Benefits of Early Prosthetic Management of Transtibial Amputees: A Prospective Clinical Study of a Prefabricated Prosthesis

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ABSTRACT

To evaluate the use of an immediate postoperative prosthesis (IPOP) for transtibial amputees, we compared patient outcomes from a prospective clinical study of 19 patients managed with an IPOP with those of a retrospective review of a matched historic control group of 23 patients managed with standard soft dressings. Data were analyzed with the Student's t-test, and significance was set at \( P=0.05 \). The IPOP patients had no surgical revisions, whereas the patients with standard soft dressings had 11. This was a significant difference. IPOP patients also had significantly fewer postoperative complications and shorter times to custom prosthesis than did controls.

Key Words: Amputation; Transtibial; Prosthesis, Prospective

INTRODUCTION

Postoperative management of patients with amputations varies from center to center. A popular standard of treatment is to apply a soft dressing (SD) and elastic bandages to the residuum and await complete tissue healing and reduction in swelling before applying the first temporary prosthesis. In the 1960s, an alternative technique using an immediate postoperative prosthesis (IPOP) made from plaster was introduced. Since that time, it has been successfully used in many hospitals worldwide, despite the fact that the method is labor-intensive, requires three or four cast changes, precludes continual wound observation, and may be contraindicated for some higher-risk patients. Nevertheless, various studies have demonstrated the benefits of IPOP systems. These include pain reduction, edema control, fewer complications, faster time to custom prosthetic fitting, reduced cost, decreased time for rehabilitation, and decreased length of hospitalization compared with management with SDs. Recently, a removable, adjustable, prefabricated IPOP has been introduced that may offer some potential advantages over the plaster systems.

The hypotheses of the current investigation were that, compared with an SD protocol, a removable, adjustable, prefabricated IPOP or early postoperative prosthesis with pneumatic air bladders (Air-Limb, Aircast, Summit, NJ) would reduce postoperative complications, reduce falls, and permit controlled ambulation without compromising the residuum (Figs. 1, 2).

MATERIALS AND METHODS

Patient Population

IPOP group. From October 1998 to February 2000, 31 patients underwent transtibial amputation. Study exclusion criteria included a patient undergoing a guillotine amputation, a patient incapable of ambulating (or without the potential to ambulate) with or without assistance, pendulous thigh, lower thigh ulceration, and residual limb less than three inches long or more than eight inches long as measured from the midpatella tendon to the distal residuum. Therefore, with Institutional Review Board approval, consecutive, consenting patients were prospectively enrolled in the study before unilateral amputation. One patient was excluded from the study after amputation because the residuum was too large to fit into the IPOP. The remaining 18 men and 12 women, with an average age of 53 years (range, 23 to 79 years), formed our study IPOP group (Table 1). Primary reasons for amputation included infection (16), ischemia (4), acute trauma (4), chronic pain (5), and
Table 1: Patient Demographics

<table>
<thead>
<tr>
<th>Group (n)</th>
<th>Men/Women</th>
<th>Mean (Range) of Age (years)</th>
<th>Patients with diabetes mellitus</th>
<th>Patients with vasculopathy</th>
<th>Diabetic patients with vasculopathy</th>
<th>Vasculopathic patients with diabetes</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPOP (30)</td>
<td>18/12</td>
<td>53 (23 to 79)</td>
<td>17/30 (57%)</td>
<td>11/30 (37%)</td>
<td>10/17 (59%)</td>
<td>10/11 (91%)</td>
</tr>
<tr>
<td>SD (23)</td>
<td>16/7</td>
<td>54 (33 to 90)</td>
<td>12/23 (52%)</td>
<td>5/23 (22%)</td>
<td>5/12 (42%)</td>
<td>5/5 (100%)</td>
</tr>
</tbody>
</table>

The Air-Limb IPOP in use by a patient.

Fig. 2: Cut-away view of the Air-Limb IPOP showing the air bladders filling the void between the adjustable plastic shell and the residuum.

Fig. 1: The Air-Limb IPOP in use by a patient.

Of those 30 enrolled patients, 20 were fitted with an IPOP in the operating room and 10 had the prosthesis applied within five days of surgery (early postoperative prosthesis, or EPOP). Eleven of the 30 patients did not continue with the IPOP/EPOP protocol until custom prosthetic fitting for one or more of the following reasons: mental incompetence and/or inability to follow instructions (four, including one patient who had a stroke); lack of confidence with ambulation on the residuum and withdrawal from the IPOP protocol (3); advice from the subsequent treating physiatrist (2); noncompliance (1); and inability to put on and take off the device (1). The time to discontinuance of the IPOP/EPOP ranged from two to 14 days, mean 5.6 days. Therefore, of the 30 patients, 19 used the postoperative prosthesis and protocol until full residuum maturation and custom prosthetic fitting.

None of the patients who discontinued use of the IPOP protocol had any major adverse effects from using the IPOP. A major adverse effect was defined as a fall, wound dehiscence or necrosis, or need for revision at the same or higher level. We wished to consider all patients as candidates for the IPOP in an effort to investigate new parameters for IPOP use. The discontinuing patients are seen as possible candidates for IPOP use under a revised protocol, and thus they were not considered failures in the current study.

SD group. By retrospectively reviewing charts and conducting patient interviews, we identified a group of 23 patients whose diagnosis, age range, and inclusion/exclusion criteria matched those of the IPOP group and who had undergone transtibial amputation from December 3, 1989, to November 18, 1998. These patients had been treated at the same institution by the same surgeons using a similar surgical technique and postoperatively managed with SDs, elastic bandages, and no early weightbearing. These 16 men and seven women had a mean age of 54 years (range, 33 to 90 years) (Table 1). Reasons for amputation included infection (14), ischemia (4), chronic pain (3) and acute trauma (2). Of these 23 patients, 20 (87%) returned for follow-up examinations. There was no statistically significant difference between groups with regard to age, diabetes, or vasculopathy.
Although there were limitations in using a retrospective control group for a prospective study, the control group was useful in providing a point of reference. This was seen as better than no reference point, as long as the results of the comparison were viewed with these limitations in mind.

Preoperative and Surgical Procedures

Preoperative evaluation, including medical and social history, functional levels, ambulatory status, and activities of daily living, were determined by patient or family interview and chart review. Functional levels were recorded for the time just before surgery and for the highest level in the previous six months. In those patients with traumatic emergency amputation, evaluation forms were completed postoperatively. When possible, patients were educated regarding their postoperative treatment in the IPOP, rehabilitation (including weightbearing limitation in the device), and normal sequence for definitive limb fitting. All patients completed informed consent through a protocol approved by the Institutional Review Board at our institution. Amputation was performed in both groups using a standard protocol for below-the-knee amputations.13

Postoperative Care

For the IPOP group, the residuum was covered with a nonadherent dressing over the suture line, sterile 4x4 pieces of gauze, absorbent pads anteriorly and distally, and gauze wrap. A postoperative sock was placed over the residuum and extended up to the thigh. The IPOP was applied by opening the posterior flaps and inserting the limb. After the buckles were secured, the four air cells that lined the socket and surrounded the residuum were inflated to between 20 and 30 mmHg (Fig. 2). Condylar air cells were then inflated to between 30 and 40 mmHg, and the knee suspension sleeve was applied. The knee immobilizer/stabilizer was secured, and the patient was taken to the recovery room (Fig 3).

The postoperative protocol permitted controlled partial weightbearing of 20 to 25 lbs. in the IPOP, depending on patient compliance and wound status (Fig. 1). Weightbearing was initiated as early as postoperative day one and continued until the wound was healed. During inpatient hospitalization, dressings were changed and the surgical limb was evaluated daily. Wound status was recorded in the patient chart. If there was evidence of erythema or skin irritation or if the patient complained of severe pain, the IPOP was removed for short periods and then reapplied. The treating physician was notified if symptoms did not diminish readily. After wound healing and suture removal (typically, two to three weeks), weightbearing progressed to patient tolerance until swelling stabilized and the residuum was well formed.

Each patient was followed every week or every other week thereafter, depending on progress, until the first custom prosthesis was applied. This new socket was fitted when the wound had completely healed, the residuum was no longer fluctuating in size or shape, and edema was minimized. No attempt was made to expedite the casting for the custom prostheses because patients were ambulating at nearly full weightbearing on the IPOP, and it was believed that a delay in prosthetic casting would facilitate a better and longer lasting prosthetic fit.

Postoperative dressings for the SD group were similar to those for the IPOP group, with the addition of a thick gauze outer layer and elastic bandages extending above the knee. Dressings were changed on an every-other-day basis at the discretion of the surgeon. Patients received similar rehabilitation except that there was no weightbearing on the amputated limb. After healing of the operative site and removal of sutures, shrinker socks were used to reduce edema. A temporary prosthesis was fitted when the residual limb was no longer fluctuating in size and edema had been minimized.

Data Collection and Analysis

From the time of amputation to the time of successful temporary prosthesis fitting, the following data were collected: number of postoperative complications, number of falls, and number of revisions. (These data were retrospectively collected for the SD group.) Data were analyzed with a Student’s t-test. Significance was set at P<0.05.

RESULTS

Complications

Complications were defined as any problem that delayed healing of the wound and thus delayed prosthetic fitting in patients with soft dressings or temporarily prevented use of the IPOP and delayed patient gait training on the device. Complications included infection,
wound dehiscence, delayed closure of the suture line, new areas of skin ulceration, and skin breakdown. Of the 19 IPOP patients, three patients had one complication each: a blister under the condylar air bladder, a superficial pretibial ulcer, and a blister at the end of the residual limb caused by pressure when the patient bore weight through the prosthetic foot onto the end of the bed while in reverse Trendelenburg position overnight. All complications resolved with temporary discontinuation of the device for an average of five days (range, three to seven days). Of the 23 SD patients, 11 had a total of 15 complications: nonhealing suture line (5), infection (4), wound dehiscence (3), and partially healed suture lines with eschar (3). The mean number of complications/patient/month in the IPOP and SD groups was 0.043±0.026 (range, 0 to 0.44) and 0.181±0.091 (range, 0 to 0.67), respectively (Table 2). This difference was statistically significant.

**Falls**

Before custom prosthetic fitting in the IPOP group, none of the 19 patients had any falls while wearing the IPOP. In the SD group, 12 of 23 patients had a total of 34 falls before custom prosthetic fitting. This difference was statistically significant. Eleven falls did occur in the IPOP group before custom fitting when the patient was not in the IPOP. Taking these falls into consideration, the mean number of falls/patient/month in the IPOP and SD groups was 0.183±0.057 (range, 0 to 0.68) and 0.420±0.219 (range, 0 to 5), respectively (Table 2). Although this difference was not statistically significant, it showed a trend (P=0.113).

**Revisions**

Before fitting of the first custom prosthesis, there were no revisions in the IPOP group, but eight patients in the SD group required 10 revisions to a higher transfemoral level to heal (Table 2). Four of those revisions were related to falls. There were no revisions to the transfemoral level. This difference was statistically significant.

**Time to First Custom Prosthesis**

The mean time to first custom prosthetic fitting was 3.4±0.3 months (range, 1.55 to 5.93 months) and 5.1±1.0 months (range, 1 to 21 months) in the IPOP and SD groups, respectively (Table 2). This difference was statistically significant. All patients in both groups ultimately healed and eventually used prostheses.

**DISCUSSION**

Postamputation treatment protocols that use various devices for the residuum include SDs, semirigid dressings (SRDs), rigid dressings (RDs), rigid removable dressings (RRDs), and IPOPs. SDs (e.g., elastic wraps, stockings, or silicone sleeves) offer the advantages of being lightweight, readily accessible, easy to apply, and perceived by doctors and patients as not harmful. Their disadvantages include a lack of uniformity of application (with variable compression), which may result in localized ischemia and skin breakdown. In addition, there is little to no protection of the limb in the event of a fall, and they offer no assistance regarding balance or weightbearing. Success rates (defined as fitting with a definitive prosthesis) with SDs have ranged from 30% to 94%.

With these protocols, the need for revision surgery to the transfemoral level has been reported as 0 to 32%.

SRDs, such as Dome Paste™ (Miles, Inc., Pharmaceutical Division, West Haven, CT), are believed to provide more uniform compression and better edema control and to be easier to apply than SDs. MacLean and Fick determined that the time to readiness for prosthetic fitting of patients treated with SRDs was approximately half that of those managed with SDs. Neither type of dressing, however, affords the limb much protection from direct trauma, and neither is compatible with weightbearing.

RDs and RRDs (i.e., without the pylon and foot attached), such as plaster casts and plastic shells, have been used to protect the residuum. RRDs, made of plaster or plastic, permit access to the wound and allow free knee motion, but they need to be specially ordered or custom made. Application often requires some skill by the patient as well as by the prosthetist. Mueller found a statistically significant decrease in volume and circumference when using plaster RRDs compared with SDs (e.g., elastic bandages). Early graded weightbearing onto a RRD as described by Wu and Krick was initiated at 10 to 14 days postoperatively by placing the stump with the RD on a soft stool and shifting the patient's weight. Plaster and fiberglass RDs, which maintain knee extension, do not permit easy access to the limb for evaluation and require weekly removal and reapplication to maintain adequate compression of the residuum. Even though the RD does not help the patient's balance, it encases, and thus protects, the residuum in the event of a fall.

Rigid plaster IPOPs, used in the United States since the 1960s, require skill to apply and are typically not removed for up to one week. In a clinical prospective study by Mooney et al., 74% of patients treated with plaster IPOP had successful outcomes (i.e., successfully fitted with a temporary prosthesis) compared with 65% of patients treated with plaster shells and 45% treated with SDs. Burgess and Romano reported similar results in a series of 151 transtibial amputees treated with rigid plaster IPOPs, all of whom subsequently used prostheses successfully. Malone et al. compared a series of 90...
amputees who used plaster IPOP and early ambulation after transtibial amputation with 53 transtibial amputees treated with conventional dressings and no early weight-bearing. All of the amputees treated with IPOP who had been ambulators preoperatively subsequently used temporary prostheses and then definitive prostheses. Only 69% of patients treated with conventional dressings who had been preoperative ambulators later successfully ambulated with definitive prostheses. The patients with IPOP also had significant shorter hospitalizations and times to ambulation with a custom prosthesis. None of these reported studies compared complication and fall rates for the studied groups.

In a retrospective review, Pinzur et al. 22 studied the use of various dressings and devices for post-amputation management in 299 patients with peripheral vascular insufficiency, with 225 patients being treated with rigid plaster dressings, 42 with pneumatic dressing and early weightbearing, and 32 with soft dressings. Forty patients (13.4%) had wound complications, with 20 (6.7%) requiring revision to a higher amputation level. These investigators noted that 146 of 168 (86.9%) preoperative community ambulators maintained their functional independence after amputation, and 229 of 264 (86.7%) were able to use a prosthesis to some degree. They concluded that rehabilitation of amputation patients with peripheral vascular compromise should be pursued as quickly as possible because of the short life expectancy of these patients. 22

Cohen et al. 3 compared amputation outcomes for transtibial amputees treated with SDs and physical therapy with those treated with plaster IPOP and early weightbearing. In contrast to the previously mentioned studies, they found a 97.3% eventual healing rate in the patients treated with conventional dressings compared with 66.7% in the IPOP group. These results were likely influenced by the small number of patients in the IPOP group (nine) as compared with the SD group (39). Further, the IPOP protocol allowed progressive weight-bearing at a relatively early point whereas other studies have allowed weightbearing only later or not at all, 3 and a higher percentage of patients in the IPOP group were diabetic as compared with the SD group.

The current study is the first to examine use of the Air-Limb, a prefabricated, plastic, adjustable IPOP with pneumatic air bladders to customize the fit, for transtibial amputees. We found that patients treated with the Air-Limb as an IPOP or EPOP had fewer falls and statistically significant fewer limb complications, fewer surgical revisions, and shorter time to first custom prosthesis compared with the control group.

Falls, a common anecdotal problem in the patient with lower extremity amputation, typically result in direct trauma to the healing residuum. There was a significant difference in the number of falls between the IPOP group and the SD group in the current study for falls that occurred when the device or dressing was being worn. Of the few studies available that give details on falls in amputee patients, Monga and Symington 11 reported two falls in 24 patients using the Airsplint (Jobst Institute, Inc., Toledo, Ohio 43694) IPOP, and Malone et al. 12 reported three falls in 58 patients using plaster IPOP. In both studies, the falls occurred when patients were not using the respective IPOPs. Whether through improved balance or as a proprioceptive reminder of the limb deficit, the Air-Limb and other IPOPs seem to have reduced the number of falls in amputees.

In the current study, complications relating to the residuum, such as wound infection and nonhealing or dehiscence of the surgical wounds, were significantly less than in patients treated with the IPOP than in those treated with SDs. Additionally, complications (two blisters and a pretibial ulcer) in the IPOP group were peripheral to the suture line and were resolved by changing bed position, maintaining a sock between skin and the IPOP, modifying the IPOP shell, and/or temporarily removing and then reapplying the IPOP within one week. The 11 complications in the SD group primarily involved the surgical site and required a total of five surgical debridements and 10 revisions in eight patients to a higher transtibial level to attain healing. Thus, the IPOP reduced extrinsic risks (i.e., falls, wound complications, etc.), facilitates limb healing, and promotes early prosthetic fitting and training.

In the current study, the preliminary findings regarding shorter length of stay and time to temporary prosthesis were similar to those of Malone et al. 12 Such reductions help reduce the overall cost, as do the lower number of falls, complications, and revisions for the IPOP group. In addition, in the Air-Limb IPOP, the components below the knee are all transferable to the first custom prosthesis, another cost-efficient element.

Risk assessment is critical to appropriate patient selection for use of an IPOP. The mental and physical status of the patient will influence outcomes and the ability to use a prosthesis and therefore must dictate optimal postoperative care. Because 11 patients in the current study did not complete the IPOP treatment protocol, the original exclusion criteria were modified to include those who have impaired mental status, are incapable of communicating physical discomfort, are noncompliant, cannot comprehend or follow instructions, or are unable to control weightbearing (unless the surgical site is completely healed). Patients with severe lower limb vascular disease may not be candidates for the IPOP if, after amputation, the surgeon believes the vascular status to be too tenuous. For such patients, an IPOP/EPOP, with or without weightbearing, may be fitted when limb viability is more certain.
In conclusion, the universal size of the Air-Limb provides an IPPO/EPO that is applicable to many patients. In the current study, it was used until definitive limb fitting for approximately 60% of the patients, who benefited from fewer falls, postoperative complications, and revisions and a shorter time to custom prosthetic fitting. Studies are under way to examine alternative postoperative management for the patients who were excluded from IPPO treatment in the current study.

REFERENCES

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