



The ideal, non abrasive Cleaning Solution for all common types of rigid gas-permeable as well as hydrophilic soft contact lenses

Conception

The ideal cleaning solution for contact lenses of all types. Due to the special ingredients, a very efficient, long-lasting removal particularly of heavy deposits of foreign substances on the contact lens surface is achieved. The "i-clean!" cleaning solution must be thoroughly rinsed off with an appropriate solution before inserting the lens into the eye. In addition, soft hydrophilic contact lenses should be stored 1-2 hours after cleaning or overnight in an appropriate storage solution.

The somewhat watery cleaning solution for contact lenses of all types produces a stronger mechanical cleaning performance than a "soapy" cleaner, even without any abrasive components. Thus a mild cleansing effect is obtained, primarily for contact lens types with specially treated and/or coated surfaces. Due to the considerable cleaning efficiency increased wearing comfort of the cleaned lenses is achieved.

The solution is recommended for all currently available rigid gas-permeable as well as soft hydrophilic contact lens types and is especially suitable for the care of different contact lens types with the same users.

"i-clean!" is the result of intensive research collaboration conducted with highly qualified contact lens specialists. The new solution is a synthesis of practical years of experience relating to contact lenses and their care and the persistent efforts to keep the care convenient for wearers. Yet this is achieved without making any concessions in terms of safety and comfort for the eye and contact lens system.

Eyes and contact lenses

The long-lasting tolerance of contact lenses on the eye depends not only on the physiological situation but also on the compliance of the users. An important aspect is the type of application and, above all, the care. Besides the individual coordination of product use, contact lens type and user circumstances, the selection of optimal care is equally important.

Development principles

New basic knowledge about the manufacture of materials as well as contact lenses and their finishing have served as the basis for the development of a highly effective, non-abrasive cleaning solution. The new solution aims at protective, effective cleaning of the lenses without damaging their physical properties, which is of particular significance for surface-treated materials.

What is so special about the "i-clean!" cleaning solution!

The optimal composition of tensides in combination with isopropanol achieves a significant dissolving action. Furthermore, the aqueous-alcoholic tenside system in "i-clean!" is the optimal mixture to remove cell membrane containing protein deposits (glycoproteins) on the surfaces of the contact lens, which can be achieved only with abrasive formulations in other products.

This combination counteracts any significant deposit of organic as well as inorganic substances without requiring an abrasive action - prevention instead of repair!

Our investigations

Preclinical studies

The focus of the investigations has been on the effects of the "i-clean!" solution on the physical properties¹ of existing gas-permeable CL types. Besides parameter fidelity, the surface structures of the treated, rigid contact lenses have been investigated to achieve the highest possible safety level for the users. All of the measurement results met all of the requirements of the relevant standards¹.

In an initial preclinical study recently manufactured rigid contact lenses from material group III were cleaned manually for 15 seconds, rinsed and stored without being worn every day for over 60 days. In addition, the "i-clean!" cleaning solution was used in group 1 and compared with an abrasive cleaning solution used in group 2. The contact lenses of group 3 served as a control and were left untreated.

Verification of the physical properties

Then the actual parameters of all of the lenses from groups 1-3 were measured again and compared with the production data.

The measurement results from the geometric data for the contact lenses treated with "i-clean!" showed absolute parameter fidelity after the 60 day period of use.

To determine the surface condition the contact lenses were sent to the Anatomical Institute of the University of Bern to be assessed with the scanning electron microscope.

Verification of the surfaces after application of the solution

To examine the surfaces the lenses were dried, attached to a mounting support with conductive carbon and then vapour-coated with gold under high voltage. Different enlargements of the photos allowed good visualisation and evaluation of the lens surfaces. *No structural changes could be ascertained in the contact lens surfaces treated with "i-clean!" (Fig. 1 and 2).*

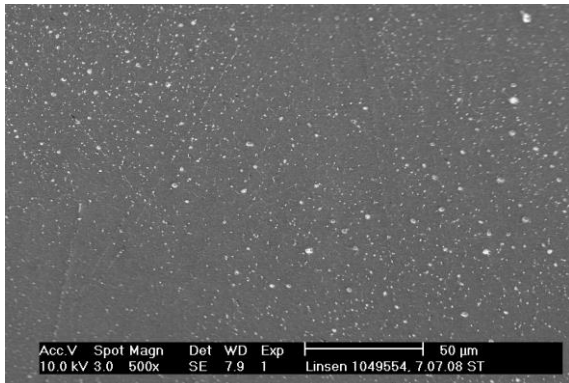


Fig. 1: Contact lens surface after 60 days of treatment with "i-clean!" with 500x magnification

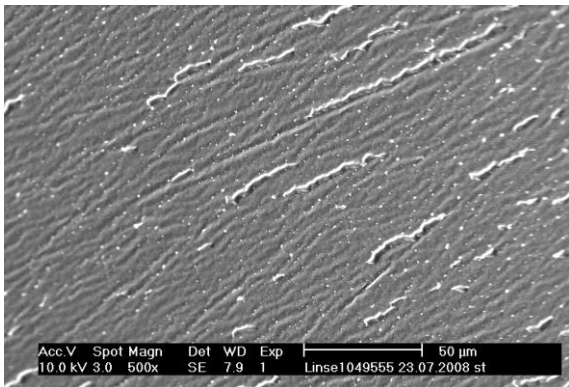


Fig 2: Contact lens surface after 60 days of treatment with an abrasive cleaner with 500x magnification

Investigations regarding the cleansing effect on contact lenses

In a further investigation "i-clean!" was used as a surface cleaner in various actual cases of contaminated contact lenses. The deposits came from different sources such as lipids and other debris from the tear film. Fats from fingerprints or the remains of make-up. By manually massaging the lens surfaces with "i-clean!", all of the deposits could be optimally eliminated.

Likewise contact lenses right from the factory that were difficult to wet because of possible production residues had them completely removed with "i-clean!" After the application it was possible to demonstrate optimal surface wetting of the contact lenses on the eye (Fig. 3 and 4).

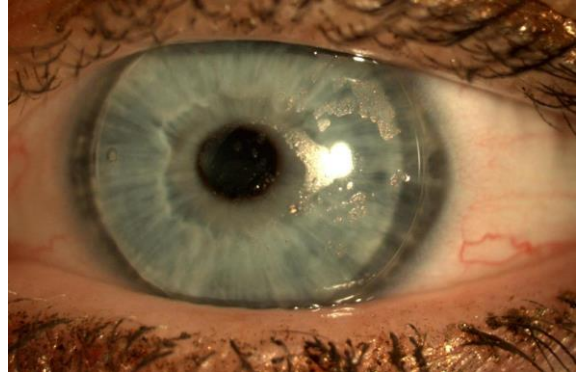


Fig. 3: Deposits of cosmetics with metallic particles on contact lens²⁾

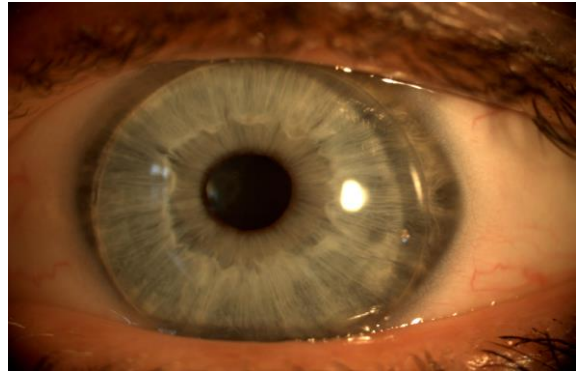


Fig. 4: Contact lens from Fig 3. After cleaning with "i-clean!"²⁾

Studies regarding the application

As a result, two application studies concerning the suitability of the practical application were carried out on probands¹. The multi-centre, randomised studies were consistent with today's gold standard for clinical trials and showed that the solution was well accepted by the test subjects.

Study for application

Over a period of 30 days 60 wearers of soft and rigid contact lenses used the new "i-clean!" cleaning solution.

Besides the subjective evaluation of its effectiveness and tolerance by the probands, the contact lenses that had been worn as well as the physiological circumstances of the eye were also assessed objectively by the clinical investigators.

At the end of the test phase an examination of the eyes with a slit lamp showed no significant changes.

The tolerance as well as the cleaning action were found by a majority of the probands to be better or as good when compared with the previously used cleaning solution (Chart 1).

The objective evaluation of the contact lens surface by the clinical investigators showed comparable or better cleaning efficiency for the most part (Chart 2).

The new "i-clean!" cleaning solution convinced not only users but contact lens specialists as well.

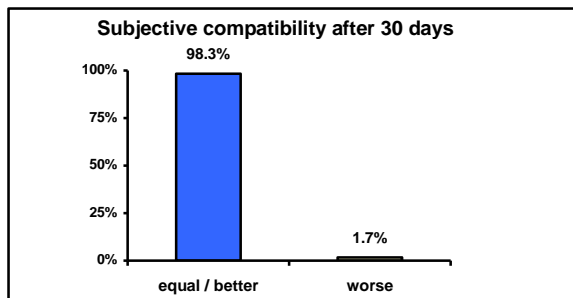


Chart 1: Assessment of the compatibility by the subjects in comparison to the previously used cleansing solution

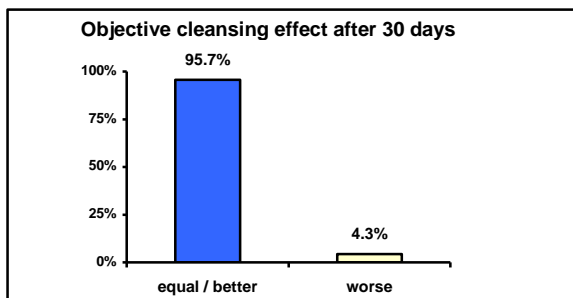


Chart 2: Evaluation of the cleaning effect by the specialist in comparison to the previously used cleansing solution

Enhanced study for application

In a further, broad-based international study with additional test sites "i-clean!" was used by 170 wearers of rigid gas-permeable as well as soft hydrophilic contact lens for a period of 30 days under everyday conditions. So the results of the first study were re-validated as to acceptance.

In contrast to the previous application study the procedure concentrated on subjective perceptions. The probands assessed the subjective cleaning action according to the duration of use as well as the comfort of the contact lenses, both right after insertion and during the course of the day.

The analysis of the assessment by the probands reflected the excellent cleaning action and the high level of initial comfort of "i-clean!" compared to the previously used cleaning solution.

Some of the feedback received from the test subjects:

- ✓ Contact lenses were perceived to be more comfortable in the evening
- ✓ Contact lenses remained cleaner with less need for re-wetting
- ✓ Noticeably better cleansing effect
- ✓ Fatty deposits were easier to remove
- ✓ Convenient to use

The experiences from the initial application study were confirmed in the enhanced application study.

Other instructions, use and care

In principle, the cleaning of the contact lenses should occur immediately after removal.

Rigid gas-permeable contact lenses: have to be rubbed between the index finger, middle finger and the thumb for 20-30 seconds.

Hydrophilic soft contact lenses: need to be cleaned on both sides with the palm of one's hand with the aid of the index finger of the other hand for 20-30 seconds.

Thoroughly rinse off any dirt particles that have been loosened and the cleaning solution with a rinsing solution suitable for the lens type or a sterile saline solution. Do NOT store the contact lenses in the "i-clean!" solution!!!

Rigid gas-permeable contact lenses can be used well conditioned immediately after the thorough rinsing.

Hydrophilic soft contact lenses should be stored in a suitable conditioning solution for 1-2 hours before insertion.

Summary

As an enhancement of the basic improvements achieved with the new contact lens care solutions and systems from CONTOPHARMA, the "i-clean!" cleaning solution addresses the special needs and requirements of contact lens wearers.

"i-clean!" efficiently counteracts, with a long-lasting effect, any increased secretion of mucins, sebum and lipids and an associated greater predisposition for deposits on the contact lens surfaces.

To date no types of contact lenses are known with which the solution should not be used.

Literature

- 1) Data on file: Contopharma AG and Laboratorium Dr. G. Bichsel AG, Interlaken
- 2) Figures - photographs courtesy of K. Spohn, MediLens AG, St. Gallen

New developments can be achieved today only through the networking of existing resources. For the design of the new "i-clean!" cleaning solution new basic knowledge about the manufacture of materials as well as contact lenses and their finishing were transformed into new possibilities for pharmacological production. Therefore, an optimal, research-based, compatible and effective solution was developed using the instruments of manufacturing techniques (chemical-physical processes, in-vitro trials, physical measurements) and the various application studies.

- Prof. Dr. R. Schäfer, Institute Schäfer AG, Bubendorf
- Dr. med. / Dipl. Ing. FH S. Tschanz
University of Bern, Medical Faculty, Institute for Anatomy
- Laboratorium Dr. G. Bichsel AG, Interlaken
- Contopharma AG, Interlaken
- Techno-Lens AG, Le Mont-sur-Lausanne
- Hecht Contactlinsen GmbH, Au bei Freiburg im Breisgau
- MediLens AG, St. Gallen
- U. Businger, O.D., Lucerne
- R. Eschmann, M.S.Optom., Bern

Adjunct Clinical Investigators:

- Aeschmann Optik, Solothurn, Mr Aeschmann
- Eschmann Contactlinsen, Bern, Ms Kreuter / Mr Neuweiler
- Augenoptik Keller, Schwyz, Messrs Keller and Borner
- prima vista augenoptik, Lyss, Mr Lutstorf
- Pfarrer Contactlinsen Zentrum, Bern, Messrs Mange and Flury
- Ottico Cervo, Bellinzona, Mr Michel
- Miller Contactlinsen-Institut, Innsbruck, Mr Rehnert
- MediLens Contactlinsen, St. Gallen, Ms Spohn
- Wolf Contactlinsen-Studio, Munich, Mr Wolf