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CLINICAL REPORT

Clinical Evaluation of the Franklin Applied Physics Cosmetic Cover for Lower Limb Prostheses: A Preliminary Report

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Abstract—The Franklin Applied Physics (FAP) Cosmetic Cover is the result of research and development directed by Dr. Robert Erb at the Franklin Research Center, Norristown, PA. The FAP Cover is a silicone rubber cosmesis designed to improve the appearance of lower limb prostheses and provide wider social integration for the wearer.

The Technology Transfer Section, Rehabilitation Research and Development Service, Department of Veterans Affairs, coordinated a pilot study of four pre-commercial covers at selected sites. Participating prosthetists and subjects evaluated fit, relevant physical criteria, and overall potential value of the cover.

The following statements summarize responses of the participants: 1) well accepted with regard to overall fit, appearance, and ease of donning/doffing; 2) lightweight, highly elastic, and easy to maintain; and 3) split toe and closed toe versions are needed for above-knee and below-knee models.

Data gleaned from the pilot study were used to define dimensions for standardized off-the-shelf sizing and to make recommended modifications, resulting in pre-market models that are ready for a national field evaluation.

Key words: *above-knee amputations, above-knee prostheses, below-knee amputations, below-knee prostheses, technology transfer.*

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INTRODUCTION

In 1985, responding to the need for a life-like, durable, functional, and affordable cover for lower limb prostheses, the Department of Veterans Affairs (then called the Veterans Administration), Rehabilitation Research and Development Service (VA Rehab R&D) sponsored the Franklin Research Center (FRC), Norristown, PA, in developing a silicone rubber cosmesis. During the next 5 years, Dr. Robert Erb directed this pioneering research at FRC. Over this period, several design prototypes were developed and tested, leading to the current process and materials used. Laboratory tests conducted at FRC on the prototypic models proved successful and FRC eventually submitted a Request for Evaluation (RFE) for review and consideration as a technology transfer project. After review, the device was deemed ready for clinical evaluation as a desirable prosthetic component.

Franklin Applied Physics, Inc. (FAP) in Oaks, PA,[1] under the direction of Christine Felser (formerly with the research team at FRC), with Dr. Robert Erb and Harold Heller serving as consultants, produced four covers for the pilot evaluation. The FAP Cosmetic Covers (three medium-sized right below-knee covers and a large left above-knee cover) were fabricated with a split between the great toe and second toe to fit the M + IND Seattle Lite Foot (SLF).

[1] The Franklin Research Center was closed on January 31, 1993.

Since the FAP Cosmetic Cover had never been clinically evaluated, the Technology Transfer Section (TTS), VA Rehab R&D Service, Baltimore, MD with collaboration from Frederick Downs, Jr., Director, and John Clements, VA Prosthetic and Sensory Aids Service (PSAS), accomplished a pilot evaluation prior to implementing the national field study. It was felt that results gleaned from this pilot would greatly assist in ensuring an efficient and effective multicenter evaluation.

PRODUCT DESCRIPTION

FRC researchers developed procedures for molding, casting, intrinsically coloring, and applying silicone prosthetic covers. The manufacturing process involves fabricating the covers using a multistep molding procedure of a two-part room temperature vulcanizing (RTV) silicone rubber to provide highly detailed, dimensionally stable molds. The seamless molds replicate skin texture to give a realistic appearance to the outer layers of the cosmeses. These molds are now being targeted for standard off-the-shelf sizes to reduce costs and to increase availability.

The cover is a thin-walled silicone rubber cosmesis (**Figure 1**) designed for veterans (and others) with lower limb prostheses. The developers state that the advantageous properties of the FAP Cover are its life-cast surface features, realistic appearance, and elasticity. The water-repellent cover is designed to improve the appearance of a prosthesis; thus, providing wider social integration for the wearer (e.g., where informal clothing, such as shorts or skirts, is being worn and in situations where the wearer is barefoot).

The outer layers of the silicone rubber used for fabrication are pigmented with low levels of dry pigment to achieve the realistic semitransparency of human skin. The permanent intrinsic coloration process allows for standardization of the representative colors for the range of average human pigmentations. The intrinsic coloration process also permits the introduction of realistic heterogeneous mottling and spotting (**Figure 2**).

The intrinsic painting is done in multiple layers, which may include a base color, blush, and vein color. If necessary, FAP can select the base color by matching the veteran's skin shade to a color chip from the Munsell Skin, Hair, and Eye coloration chart. The Munsell color chart provides a systematic representation of the range of human skin colors in a format that allows the color chips to be placed next to the client's skin. An accurate color match of the hue, chroma, and value within the epidermis can be matched on the artist's pallet. By using quantitative measurements of silicone and pigments, the skin tones of all races of people can be duplicated. The pigments are then sealed within the layers of silicone, enabling the cover to retain this coloration during everyday wear and cleansing.

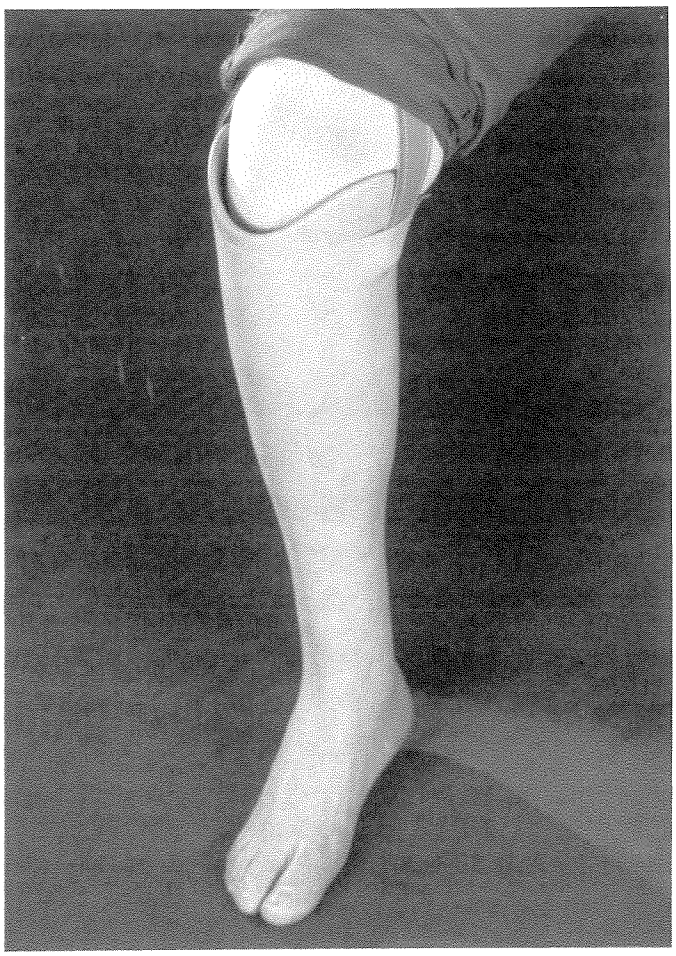

Figure 1.
Franklin Applied Physics (FAP) Cosmetic Cover.

Since the cosmesis is fabricated from high tear-strength silicone rubber, it has excellent abrasion resistance and durability. The silicone is comparable in tensile strength and tear strength to latex rubber, but is inherently superior to polyurethane. Silicone rubber is stable from chemical and photo-oxidative attack and also provides flexibility and stretching where needed (e.g., at the ankle and knee joint areas). The cover is essentially maintenance free. It may be cleaned, when necessary, with soap and water. Chemicals (e.g., rubbing alcohol), may be used to lift off ink marks and other small soil marks, if required.

Figure 2.
Close-up of FAP cosmetic cover showing realistic heterogeneous mottling and spotting.

The wearer may use a disinfectant to prevent microbial growth.

Additional features of the FAP Cosmetic Cover are:

- The silicone used is a tear-resistant elastomer providing up to 800 percent elongation before breaking
- It is available for both below-knee (B/K) and above-knee (A/K) prostheses in medium and large sizes
- The surface texture is replicated directly from human skin
- The color is permanent; it will not fade or migrate.

SUBJECT CRITERIA

Male subjects with unilateral or bilateral B/K and A/K amputation who had worn a prosthesis for at least 1 year, and had worn their current prosthesis daily for the last 3 months, were selected to participate in the evaluation trials.

For the purposes of this study, the principal investigator (PI) or designee screened potential subjects according to the following criteria:

1. Ability to wear the prosthesis all day and leaves his residence a minimum of three times per week.
2. Ability to negotiate stairs and other common features of the residence.
3. Ability to independently perform all relevant activities of daily living (ADL).

The subjects were required to be active, alert, cooperative, and have a desire to participate in the evaluation and complete all data instruments.

The participating prosthetists and/or subjects were provided with detailed instructions for fitting by Franklin Applied Physics. The prosthetist and/or subject donned the cosmetic cover and the fit was observed. If the prosthetist and subject concluded that the fit was not satisfactory, the probable reason for failure was assessed and the locations and amounts of required modifications recorded. If a successful fit was obtained, the prosthetist and wearer assessed ease of donning/doffing. The cosmetic covers were reevaluated after a 3-month trial period. The subjects were allowed to keep the covers if they so desired.

RESULTS

The results were formulated from responses contained in the data instruments. Due to the limited clinical exposure, results are qualitative rather than quantitative. The following summarizes the results for the four participating facilities.

Cosmetic Cover for Below-Knee Prostheses

Clinical Evaluation

One subject was fit with a medium right B/K cosmetic cover at each of the selected PSAS Prosthetic Treatment Centers. Each subject had worn a prosthesis for 17 or more years and the current prosthesis for 6 or more years; all wore their prostheses 13 or more hours per day, 7 days per week. Information describing the subjects' current prostheses is included in **Table 1.**

All subjects rated the fitting instructions as adequate. For each wearer, the total time required to complete the fitting was from 30 to 60 minutes. Donning/doffing was rated as easy; on the first attempt, one user was able to

Table 1.
Current Prosthesis of Subjects.

	Subj. A	Subj. B	Subj. C
Type of Prosthesis	Exoskeletal	Exoskeletal	Endoskeletal
Type of Foot	SLF	SLF	SLF
Foot Size	26 cm	26 cm	28 cm

Table 2.
Subject Rating of FAP Cosmetic Cover Criteria.

Feature	Excellent	Good	Fair	Poor
Fit	A	B	C	
Stretchability	A, B	C		
Weight	A, B	C		
Overall Shape		A, B, C		
Feel	A	B, C		
Surface Texture	A	B	C	
Skin Coloration	A	B, C		
Wall Thickness	A, B	C		
Ease of Cleaning	A, B	C		
Ease of Keeping Clean	A, B	C		
Overall Appearance	A	C	B	
Overall Satisfaction	A, B	C		

don/doff the cover independently. One wearer required no adhesive and two subjects used adhesive to secure the cover to their prostheses.

Overall fit was rated as fair to good. Some wrinkling was noted between the great and second toe; the cover was loose over the dorsum of the foot, and posteriorly in the mid-calf area.

The subjects were also asked to rate the following items related to cover performance. Results are indicated in **Table 2.**

Neither environmental factors (e.g., heat, cold), nor household chemicals affected the cover. Soiled areas were easily removed with soap and water and clothing dye stains were removed with cleaners (e.g., rubbing alcohol). There were no reports of tearing, pin holes, or other damage to the appliances. No skin irritation was noted.

Advantages over other covers that the subjects had used included greater tear strength and a more life-like appearance. One wearer noted that the cosmesis frequently clung to his pant leg while he donned his trousers or when he sat down.

Suggested modifications included developing both closed toe and split toe versions of the cover and establishing standardized sizes in accordance with the M + IND (M + IND, Seattle, WA) Seattle Lite Foot/polyurethane endoskeletal (under) cover dimensions. Other suggestions were to increase the overall length of the B/K model by several inches and to include a wider band at the top for the trim edge.

All wearers said they would readily use the FAP Cosmetic Cover if these modifications were made and the device was commercially available.

Prosthetic Laboratory Fitting Evaluation

The initial selection of sizes for the men's medium and large cosmetic covers were arrived at through a combination of methods. The FAP developers physically measured a large number of men's feet and legs in the Philadelphia, PA area and combined those data with information from a size chart for adult male prosthetic feet supplied by M + IND, Inc.

Judy Johnson, Prosthetist-Orthotist, Acting Chief, Orthotics Laboratory, VA Medical Center, Richmond, VA, and the TTS Project Manager, Baltimore, MD, conducted a fitting evaluation of the FAP medium right B/K cosmetic cover with a series of Seattle Lite Feet to determine which sizes could be fit with the cover.

The results of the evaluation were as follows:

1. The FAP Cover was too large for the 25-cm SLF.
2. The Cover fit the 26-cm SLF, but was too loose over the dorsum of the foot in the area from the proximal edge of the toes back to the ankle. This space could be filled with foam or another type of filler.
3. The Cover fit the 27-cm foot well, except for wrinkling at the proximal crease between the great toe and second toe.
4. The Cover fit the 28-cm foot well, but due to cosmesis stretching, the second toe became too big (about one-third wider than normal) and the proximal crease wrinkling described in #3 (above) persisted.
5. The Cover fit the 29-cm SLF also, but the area over the lateral maleolus became stretched; the proximal crease wrinkling and large second toe persisted.

It appeared from the laboratory evaluation that with minor modifications, the pilot medium right cover would fit the three largest sizes of the SLF (27–29 cm). We felt that fabrication of a second, smaller FAP Cosmetic Cover, to accommodate prosthetic wearers utilizing 25- and 26-cm SLF, would adequately encompass the range of Seattle Lite Feet (and other split-toed feet) utilized by male veterans.

Cosmetic Cover for Above-Knee Prostheses

A large, left A/K cover was delivered to the Prosthetic Research Study (PRS), Seattle, WA for evaluation. The cover proved to be too large to fit any of the available subjects. However, the PI attempted to determine the potential inhibitory effect of the cover on an A/K prosthesis wearer during ambulation. Placing Yates clamps vertically down the posterior side of the cosmesis to take up most of the excess material and simulate a tight fitting cover, the PI conducted an ambulation evaluation with one subject. The PI was pleased with the unrestricted motion allowed by the FAP Cover. While the cosmesis was being worn, it did not appear to significantly inhibit knee movement.

PRS felt the cover was not long enough and suggested increasing the overall length by 8 inches. The PI recommended using a protective sleeve over the prosthetic knee joint or placing compressed foam donuts above and below the knee joint to prevent the cover from being pinched by the joint during ambulation. PRS has supplied the developer with a series of recommended thigh circumferencial dimensions for both the medium and large size covers. A second A/K cover, which has been fabricated in accordance with the recommended dimensions, is being forwarded to PRS for evaluation.

DISCUSSION

The FAP Cosmetic Cover was well accepted by all the subjects participating in the pilot trials. For the B/K version, the overall fit was rated as good and all wearers felt that, with practice, they could easily don and doff the cover independently.

Trials for the B/K cover confirmed that the intrinsic coloration did not fade or migrate. For appearance, stretchability, and ease of maintenance, all subjects preferred the FAP Cover to previous covers they had worn.

The overall reaction to the FAP Cosmetic Cover was favorable, but the following changes and modifications were identified:

1. The large model was too large for all candidates in the PRS subject pool.
2. The medium cover, with minor modifications, will adequately serve as the large size cover.
3. A second size (medium) is being developed to fit wearers using 25–26 cm prosthetic feet.
4. The new molds for the medium and large cosmetic covers will be based on dimensions utilized for the 25-cm and 27-cm M + IND SLF/polyurethane endoskeletal (under) cover componentry.
5. Thigh dimensions recommended by PRS will be incorporated into both A/K models.
6. Both A/K and B/K versions will be lengthened and the trim band increased in width.
7. Closed toe and split toe models will be developed for all covers.

It was the general consensus of all users and staff that changes to these areas would lead to an improved cosmetic cover that is desirable by persons with lower limb prostheses.

Based on the results of this pilot study, it is recommended that the next phase proceed: a national evaluation of 46 additional FAP Cosmetic Covers to validate the optimal dimensions for standardized sizing, durability, and relevant physical characteristics. Only through this mechanism can we fully determine the device's practicality, clinical utility, and commercial readiness for veterans (and others) with lower limb prostheses.

The following areas will be scrutinized in this evaluation:

- Fitting
- Functionality (stretchability) when applying the device onto prosthetic limbs and during ambulation activities (for A/K Covers)
- Durability
- User acceptance of aesthetics (color tone, texture and shape)
- Comparative acceptance to currently used lower limb cosmetic devices
- Maintenance and repair
- Readiness for commercial availability.