

THERAPEUTIC AND ECONOMIC IMPACT OF A MODERN AMPUTATION PROGRAM^{a b}

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ABSTRACT

The experience with 142 below-knee amputations for vascular occlusive disease and/or diabetes mellitus in 133 patients has been reviewed. The program utilized Xenon¹³³ skin bloodflow measurement for the selection of amputation level, emphasized the use of the long posterior skin flap as an important part of surgical technique, and employed immediate postoperative prosthesis with accelerated rehabilitation for postoperative management.

The results of this program yielded a 0 percent postoperative mortality, 89 percent amputation healing, and 100 percent prosthetic rehabilitation of all unilateral below-knee amputees, and 93 percent rehabilitation of all bilateral below-knee amputees. The average time interval between amputation and fitting of a permanent prosthesis was 32 days.

The use of Xenon¹³³ clearance as a measurement of capillary skin bloodflow for purposes of amputation level selection continues to be valid. All amputations with flows in excess of 2.6 ml/100 g tissue/min healed primarily, including the last 58 consecutive amputations.^c

The total amputation experience of the 172-hospital VA system was

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^c In a progress report in this issue of BPR, Dr. Moore comments on results of this program through June 1979. See VA Rehabilitative Engineering R&D Service Programs.

surveyed, and a cost analysis based upon duration of postamputation hospitalization, comparing immediate postoperative prosthesis with conventional techniques, was performed. The savings to the system, taking into account start-up and maintenance costs for a program which employs immediate postoperative prosthesis, was projected to be \$80,000,000 over 5 years.

We conclude that a modern amputation program, employing Xenon¹³³ clearance for amputation level selection and immediate postoperative prosthesis with accelerated rehabilitation, is well-justified based upon reduced morbidity, negligible mortality, and optimum patient prosthetic rehabilitation at a marked reduction in overall cost.

There are approximately 30,000 lower-extremity amputations performed in the United States each year (11, 23). Most of these amputations are performed on geriatric patients with peripheral vascular disease and/or diabetes mellitus. The financial burden to the patient and society for prolonged hospitalization and varying degrees of subsequent disability can be enormous. Wide variation in surgical morbidity and mortality exists among various hospitals and institutions, depending upon the level of amputation, the accuracy of predicting the lowest level at which an amputation will heal, and the aggressiveness of postoperative rehabilitation. This report documents the results of a modern amputation program that utilizes quantitative preoperative determination of amputation level, advanced surgical techniques, and accelerated rehabilitation made possible by the advent of immediate postoperative prosthesis. These data are contrasted with reports using conventional amputation and rehabilitation techniques. The parameters for analysis include surgical morbidity and mortality, amputation healing, success of prosthetic rehabilitation, and cost with respect to the duration of required institutional care. Finally, these data will be extrapolated to the combined amputation experience in the 172-hospital system of the Veterans Administration to assess the cost effectiveness of a modern amputation program when structured as a multi-disciplinary medical program.

CLINICAL MATERIAL AND METHODS OF STUDY

Review of the amputation registries at the San Francisco VA Hospital, for December 1966 through June 1977, and at the Tucson VA Hospital from July 1977 through August 1978, produced 142 below-knee amputations performed on 133 patients. All operations were performed using previously described surgical technique and emphasizing the use of the long posterior flap together with the applica-

tion of immediate postoperative prosthesis and rehabilitation (4-6, 8, 12-14, 16, 17, 22, 24, 25, 26).

Patients' ages ranged from 22 to 93 yrs., with a median age of 61 and a mean age of 62 yrs. One hundred percent of the patients were smokers. In addition to a high incidence of diabetes mellitus (88 patients, 66 percent), two-thirds of the patients (89 patients) had cardiovascular disease with symptoms of coronary artery insufficiency, congestive failure, cerebrovascular insufficiency or hypertension.

The indications for below-knee amputation in our patients included ischemia (117 patients, 82 percent), infection (22 patients, 15 percent), trauma (one patient, 1 percent), osteomyelitis (one patient, 1 percent), and frostbite (one patient, 1 percent).

Prior to amputation, all patients were evaluated for possible limb-salvage arterial reconstruction. Forty-five percent (60 patients) had at least one attempted arterial reconstruction prior to amputation, and 36 percent (48 patients) had previously undergone ipsilateral sympathectomy.

Since 1971 all patients have had preoperative determination and/or verification of amputation level selection by the use of Xenon¹³³ clearance technique, as has been previously described (18). Although we have reported that Xenon¹³³ bloodflows greater than 2.6 ml/100 g tissue/min have been associated with 100 percent incidence of primary healing (18, 22), our policy has been to offer trial amputation at a conservative level when Xenon flows are greater than 2.0 ml/100 g tissue/min in order to salvage maximum extremity length at the expense of a few cases of healing failure necessitating higher amputation. Data on the number of lower-extremity amputations, as well as specific amputation levels, performed within the VA Hospital system were obtained from the Patient Treatment Files (PTF No. 891), VA Central Office, with the help of the Biometrics Division, Reports and Statistics Office, Office of the Comptroller (20). Per diem costs data were obtained from local hospital sources, as well as from appropriate state and federal agencies.

RESULTS

Mortality

There were no deaths within 30 days of operation in the 133 patients of our personal series.

Healing.

The overall healing rate for this series is 89 percent. This included our experience prior to the introduction of Xenon¹³³ clearance for

amputation level determination, as well as the period during which the minimum capillary flow rate consistent with primary healing was being determined. All patients with flows in excess of 2.6 ml/100 g tissue/min went on to heal, including the last 58 consecutive cases. When skin bloodflows ranged between 2.0 and 2.6 ml/100 g tissue/min, only 50 percent of the amputations healed, and when flows were below 2.0 ml/100 g tissue/min, no amputation healed.

Rehabilitation.

One hundred and twenty-four patients had been ambulatory prior to their need for lower-extremity amputation, and as such were considered candidates for prosthetic rehabilitation following healing. Ninety-one patients underwent unilateral below-knee amputation, and all these patients successfully used a below-knee prosthesis.

Thirty-three patients became bilateral amputees. Fourteen of these 33 were bilateral below-knee amputees, and 13/14 (93 percent) became ambulatory on bilateral below-knee prostheses. Only two of the remaining 19 patients, all of whom had at least one above-knee amputation, became ambulatory.

The average time between amputation and fitting of a permanent below-knee prosthesis was 32 days.

Cost analysis.

The amputation experience for the total VA system is summarized in Table 1 (20). Nineteen-hundred and thirty-three amputations (46 percent) were performed at the below-knee level. According to best available data, no more than 15 percent (290) of the amputations had immediate postoperative prosthesis utilized. The remainder were performed by conventional techniques. In order to ascertain costs, we have used an amortized per diem cost for total hospital care: this figure for the study-year of 1976 in the VA system was \$116 per day. Using the time interval between operation and prosthetic fitting of 125 days for conventional amputation, and 32 days for immediate postoperative prosthesis, we can calculate the minimum total cost to the VA system for amputation care in the study-year 1976. Table 2 summarizes the data, which indicates that the overall cost was at least \$24,899,980.00.

If all amputations had been performed using immediate postoperative prosthesis with an average hospital stay of 32 days, the total cost would have been \$7,175,296.00.

Table 3 summarizes the potential cost savings that might be achieved by converting to modern techniques. However, the ability to achieve rapid rehabilitation results requires the establishment of

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TABLE 1. — *Amputation of the Lower Extremity, Veterans Administration Hospitals
Fiscal Year 1976²⁰*

Procedure	Age of patients:		Total surgical procedures
	Under 55	Over 55	
Amputation of foot	123	216	339
Amputation of lower leg	452	1,481	1,933
Amputation of thigh and Disarticulation of knee	324	1,636	1,960
Totals	899	3,333	4,232

TABLE 2. — *Cost Analysis: Below-Knee Amputation in Veterans Administration Hospital
System — Fiscal Year 1976*

Technique	Number of amputations	Daily cost (\$)	Average time operation to rehabilitation (Days)	Cost of amputation and rehabilitation (\$)
Conventional	1,643	116.00	125 ^a	23,823,500.00
IPOP	290	116.00	32 ^a	<u>1,076,480.00</u>
			Total cost	24,899,980.00

^a Based upon San Francisco VA Hospital Data (17)

specialized facilities, including a nuclear medicine capability to perform Xenon¹³³ flow measurement for amputation level determination, the recruitment of a full-time prosthetist skilled in the application of immediate postoperative prosthesis and capable of fabricating temporary prostheses, the availability of a prosthetics laboratory, and, finally, upgraded facilities for physical therapy and rehabilitation.

TABLE 3. — *Comparison Total Cost of Below-Knee Amputation in
Veterans Administration Hospital System — Fiscal Year 1976*

Actual cost	\$24,899,980.00
Projected cost if all amputations IPOP	<u>7,175,296.00</u>
Projected one-year savings	\$17,724,684.00

We have recently budgeted for these services at the Tucson VA Hospital. The costs for establishing and maintaining these upgraded facilities are summarized in Table 4. Since it would be a poor economy for each hospital in the system to undergo this expenditure, we would propose the establishment of 25 regional referral amputation centers to serve the entire VA population. This would provide maximum utilization of resources, as well as ensure an optimum workload to provide the best treatment outcome. If one budgets for the center's start-up and maintenance costs, plus the total amputation costs using immediate postoperative prosthesis and modern techniques, and projects these costs over a 5-year period, the resulting total costs for amputation care within the VA system are as summarized in Table 5, and total \$44,138,980.00. The 5-year cost for the modern center approach is compared, in Table 6, to the projected cost of amputation care if the existing conventional practice is continued.

The 5-year cost saving to the system employing a modern center approach would be \$80,360,920.00.

TABLE 4. — *Projected Costs for Establishing and Maintaining an Amputation and Rehabilitation Center Tucson VA Hospital, 1977*

Establishment costs (non-recurrent)	\$126,100.00
Maintenance costs (recurrent)	51,100.00

DISCUSSION

The results of immediate postoperative prosthesis appear to demonstrate a striking improvement when compared to the results of conventional amputation. Table 7 represents a composite analysis of several current amputation series using conventional techniques. The average healing rate was 82 percent (range 61.4–95.0 percent), mortality 6.7 percent (range 3.5–17.0 percent), rate of rehabilitation 63.8 percent (range 29.5–83.0 percent), and average interval between amputation and fitting of permanent prosthesis, 133 days (range 70–270 days). The results with immediate postoperative prosthesis show improvement not only in contrast to the cumulative results seen in the literature, but also in comparison with results in our own institution prior to the inception of immediate postoperative prosthesis. Our own mortality rate was lowered from 16 percent to 0 percent; our rate of rehabilitation was raised from 81 percent to 100 percent; and the interval between amputation and fitting of a permanent prosthesis

TABLE 5. — *Projected Five-Year Costs Analysis: Below-Knee Amputation
Veterans Administration Hospital System 1978-1982.*

Year	Technique	Number of amputations	Daily cost (\$)	Average time operative to rehabilitation (Days)	Number of amputation centers	Establishment cost/center (\$)	Maintenance cost/center (\$)	Cost of amputation and rehabilitation (\$)
1978	IPOP	1,933	116.00	32	25	126,000	—	10,327,796.00
1979-82	IPOP	<u>7,732</u>	116.00	32	25	—	51,100	<u>33,811,184.00</u>
Totals		9,665						44,138,980.00

TABLE 6. — *Cost Savings: Five-Year Projection
Below-Knee Amputation in Veterans Administration
Hospital System, 1978-1982*

Actual estimated cost (Conventional technique)	\$124,499,900.00
Projected cost if all amputations IPOP	<u>44,138,980.00</u>
Projected 5-Year Savings	\$ 80,360,920.00

was lowered from 125 days to 32 days (17). While our overall healing rate was not dramatically changed, 89 percent (immediate postoperative prosthesis) compared to 83 percent (conventional), it is noteworthy that since we have begun to employ Xenon¹³³ flow determination as a means of preoperative level-selection, the last 58 consecutive amputations all went on to primary healing.

While the medical and economic impact to the individual patient undergoing amputation is quite evident, the overall impact to the health delivery system and to the agencies responsible for underwriting costs (private insurance, as well as federal, state, and local governments) can be staggering when it is pointed out that there are over 30,000 amputations performed each year in the United States, and this number is steadily increasing (11, 23). The treatment records of the 172-hospital system of the Veterans Administration provide a unique opportunity to see the cost impact of alternative methods of therapy, since approximately 12 percent of the total amputation experience (24 percent of the amputations performed for vascular occlusive disease and diabetes) is concentrated within that hospital system, and treatment information is available in a computer data bank.

Based upon the average hospital stay for patients undergoing 1,933 below-knee amputations in the study-year 1976, the cumulative cost accounted on a per diem basis amounted to nearly \$25,000,000.

Had all patients been treated with immediate postoperative prosthesis, and assuming results equal to our own, the cost would have been reduced to just over \$7,000,000, representing a savings to the system of about \$18,000,000.

It must be recognized that, in order to develop an optimum amputation program, there will be substantial development and maintenance cost for those aspects of the program not usually available in the average hospital setting. These include: nuclear medicine capability to perform Xenon flow studies for accurate and optimum amputation level determination; the availability of a skilled prosthetist (in-hospital) for application of immediate postoperative prosthesis, prosthesis changes, and rapid fabrication of intermediate and permanent prostheses; and an active physical therapy program as well as prosthetic and social rehabilitation programs. Recently, in establishing such a program at the Tucson VA Hospital, we budgeted \$126,000 for start-up costs and approximately \$51,000 per year recurring or maintenance costs. Clearly, if every hospital in the country were to incur this expense, there would be a rapid deterioration in the cost effectiveness for the management of the individual amputee. The only way to make this work is to recognize that the discipline of modern amputation represents a special medical program, which should

TABLE 7. — *Below-Knee Amputation: Conventional Techniques*

Reference, No.	Number of amputations	Primary healing (percent)	Eventual healing (percent)	Mortality rate (percent)	Rehabilitation with prosthesis (percent)	Average time operation to rehabilitation (Days)
Warren & Kihn (23)	121	48.8	66.9	4.1	69.4	180-270
Chilvers et al. (7)	53	50.0	67.9	7.5	60.4	—
Robinson (21)	47	77.0	—	17.0	83.0	—
Bradham & Smoke (3)	84	85.7	88.0	—	— ^a	—
Block & Whitehouse (2)	43	88.0	95.0	0.0 ^b	53.5	120-180
Cranley et al. (9)	101	76.0	86.0	7.0	73.3	—
Lim et al. (15)	55	53.0	83.0	16.0	51.0	70
Ecker & Jacobs (10)	69	77.0	85.0	8.7	52.2	201
Wray et al. (26)	174	92.0	—	3.5	70.0	49-77
Nagrendran et al. (19)	174	80.5	91.4	—	—	—
Berardi & Keonin (1)	44	—	61.4	4.5	29.5	111
Averaged Totals	965	74.9	82.0	6.7	63.8	133

^a Authors commented that very few patients attained ambulation; however, no numbers were given.

^b Two patients died before discharge, and were not included as postoperative deaths.

be allocated to a limited number of amputation centers. We estimate that, within the VA system, this would amount to about 25 centers within which the entire amputation experience could be concentrated. This would ensure a generous volume of cases per center which would result in optimum utilization of specialized facilities, and the assurance of development and maintenance of professional expertise.

The total amputation experience within the VA, cost-accounted and projected over 5 years, including center start-up and maintenance costs, would amount to approximately \$44,000,000 expenditure, in contrast to the current practice which is running at a cost that would amount to over \$124,000,000 in the same time interval. Thus, the new approach should result in a saving to the taxpayers of approximately \$80,000,000 over 5 yrs. This financial windfall is over and above the clear benefits to individual patients, to whom lowered mortality and morbidity, and increased rehabilitation with return to productive life, cannot begin to be measured in economic terms.

REFERENCES

1. Berardi, R. S., and Y. Keonin: Amputations in Peripheral Vascular Occlusive Disease. *Amer. J. Surg.*, 135:231-235, 1978.
2. Block, M.A., and F. W. Whitehouse: Below-Knee Amputation in Patients with Diabetes Mellitus. *Arch. Surg.*, 87:166-173, 1963.
3. Bradham, R. R., and R. D. Smoke: Amputation of the Lower Extremity Used for Arterial Sclerosis Obliterans. *Arch. Surg.* 90:60, 1965.
4. Burgess, E. M., and R. L. Romano: The Management of Lower Extremity Amputees Using Immediate Postsurgical Prosthesis. *Clin. Orthoped.* 57:137, 1968.
5. Burgess, E. M., R. L. Romano, J. H. Zettl, et al.: Amputation of the Leg for Peripheral Vascular Ischemia. *J. Bone & Joint Surg.*, 53-a:874, 1971.
6. Berlemont, M.: Notre expérience de l'appareillage précoce des amputés des membres inférieurs aux Etablissements Hélio-marins de Berck. *Ann. de Médecine Physique*, 4(4) 6 pp., Oct.-Nov.-Dec. 1961.
7. Chilvers, A. S., J. Briggs, and N. L. Browse: Below-Knee and Through-Knee Amputation in Ischemic Disease. *Br. J. Surg.* 58:824, 1971.
8. Condon, R. E., and P. H. Jordan, Jr.: Immediate Postoperative Prosthesis in Vascular Amputations. *Ann. Surg.* 170:435, 1969.
9. Cranley, J. J., R. J. Krause, E. S. Strasser, et al.: Below-Knee Amputations for Atherosclerosis Obliterans: with and without Diabetes Mellitus. *Arch. Surg.* 98:77, 1969.
10. Ecker, M.L., and B. S. Jacobs: Lower-Extremity Amputation in Diabetic Patients. *Diabetes* 19:189, 1970.
11. Engstrand, J. L.: Rehabilitation of the Patient with a Lower Extremity Amputation, *Nurs. Clin. of N. Am.*, 11:659-669, 1976.
12. Jones, R. F., and G. G. Burniston: A Conservative Approach to Lower Extremity Amputations: Review of 240 Amputees with a Trial of Rigid Dressing. *Med. J. Aust.* 2:711, 1970.
13. Kihn, R. B., F. L. Goldbranson, R. H. Hutchinson, W. S. Moore, et al.: The

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- Immediate Postoperative Prosthesis in Lower-Extremity Amputations. *Arch. Surg.* 101:40, 1970.
14. Kreger, R. R.: Amputation with Immediate Fitting Prosthesis. *Amer. J. Surg.* 120:634, 1970.
 15. Lim, R. J., F. W. Blaisdell, A. D. Hall, et al.: Below-Knee Amputation for Ischemic Gangrene. *Surg. Gyne. & Obst.* 255:493–501, 1967.
 16. Moore, W. S., A. D. Hall, and E. J. Wylie: Below-Knee Amputation for Vascular Insufficiency: Experience with Immediate Postoperative Fitting Prostheses. *Arch. Surg.* 97:886, 1968.
 17. Moore, W. S., A. D. Hall, and R. J. Lim: Below-Knee Amputation for Ischemic Gangrene: Comparative Results of Conventional Operation and Immediate Postoperative Fitting Technique. *Amer. J. Surg.* 124:127–134, 1972.
 18. Moore, W. S.: Determination of Amputation Level: Measurement of Skin Bloodflow with Xenon¹³³. *Arch. Surg.* 107:798–802, 1973.
 19. Nagendran, T., G. Johnson, Jr., W. J. McDonald et al.: Amputation of the Leg: an Improved Outlook. *Ann. Surg.* 175:994–999, 1972.
 20. Patient Treatment File #891, Biometrics Division, Reports and Statistics Service, Office of the Comptroller, Veterans Administration Central Office.
 21. Robinson, K.: Long Posterior Flap Myoplastic Below-Knee Amputation in Ischemic Disease: Review of Experience 1967–1971. *Lancet* 1:193–195, 1972.
 22. Roon, A. J., W. S. Moore, and J. Goldstone: Below-Knee Amputation: A Modern Approach. *Amer. J. Surg.* 134:153, 1977.
 23. Warren, R., and R. B. Kihn: A Survey of Lower Extremity Amputation for Ischemia. *Surg.* 63:107, 1968.
 24. Warren, R., and R. V. Mosely: Immediate Postoperative Prostheses for Below-Knee Amputation: A Preliminary Report. *Amer. J. Surg.* 116:429, 1968.
 25. Weiss, M., with the collaboration of J. Wirski and A. Gietzynski: Neurological Implications of Fitting Artificial Limbs Immediately After Amputation Surgery. Report of Fifth Workshop Panel on Lower-Extremity Prosthetics Fitting. Attachment 1, 30 pp. Subcommittee on Design and Development, Committee on Prosthetics Research and Development, National Academy of Sciences—National Research Council. Feb. 1966.
 26. Wray, C.H., J. M. Still, and W. H. Moretz: Present Management of Amputation for Peripheral Vascular Diseases. *Amer. Surgeon* 38:87–97, 1972.