DIMENSIONAL STABILITY
OF THE ULTRACON
CONTACT LENS

FERRIS STATE UNIVERSITY
COLLEGE OF OPTOMETRY

BY: Anthony Y.C. Wong

March 31,1994

ABSTRACT:

The new non-toric UltraCon contact lens may be the most significant breakthrough in contact lens technology in over twenty years. It offers an alternative to better and easier fitting of astigmatic patients with the characteristics of both RGP's and hydrogel contact lenses. UltraCon is a non-water based, flexible, high Dk lens[2] soon to be introduced in Canada and will be available in the U.S.A. by 1995, pending FDA approval. This lens has been the product of five years of joint research and development by Specialty Contact Lens of Calgary, Alberta, Rasor Associates of Sunnyvale, California and the University of Alabama, College of Optometry and has yielded a remarkable new contact lens material. This study is part of the continuing clinical trials to test the dimensional stability of the UltraCon lens in a variety of commercial contact lens solutions.

INTRODUCTION:

In fitting astigmatic patients, practitioners have sometimes had to choose between the comfort of a soft lens and the acuity of an RGP. A new alternative to both of these lens types will soon be available. The new UltraCon contact lens may just be the most significant breakthrough in contact lens technology in over 20 years as it may solve some of the problems of the two types of contact lens materials that exist today.

The origination of the UltraCon lens started more than five years ago when Rasor Associates, a medical research group produced a membrane to oxygenate blood during heart and lung surgery. One of the shareholders, Dr. Irv Fatt, PhD, a well known person in the contact lens industry realized several essential characteristics in this membrane that could serve well in a contact lens. Rasor Associates teamed with Specialty Contact Lens in 1988 to produce a lens from this material. By 1991, clinical trials were started with the new UltraCon lens. The last five years of joint research and development with UAB has yielded a non-water based contact lens that combines the comfort, fit and design of a soft contact lens with the convenience, low maintenance and sharp vision of an RGP.

The UltraCon lens is a non-hydrogel, flexible high Dk lens[2]. It has undergone much testing of its' parameters. In testing dimensional stability, the fabrication technique avoids residual stress and the material has been found to be highly stable[5]. The primary purpose of this study was to investigate this dimensional stability of the UltraCon contact lens by measuring several pre-determined parameters before and after soaking in various contact lens solutions and enzymes. From the results, it can then be determined which solutions provide the greatest stability for daily disinfecting and weekly enzyme use.

LENS CHARACTERISTCS AND DESIGN:

The UltraCon Lens is fabricated using simple standard thermo-molding techniques that also ensures accurate reproducibilty and contoured edges. The manufacturing process starts with pressure molding of the UltraCon material between two nickel moulds at high temperatures. A male and female mould, with an UltraCon blank in between are placed into a holder and then placed into a press. The moulds are subject to pressure and relatively high temperatures. After cooling, the lens is removed from the mould and edged slightly. There is minimal polymer waste, thus manufacturing costs can be kept minimal.

The UltraCon lens has several characteristics that combines the best of soft and RGP lenses. Researchers of the UltraCon lens realized that an overall Dk of greater than 100x10 -11 was desireable in order to adequetly supply the cornea with oxygen. This was accomplished in this material with Dk's ranging from 80x10 -11 in the lower end to greater than 265x10 -11 at the upper end.[5] The Dk of this material is relative to the flexibility . Less lens flexibilty resulted in a lower Dk while a greater flexibilty resulted in a higher Dk. The lenses supplied for this study came in three stiffness/flexibilty parameters labelled in percentages: 3%, 7% and 12% in various plus and minus powers. The percentages represent the stiffness of the material with 3% being the most flexible and 12% the least or most stiff. The flexibility and large diameter (14.0mm) enables the ease of soft lens fitting and comfort but serves also to control the amount of tear pump action that occurs between the contact lens and the cornea.

A special set of posterior curves both spherical and aspheric in design[5] lets the UltraCon lens behave on the eye in similar fashion to a soft lens. The lens is also not as elastic as those composed of silicone,[5] so there is no suction cup effect on the eye.

Currently, four base curves and one diameter have been designed. The powers available are -8.00D to +6.00D and is lenticulated in all plus and minus powers.[5] It has a nominal center thickness of 0.10mm and feels like a thick soft lens[5] in the hand with similar insertion, removal and fitting procedures.

The UltraCon lens is designed for a relative normal population of eyes that require visual correction of myopia, hyperopia and astigmatism. The lens corrects astigmatism similar to an RGP by maintaining its shape such that the astigmatic condition or irregularity of the cornea is masked by the tear layer. Clinical studies have shown that the UltraCon lens can correct up to 3.00D of corneal astigmatism without any cylinder refracting through, provided the astigmatism is due to corneal toricity and not lenticular.[2] Another similarity to RGP lenses is that it has the simplified care of rigid lenses. A wetting or pre-soaking is not required, just the application of the wetting solution before insertion. An advantage of the UltraCon lens is that it does not rock on the eye as an RGP does. This is due to the stabilization of the design and contact with the sclera.[5] It is also superior in terms of surface wettability. Clinical applications have demonstrated tear break-up times in excess of 42 seconds for the UltraCon lens compared to 16 seconds for some RGP's[5]. Since wettibility and surface deposits have shown to be related[5], it is desirable to increase wettibility to increase deposit resistance. Even when tear break-up begins, it does not unsheet as does an RGP lens does, resulting in little or no deposits of the lens surface even after several months of wearing. The increased wettibility is a proprietary process that has shown to be durable[5].

The specific gravity of the lens material is approximately 1.01[5]. Flexibility is a factor as the specific gravity decreases as the flexibility increases. This decrease in specific gravity is slight and has no effect on the stability of the lens.

METHODS:

The UltraCon lenses used in this study were supplied by Ultravision of Calgary. Base curves were not specified on the labels, only the stiffness percentages and powers. the powers available were -0.62, -0.75, +0.50, +0.62, +0.75, +0.87, +1.00D.

The lenses were separated into two groups each having lenses represented by the three stiffness percentages indices. Plus and minus lenses were used in each stiffness index.

The lenses were shipped dry and were measured as such for base curves, power, diameter, center thickness and optical quality/warpage. Base curves were measured with a Reichert Model 11200 Radiuscope, power with a Marco Model 101 lensometer, center thickness with a Peacock caliper and diameter with a Bausch and Lomb 7X magnifying lens. Optical quality were assessed by visual inspection and clarity of mires as viewed under the radiuscope and lensometer. Lenses were handled with a standard plastic contact lens tweezer and latex gloved hands.

Group one lenses were soaked for three weeks in either Alcon Opti-Free disinfecting solution, Allergan Ultracare disinfecting solution (with neutralizing tablet) or Ultravision X-Stat solution. Group two lenses were soaked in either Opti-Free disinfecting solution, Bausch and Lomb Multipurpose/Renu solution or Ultracare disinfecting solution(with neutralizing tablet). Group two lenses were also enzymed once a week for three weeks with their respective company's recommended enzyme brand and replaced with fresh solution at each time. Due to manufacturer's suggestion and peroxide nature of the Ultacare disinfecting solution, lenses soaked in this solution from group one was changed weekly as well. After the three week soaking period, the lenses from both groups were individually blotted with Kimwipe tissue and the same parameters reassessed.

TABLE 1

BASELINE PARAMETERS FOR THE ULTRACON LENSES USED IN THE STUDY[6]

Parameters:

Diameter(mm)	13.80-14.10
Base Curves(mm)	7.57-7.86
Center Thickness(mm)	0.109-0.223
Power (Diopters)	-0.50- +1.00

TABLE 2

SOLUTIONS AND ENZYMES USED AND THEIR INGREDIENTS[6]

Group 1:

Alcon Opti-Free Rinsing, Disinfecting and Storage Solution
- Citrate buffer system
- Sodium chloride
- Edetate disodium
- Polyquad 0.001%

Allergan Ultracare Disinfecting Solution	Neutralizing Tablet
Hydrogen peroxide 3%	Catalase
Sodium stannate	Hydroxypropyl methylcellulose
Sodium nitrate	Buffering and tableting agents
Phosphate buffers	
Purified water	

Ultravision X-Stat Solution
- Citrate buffer system
- Tetra sodium edetate
- Linoleamide deo
- Sodium chloride
- Sodium C-14,16
- Olefin sulfanate
- Sodium sulfate
- Sodium laurate
- Glycerin-formalin
- Glycol-distearate
- Cacamide dea
- Water

Group 2:

Alcon Opti-Free
Opti-Zyme
- Pancreatin

Bausch and Lomb Renu/Multi-Purpose Solution
- Boric acid
- Poloamine
- Sodium borate
- Sodium chloride
- Dymed 0.00005%
- Edetate disodium 0.1%

Bausch and Lomb Effervescent Enzymatic Cleaner
- Subtilisin
- Polyethylene glycol
- Sodium carbonate
- Sodium chloride
- Tartartic acid

Allergan Ultracare Disinfecting Solution, Neutralizing Tablet
Allergan Ultrazyme
- Subtilisin A

RESULTS:

The baseline parameters for the lenses in the study are given in Table 1. The baseline measurements of the overall diameters had a standard deviation of 0.062mm Therefore, it can be assummed that the diameter could be measured quite accurately. The standard deviation of the base curve measurements ranged from 0.030-0.071mm. The standard deviation for center thickness ranged from 0.010-0.037mm. Since the baseline overall diameter, base curve, center thickness and powers for these lenses varied, the results were calculated in percentage change.

Figure 1 shows the change in the overall diameter of the UltraCon lenses soaked in group 1 solutions and figure 2 shows the change in the overall diameter of the lenses soaked and enzymed from solutions in group2. Figure 3 shows the effect of the solutions from group 1 on the base curve of the UltraCon lens and figure 4 shows the effect of group 2 solutions and enzymes on the base curve of the lenses. Figure 5 shows the effect of group 1 solutions on the center thickness of the lenses and figure 6 shows the effect of the group 2 solutions and enzymes on the center thickness of the lenses. Figure 7 shows the effect of group 1 solutions on the power of the lenses and figure 8 shows the effect of group 2 solutions and enzymes on the power of the lenses. Each bar on the graghs represents the average of 3 or 4 lenses as results were not consistent for individual lenses.

The graphs show that there was a significant change in all parameters measured after soaking as they did not stay within standard deviations of the baseline ranges. In group 1, X-Stat solution had the greatest change on the overall diameter and power. In the same group, Opti-Free had the greatest change on center thickness and Ultracare solution had the greatest change on the base curve. From group 2, the Ultracare products showed the greatest change in overall diameter and base curve. Plus values on the base curve graphs indicate flattening and minus values indicate steepening. Opti-Free and Opti-Zyme showed greatest change to center thicknesses and B&L MPS and Effervescent Enzyme the greatest change in power.

Standard deviations were calculated and from this, only X-Stat solution was found to affect the overall diameter and power greater than 1SD. From group 2, only Ultrazyme and Ultracare was found to affect the overall diameter greater than 1 SD.

Mires were variable when viewed under the radiuscope and could not be assessed accurately. Visual inspection of the lenses after soaking showed some pink colored deposits on all the lenses soaked with X-Stat solution and slight haze on the surface of 2 of the 3 lenses soaked with Ultracare disinfecting solution in group 1. All others lenses appeared clear.

DISCUSSION:

Consumer reports show a trend towards greater use of multipurpose contact lens solutions and this study attempted to use two of the leading brands most likely to be used with the new UltraCon contact lens in assessing material stability. Ultravision's own solution and a hydrogen peroxide disinfecting solution were also used for comparison. Enzyme cleaner was not supplied or recommended for Ultravision's X-Stat solution so it could not be included in group 2's study of the effects of the solutions and their enzyme use.

Statistically,it appears that the solutions used in the study did significantly alter the parameters measured prior to soaking. The percentage change in these parameters were greatly outside the baseline measurements. This discrepancy was most likely due to hydration effects. A more accurate method to ensure results closer to baseline could be to soak all the lenses for a period of time in unpreserved saline to hydrate and standardize before taking mesurements of the parameters and then soak in the various solutions. All attempts to decrease moisture effects on the lenses were made with the use of latex gloves and plastic contact lens tweezer for handling. Air moisture was an uncontrollable variable in the room used. Standard deviations were used to see if the percentage changes were significant. The results show that Ultravision's X-Stat solutions did cause a significant change in overall diameter and power of the UltraCon lens. In group 2, Allergan's Ultracare system showed significant change to the overall diameter of the UltraCon lens. These changes are most likely due to swelling of the lens. In group 2, B&L MPS and Effervescent enzyme cleaner did not significantly cause lens swelling. Since Allergan Ultrazyme and B&L Effervescent enzyme cleaner both are composed of the enzyme Subtilisin, it appears then that the contact lens swelling from the Ultracare system was due to the peroxide disinfecting solution alone and not by the enzyme. The percentage change in base curve, center thickness by all solutions fell within 1 SD and were considered insignificant. Based on previous contact lens hydration studies, minus lenses go through different changes than plus lenses[1]. Also base curve changes are probably related to both the amount of swelling and the power of the lens[4]. Lenses used in this study consisted of plus and minus lenses randomly placed in a particular solution type and did not display any consistent increase/decrease in center thickness or flattening/steepening in base curves in relation to the lens power. For example, plus and minus lenses both exhibited flattening or steepening characteristics after soaking. Experimental error in measurement can account for some of these inconsistencies. The thinness and flexibility of the UltraCon lens certainly made base curve readings difficult to measure and the variable spring mechanism of the thickness calipers may have contributed to some of the experimental error. Consistency in similar future studies can be improved by using only all plus lenses or all minus lenses. Again, due to the thinness and flexibility of the UltraCon lens, warpage characteristics after soaking could not be reliably assessed when comparing pre-soak mire quality with post-soak.

Due to proprietary reasons, Ultravision and Rasor Associates would not release the material composition of the UltraCon lens. Through some research, I can only speculate that this material may have been developed from a porous teflon membrane or similar related material. This membrane was first produced in Poland in 1985 and an American version around the same time. It was one of the most promising types of membranes applied in membrane oxygenators. The teflon membrane characteristics share many of the same characteristics of the UltraCon lens: high oxygen permeabilty, hydrophobicity and the resistance of proteins adsorbing to the surface[3].

As the UltraCon lens is non-water based, the microorganisms on its surface is minimized such that a bacterial-static disinfecting solution would be adequate for this lens. It appears from this study of the effects of varius solutions on the parameters of the UltraCon contact lens that both B&L and Alcon's products have the least effect on the parameters studied. Therefore the care products that can be recommended for the new UltraCon contact lens include B&L MPS/Renu soution with the Effervescent enzyme or Alcon Opti-Free with Opti-Zyme. With the len's comfort, ease of fitting, astigmatic correcting properties and ease of care, the UltraCon lens certainly appears to be a promising revolution in contact lens design.

REFERENCES:

1. Gordon S: Contact lens hydration: a study of the wetting-drying cycle. Optometry Weekly 1965 Apr 8;56(14):55-62

2. Hammock G: A new approach to Correcting Astigmatism. Contact Lens Spectrum 8(10):42-44 1993

3. Krajewska B. and Leszko M: Porous tarflen as a possible membrane material in membrane blood oxygenators: structural properties. Polish Medicine 1985;15(1-2):5-20

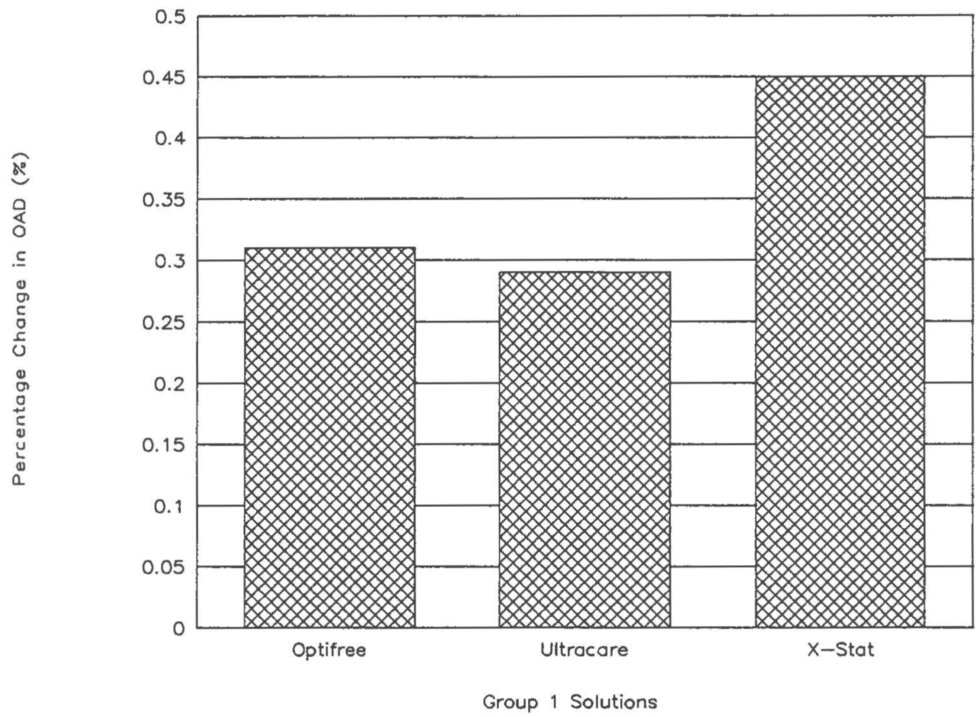
4. Lowther G: Effect of some solutions on HGP contact lens parameters. Journal of the American Optometric Association. 1987 Mar;58(3):188-92

5. Sturm B: Development of the UltraCon and EpiCon. Optical Prism. 1994 Jan:24-28

6. White P. and Clifford S: Contact lens and solutions summary. Supplement to Contact Lens Spectrum. 1992 Aug:23

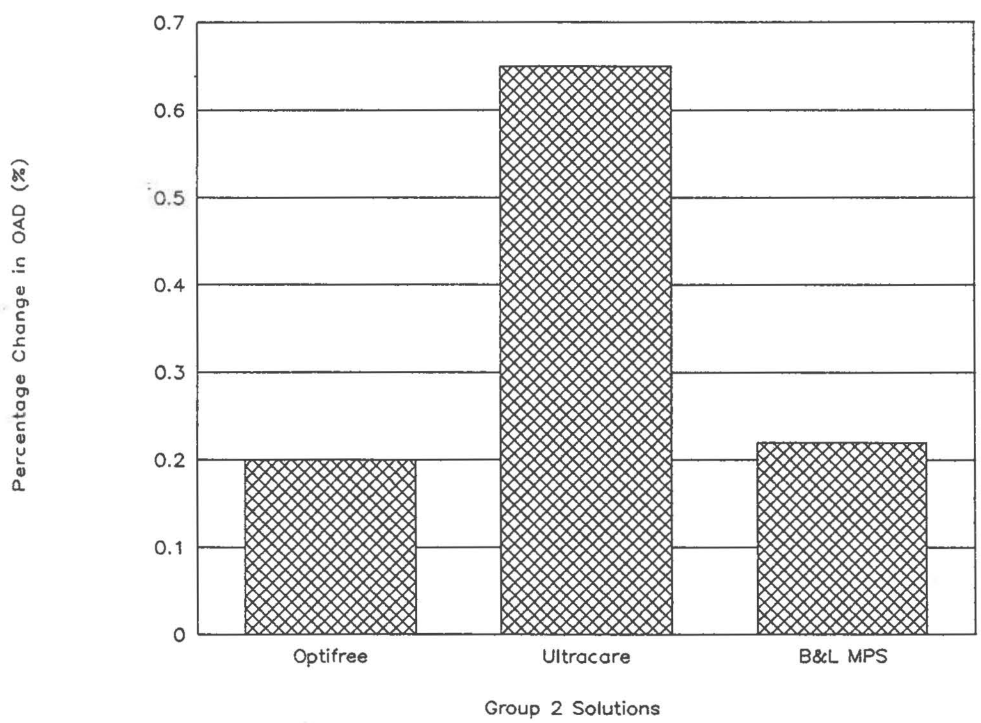
Group 1 - Figure 1

Effect of Solutions on OAD of UltraCon



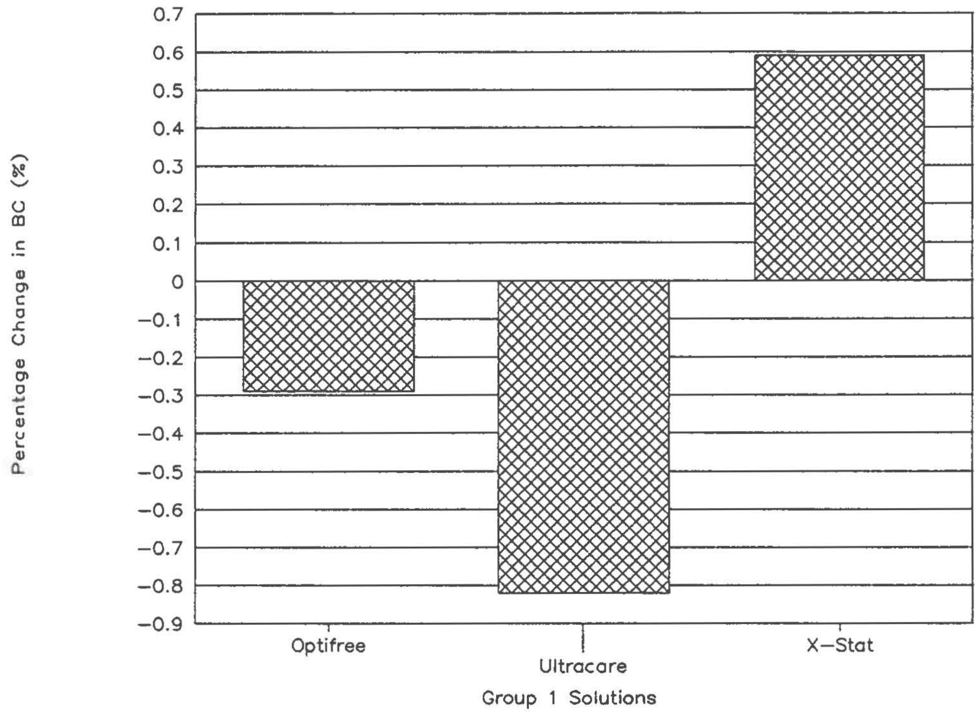
Group 2 - Figure 2

Effect of Solutions on OAD of UltraCon



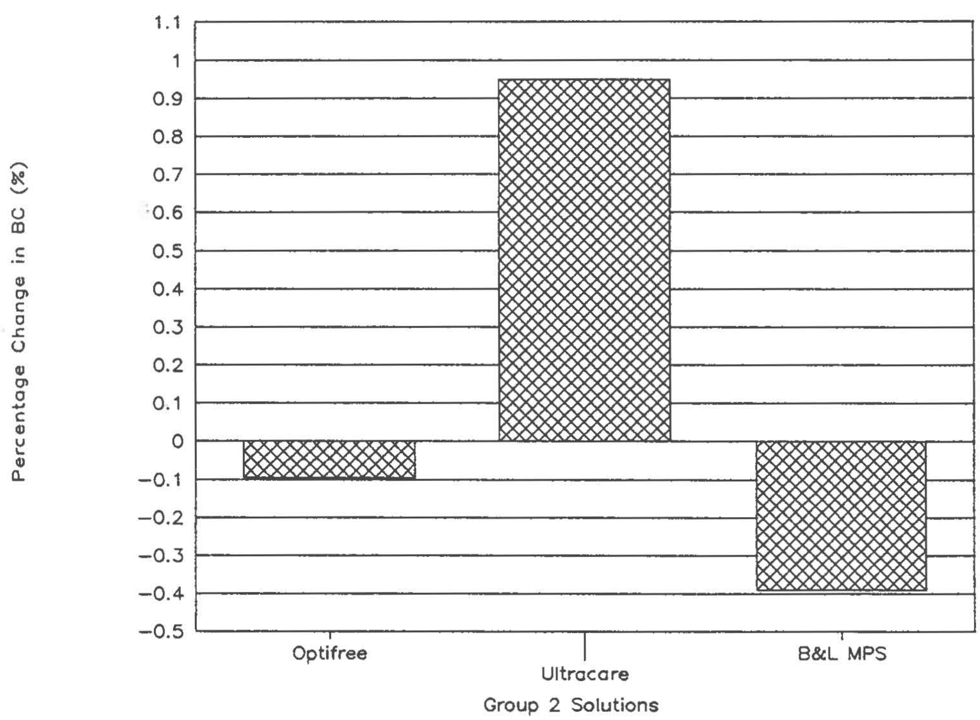
Group 1 - Figure 3

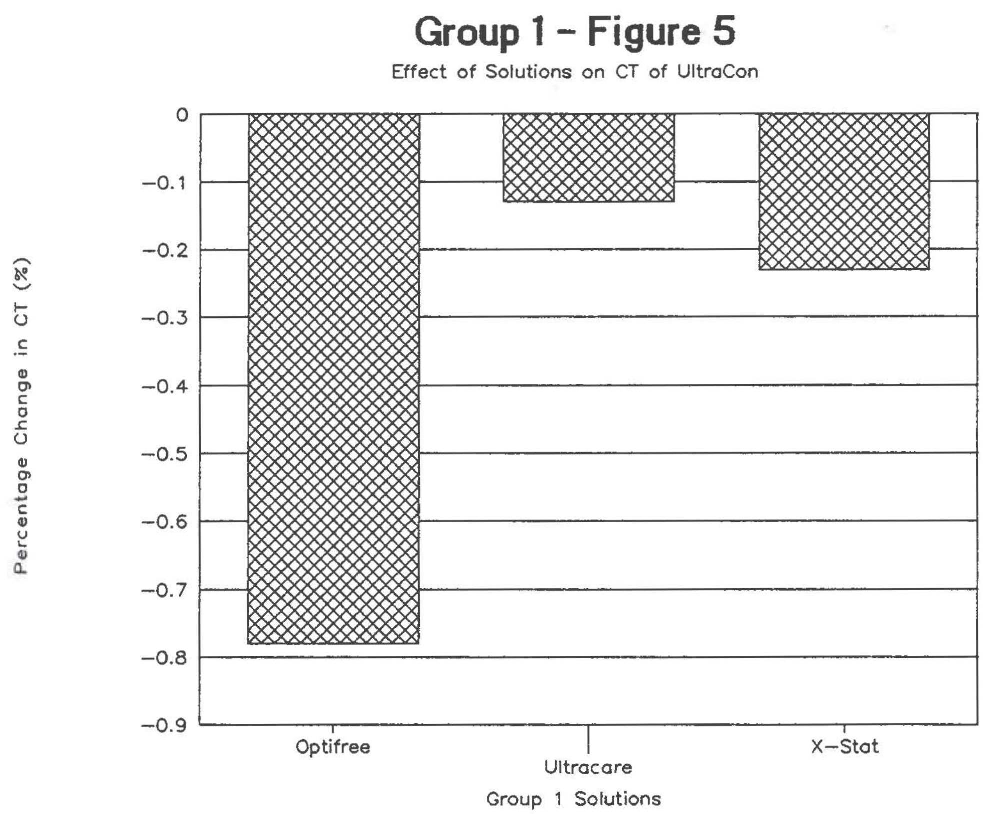
Effect of Solutions on BC of UltraCon



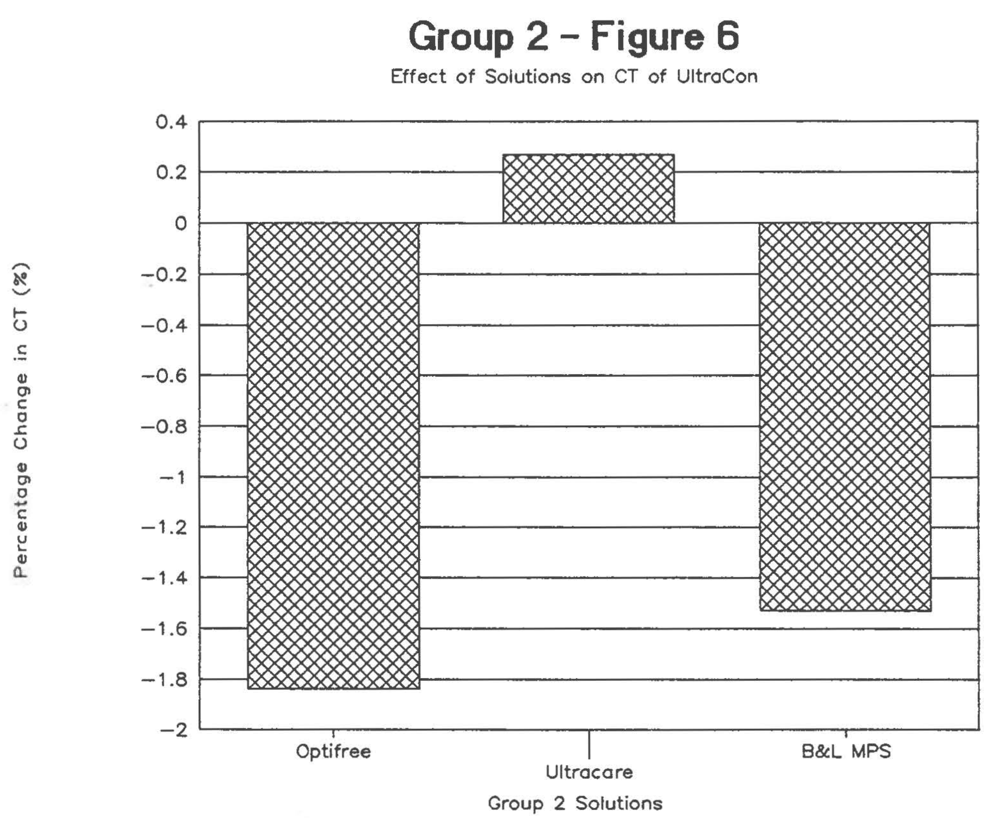
Group 2 - Figure 4

Effect of Solutions on BC of UltraCon





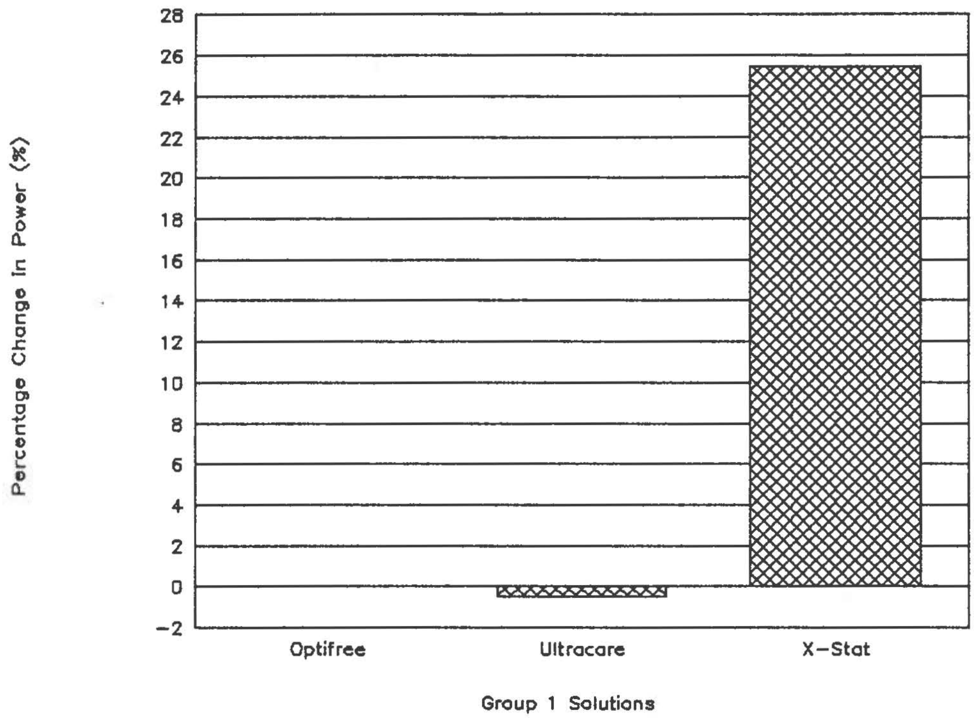
Group 1 - Figure 5
Effect of Solutions on CT of UltraCon
Percentage Change in CT (%)
0
-0.1
-0.2
-0.3
-0.4
-0.5
-0.6
-0.7
-0.8
-0.9
Optifree
Ultracare
X-Stat
Group 1 Solutions



Group 2 - Figure 6
Effect of Solutions on CT of UltraCon
Percentage Change in CT (%)
0.4
0.2
0
-0.2
-0.4
-0.6
-0.8
-1
-1.2
-1.4
-1.6
-1.8
-2
Optifree
Ultracare
B&L MPS
Group 2 Solutions

Group 1 - Figure 7

Effect of Solutions on Power of UltraCon



Group 2 - Figure 8

Effect of Solutions on Power of UltraCon