CHAPTER - 3

SELECTION OF THE WORK AND MAIN OBJECTIVES
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The aim or goal of the present work is to formulate single step multipurpose solution for hydrophilic contact lenses. Different steps have been discussed and experimentally worked out for obtaining a multifunctional solution. Six separate solutions were combined to give one multipurpose solution for hydrophilic contact lenses. The Indian market has a big vacuum in this field and only MNC products are available as single step. This is first attempt in India to produce a well balanced multipurpose solution which fulfills the following criteria of

(i) cleaning
(ii) disinfecting
(iii) lubricating and wetting
(iv) rinsing
(v) soaking and
(vi) deproteinising

All six steps combined in an optimised way to give a well balanced solution and optimised using many factors that include tonicity, viscosity, pH, stability, corneal contact time, preservative efficacy, stability and irritation effects.

3.1 The Problem to be Investigated

Despite several advantages and immense popularity of hydrophilic lenses, they require far more care than their hard counterpart. This is mainly due to the very basic nature of the material of construction which allows penetration of contaminants deep into the lens matrix. This sorption of contaminants leads to deposition of various unwanted components which leads to may complications. Soft contact lenses therefore suffer from the following disadvantages:
1. Surface Deposits: Various types of surface deposits tend to build on its surface mainly dirt, lipids, protein, mucin, pigments, calcium, iron and mercury salts and chemical preservatives etc.

2. Microbial Contamination: Bacteria, fungi and yeast contaminate the lens easily. These deposits result in a variety of problems like reduced comfort, decreased wearing time and decreased visual acuity. There is an increased risk of infections like conjunctivitis, inflammation of eyes, corneal ulcer, lagophthalmos, insensitive cornea, neuroparalytic keratitis and microbial keratitis. It may result in corneal scarring or even perforations of the eye with permanent visual damage.

So an ideal lens care regimen is one which takes care of the following need of the lens wearers

i) It should remove all types of surface deposits like dirt, fats, tear deposits, protein cosmetics and chemicals.

ii) It should provide maximum anti-microbial coverage against bacteria, fungi, yeast and virus etc.

iii) It should be isotonic to the lenses and keep the lens in an optimum shape.

iv) It should be compatible with tears so as to provide maximum comfort.

v) It should not sensitise eye tissue and should be free from all allergic syndromes.

To fulfill the diverse criteria of the lens care regimen separate solutions have been developed by various manufacturers. These are

i) Cleaning Solution: To remove dirt, lipids, fats, cosmetics, pollutants, etc.

ii) Rinsing Solution: To rinse the lens after cleaning.

iii) Soaking Solution: Overnight storage to restore hydration and antimicrobial treatment.

iv) Lubricating Solution: To lubricate and rewet the lens during wear.

v) Deproteinising: Weekly treatment to remove protein deposits or Deproteinising agent added in Multipurpose Solutions.
vi) Disinfecting Solution: To disinfect the contact lenses.

For comprehensive lens care regimen, the wearer use the multi product system involving different solutions. This needs a lot of dedication, inclination, time and money on the part of the wearers. As a direct result the lens care regimen becomes cumbersome with every chance of omitting one or two steps leading to non-compliance by the wearer. This leads to various lens related complications like conjunctivitis, discomfort, itching, corneal oedemas, keratitis, decrease in lens adaptability, eye allergies and severe eye infections caused by bacteria, fungi and yeast. It was, therefore, realised in 1989 onwards to develop a lens care regimen which should be simple, multipurpose yet effective in wearer's requirements i.e. cleaning, disinfecting, soaking, lubricating, deproteinising and rinsing. Industry responded positively to this challenge and soon multipurpose solutions started hitting the market but unfortunate part is that these products were patented by the large multinational corporations and their prices are also very high. There is no Indian company which produces single step all in one that is multipurpose solution. This is primarily due to lack of R & D effort and resources, hence it is very much relevant to develop indigenous Indian multipurpose single step solution with R & D effort.

Therefore this cumbersome method of lens care regimen has to be condensed to be single step multipurpose solution. This, in fact, is the challenge especially to Indian market.

3.2 Relevance to the Present Day Need in Indian Context

There was a strong need to formulate a single step multipurpose solution for contact lens wearers due to the non-compliance of the traditional 5-6 steps solution by the wearer. The market survey clearly shows that most of the time, the patients or wearers tend to omit one or two steps leading to incorrect care system, damage of lenses and eye infections. Therefore it was felt to design solutions which could result in better compliance at the same time giving maximum protection and safety to the contact lens user. In this direction, a lot of product development was undertaken mainly by Multinationals and that
resulted in better acceptance by the contact lens wearers. The contact lens wearers dramatically increased in numbers, however less work has been carried in this field in India.

In view of the requirement of multipurpose eye care systems, an effort has been made to develop and evaluate such type of system which improves patient compliance. This work will have great potential for filing a patent.

3.3 Objectives of the Research Work:

The main objective of the present research work was to formulate and evaluate a single step multipurpose solution for contact lenses in an effective manner. The concept of using lens care solution along with contact lenses is as old as contact lenses. With the advancement and development of contact lenses there is a constant up-gradation and development of lens care products. From the earlier days of five steps lens care regimen - cleaning, disinfecting, deproteinsing, rinsing and soaking, the work was carried upto a stage where single product or solution performed all the jobs. This has greatly reduced the earlier cumbersome method of contact lens maintenance and care.

The other objectives of the present research work are related to patient compliance and contribution to the research work in this field in context with Indian scenario. The patient compliance is an ultimate goal for maintenance of lens through lens care regimen i.e. multipurpose single step solution.

Another aspect of the present research work is to add knowledge in the field of lens care regimen research in an Indian context. Most of the multipurpose solutions are prepared by other countries and hence these are imported in India and hence sold at too high a price in the Indian market. Hence it was felt that a multipurpose solution as a lens care system is to be prepared and evaluated for its efficacy in India.