	
Writing Styles[5, 10, 13-16, 31, 32,34]		Writing styles should be user friendly in order to be effective, through the use of large print and simple words.[10,15]The pictures are easier to understand when the accompanying text is made visible and clear.[13, 14, 16,31] The use of less information is better for the accompanying use of oral instructions.[32] To increase the usability of the posters, the reading level should be below 8th grade.[5]	The use of shortened/simple words, substitution of general terms for jargon, simplifying sentence structure, use of active voice, elimination of extraneous words, concrete examples rather than abstract principles, 12 point or higher clear font, no cross-referencing, and simple layout are important in regards to readability.
Target Population[2, 5, 8, 10, 12, 15, 16, 32-36]		The materials should be culturally appropriate and represent a diversity of populations. As an example, the materials are in four different languages and have the ability to represent the ethnic group. The colors can better reflect specific cultures upon viewing.[33] Patient compliance and satisfaction increase when beliefs are taken into consideration.[12]	Overall the materials should reach the target population. Therefore, materials should be specific to the patient. It also needs to adapt to the local culture in regards to ethnic values. The educational materials should incorporate values, beliefs, and language barriers.
Organization[15]		The information should be sequenced so that the most important information is in the beginning. The use of bullet points instead of solid text, and headings are easier to interpret when looking for information.[15]	Sequencing of information in an appropriate way is important for better interpretation of materials.

Table 2: Demographics of the Test Populations

Country (population type)	No. of participants	Primary language	Age, x (SD)	Yrs. of education, x (SD)	Yrs since amputation x (SD)	Travel minutes to clinic x(SD)
United States (amp)	16	English	51 (12)	14.8 (3.2)	13.1 (11.6)	27 (18)
Peru (amp)	10	Peruvian Spanish	28 (17)	10.5 (1.4)	6.6 (7.3)	98 (70)
East Africa (amp)	17	Mixed (3 fluent and 5 intermediate English)	47 (19)	6.6 (.51)	20.7 (18.6)	137 (139)
United States (ESL students)	18	Mixed (low and intermediate English)	Not recorded	Not recorded	Not applicable	Not applicable

RESULTS

Because of the unique constraints of testing across several international locations, it was not possible, nor advantageous, for each subject to answer every question. Therefore, the analysis of the field testing was primarily considered separate for each group (Table 3). However, a few common themes across groups were evident and are noted below. Figure 2 depicts bar graphs of the results.

Persons with amputation in the United States

There was no significant correlation between age and PR suggesting that the images were suitable for all adult ages. The low poster rating score on PR 6 suggests that clinicians should allow time for patients to ask questions. Researchers addressed the low sequence comprehension score on hip extension (SC 5) by including a shadow in the revised images and suggest that demonstration should be provided. Object identification scores for ID2 and ID6 were highest indicating that this information was conveyed most clearly. The ID+SC percentile score was used as a measure of poster understandability. There was a negative correlation (R=0.55; p=0.028) between age and ID+SC score. Older patients may therefore require additional explanation time compared to younger patients. No correlations were found between education and ID+SC or between experience and ID+SC.

Table 3: Results

Country and Population	Questions Answered	Poster Ratings	Sequence Comprehension	Object Identification
United States (amp)	PR1—PR9 ID1-ID6 All SC	x=93%	x=89%	x=72%
Peru (amp)	PR1—PR9 ID1-ID6 (n=8) All SC (n=6)	x=87%	x=86%	x=56%
East Africa (amp)	PR7and PR10 (n=16) ID3 and ID5 (n=15), ID 7 (n=12)	x=96%	Not tested	x=59%
United States (stu)	PR1—PR9 ID1-ID6 All SC	x=90%	x=56%	x=68%

PR- poster ratings ID- object identification SC-sequence comprehension

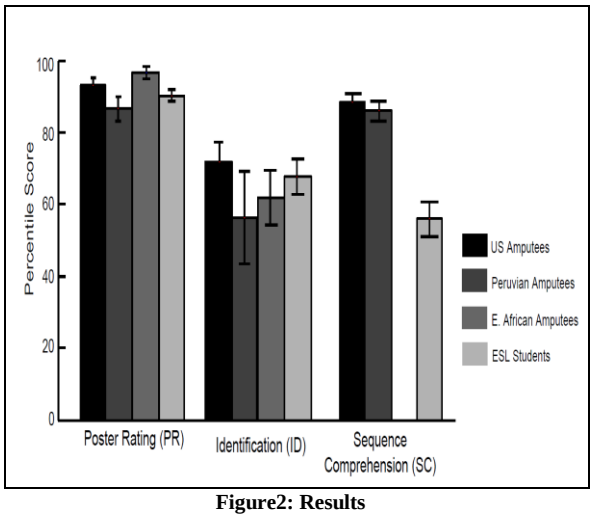

Figure2: Results

Persons with amputation in Peru

There was also no significant correlation between age and PR score. Similar to US patients, the low score for PR6 underscores the need to provide time for patients to ask questions. To improve comprehension of SC4, the symbol of a hill was replaced with a literal hill that a person walks up (Figure 4C). To improve object identification, one image on the skin care poster (ID5) was modified to clarify scratching (Figure 4B). There were no significant correlations between ID+SC percentile scores and age, education, or experience, suggesting that understanding of the material was not influenced by these demographic variables in the Peru field testing.

Persons with amputation in East Africa

There was no significant correlation between age and PR. Scores on ID5 were lowest, similar to Peruvian patients and addressed in Figure 4B.Researchers also noted that the mirror in ID7 was commonly misperceived as a magnifying glass, and was therefore modified after the pilot study was completed, illustrated in figure 4A.There were no significant correlations between ID percentile scores and age, education, or experience; but there was a significant positive correlation (R=0.72; p=0.0036) between language and ID scores. One explanation of this correlation could be that poster words were written in English and many of the answers to the ID questions were on the posters. In contrast, this

correlation would not be expected in US persons with amputation because all spoke English or persons with amputation in Peru because the posters were translated into the local language, nor ESL students because all students were at a similar language level. The variety of local dialects in East Africa limited the ability to translate the posters during data collection; however, the positive correlation between language and ID score indicate that local translations will be an important improvement to make during clinical implementation.

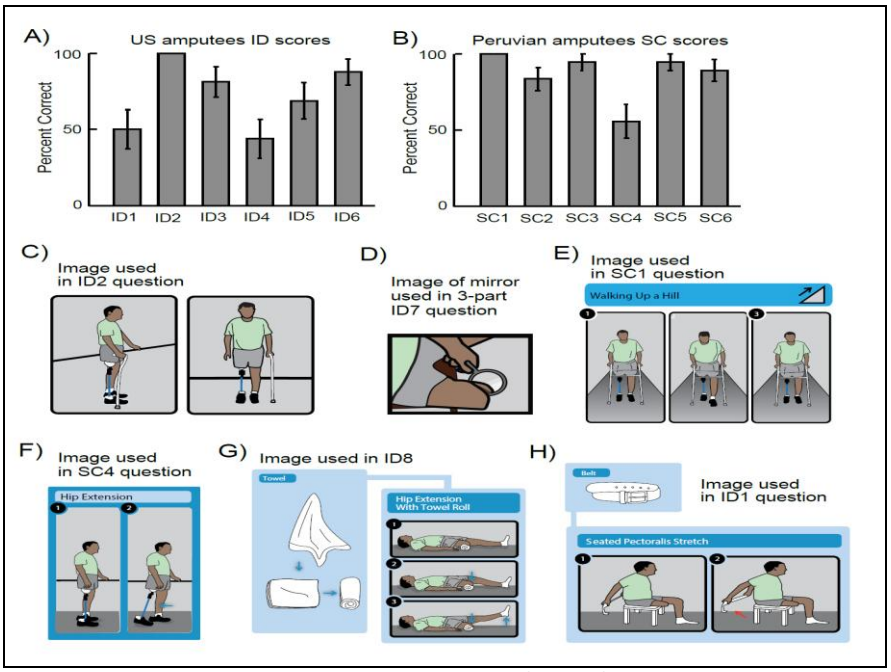

Figure 3: Results (A and B) and Examples of some of the images (C-H)

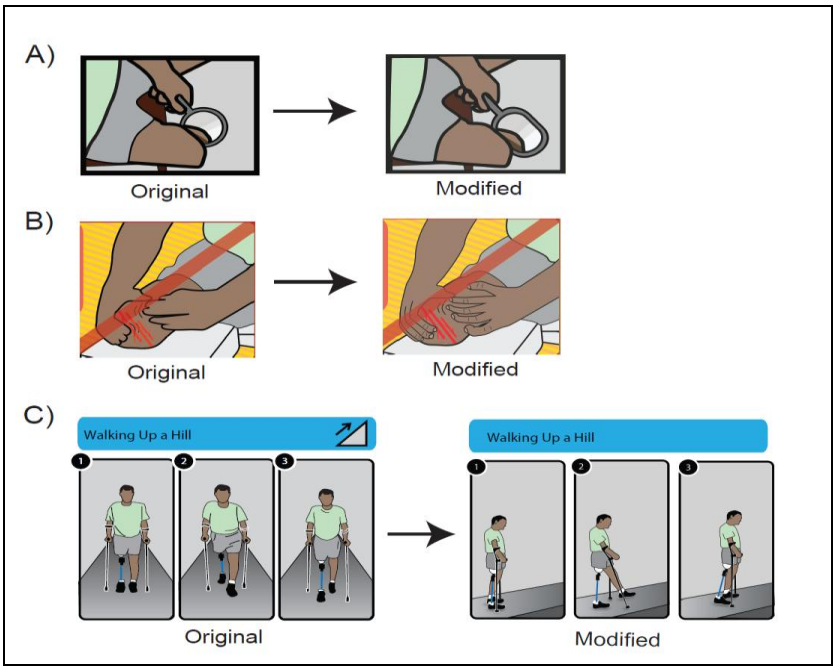

Figure 4: Modifications made to posters

ESL students in the United States

Consistent with persons with amputation in the US and Peru, the lowest poster rating score was on PR6, further suggests that patients need plenty of time to view rehabilitation images. Sequence

comprehension scores were comparable to those of persons with amputation in the US. Though scores were low, images associated with ID2 and ID3 were not modified because most patients identified these objects as items that would still promote successful rehabilitation. For example, the belt was often identified as a cane, which could in fact be used as a substitute. Researchers observed that the high scores on ID1, which was lowest in US patients, may have been more a matter of subjects copying the word off the poster.

DISCUSSION

The aim of this project was to create and test education materials for international clinicians and patients in developing countries related to prosthetic rehabilitation. Strategies used to create education materials for persons with low health and reading literacy consider several principles. [2-6,12,13,15,17,20,32,33,36,39,40] It has been acknowledged that pictures should not be used as the sole communication source, as alone they have been associated with low recall of information and they do not convey the level of detail needed for proper comprehension of information related to medicine. [31] Their ultimate value in practice depends largely on appropriate use by healthcare providers, who must offer the accompanying, explanation to patients. Visuals used in this context serve as a memory aid rather than a primary source of information, and research has shown pictograms to be a highly effective means of stimulating recall of spoken information in people with poor literacy skills. [13] It is important to ensure that both recall and comprehension of education materials is achieved, as individuals may be able to remember information without necessarily understanding it.

Application of these principles to develop education materials for persons with low literacy skills transferred well to this project. The posters consist of mostly straightforward images with a few organizing words; these images are modifiable to reflect various cultures. Images and key words were created to stimulate and support dialogue. The size of the posters is congruent with actual clinical use. Moreover, consistent with Dowse et al. (2001), the education materials were designed to supplement instruction provided by a clinician. [31] The education materials developed for this project were specifically designed to target patients with low health and reading literacy. These materials were developed to supplement verbal instruction and demonstration provided by the clinician. The addition of oral instructions to written materials and pictographs has been shown to improve comprehension. [3,7,32] However, during the research testing, no instruction was provided with the posters to remove any bias in the results. Thus, actual patient comprehension in a clinical setting is expected to be higher than the results of this project.

Additional conclusions can be drawn as a result of this study. First, preliminary testing and evaluation of the materials locally was helpful prior to international use. Performing the SAM on the posters and clinician manual, field testing the education materials and data collection procedures as a preliminary step yielded better educational products for the actual pilot study and saved time and money considering their international application. Testing locally also afforded researchers the opportunity to compare data of lay-persons with persons with amputation. Since persons with amputation locally did not score perfectly, the results suggest that the education materials may be helpful to instruct persons in the US. Collaborating with professionals in different disciplines was initially time consuming but ultimately beneficial. Secondly, this project filled an important gap in international education materials. Existing material related to prosthetic education is not ideal for patients in developing countries. Finally, this study supports the idea that international testing is valuable, albeit challenging.

The international data collection was interpretable and consistent, leading to specific modification and ideas for future content expansion. The design of this study was participatory as it allowed subjects the opportunity to express ideas to improve clarity, particularly any confusion related to cultural differences. However, like most international studies, several hurdles needed to be negotiated. Limited time spent internationally, limited access to interpreters and subjects were considerations that influenced the design of the pilot study. In addition, further modifications to the testing procedures were made in the field because of these same variables. Cost and time of international travel account for much of the restriction related to this project. Because of the various groups of local and international populations, the IRB approval process necessitated separate IRB proposals for each. Furthermore, researchers had to ensure that international researchers were Collaborative Institutional Training Initiative (CITI) trained. The informed consent document had to be translated to the local language and authored at a 5th grade reading level.

CONCLUSIONS

Multi-modal testing is a practical way to identify suitability and understandability of education materials. In this study, testing was done with poster rating (PR), object identification (ID) and sequence comprehension (SC). An effective way to test comprehension is to ask for a return demonstration/explanation; this was accomplished with the ID and SC. Clinicians do not always realize what patients actually know until they ask for a return explanation. The PR helped identify the overall acceptance by the subjects, but these questions alone could not be used to assess understandability. Having multiple sources of information proved useful as the PR scores did not indicate knowledge translation as the ESL students demonstrated high PR scores and had high ID but scored low on the SC. It is possible that the ESL students did not value the details in the images of prosthetic rehabilitation since they held no real significance to them. Health care providers should be wary of how much knowledge patients actually obtain during clinical visits as this study indicates that persons with amputation in the US did not score 100%. A knowledge comprehension test added to a future study would refute or support this point.

A second implication of this study is that multi-disciplinary approaches to design patient educational material can improve outcomes. This project originated from a team of biomedical engineers whose aim was to teach technicians in developing countries how to fabricate low-cost, high-functioning lower limb prosthetics. Although the biomedical engineers were successful, they realized that patients required training to optimally utilize their prosthetic limbs. To address the rehabilitation component, physical therapists developed the content for the clinician and patient education materials. The therapists realized that barriers exist in communicating information visually and collaborated with Visual Communication Designs artists to design and professionalize the products ensuring their usability on an international basis. Since the pilot study, the education materials have been utilized in a Mexican community under the supervision of a community development worker. The development of a certification protocol for rehabilitation specialists is included in the next phase of the project, along with revision and re-testing of the education materials and expansion of the study to include assessment of knowledge comprehension. This study represents a segment of a long-term project that combines partnerships among engineers, physical therapists, prosthetists, visual communication design artists and community development workers to provide multi-disciplinary patient education and care internationally.

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