

Follow-Up Study of Amputees Using Below Knee Exoskeletal Jaipur Prosthesis with Total Contact High Density Polyethylene Socket

Dr MK Mathur, MBBS, MS (Ortho), Ex-Prof and Head, PMR, SMS Hospital, Jaipur

Dr Anupam Gupta, MBBS, MD (PMR), Research Associate

Bhagwan Mahaveer Viklang Sahayta Samiti, Jaipur

Abstract

100 cases of BK amputation who were provided with B-K Jaipur prosthesis with total contact socket, made up of high-density polyethylene sheet, using vacuum forming technique were followed up 6 months after receiving this prosthesis. All cases were living in urban or rural areas in and around Jaipur (This is for the convenience of the cases as well as to conduct study so that they can report back to the center when asked without problem)

84 Males and 16 female cases were given this prosthesis, age ranging from 18 yrs. to 52 years. Most common cause of amputation was road traffic accident.

Majority of the cases had had no complaints in negotiating architectural barriers or in carrying out activities of daily living (ADL). Alignment of the prosthesis with total contact socket was satisfactory with amputees could easily don and doff the prosthesis, no or minimum piston action in the swing phase was noted. Most of the cases used prosthesis for between 9-16 hrs./day without any discomfort. Average distance walked by amputees with prosthesis in single stretch was nearly 2 kms. ranging from 0.4 km. to 8 kms.

Pain (n=8), ulceration (n=9), instability and improper fitting (n=12), difficulty in donning and doffing (n=6) and soft socket immersed with perspiration (n=8), were few causes of dissatisfaction among the cases on follow up.

Overall most amputees were highly satisfied with this Jaipur prosthesis with total contact socket made up of high-density polyethylene sheet. Now this prosthesis has totally replaced the older conventional BK prosthesis with open-ended socket manufactured earlier in this center.

Key Words:

High-density polyethylene total contact socket, BK prosthesis.

Introduction

Total Contact sockets made up of high-density polyethylene sheet, using vacuum forming technique in B-K Jaipur prosthesis for B-K amputees has been a new concept in this center. Although in vogue in the western world, it was started in the center in the year 2000. Although follow-up was done of the amputees receiving this type of prosthesis, no extensive follow up study was done thus far. This study included 100 cases receiving this B-K Jaipur prosthesis with High-density polyethylene total contact socket. All patients were living in and around Jaipur. Cases were selected with the obvious purpose of

their convenience to report back to the center 6 month after receiving this prosthesis.

The prosthesis has been made considering habits of the amputees and environment and climate they face locally. Ideal B-K prosthesis should have following characteristics;

1. Length of prosthesis should be correct.
2. Static & dynamic alignment should be proper.
3. Easy to don & doff.
4. Antero-posterior and medio-lateral diameter of the prosthesis should be proper.
5. Height of anterior wall should be proper.
6. Minimum piston action during swing phase.

Address for Correspondence: Dr MK Mathur, 304, Pratap Enclave, Bihari Marg, Bani Park, Jaipur 302016, India. email: drmk1@yahoo.com

7. Weight distribution of stump over proper areas of the socket.
8. Easiness in performing ADL & negotiating architectural barrier.
9. It should not be too heavy as to cause difficulty in walking and wearing for prolonged period.
10. No pain & ulceration at weight bearing areas of the stump.
11. Good cosmesis.

To look into all these attributes & level of patient's satisfaction with this Jaipur Prosthesis, was this study conducted in BMVSS, SMS Hospital, Jaipur.

Material and Methods

100 B-K amputees wearing B-K Jaipur prosthesis with total contact socket made up of high-density polyethylene sheet using vacuum forming technique, for more than 6 months were included in the study.

Inclusion Criteria

1. Uncomplicated, Unilateral below knee amputee.
2. Consent of the cases.
3. Who could report back to the center after 6 months.
4. Living in and around Jaipur

Exclusion Criteria

1. Bilateral amputees.
2. Unmotivated cases.
3. Cases, who could not come for follow up after 6 months.

Information was collected from the cases about their satisfaction with the prosthesis and results were drawn on the basis of the information.

Observation

Out of 100 amputees 84 were males and 16 females. Age of the amputees varied between 18-52 yrs. Most common cause of amputation was road traffic accident (n=64), followed by neurotrophic ulcers (n=15) and train accident (n=8). Most of the patients were given B-K prosthesis with HDPE shank (n=90). Mean length of the stump was 14.2 cm. Most of the amputees were self-employed (n=62) or doing private jobs (n=17). 13 out of 16 females were housewives. Mean weight of the prosthesis was 1.6 kg. 68 patients were given hard sockets whereas remaining 32 were given socket with soft insert for various reasons. Majority had conical shaped stump (n=72). Scars were non-tender in vast majority (n=94), healed in all cases, bones were bevelled in all cases & musculature was average (n=78) in most cases. Size of the stump was medium (34-67% of the sound side length) in most cases (n=78).

Table 1. Duration of PTB prosthesis with TCS using per day

| <i>Duration (in hrs./day)</i> | <i>No. Of Cases</i> | <i>%</i> |
|-------------------------------|---------------------|----------|
| 0-4 | 8 | 8 |
| 5-8 | 14 | 14 |
| 9-12 | 48 | 48 |
| 13-16 | 29 | 29 |
| 17-20 | 1 | 1 |

Most of the patients used prosthesis for 9-16 hrs/day (n=77) without any discomfort (Table no. 1).

Table 2. Average distance covered in single stretch by amputee with new prosthesis

| <i>Distance covered in single stretch (In kms)</i> | <i>No. of case with aluminium shank (n=10)</i> | <i>%</i> | <i>No. of case with HDPE shank (n=90)</i> | <i>%</i> |
|--|--|----------|---|----------|
| 0-2 | 6 | 60 | 23 | 25.56 |
| 2-4 | 2 | 20 | 48 | 53.33 |
| 4-6 | 1 | 10 | 13 | 14.44 |
| 6-8 | 1 | 10 | 3 | 6.67 |

Average distance walked by the amputee was 2 kms. ranging from 0.4km to 8 kms. (Table no. 2).

Table 3. Effect of PTB prosthesis with total contact socket on ADL & Negotiating architectural barriers

| <i>S. No.</i> | <i>Activity</i> | <i>No. of Amputees</i> | | | <i>Total</i> |
|---------------|-----------------------------|------------------------|-------------|-------------|--------------|
| | | <i>Excellent</i> | <i>Good</i> | <i>Poor</i> | |
| 1. | Squatting | 40 | 48 | 12 | 100 |
| 2. | Sitting cross legged | 62 | 30 | 8 | 100 |
| 3. | Running | 21 | 64 | 15 | 100 |
| 4. | Standing on affected leg | 40 | 48 | 12 | 100 |
| 5. | Walking on the plane | 64 | 32 | 4 | 100 |
| 6. | Walking on rough terrain | 60 | 32 | 8 | 100 |
| 7. | Walking on inclined surface | 32 | 57 | 11 | 100 |
| 8. | Going up and down stairs | 28 | 56 | 16 | 100 |

Effect of PTB prosthesis with total contact socket, on ADL & negotiating architectural barriers such as: steps/staircase, walking on rough terrain, walking on inclined surface, was favourable & very few of them complained of any difficulties in such activities (Table no. 3).

Table 4. Alignment of the PTB prosthesis with total contact socket

| S. No. | Alignment of prosthesis with patient wearing it | Correct | Incorrect | No. of cases |
|--------|--|---------|-----------|--------------|
| 1. | Donning of prosthesis | 92 | 8 | 100 |
| 2. | Patient comfortable while standing with heels 6" apart | 98 | 2 | 100 |
| 3. | Length of the prosthesis | 94 | 6 | 100 |
| 4. | A-P diameter of prosthesis | 94 | 6 | 100 |
| 5. | M-L diameter of prosthesis | 92 | 8 | 100 |
| 6. | Minimal piston action in swing phase | 90 | 10 | 100 |
| 7. | Ht. of anterior, medial and lateral wall | 100 | 0 | 100 |
| 8. | Weight distribution over proper areas of stump | 96 | 4 | 100 |

Alignment of the PTB prosthesis with total contact socket, was satisfactory with majority had no difficulty in donning & doffing the prosthesis, length, A-P & M-L diameter of the prosthesis, weight distribution over proper areas of the stump, no or minimum (< 3 mms) piston action (Table No. 4).

Table - 5. Causes of dissatisfaction with PTB prosthesis with total contact socket

| S. No. | Causes of dissatisfaction | No. of Cases (n=100) | % |
|--------|---------------------------------------|----------------------|------|
| 1. | Prosthesis heavy | | |
| | Aluminium | 2/10 | 20 |
| | HDPE | 5/90 | 5.56 |
| 2. | Pain | 8 | 8 |
| 3. | Ulceration | 9 | 9 |
| 4. | Instability and improper fitting | 12 | 12 |
| 5. | Difficulty in donning & doffing | 6 | 6 |
| 6. | Poor cosmesis | 11 | 11 |
| 7. | Soft socket immerse with perspiration | 8/32 | 25 |
| 8. | Breakage in foot | 6 | 6 |
| 9. | Broken or cracked socket | 9 | 9 |

Prosthesis heavy, pain & ulceration, instability and improper fitting, poor cosmesis, soft socket immersion

with perspiration, were few causes of dissatisfaction in few cases. They were properly taken care of in the follow-up alignment of the PTB prosthesis with total contact socket, was satisfactory with majority had no difficulty in donning & doffing the prosthesis, length, A-P & M-L diameter of the prosthesis, weight distribution over proper areas of the stump, no or minimum (<3 mm) piston action (Table No. 5).

Discussion

Fitting of total contact sockets made up to high-density polyethylene sheet using vacuum forming technique with B-K prosthesis to the B-K amputee has been in progress since the year 2000. Nearly 1000 amputees have been fitted with this prosthesis since then.

In the present study 100 unilateral B-K amputees, living in and around Jaipur who could report back to the center after 6 months of receiving prosthesis, were fitted with B-K prosthesis with total contact socket. Male / female ratio in the study was 5:1. As males are mostly involved in outdoor activities and females lead a comparatively sheltered life, this ratio is expected. Majority of the patients belonged to the 21-40 yrs. age group (n=81). As the data show that this age group is most mobile & active as they have to shoulder the responsibility of the family & socialize and hence they are more exposed to injuries.

Road traffic accident was the most common cause of amputation among the cases (n=64). As has been proven in some previous studies, RTA remains the most common cause of B-K amputation in India. Present study also corroborated this observation.

Mean weight of the prosthesis was 1.6 kg. When the manufacturing was started of this type of prosthesis in the center, the mean wt. of the prosthesis used to be 1.8 kg. After making few adjustments in the trimming of socket & shank, this has been reduced to 1.6 kg. and fewer patients are complaining about the weight of the prosthesis. Most of the complainers were wearing old conventional prosthesis, which was lighter than this prosthesis. So they took some time to get 'used to' to the newer prosthesis.

32 out of 100 patients were given soft inserts. Diabetes, Leprosy (n=6), neurotrophic ulcers or too many bone prominence were the reasons for providing this soft insert in the socket. Immersion of the ethaflex soft insert with perspiration was a frequent complaint (25%). They were instructed to wear cotton stockinettes in case they have difficulty coping with the wet soft insert. Their soft inserts were replaced with new soft inserts in the follow up.

90 out of 100 patients had been provided with HDPE shank. This center has abandoned manufacturing aluminium shanks. 10 patients, who were used to wearing older aluminium shank prosthesis, insisted that they are

more comfortable wearing this older prosthesis with total contact socket & requested not to change it to HDPE.

Majority of the amputees (n=77) wore prosthesis for between 9-16 hrs./day. On the average amputees had utilized this prosthesis for more than 10 hrs. / Day. This figure speaks very highly in favour of the usefulness and comfort of the prosthesis as the amputees were not using this prosthesis merely for cosmetic purpose but it was useful to them functionally also.

The walking distance covered by most of the amputees in single stretch in the study, varied between 0.4 km to 8 kms. As most of the patients have already had the experience of walking with their older prosthesis, they have not had any difficulty in adapting to this newer, heavier (by 200 – 400 gms.) prosthesis. Energy consumption is directly proportional to the weight of the prosthesis, so heavier the prosthesis, more energy consumed in the walking and lesser distance covered in the single stretch. As this prosthesis provides better proprioception, better fitting of the socket and better alignment of the prosthesis to the user, the walking distance covered in single stretch actually increased with this prosthesis.

In Indian conditions no prosthesis can be accepted by the patient, which interferes with squatting or cross-legged sitting. As Jaipur foot was incorporated in these B-K prosthesis majority of the amputees had no difficulty in doing these activities.

The Jaipur Foot helps a great deal in walking on rough terrain & walking on inclined surfaces with its attributes of dorsiflexing at ankle (required in squatting & walking on inclined surface), adduction and supination of forefoot, inversion of heel and transverse rotation at the foot shank joint (required in cross legged sitting), inversion and eversion of foot (required for walking on rough terrain). No patient had difficulty in walking on plain surface and standing on the affected leg.

In majority of the patients, alignment between various components of prosthesis was very satisfactory because of the simple in-production alignment systems being used. Almost all patients were able to stand comfortably with heels 6" apart. Donning & doffing was convenient in majority. Length of the prosthesis, Antero-Posterior and Medio-Lateral diameter of the prosthesis were correct & there was no or minimum (< 3mm) piston action in the swing phase.

7 patients complained that the prosthesis was heavy, in the follow-up. 5 out of these 7 were 'first timers' with the prosthesis. No amputee complained that this new prosthesis hindered his or her day-to-day activities; it rather enhanced their ADL, because of a very close stump socket interface.

8 cases complained of pain & 9 cases came with ulceration in the stump on walking with this prosthesis, in the follow up. It was because of improper alignment and friction between skin of the stump and socket of the prosthesis. It was immediately corrected by using heat gun over pressure points in the socket & cases had no such complaints later. 6 patients complained improper fitting, difficulty in donning and doffing of prosthesis. Main causes were with the incorrect height of the socket wall or improper weight distribution in the socket. Trimming the socket wall and using heat gun to correct weight distribution of the stump in the socket corrected these.

8 patients complained excessive sweating and immersion of soft inserts with perspiration in the socket. It was specially noted in the summer months. It is expected in the hot climate of Rajasthan with temperature hovering around 45° C in summer. These patients were indulged in outdoor activities in the daytime. They were advised to wear one or more cotton socks to avoid discomfort while at home or come to the center for change of soft insert.

9 patients came with cracked or broken sockets in the follow up. No particular pattern or site was noted on examination and reason for this break down could vary from faulty weight distribution in the socket, too much weight of the patient, fall of prosthesis from height to fatigue wear of the socket material.

References

1. Boot DA, Young NJ. A new directly moulded patellar tendon bearing socket. *Prosthet Orthot Int* 1985; 9 (2): 112-114.
2. Burger. The management of lower extremity amputation. TR 10 6 August 1969.
3. Coombes AGA, Davies RM. The use of biocomponent fabrics for bonding high-density polyethylene sockets in prosthesis. *Prosthet Orthot Int* 1985; 9:145-53.
4. Davies RM, Russell D. Vacuum formed thermoplastic sockets for prosthesis. In: Kennedy RM, Paul Hughes J. (eds). *Disability*. London: Macmillan; 1979, 385-90.
5. Foort J. The Patellar tendon bearing prosthesis in below knee amputees, a review of technique of criteria. *Artificial Limbs* 1965 Spring; 9 (1): 4-13.
6. Holden JM, Fernie GR. Results of the pilot phase of a clinical evaluation of computer aided design of trans-tibial prosthesis sockets. *Prosthet Orthot Int* 1986;10 (3) 142-48.
7. Katz K. et al. End bearing characteristics of patellar tendon bearing prosthesis a preliminary report. *Bulletin of Prosthetic Research* 1979 fall; 16 (2): 55-68l.
8. Liners for the PTB below knee socket (and its variants) technical note I.S.P.O. Bulletin, Jan. 1972.
9. Mathur MK. Jaipur Artificial Limbs. BMVSS, SMS Hospital, Jaipur. 1998.
10. Mowery CA, Herring JA, Jackson D. Dislocated patella

- associated with below knee amputation in adolescent patients. *J Pediatric Orthopedic* 1986; 6 (3): 299-301.
11. Nilo Z Kiba, U Singh, AK Joy Singh, Gita Handa. Comparative study of HDPE below knee prosthesis with Jaipur foot and Laminated below knee prosthesis with SACH foot – Cost efficacy and utility in rural setting. *IJPMR* 1999-2000; Vol.: 10 & 11: 11-15.
 12. Radcliffe CW and Foort J. The Patellar tendon bearing below knee prosthesis. University of California, Berkeley;1961.
 13. Sethi P.K. et al. Vulcanized rubber foot for lower limb amputees. *Prosthet Orthot Int* 1978; 2: 125-36.
 14. Staats TB, Lundt J. The UCLA total surface bearing suction below-knee prosthesis. *Clin Prosthet Orthot* 1987, 11: 118-30.
 15. Grevesten S, Eriksson U. Stump-socket contact and skeletal displacement in a suction patellar tendon bearing prosthesis. *J Bone Joint Surg Am.* 1974 Dec;56 (8): 1692-6.
 16. Manual of below knee prosthesis. San Francisco Biomechanics Laboratory: University of California; 1959.
 17. Stewart RE. Variants of the PTB (patellar-tendon-bearing) below-knee prosthesis. *Bull Prosthet Res.* 1970 Spring;10(13):120-34.
 18. Wevers HW and Durance JP. Dynamic testing of below knee prosthesis assembly and components. *Prosthet Orthot Int.* 1987; 11: 117-23.
 19. Wilson AB Jr. Recent advances in below knee prosthetics. *Artificial limbs* 1996; 13 (2): 1-12.
 20. Yaramenko DA, Sytenko AN, Bazhina EN, Krasnov AI, Borisov AI. Prosthetic sockets of polymerized metal: Material, design, technology. *Prosthet Orthot Int.* 1987 Dec;11(3):135-6.