## PERIPHERAL ARTERIAL DISEASE VOLUME II

## **Table of Contents**

INTRODUCTION	1
THE DISEASE	1
SYMPTOMS AND CONSEQUENCES	1
INTERMITTENT CLAUDICATION IS UNCOMMON	2
MOBILITY IMPAIRMENT, MUSCLE AND NERVE DAMAGE	3
MOBILITY IMPAIRMENT	3
MORTALITY	5
HEART ATTACK AND STROKE—THE MAIN CAUSES OF DEATH	
AN INDICATOR OF SILENT CARDIOVASCULAR AND CEREBROVASCULAR DISEASE	5
INITIAL DIAGNOSIS—ABI	6
DISEASE SEVERITY ASSOCIATED WITH LOWER ABI	6
PAD IS NOT BENIGN	7
DISEASE PROGRESSION—RECENT RESEARCH	8
TREATMENT OPTIONS	8
REVASCULARIZATION	9
DIAGNOSTIC MODALITIES	10
Invasive	
Intravascular Ultrasound	10
Noninvasive Diagnostic Modalities	11
Magnetic Resonance Angiography (MRA)	11
CT Angiography	
REVASCULARIZATION METHOD DEPENDS ON DISEASE SEVERITY, LOCATION AND TYPE OF LESION	
TYPES OF ATHEROSCLEROSIS	13
Type I—Aortoiliac Disease	
Type II Disease	13

Type III—Diffuse Disease	13
SYSTEMS FOR CATEGORIZING DISEASE SEVERITY	13
FONTAINE DISEASE CLASSIFICATION SYSTEMRUTHERFORD CLASSIFICATION SYSTEM	
INTERVENTIONAL GUIDELINES AND LESION CLASSIFICATION	
TASCAHA and SIR	
DEFINITION OF SUCCESS	15
PROBLEMS COMPARING DIFFERENT REVASCULARIZATION	METHODS
	17
QUALITY OF LIFE	17
NEW METHODS FOR MEASURING QUALITY OF LIFE	17
LOWER EXTREMITY GRADING SCALE (LEGS)	
PERIPHERAL ARTERY QUESTIONNAIRE (PAQ)	
THE ALEVE REGISTRY	
BYPASS SURGERY	19
THE GOLD STANDARDADVANTAGES OF BYPASS SURGERY	
ADVANTAGES AND DISADVANTAGES OF BYPASS SURGERY	
Type of Disease and Lesions Determine Use of Surgery	
OUTCOME MEASUREMENTS	
Location of Surgery and Type of Graft Affect Patency	
COMPLICATIONS	
RESTENOSIS—BYPASS	
GRAFTS	24
TYPES	2 .
Manufacturers	
BLOOD CLOTS	25
CLOT REMOVAL	
Thrombolysis	
Thrombectomy Devices	
ENDOVASCULAR THERAPY	
PTA	29
INDICATIONS AND CONTRAINDICATIONS	
VARIABLES IN SUCCESSFUL PTA	
COMPLICATIONS PREVENTION OF BLOOD CLOTS	
The Parties of Beoop Ceoff	

Antiplatelets	
Reduce Risk of Vascular Occlusion	
Protective Effect Against Heart Attack, Stroke and Death	
Plavix Reduces Risk of Adverse Events in Coronary Interventions Plavix Clinical Trials in PTA and Peripheral Bypass	
ANTICOAGULANTS	
RESTENOSIS—PTA	
HIGHER AFTER PTA THAN BYPASS	34
MECHANISMS OF RESTENOSIS	
Intimal Hyperplasia	
Elastic Recoil	35
Arterial Remodeling	
LATE RESTENOSIS	
PTA BALLOON CATHETERS AND RELATED ANGIOPLASTY PRODUCT	ΓS 36
TYPES OF PRODUCTS	
Manufacturers	36
STENTS	36
BALLOON-EXPANDABLE	36
Self-expandable	
COMPLICATIONS	37
ATHERECTOMY	
ATHERECTOMY DEVICES	
SilverHawk System	40
ILIAC ARTERIES AND AORTOILIAC DISEASE	40
ENDOVASCULAR HAS BECOME FIRST-LINE THERAPY	
GENERAL PRINCIPLES FOR CHOICE OF INTERVENTION	
TYPES OF LESIONS AND TREATMENT CHOICE	
PTA COMPARED TO BYPASS SURGERY	
PTA More Cost-Effective in Treatment of IC	
ILIAC STENTING	
STENTS IMPROVE PTA OUTCOMES	
OCCLUSIONS	
Low Restenosis Rates	
DISEASE PATTERN AND GENDER AFFECT OUTCOME AND COMPLICATIONSSELECTIVE STENTING IS MORE COST-EFFECTIVE THAN PTA ALONE	
PRIMARY STENTING IS THE NORM	46
DEBATE OVER PRIMARY STENTING	4/ 47
Cost-Effectiveness	
STENTS CURRENTLY EMPLOYED IN ILIAC DISEASE	
BALLOON-EXPANDABLE STENTS	48

SELF-EXPANDING STENTS	. 49
Comparison of SMART and WALLSTENT-CRISP US Study	. 50
PERIPHERAL COVERED STENTS	. 51
STENT-GRAFTS IN TREATMENT OF ILIAC OCCLUSIVE DISEASE	. 52
Potential Complications and Costs	. 52
Early Stent-Grafts Had Poor Patency and High Rate of Complications	. 53
PROMISING RESULTS WITH NEW STENT-GRAFTS	
Viabahn Endoprothesis	. 53
Early Results <sup>i</sup> n Treatment of Diffuse Aortoiliac Disease—Wallgraft, Viabahn an aSpire	
FEMOROPOPLITEAL DISEASE	
THE ACHILLES HEEL OF THE VASCULAR SPECIALIST	
CHARACTERISTICS	
ANGIOPLASTY IN FEMOROPOPLITEAL DISEASE	
COMPARISON OF FEMOROPOPLITEAL AND AORTOILIAC PTA	
COMPARISON OF FEMOROPOPLITEAL PTA AND BYPASS SURGERY	
Mode of Failure	
Cost-Effectiveness and Quality of Life	
PTA — Generally the Preferred Initial Treatment Strategy	
COMBINED REVASCULARIZATION APPROACH: PTA FOLLOWED BY SURGERY	. 63
Total Patency—A Measure of the End Result of All Invasive Treatments	
Invasive Treatment Might Delay Development of CLI	. 64
FEMOROPOPLITEAL STENTING	. 65
PATENCY AND RESTENOSIS RATES	. 66
Lesion Location Affects Restenosis	. 66
VARIABLES IN SUCCESSFUL SFA STENTING	
Poor Patency with Stainless Steel Stents	
COMPARISON OF STENTING WITH BYPASS SURGERY	
Bypass—Higher Patency But Higher Morbidity and Mortality	
RESULTS OF OLDER SFA STENT STUDIES NOT COMPARABLE TO THOS	
OF RECENT STUDIES	
NEW DESIGNS AND MATERIALS	
ADVANCES IN DELIVERY TECHNOLOGY AND TECHNIQUE	
IMPACT OF ANTI-CLOTTING THERAPY	
STENTS EMPLOYED IN THE INFRAINGUINAL ARTERIES	
MOST ARE USED OFF-LABEL	. 71
NITINOL STENTS	
Restenosis Rates Considerably Lower	
Excellent Patency May Change the Role of Stenting in Femoropopliteal Disease.	
STENT FRACTURE	. 74

A Note of Caution Regarding Role of Current Stent Technology in the SFA
STENT-GRAFTS IN THE FEMORAL ARTERIES
DRUG ELUTING STENTS 79
PROMISING EARLY DATA IN THE SFA 79
PROMISING EARLY DATA IN THE SFA
SIROCCO II
JOSTENT INFRAPOPLITEAL FEASIBILITY STUDY
STENT FRACTURE AND LATE RESTENOSIS RATES RAISE QUESTIONS
NEW STENT CONCEPTS—MATERIALS, COATINGS AND ABSORBABLE
STENTS 81
CRYOPLASTY—A NEW APPROACH TO TREATING SFA DISEASE
TOTAL OCCLUSIONS
NEW TREATMENT MODALITIES
Frontrunner
Safe-Cross Radiofrequency Total Occlusion Crossing System
Excimer Laser in Total Occlusions
TIBIOPERONEAL DISEASE
LIMITED INDICATIONS FOR PTA
AGE AND SERIOUS CO-MORBIDITIES COMPLICATE TREATMENT OF TIBIAL DISEASE 89
PTA FOR LIMB SALVAGE AND PAIN RELIEF
STENTS IN THE TIBIAL ARTERIES
CRITICAL LIMB ISCHEMIA90
PTA As Primary Therapy—Recent Evidence
SURGERY AND LIMB SALVAGE IN CLI
In Diabetic and Non-Diabetic Patients
Pedal Bypass Grafting in Patients with Serious Co-Morbidities
ENDOVASCULAR MAY BECOME PRIMARY THERAPY IN LIMB SALVAGE
LIMB SALVAGE WITH CUTTING BALLOON AND EXCIMER LASER94
CUTTING BALLOON95
Promising Early Evidence in Limb Salvage
Restenosis in Bypass Grafts
EXCIMER LASER
LACI Trial
AND LASER
LACI Equivalent Study98
Ansel Cutting Balloon Study

AMPUTATION	99
MORBIDITY AND MORTALITY	99
HIGH COST TO SOCIETY	99
AMPUTATION COMPARED WITH REVASCULARIZATION—MORBIDITY, MORTALITY A	and 99
ARGUMENT FOR EARLIER AND MORE FREQUENT INTERVENTIONS.	100
PAD A SIGNIFICANT MARKET OPPORTUNITY	101
MARKET TO INCREASE WITH THE GRAYING OF AMERICA	101
PAD UNDERDIAGNOSED AND UNDERTREATED	101
LESS THAN 20% OF PAD PATIENTS ESTIMATED TO HAVE BEEN DIAGNOSED	
NHLBI and Coalition of Professional and Nonprofit Vascular Groups AHA Launches First PAD Program	102
INTERVENTIONAL PROCEDURES 1983-2000	103
PERIPHERAL BYPASS PROCEDURES	103
INCREASING UTILIZATION OF ENDOVASCULAR PROCEDURES	104
Factors Stimulating Growth	104
CHANGING PRACTICE—ENDOVASCULAR NOW PRIMARY TREATMENT FOR IC	
THE NUMBER OF PAD-RELATED AMPUTATIONS REMAINS HIGH  Disease Often Not Diagnosed Until the Advanced Stages	
UNTAPPED MARKET FOR INTERVENTIONAL THERAPY	
ESTIMATED MARKET FOR INTERVENTIONAL THERAPY BY DISEASE SEVERITY—2000	E
ESTIMATED MARKET FOR BYPASS AND ENDOVASCULAR THERAPY DISEASE SEVERITY—2000	BY
ESTIMATED BYPASS MARKET POTENTIAL IN MILLIONS OF LIMBS B DISEASE SEVERITY—2000	
ESTIMATED ENDOVASCULAR MARKET POTENTIAL IN MILLIONS OI LIMBS BY DISEASE SEVERITY—2000	F 110
MARKET POTENTIAL FOR INTERVENTIONAL THERAPY 2000-2020	111
COMPARISON OF CURRENT MARKET FOR PRIMARY BYPASS SURGE WITH POTENTIAL MARKET—2003	
COMPARISON OF BYPASS MARKET GROWTH PROJECTIONS 2000-201	10112
CURRENT BYPASS MARKET AND POTENTIAL MARKET AS PERCENTAGE OF PAD PATIENTS DIAGNOSED INCREASES TO 30% CURRENT BYPASS MARKET AND POTENTIAL MARKET AS PERCENTAGE OF PAD PATIENTS DIAGNOSED INCREASES TO 35%	
COMPARISON OF CURRENT MARKET FOR PRIMARY ENDOVASCULATHERAPY WITH POTENTIAL MARKET—2003	

2000-2010
CURRENT ENDOVASCULAR MARKET AND POTENTIAL MARKET AS PERCENTAGE OF PATIENTS DIAGNOSED INCREASES TO 30%
CURRENT ENDOVASCULAR MARKET AND POTENTIAL MARKET AS PERCENTAGE OF PATIENTS DIAGNOSED INCREASES TO 35%
PAD MARKET POTENTIAL FOR PRIMARY AND REDO BYPASS SURGERY—2003
PAD MARKET POTENTIAL FOR PRIMARY AND REDO BYPASS SURGERY—2000-2020 1
PAD MARKET POTENTIAL FOR PRIMARY AND REDO ENDOVASCULAR THERAPY—2003 1
PAD MARKET POTENTIAL FOR PRIMARY AND REDO ENDOVASCULAR THERAPY—2000-2020 1
COMPANY INFORMATION1
REFERENCES
LIST OF STUDIES/ACRONYMS 1
INDEX OF TABLES AND FIGURES
GLOSSARY 1
TRADEMARKS1
DISCLOSURE STATEMENT 1
CONTACT INFORMATION1