Edited by Jack Hartstein

EXTENDED WEAR CONTACT LENSES

FOR APHAKIA AND MYOPIA

EXTENDED WEAR CONTACT LENSES FOR APHAKIA AND MYOPIA

Edited by

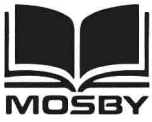
JACK HARTSTEIN, M.D.

Associate Professor of Clinical Ophthalmology,
Washington University School of Medicine;
Director of the Contact Lens Clinics,
Barnes Hospital, St. Louis, Missouri

with **68** *illustrations and* **4** *color plates*

THE C. V. MOSBY COMPANY

ST. LOUIS • TORONTO • LONDON 1982



A TRADITION OF PUBLISHING EXCELLENCE

Editor: Eugenia A. Klein
Assistant editor: Kathryn H. Falk
Manuscript editor: Judi Wolken
Book design: Nancy Steinmeyer
Cover design: Suzanne Oberholtzer
Production: Susan Trail

Printed in the United States of America

The C.V. Mosby Company
11830 Westline Industrial Drive, St. Louis, Missouri 63141

Library of Congress Cataloging in Publication Data

Main entry under title:

Extended wear contact lenses for aphakia and myopia.

Bibliography: p.
Includes index.
1. Contact lenses, Hydrophilic. 2. Aphakia—Treatment. 3. Myopia—Treatment. I. Hartstein, Jack. [DNLM: 1. Aphakia, Postcataract—Rehabilitation. 2. Contact lenses. 3. Myopia—Therapy. WW 355 E96]
RE977.C6E97 617.7'523 81-18954
ISBN 0-8016-2109-7 AACR2

AC/CB/B 9 8 7 6 5 4 3 2 1 02/D/272

EXTENDED WEAR CONTACT LENSES FOR APHAKIA AND MYOPIA

CONTRIBUTORS

GERALD L. FELDMAN, Ph.D.

Formerly Vice President of Hydrocurve Soft Lenses, Inc., San Diego, California

MELVIN I. FREEMAN, M.D., F.A.C.S.

Clinical Associate Professor of Ophthalmology, University of Washington School of Medicine; Head, Section of Ophthalmology, The Mason Clinic and Virginia Mason Research Center, Seattle, Washington

JAMES M. GORDON, M.D.

Assistant Professor of Clinical Ophthalmology, Washington University School of Medicine, St. Louis, Missouri

KEITH W. HARRISON, M.O.C.L.A.

Director of Education, Ontario Contact Lens Association, Toronto, Ontario, Canada

JACK HARTSTEIN, M.D.

Associate Professor of Clinical Ophthalmology, Washington University School of Medicine; Director of the Contact Lens Clinics, Barnes Hospital, St. Louis, Missouri

RICHARD H. KEATES, M.D.

Professor of Ophthalmology, Department of Ophthalmology, Ohio State University, Columbus, Ohio

DONALD R. KORB, O.D.

Boston, Massachusetts

RICHARD G. LEMBACH, M.D.

Assistant Professor of Ophthalmology, Department of Ophthalmology, Ohio State University, Columbus, Ohio

EZRA MAGUEN, M.D.

Assistant Clinical Professor, Department of Ophthalmology, University of Southern California School of Medicine, Los Angeles, California

JOHN F. MORGAN, M.D., F.R.C.S.(C)

Professor, Department of Ophthalmology, Queen's University, Kingston, Ontario, Canada

ANTHONY B. NESBURN, M.D.

Associate Clinical Professor, Department of Ophthalmology, University of Southern California School of Medicine, Los Angeles, California

NIKOLAOS A. PEPPAS, Sc.D., Chem.Eng.

Associate Professor, School of Chemical Engineering, Purdue University, West Lafayette, Indiana; Zyma Foundation Fellow for the Advancement of Medical and Biological Sciences

HAROLD A. STEIN, M.D., MSc.(Ophth.), F.R.C.S.(C)

Associate Professor of Ophthalmology, University of Toronto;
Chairman, Department of Ophthalmology,
Scarborough General Hospital, Toronto, Ontario, Canada

To
the advancement of knowledge
in the field of extended wear contact lenses

To
Merle, Anne, Morris, and **Larry**

FOREWORD

The ophthalmic surgeon has always had to face the challenging problem of correcting aphakia, both monocular and binocular. When I was a resident at the Wilmer Institute some 30 years ago, almost all aphakia was corrected by spectacles, and this introduced many problems for the patient. These were impressed on us by Alan Woods who summarized his personal experiences in his usual eloquent fashion in an editorial written for the *American Journal of Ophthalmology* (**35:**118, 1955). Of course, over the years cataract glasses have been vastly improved, but most of the difficulties and limitations have remained.

In an effort to overcome some of the problems associated with cataract spectacles, ophthalmologists have attempted the fitting of both hard and soft contact lenses. The obvious optical advantages of contact lenses included less magnification, less distortion, less marginal aberration, and so forth. Unfortunately, the elderly aphakic patients who most needed these lenses were often unable to insert and remove them. In recent years many surgeons have opted for the alternative of much improved intraocular lenses. The widespread use of intraocular lenses, however, has been a consequence not only of the failure of cataract glasses and daily wear contact lenses, but also of their ideal correction of the aphakic eye.

An additional means of correcting aphakia has now become legal for United States ophthalmologists, that is, extended wear aphakic contact lenses. These have provided an alternate solution to the problem for aphakic patients who were unable to insert and remove contact lenses. Although they avoided the many significant problems and complications of intraocular lenses, extended wear contact lenses have introduced new and different complications.

Ultimately the ophthalmologist must decide what is best for each patient. To do so, authoritative information from experts in this rapidly advancing field is needed. In this new book on extended wear contact lenses, Dr. Hartstein brings together the views of leading academic and clinical investigators on the presently approved extended wear contact lenses. Here in one volume

the information is readily available to the practicing ophthalmologist in a most practical and useful manner. Each particular lens is discussed in detail with indications, contraindications, step-by-step fitting procedures, and recognition of complications and their management.

This book can serve as a teaching manual for the practicing ophthalmologist and the resident, enabling them to fit and prescribe extended wear contact lenses wisely in the management of their cataract patients.

Bernard Becker, M.D.

Chairman, Department of Ophthalmology,
Washington University School of Medicine;
Ophthalmologist-in-Chief, Barnes Hospital,
St. Louis, Missouri

PREFACE

Approximately 450,000 cataract operations are performed each year in the United States. Successful completion of the operation is only part of the task. The satisfactory correction of the resulting aphakia is equally important to the successful conclusion of the surgery. Cataract spectacles, daily wear contact lenses, and intraocular lenses have been used to correct aphakia in the past and are currently being used with improvements in all modalities. The latest development in the correction of the aphakic eye is extended wear contact lenses; thus another means of correcting aphakia is now available to the ophthalmologist. The extended wear lens may serve as an alternative for those ophthalmologists who do not use intraocular lenses or who are undecided about their use. The various types of extended wear aphakic contact lenses have been under investigation by the Food and Drug Administration, and recently a number of these have been fully released for public use.

The latest information on these approved extended wear contact lenses is provided in this text by seven chief investigators of the lenses. Each author discusses patient selection, indications, contraindications, physical description of the lens, step-by-step fitting procedures, and complications and their management. Extended wear contact lenses have been approved by the Food and Drug Administration for the correction of myopia. I believe this is a tremendous advancement that frees many patients of the need for daily care of contact lenses and also offers the ophthalmologist an alternative to the recently popularized surgical correction of myopia. These are also discussed and described in this book.

Preceding the chapters on the specific extended wear lenses is a chapter on the properties of extended wear lens materials that will give the reader a better appreciation of this entire subject.

Jack Hartstein

EXTENDED WEAR CONTACT LENSES FOR APHAKIA AND MYOPIA

CONTENTS

COLOR PLATES

1 INTRODUCTION

Jack Hartstein

APHAKIC EXTENDED WEAR LENSES

In July 1979 the Food and Drug Administration (FDA) fully approved two soft lenses for continuous wear in aphakia. These were the Permalens manufactured by Cooper Laboratories and the Hydrocurve II lens. In April 1980 the FDA approved the Sauflon lens made by the Heyer-Schulte Medical Optics Center Division of American Hospital Supply Corporation for extended wear in aphakia. All these lenses are now available throughout the United States (Table 1-1). The silicone (Silsoft) lens made by Dow Corning and the Corneal Sciences lens are near approval.

All aphakic patients are not good candidates for extended wear lenses. Those aphakic patients with anterior segment infection, blepharitis, and dry eyes and those who have increased risk of corneal infection should be excluded. Uncooperative patients, patients with poor personal hygiene, retarded persons, and especially persons who are unable to return for the required follow-up visits are not good candidates. Thus the very elderly or infirm might fall into this group and might be better accommodated with intraocular lenses.

Aphakic patients considered to be good candidates for extended wear lenses include:

1. Patients who have arthritis or Parkinson's disease that would prevent them from inserting and removing their daily wear lens
2. Monocular aphakic patients who are unable to insert and remove a daily wear lens (This is the single most important reason for contact lens failure in elderly aphakic patients.)
3. A child with monocular aphakia whose parents are not able to remove a daily wear lens
4. Intraocular lens candidates who do not have a lens implanted at the time of surgery because of contraindications such as vitreous pressure (This contraindication may be greatly reduced with the use of Healon.)

TABLE 1-1. FDA-approved aphakic extended wear lenses

	Sauflon	Permalens	Hydrocurve
H_2O content	79%	71%	55%
O_2 permeability	47%	33%	14%
Visual acuity (20/40 or better)			
With overcorrection	88%	85%	N/A
Without overcorrection	76%	74%	60%
Material	MMA-based* copolymer	HEMA-based† copolymer	HEMA-based copolymer
Optical zone	8.0 mm	6.6-7.4 mm	7.0 mm+
Center thickness	0.46-0.67	0.43	0.25-0.48 mm
Chord diameters	14.4 mm	14.0, 14.5 mm	13.5, 14.0, 15.5, 16.0 mm
Base curves	8.1, 8.4, 8.7	8.0, 8.3, 8.6	8.5, 8.6, 8.9, 9.2, 9.5, 9.8
Powers	+10-+17	+11-+17	+10-+20

*MMA, Methylmethacrylate.
†HEMA, Hydroxyethylmethacrylate.

5. A patient who has an intraocular lens in one eye and aphakia in the other eye and is being considered for a secondary intraocular lens implantation (Such a patient deserves a trial with an extended wear lens before undergoing a second surgical procedure.)

Permalens

In my study of the Permalens, 44 patients (62 eyes) were followed; in 44 of the eyes the lens was in 25 to 30 months and in 18 of the eyes the lens was in 18 to 24 months, 92.5% are continuing in the study and 7.5% were discontinued. Within the first month of wear 8% of the failures occurred, so that there was a minimal investment of time. None of these patients had any permanent visual loss.

Visual acuity studies were quite interesting: 70% achieved 20/40 vision or better and 90% achieved 20/70 vision or better. Of the last 30 patients, 83% achieved 20/40 vision or better without overcorrection and 97% achieved 20/70 vision or better.

I sent in 806 visit reports and the findings were most interesting. The following percentages, which are quite low, are noted in a list of subjective responses that were obtained:

1. Excessive movement, 2.6%
2. Excessive blink rate, 0.7%
3. Variable visual acuity, 5.5%
4. Excessive tearing, 0.1%
5. Light sensitivity, 0.1%
6. Glare and halos, 0.2%
7. Itching and burning, 1.9%
8. Unusual eye secretions, 0.7%

The objective findings that were noted on these 806 visit reports include the following:

1. Edema, 1%
2. Vascularization, 2%
3. Staining, 0.1%
4. Injection, 0.1%
5. Iritis, 0.2%
6. Upper tarsal plate involvement, 0%

I believe this is a remarkable record.

Sauflon lens

The Sauflon report covered 67 patients on whom 534 reports were filed. Considering visual acuity, 52% had 20/25 vision or better without overcorrection, and an additional 25% had 20/40 vision or better, so that 75% achieved 20/40 vision or better without overcorrection. Another 10% had vision between 20/50 and 20/80 without overcorrection.

The symptoms reported on these 534 case reports included:

1. Excessive lens movement, 3.3%
2. Excessive tearing, 0.37%
3. Excessive light sensitivity, 0.37%
4. Glare, 0.37%
5. Halos, 0.37%
6. Pain, burning, and itching, 1.12%
7. Spectacle blur, 0.19%
8. Unusual eye secretions, 0.19%
9. Awareness of the lens, 3.0%
10. Excessive blink rate, 1.12%
11. Variable vision, 2.62%
12. Distance vision blurred, 30.52% (that is, without overcorrection)
13. Near vision blurred, 49% (but this also is without a bifocal correction)

There were no reports of edema, vascularization, staining, injection, iritis, or upper tarsal plate involvement on the slit-lamp portion of the form. However, deposits were noted in 10% or 50 of the 534 reports and appeared to be the major problem with the Sauflon extended wear contact lenses.

Extended wear silicone (Silsoft) lens

In my brief experience with the Dow Corning extended wear silicone (Silsoft) lens for aphakia, which is currently being investigated and may soon be approved. I have noted the following:

1. Excellent patient acceptance, which indicates the lens is quite comfortable
2. Vision improved over the basic HEMA lens
3. No glare or glare problem
4. No vascularization
5. A decrease in deposit formation
6. No giant papillary conjunctivitis thus far

This lens has somewhat different requirements from the previous three lenses discussed. The silicone lens must move; this is quite important. Fluorescein must be able to pass under the lens without difficulty and can also be used to check this lens for tightening. If the lens stops moving, even if the patient is quite comfortable, it must be removed and a looser lens fitted because of the possibility of a suction phenomenon occurring.

The Hydrocurve lens

The principle of the Hydrocurve lens (a lower water content lens—55%) for extended wear is to provide for maximum gas transmissibility by fabricating a lens as *thin* as possible for a given power. This lens has an approximate gas permeability of Dk = 15×10^{-11} (cm2) (mm O_2) (sec) (ml) mm Hg and transmits 5.6% oxygen at a thickness of 0.3 mm, which is typical for high plus lenses in this ultra-thin design. This compares favorably with the typical values of the higher water content lenses and is Hydrocurve's approach to creating a lens for extended wear.

Discussion

Opthalmologists would do well to acquaint themselves with the techniques of fitting extended wear lenses, to watch for and treat any problems that may arise, and to increase their knowledge of intraocular lens surgery.

Only in this manner can ophthalmologists truly do what is best for each patient.

EXTENDED WEAR LENSES FOR MYOPIA

Contact lenses are now also approved for extended wear in myopia. Is there a need for extended wear lenses in myopia? Are there any advantages for having such lenses for myopic patients? What are the unique differences between myopic extended wear lenses and aphakic extended wear lenses that make the myopic extended wear lenses more physiologic? What advantages do myopic patients have over aphakic patients in wearing extended wear lenses? What are the risks?

In the following chapters, it is hoped that answers to these questions will be provided so that the extended wear lenses for myopic patients can be placed in proper perspective. Briefly, two lenses have already been approved for extended wear in myopia and one is near approval. The Hydrocurve lens is available in two sizes: one lens with a base curve of 8.5 mm and a diameter of 14.00 mm and another lens with a base curve of 8.8 mm and a diameter of 14.5 mm. The second is the most frequently used and is available in powers from plano to −12.00 diopters (D). The second lens, the Permalens, is available in three base curves, 7.7 mm, 8.0 mm, and 8.3 mm, with a single diame-