

COMPARISON OF A SIMPLE AND CHEAP IMMEDIATE POSTOPERATIVE PROSTHESIS WITH SOFT DRESSING IN LOWER LIMB AMPUTATIONS

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ABSTRACT

BACKGROUND

Removal of a part of a limb through one or more bones termed amputation is done for various causes. Properly performed amputation is a reconstructive procedure. Effective postoperative rehabilitation reduces disability and helps in proper shaping of the residual limb leading to final prosthetic fitment.

The aim of the study is to compare effect of rigid dressing and Immediate Postoperative Prosthesis (IPOP) using a simple and cheap pylon developed by the first author with soft dressing in respect of stump maturation and function in lower limb amputees.

MATERIALS AND METHODS

Fifty one patients with lower limb amputations were included in the study and randomised into two groups. Twenty four patients completed follow-up in the study group of rigid dressing with early postoperative prosthetic fitting while twenty patients completed with soft dressing. Stump maturation as measured by girth and volumetric assessment and complications of residual pain and phantom pain were compared at six weeks and twelve weeks with baseline data.

Statistical Analysis- Done with SPSS for Windows version 17. Independent-T test was used for comparison of continuous variables and Chi-square and Fischer exact test was used for comparison of dichotomous responses.

Settings and Design- The study was done in a multispecialty teaching hospital of a metro city. It was a well-structured comparative study done after addressing all safety and ethical issues.

RESULTS

Stump maturation was significantly better and the stump complications reduced in the study group.

CONCLUSION

Rigid dressing with IPOP has proven to be significantly superior to soft dressing in terms of maturation of stump and residual complications in lower limb amputations.

KEYWORDS

Pylon Prosthesis, Soft Dressing, Amputation Stump, Amputation Rehabilitation, Prosthesis Design.

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BACKGROUND

Removal of a part of a limb through one or more bones is termed amputation commonly occurring in lower limb due to disease, congenital deformities, trauma or ischaemia.¹ Properly performed amputation is a reconstructive procedure. Effective postoperative rehabilitation reduces disability and helps in proper shaping of the residual limb leading to final prosthetic fitment.²

Available literature compares traditionally used soft gauze dressing using elastic wrap bandaging with thigh level

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rigid plaster cast with or without immediate postoperative prosthesis.^{3,4} Our study was designed to compare the efficacy of rigid dressing and Immediate Postoperative Prosthesis (IPOP) using a simple and cheap design of pylon developed by the first author (which can be fabricated by a rural artisan also) with soft dressing in respect of stump maturation and function in lower limb amputees. The objective parameters have been analysed statistically.

MATERIALS AND METHODS

This prospective randomised comparative study was conducted from October 2010 to October 2013 and was designed to include lower limb amputation from any cause after getting clearance from Institutional Review Board/Ethical Committee of the Medical College. Medical conditions precluding use of prosthesis, crutch or walker or patients with unsound mental status were excluded. Fifty one patients were included with informed consent.

Computer randomisation was used to allocate patients to the two groups for treatment.

In the first (study) group, rigid plaster cast was applied over minimal soft dressing after drain removal (two days postoperatively) and rocker ended simple design pylon prosthesis was fixed with plaster of Paris (Figure 1 and 2). This simple design was conceived by the first author at a remote island hospital in 1985 and used for many patients. The second (control) group was treated with soft dressing consisting of sterile absorbent fluffed gauze pieces and cotton wool covered with elastic bandage wrapped in figure of eight manner for mild compression (Figure 3).

Relevant demographic and medical data was recorded with clinical examination of the stump for shape, scar, sensation, tenderness and any dermatological lesion (Table 1). Signs of stump maturation were recorded by girth measurements, four inches above the lower end of the stump and by volumetric assessment (Table 2); at six weeks and twelve weeks after intervention. Volumetric assessment of the stump was done by immersing transfemoral stumps and knee disarticulation stumps up to two inches below greater trochanter in water and transtibial stumps up to knee joint after smearing it with sterile paraffin jelly for measuring water displacement.

Complications in terms of residual stump pain and phantom pain were recorded on Visual Analogue Scale (VAS) to ascertain the quality of life of these patients after these two types of treatments (Table 3). VAS records pain from 0= no pain to 10= maximum pain as graded by the patient.

Ethics and Statistics- The study protocol was vetted and cleared by Institutional Review Board and Ethical Committee of the college formed in accordance with the regulations of Medical Council of India. Patients were enrolled after an informed consent with an option to exit from the study at any time, if so desired.

Statistical Analysis- A total of 51 patients were enrolled in the study out of which only 24 patients from study group and 20 patients from control group could complete the follow up and considered for analysis. Rest of the patients were lost to follow-up. Data was managed on Microsoft excel and analysed on SPSS for Windows version 17 software. Independent t-test was used for comparison of continuous variables and Chi-square test and Fischer test for comparison of dichotomous responses. The results were considered significant at 5%, that is $p < 0.05$.

OBSERVATIONS AND RESULTS

Out of 51 patients enrolled, 24 completed follow-up in the study group while 20 completed in the control group.

The demographic and general characteristics matched in the two groups indicating effective randomisation of the patients (Table 1).

Shrinkage and maturation of the stump was significantly better in the study group as can be seen from girth and volumetric measurements (Table 2).

Complications in the form of residual pain and phantom pain were significantly less in the study group (Table 3).

Application of this simple design immediate postoperative prosthesis over rigid plaster of Paris cast was found significantly superior to the use of soft dressing in terms of stump maturation and reduction of stump complications on objective parameters.



Figure 1. IPOP Design



Figure 2. Above Knee Amputee with IPOP



Figure 3. Soft Dressing with Crepe Bandage

Characteristics	Study Group	Control Group	p-value
Age (years)	35.58 (±11.90)	37.45 (±12.45)	0.299
Gender (male/female)	23/01	13/07	0.87
Aetiology			
Trauma	21	15	0.874
Gangrene	02	04	
Infection	01	00	
Tumour	00	01	
Type			
Transfemoral	10	12	0.55
Transtibial	14	08	

Table 1. General and Demographic Characteristics

Characteristics	Baseline*	6 weeks	12 weeks
Girth†			
Study group	35.76 (±05.41)	31.86 (±04.81)	30.26 (±04.55)
Control group	36.84 (±05.33)	34.96 (±05.05)	33.39 (±04.80)
p-value	0.513	0.044	0.035
Volumetric Assessment‡			
Study group	1789.16 (±678.34)	1421.66 (±579.72)	1304.16 (542.89)
Control group	1958 (±682.30)	1802.50 (±647.85)	1669 (±609.83)
p-value	0.417	0.046	0.042

Table 2. Shrinkage and Maturation

* Baseline= Two days postoperative.

† Girth in cms.

‡ Volume in mL.

Characteristics	Baseline*	6 weeks	12 weeks
Residual Pain†			
Study group	08.66 (±0.48)	04.29 (±0.80)	01.70 (±0.62)
Control group	08.70 (±0.57)	05.15 (±0.81)	02.55 (±0.62)
p-value	0.835	0.001	0.001
Phantom Pain†			
Study group	08.87 (±0.54)	04.45 (±0.58)	01.87 (±0.53)
Control group	09.15 (±0.67)	05.15 (±0.74)	02.50 (±01.00)
p-value	0.138	0.001	0.012

Table 3. Complications

* Baseline= Two days postoperative.

† VAS (visual analogue scale 0 = No pain to 10 = Maximum pain).

DISCUSSION

Lower extremity amputation is one of the oldest known surgical procedures. Trauma was the most common cause of amputation in our study followed by gangrene, infection and tumour, which was found in earlier epidemiological studies also.⁵

The post-amputation management is an important determinant in rehabilitation of the patients. Primary goals of postoperative management are wound healing, control of oedema and pain and shaping of the stump.² Soft dressing and elastic bandage is commonly followed treatment,⁴ but poorly wrapped elastic bandages often cause distal oedema of the stump. Rigid dressing with IPOPOP provides better oedema control, but loosening of the prosthesis demands repeated changes in the prosthesis.⁴ Shaping of the stump is faster with IPOPOP, but it limits wound inspection.

Consensus eludes on the most effective method of post-amputation management.⁶ Significantly, more improvement in girth values was observed with IPOPOP as corroborated by the studies of Kraeger RR⁷ and Golbranson F L et al.⁸

Mean volumetric assessment was significantly better in our study group, which again correlates with the studies by Kraeger RR⁷ and Golbranson F L et al.⁸ However, Harrington I J et al⁹ did not find any significant improvement in volumetric values in patients treated with IPOPOP.

Wesley S. Moore et al⁹ reported faster rehabilitation in patients with IPOPOP. Choudhary S R et al¹⁰ reported superiority of IPOPOP in reducing pain and early ambulation. Sindhu V et al¹¹ found decreased incidence of residual pain and phantom pain in patients fitted with IPOPOP. Kyte R et al¹² also found significantly faster rehabilitation in patients managed with IPOPOP.

Our study has come out with clear and significantly better results with IPOPOP in relation to maturation of the stump and reduced complications of residual stump pain and phantom pain corroborating findings of many of the authors cited above except Harrington I J et al.¹³ Thus, it seems reasonable to recommend that IPOPOP is a better method to hasten the process of rehabilitation in patients with amputations in lower limbs in terms of better objective outcome and reduced complications. The simple design used in our study has given results comparable with that of other authors though it was simple to fabricate and cheap to patients.

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