Total Surface Bearing Below-Knee Prosthesis: Advantages, Disadvantages, and Clinical Implications

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ABSTRACT. Hachisuka K, Donozo K, Ogata H, Ohmine S, Shitama H, Shinkoda K. Total surface bearing below-knee prosthesis: advantages, disadvantages, and clinical implications. Arch Phys Med Rehabil 1998;79:783-9.

Objective: To investigate the total surface bearing (TSB) prosthesis for below-knee amputee patients and to determine its clinical indications.

Design: Case series.

Setting: University hospital and the Welfare Center for the Disabled.

Patients: Thirty-two subjects who could walk with the TSB prosthesis and had already used the patellar-tendon bearing (or Kondylen-Bettung Münster) socket.

Main Outcome Measure: Subjective assessment of the TSB socket, consisting of an overall rating and ratings of 13 individual items, was performed, and results were analyzed with Fisher's exact test.

Results: Seventy-five percent of the subjects were satisfied overall with the TSB socket. Of the 13 items, comfort, ease to swing, pain, piston movement, tightness, skin irritation, appearance, and durability were regarded as good by more than 75% of the patients. Donning, perspiration, odor, and staining were regarded as poor by more than 20%. Items that were significantly related with overall satisfaction with the TSB socket were comfort, ease to swing, and piston movement, while donning was significantly related to dissatisfaction.

Conclusion: The TSB socket is suitable for and preferred by many amputee subjects, but some problems remain to be solved.

THE PATELLAR-TENDON BEARING (PTB) prosthesis was developed for below-knee (B-K) amputee patients at the University of California at Berkeley in 1957,[1] and its prosthetic socket design has been regarded as the international standard for below-knee amputee persons. Although the PTB socket provides a good fit for many B-K amputee persons, we sometimes encounter a patient wearing the socket who complains of excessive pressure on the patellar tendon area, limitation of knee flexion, adventitious bursae,[2] skin abrasions,[3] or dermatitis.[4] These problems may result from the socket design; because the socket does not suspend the prosthesis from the stump, it needs auxiliary suspension, and it cannot prevent pistoning and sliding on the skin. The Kondylen-Bettung Münster (KBM) socket is a supracondylar PTB modification in which the medial and lateral walls are high enough to enclose the femoral condyles and suspend the socket from the stump without auxiliary suspension. The KBM, sometimes prescribed for short persons with B-K amputations, has the same problems as the PTB.

To solve these problems, a total surface bearing (TSB) prosthetic socket,[5,6] a type of suction socket, may be applied. Suction suspension B-K prosthetic sockets were tested in the early 1950s,[7,8] and their advantages led to recommendations for further development and research.[9] Several studies of rigid suction sockets and semirigid insert suction sockets for B-K amputee persons were completed,[10-14] and a total-contact silicone gel-lined socket was developed[15,16] that improved the pressure seal during sitting, bending down, and athletic activities. After conducting a survey of suction sockets for persons with B-K amputations, Robert[17] described a high degree of acceptance and satisfaction by users along with decreased pistoning, better skin condition, and increased activity levels. Some problems concerning materials, casting, and fitting remained to be solved, however. In the mid-1980s Kristinsson[18] developed the Icelandic Roll-On Silicone Socket (ICEROSS), a prefabricated elastic silicone cone in six sizes that was rolled over the stump as an inner socket and suspension component to provide good total contact with the stump skin. In 1987 Staats[5] described a TSB socket design different from that of the PTB socket. This socket was a total contact suction socket in which weight was born on the entire surface of the stump, including areas previously considered pressure sensitive. Pe-lite, Surlyn, or silicone materials were used for the soft suction liner of the socket, and a latex sleeve was recommended for auxiliary suspension. Fillauer[6] introduced the Silicone Suction Socket (3S), which adopted the TSB suction socket design, and included a rigid outer socket, viscoelastic silicone inner socket, and connective equipment (shuttle lock).[6] A prosthetist laminated the inner socket with silicone resin over a positive model of the stump. In recent years the TSB socket with a laminated or prefabricated silicone inner socket has become popular for B-K subjects.

Because this socket was in contact with the entire stump surface, it was thought that the improved pressure seal provided sufficient suction suspension and that the dispersion of local pressures was more comfortable. Some prosthetists in Japan have attempted to fabricate TSB sockets for B-K amputee patients since the early 1990s. At first it was thought the socket would alleviate all the problems of the PTB socket, but some subjects with the TSB socket complained of pain at the distal end of the stump, discomfort during knee flexion, and perspiration on the stump.[19] There has been only one report of a clinical survey of the TSB socket with the ICEROSS.[20] We decided to investigate whether B-K amputee persons in Japan are satisfied with the TSB socket and what further modifications, if any, are

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necessary. This clinical investigation examined the advantages and disadvantages of the TSB socket to establish its clinical indications.

MATERIALS AND METHODS

The subjects were B-K amputee patients for whom the TSB socket (3S) had been prescribed at the Department of Rehabilitation Medicine, University of Occupational and Environmental Health, or the Welfare Center for the Disabled, Kitakyushu, Japan, from 1992 through 1995. Twenty-three outpatients who had already been fitted with the PTB or KBM socket were recommended to have the socket replaced by the TSB socket when they came to the clinics to have their prosthesis remade. Nine inpatients received both the TSB and PTB temporary prostheses for evaluation and were asked to use the two prostheses alternately every 3 or 4 days. After 2 months of temporary use, they were asked to select a preferred socket as a first appliance after amputation.

Subjects were selected according to the following inclusion criteria: ability to walk with the TSB prosthesis; experience with both the PTB (or KBM) and TSB sockets; voluntary enrollment in the clinical investigation. Thirty-two patients met the inclusion criteria. The percentage of the stump length was defined as the length between the lateral condyle and the tibial end divided by the length between the lateral condyle and the lateral malleolus on the nonamputated side multiplied by 100. For bilateral amputee patients the percentage of the stump length was calculated by assuming that the length between the lateral condyle and lateral malleolus is equivalent to subtracting the distance between head and knee plus 8cm (approximate distance from floor to ankle) from the previous height.

The prescribed TSB prostheses were of endoskeletal construction and included a rigid outer socket, laminated silicone inner socket, shuttle lock, and Seattle foot[a] or Flex Walker II[b]. The prostheses were fabricated by certified prosthetists with more than 20 years of experience, and were carefully checked and adjusted. The inpatients performed range of motion exercises, muscle strengthening exercises, and gait training under the supervision of physical therapists at the rehabilitation center.

A questionnaire designed to subjectively assess the socket was sent or handed to the patients. The questionnaire asked about overall satisfaction with the socket, and 13 individual items (see appendix, page 789). Twelve were derived from the results of our previous investigations,[19,21] and one, "durability of the socket," was newly added to the assessment. The subjects were asked to rate overall satisfaction as "satisfied," "somewhat satisfied," "undetermined," "somewhat dissatisfied," and "dissatisfied," and to rate the other 13 items as "good," "somewhat good," "undetermined," "somewhat poor," and "poor," or other corresponding 5-level scales. The concurrent validity of the assessment was not examined, but their content validity was considered good because the items of the assessment included all the advantages and disadvantages of the TSB socket the subjects reported in our previous studies. The test-retest reliability was examined for the nine inpatients using kappa coefficients, and the assessment was regarded as reliable because the obtained kappa coefficients were between 0.5 and 1.0.[22]

Some of the subjects' characteristics were presented as mean ± standard deviation, and the statistical analysis was processed with SPSS 6.1J for Windows.[c] To examine the reasons for the overall satisfaction with the TSB socket, the subjects were divided into two categories according to overall satisfaction: those satisfied ("satisfied" and "somewhat satisfied") and those not satisfied ("undetermined," "somewhat dissatisfied," "dissatisfied"). They were further divided again into two levels according to answers to each question: those giving the highest response and those giving other responses. The differences between the categories and levels were analyzed with Fisher's exact test, and p values of less than .05 were considered to indicate significance. To examine the reasons for overall dissatisfaction with the TSB socket, the same procedures were used.

RESULTS

Subject profile (table 1). The average age of the 32 subjects (27 men and 5 women) was 44.5 ± 16.0 years (mean ± standard deviation); the most common reason for amputation was trauma; and the average percentage of stump length was 45.5% ± 14.0%. Twenty-three outpatients had their PTB or KBM socket replaced with the TSB socket. The nine inpatients used both the TSB and PTB temporary prostheses, and all of them finally chose the TSB socket as their first appliance after amputation.

Overall satisfaction with the TSB socket (fig 1). Of the 32 subjects, 50% and 25% were satisfied and somewhat satisfied, respectively, with the TSB socket, and the TSB socket was accepted by most subjects. In particular, all nine subjects who had been inpatients under controlled trial were satisfied or somewhat satisfied with the TSB socket. Six percent and 6% were dissatisfied and somewhat dissatisfied, respectively, and the two dissatisfied subjects (6%) were using the PTB socket again at the time of this investigation.

Subjective assessment of 13 individual items (fig 2). Of the 13 individual items, "comfort to wear," "ease to swing the prosthesis," "pain during walking," "piston movement during walking," "tightness during walking," "skin irritation," "appearance of the socket," and "durability" were regarded as good or somewhat good by more than 75% of the subjects. There were some problems, however. "Donning and doffing the socket," "perspiration on the stump," "knee flexion and extension," "odor from the socket," and "staining of the socket" were regarded as good by fewer than 40% of the subjects, and the same items, except for "knee flexion and extension," were also considered poor or somewhat poor by more than 20% of the subjects. Seven subjects who rated "donning and doffing the prosthesis" as poor or somewhat poor

Table 1: Characteristics of Study Population

Number (male:female)	32 (27:5)
Outpatient:inpatient	23:9
Age (yrs)	44.5 ± 16.0
Cause of amputation	
Trauma	21
Diabetic gangrene	4
Vascular disease	3
Other	4
Side of amputation	
Right	12
Left	14
Both	6
Stump length* (%)	45.5 ± 14.0
Duration after amputation† (mo)	10.9 ± 13.8
First appliance after amputation	
PTB or KBM	23
TSB‡	9

* Length between the lateral condyle and the tibial end/length between the lateral condyle and the lateral malleolus × 100; the number of stumps was 38.
†The number of amputations was 38.
‡After having used both the TSB and PTB temporary prostheses, the patients chose the TSB socket as their preferred first appliance after amputation.

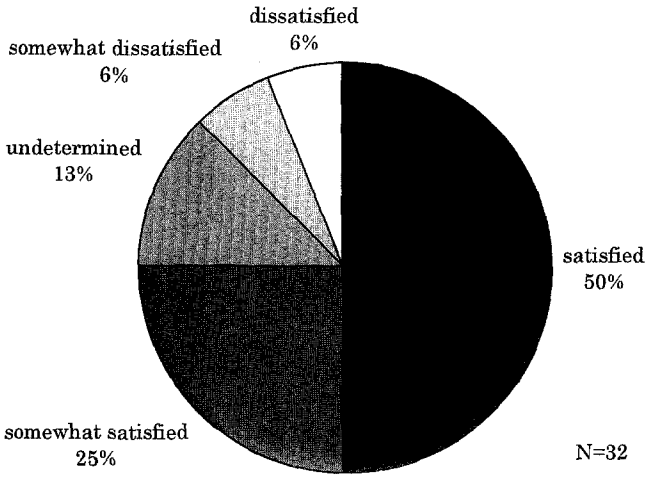

Fig 1. Overall satisfaction with the TSB socket.

included three patients with diabetic gangrene, retinopathy, and sensory disturbances of the hands and fingers. One of the three had hemiparesis. Two subjects who rated "donning and doffing the prosthesis" as poor needed 10 minutes to don the socket, were extremely dissatisfied with the TSB socket overall, and refused to use it.

Less frequent problems, which were regarded as poor or somewhat poor, were discomfort at the popliteal fossa during knee flexion and extension reported by four respondents; pain at the distal end of the stump during walking, reported by three; and scarring at the popliteal fossa (fig 3), reported by three. Discomfort and scarring at the popliteal fossa were mentioned by subjects who sat on low chairs or whose stumps had excessive soft tissue. Pain at the distal end of the stump was caused by improper fit of the socket. One subject who had a long distal end of the fibula with a bony spur (fig 4) suffered severe pain and erosion, which led to the distal end of the fibula and the spur being excised. Other less frequent problems were a periodic feeling of tightness around the midportion of the stump in two subjects who were receiving hemodialysis and fraying of the proximal end of the silicone inner socket in two subjects.

Relation of 13 individual items to overall satisfaction and dissatisfaction with the TSB socket (table 2). Three items—"comfort to wear," "ease to swing the prosthesis," and "piston movement during walking"—were significantly related with an overall rating of "satisfied" or "somewhat satisfied" (Fisher's exact test, $p < .05$), and these three items were considered advantages of the TSB socket. One item, "donning and doffing the prosthesis," was significantly related with an overall rating of "dissatisfied" or "somewhat dissatisfied" (Fisher's exact test, $p < .05$), and this item was considered a disadvantage of the TSB socket. Complaints of perspiration, odor, and staining did not affect the overall satisfaction or dissatisfaction with the socket.

DISCUSSION

Patients in this study could compare sockets because they had used the PTB, KBM, and TSB sockets. Although the subjects are not representative of the B-K amputee overall

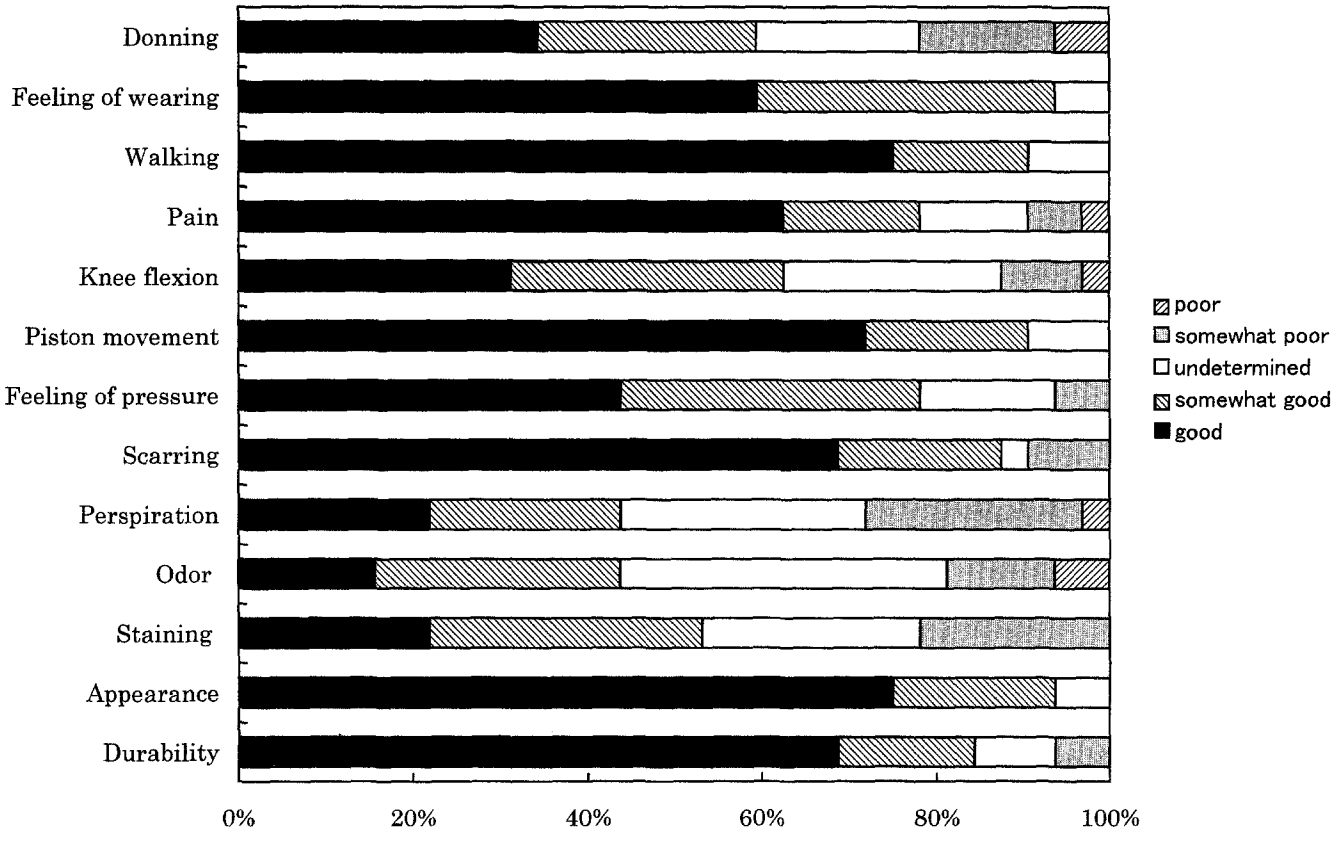

Fig 2. Subjective assessment of 13 individual items ($n = 32$). High responses include "good," "easy," "comfortable," "no pain," "no discomfort," "no looseness," "no tightness," "no skin irritation," "no excessive perspiration," "no odor," "no staining," and "durable," and low responses include their antonyms.

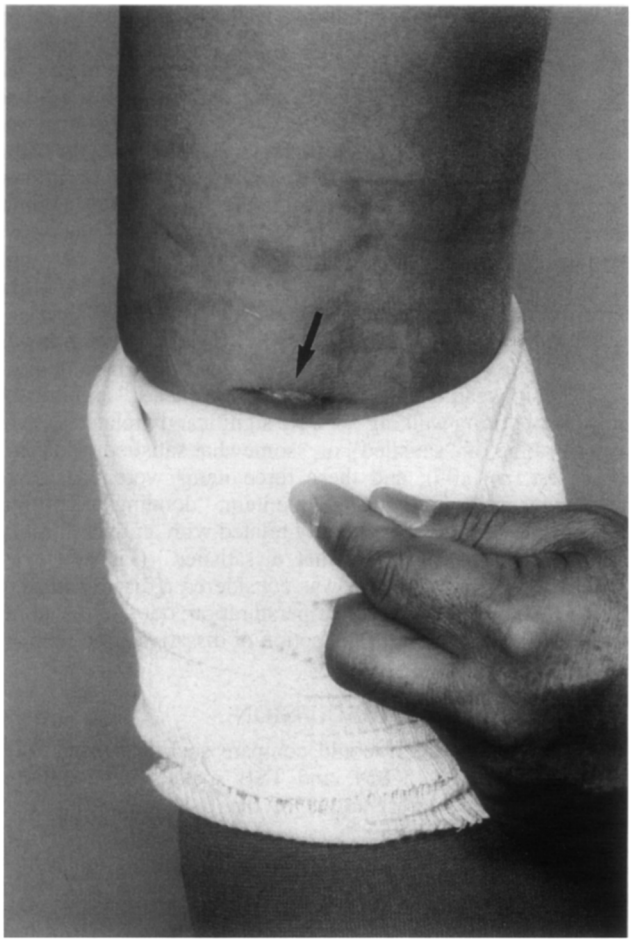

Fig 3. Fissure of the skin. The creasing of the silicone inner socket caused a fissure (arrow) of the skin at the popliteal fossa. After modification of the silicone inner socket, the fissure did not recur.

population because of the small sample size and high proportion of trauma victims, thus limiting the interpretation of the results, the advantages and disadvantages of the TSB socket can be recognized.

In general, the socket was viewed favorably. Because weight bearing is spread more evenly over the entire surface of the stump, subjects were comfortable wearing the socket and did not feel excessive pressure against the patellar tendon area. They reported less piston movement during walking, less traumatization of the skin of the residual limb, and less interference with knee flexion than experienced with the PTB socket. Further research into the relation between the subjective assessment and the pressure distribution of shear stresses[23] on the stump is needed to evaluate socket comfort more objectively.

There are, however, several problems with the socket. Patients with visual and sensory disturbances or hemiparesis may have difficulty donning and doffing it; the PTB socket is more appropriate for these patients because it is more easily donned and doffed.

Another problem is perspiration on the stump, which causes unpleasant odor and greasy staining of the socket. While Fillauer[6] reported that perspiration was not a problem, Cluitmans[20] reported complaints of perspiration and itching. Eleven of his subjects experienced increased perspiration with the prosthesis including the ICEROSS, but the degree of perspiration decreased after several weeks or months. Some subjects in our study also noticed a decrease in perspiration; however, the perspiration problem remains. Because the TSB socket is in contact with the stump's skin surface, the pressure-sweating reflex[24] may reduce to some extent perspiration on the stump. Some ventilation may occur in the PTB socket because of occasional gapping between the socket and the stump and the resulting piston movement during walking. There is no difference in vapor penetrability between the TSB and PTB sockets (unpublished data). Consequently, there is no objective evidence that the TSB socket is superior to the PTB socket in terms of perspiration. Persons using the TSB socket should alternately use and wash two silicone inner sockets. Additional basic research into the environment within the socket[25] is needed.

Amputee individuals who have excessive soft tissue sometimes complain of discomfort and scarring at the popliteal fossa, because the silicone inner socket creases at the popliteal fossa during knee flexion. Cluitmans[20] also described creasing of the ICEROSS at the back of knee during knee flexion. To reduce this discomfort, the silicone inner socket was fabricated at a 30° knee-flexed position and the number of layers of the nylon stockinet around the popliteal fossa was reduced from three to one (fig 5). These modifications make the silicone inner socket more elastic and flexible and appear to reduce discomfort and local skin trauma.

Pain at the distal end of the stump may be caused by

Fig 4. Bony spur. The fibula was excessively long and had a bony spur at the distal end (arrow). The patient had never had an erosion there until the PTB socket was changed for a TSB socket.

Table 2: Relation of 13 Individual Items to Overall Satisfaction and Dissatisfaction With the TSB Socket

Item	Subjects Giving the Highest Response to Each Item†: Overall Satisfaction§			Subjects Giving the Lowest Response to Each Item‡: Overall Dissatisfaction‖		
	Satisfied	Not Satisfied	*p* Value	Dissatisfied	Not Dissatisfied	*p* Value
1. Donning and doffing the socket	10	1		2	0	*
2. Comfort to wear	17	2	*	0	0	—
3. Ease to swing the prosthesis	21	3	*	0	0	—
4. Pain during walking	17	3		0	1	
5. Knee flexion and extension	8	2		1	0	
6. Piston movement during walking	20	3	*	0	0	—
7. Tightness during walking	12	2		0	0	—
8. Skin irritation	19	3		0	0	—
9. Perspiration on the stump	6	1		1	0	
10. Odor from the socket	4	1		1	1	
11. Staining of the socket	6	1		0	0	—
12. Appearance of the socket	20	4		0	0	—
13. Durability of the socket	19	3		0	0	—

Blank spaces in *p* value columns represent nonsignificant *p* value (dashes in column mean that item not analyzed).
* $p < .05$.
†For each item subjects were divided into 2 levels, those giving the highest response and those giving others; ‡for each item, subjects were also divided into 2 levels, those giving the lowest response and those giving others.
§ Overall satisfaction consisted of 2 categories, satisfied ("satisfied" and "somewhat satisfied") and not satisfied ("undetermined," "somewhat dissatisfied," and "dissatisfied"); ‖ overall dissatisfaction consisted of dissatisfied ("dissatisfied" and "somewhat dissatisfied") and not dissatisfied ("undetermined," "somewhat satisfied," and "satisfied").

inappropriate weight bearing. A stump with abundant soft tissue is inclined to sink more than 15mm into the TSB socket during the stance phase,[19] permitting the tibial end to impinge upon the distal anterior portion of the rigid outer socket. To prevent this problem, the fit of the distal anterior portion of the rigid outer socket should be checked carefully while the subject is standing on one leg with the prosthesis in a transparent check socket made of Durr-Plex. If necessary, the rigid outer socket in this area should be bulged. When there is a space between the stump end and silicone inner socket, negative pressure produced by swinging of the prosthesis may also cause pain or discomfort at the stump end. The gap can be removed by filling the distal end of the silicone inner socket with silicone gel. A patient with a bony spur at the distal end of the stump may have pain during stance phase. Because the entire surface of the stump, including the distal end, bears body weight, the TSB socket would not be appropriate for a patient with a bony spur.

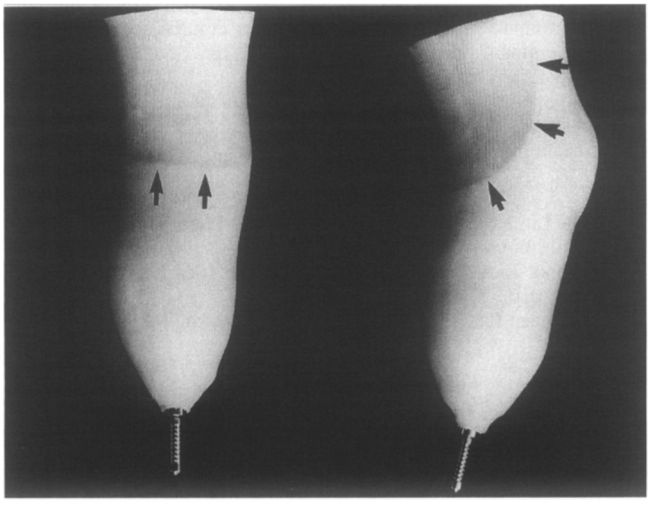

Fig 5. Modification of the silicone inner socket: right, lateral view; left, rear view. The silicone inner socket was fabricated at a 30° knee-flexed position, and the number of layers of the nylon stockinet around the popliteal fossa (arrows) was reduced from 3 to 1.

The TSB socket seems to be sensitive to change in stump circumference. The circumference of an immature stump decreases with time, while it fluctuates in a patient undergoing hemodialysis. Subjects with such stumps might benefit from modification that emphasizes patellar-tendon weight bearing (modified TSB socket, fig 6), and should be taught to adjust for changes in stump circumference by wearing a sock between the silicone inner socket and rigid outer socket. For patients undergoing hemodialysis, the model should be cast when the stump is largest, usually before hemodialysis.

The durability of the TSB socket is unquestioned. Whereas a prefabricated silicone inner socket may show an incidental fissure,[26] in this study the laminated silicone inner socket showed neither fissure nor breakage, except for fraying at the proximal end.

We suggest that the TSB prosthesis is appropriate for B-K amputee persons who can don and doff the TSB socket with ease and whose stump is mature and without excessive soft tissue and has a space (more than 5 cm)[6] between its distal end and the ankle mechanism. The prosthesis may sometimes be indicated for patients who are undergoing hemodialysis or whose stumps are immature or have abundant soft tissue. These conditions should not be considered contraindications if the model is carefully cast and the fit is adequately checked. However, the prosthesis is contraindicated for subjects who are unable to don and doff the TSB socket, have a long stump, or have a bony spur at the stump's distal end.

In conclusion, the TSB prosthesis is comfortable and is preferred by many below-knee amputee subjects, but there are several problems to be solved. Prescription criteria are defined according to the results. Objective assessment of the comfort of the TSB socket and basic research on the environment within the socket are still needed.

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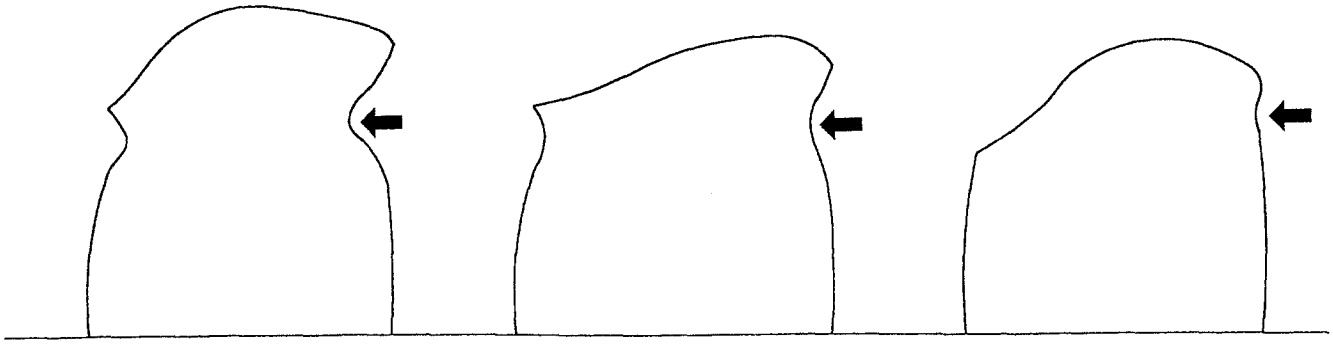

Fig 6. The modification of the TSB socket design: right, TSB socket; middle, modified TSB socket; left, PTB socket. Arrows indicate concavity at the patellar tendon. The patellar tendon area and popliteal fossa of the modified TSB socket are slightly compressed to bear more body weight than the PTB socket can bear, and its contour is intermediate between the PTB and TSB sockets. The modified TSB socket is indicated for persons with B-K amputation who have an immature or fluctuating stump.

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Suppliers

a Seattle Limb Systems, 26296 Twelve Trees Lane NW, Building One, Poulsbo, WA 98370.
b Flex-Foot Inc., 27071 Cabot Road, Suite 106, Laguna Hills, CA 92653-7010.
c SPSS Japan Inc., 2-2-22 Jingumae, Shibuya-ku, Tokyo, 150, Japan.

APPENDIX: QUESTIONNAIRE

This survey asks for your views about the TSB and PTB sockets (TSB: new socket with silicone, PTB: ordinary socket with a knee cuff). Please answer each item by selecting the most appropriate answer.

Overall, are you satisfied with the TSB socket?

( ): satisfied, ( ): somewhat satisfied, ( ): undetermined,
( ): somewhat dissatisfied, ( ): dissatisfied

The following items are about using the TSB socket.

1. Is the TSB socket easy to don and doff?
   ( ): easy, ( ): somewhat easy, ( ): undetermined,
   ( ): somewhat difficult, ( ): difficult
2. Is the TSB socket comfortable to wear?
   ( ): comfortable, ( ): somewhat comfortable, ( ): undetermined,
   ( ): somewhat uncomfortable, ( ): uncomfortable
3. When you walk with the TSB socket, do you feel easy to swing the prosthesis?
   ( ): easy, ( ): somewhat easy, ( ): undetermined,
   ( ): somewhat hard, ( ): hard
4. When you walk with TSB socket, do you feel pain in the stump during walking, particularly, in the patellar tendon area and distal end of the stump?
   ( ): no pain, ( ): almost no pain, ( ): undetermined,
   ( ): slight pain, ( ): pain
5. When you sit down and up from chair or go up and down stairs, does the TSB socket cause discomfort during knee flexion and extension?
   ( ): no discomfort, ( ): almost no discomfort, ( ): undetermined,
   ( ): slight discomfort, ( ): discomfort
6. When you walk with the TSB socket, do you feel looseness or a piston movement?
   ( ): no looseness, ( ): almost no looseness, ( ): undetermined,
   ( ): slight looseness, ( ): looseness
7. When you walk with the TSB socket, do you feel tight?
   ( ): no tightness, ( ): almost no tightness, ( ): undetermined,
   ( ): slight tightness, ( ): tightness
8. Does walking with the TSB socket cause skin irritation?
   ( ): no skin irritation, ( ): almost no skin irritation, ( ): undetermined,
   ( ): slight skin irritation, ( ): skin irritation
9. Does the TSB socket cause excessive perspiration?
   ( ): no excessive perspiration, ( ): almost no excessive perspiration,
   ( ): undetermined,
   ( ): slightly excessive perspiration, ( ): excessive perspiration
10. When you remove the TSB socket, is there any odor from the silicone inner socket?
    ( ): no odor, ( ): almost no odor, ( ): undetermined,
    ( ): slight odor, ( ): odor
11. Is there any staining of the silicone inner socket?
    ( ): no staining, ( ): almost no staining, ( ): undetermined,
    ( ): slight staining, ( ): staining
12. What is the appearance of the TSB socket, especially around the knee?
    ( ): good, ( ): somewhat good, ( ): undetermined,
    ( ): somewhat poor, ( ): poor
13. How durable is the TSB socket, especially the silicone inner socket and the connective equipment?
    ( ): durable, ( ): somewhat durable, ( ): undetermined,
    ( ): somewhat fragile, ( ): fragile