# A STUDY OF THE REPRODUCIBILITY OF SPIN CAST HYDROPHILIC CONTACT LENSES

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**ABSTRACT**

**A study was conducted using ten existing contact lens patients over a period of 10 weeks. This involved 200 lens changes to test the reproducibility of spin cast hydrophilic contact lenses to objective and subjective satisfaction. The correlation between these 2 forms of assessment, and the reliability of each form were also assessed.**

## INTRODUCTION

The purpose of this study was to test the reproducibility claims of the spin cast hydrophilic contact lens manufacturer, Bausch & Lomb Soflens.

### Reproducibility Claims

The claims as to the reproducibility of the Bausch & Lomb spun cast product have appeared on numerous occasions, particularly in professional journal advertisements marketing Soflens. On most of these occasions the clause "ensuring optimum reproducibility" with reference to spin casting was used (Bausch & Lomb, ref: a). L. D. Clements of Bausch & Lomb Soflens Division in an interview with Kaye (1975) also referred to the lenses as "highly reproducible", while the most ambitious claim appears in the Soflens International Fitting Guide (1976). In the "General Information" section of this publication it is Bausch & Lomb's claim that their "manufacturing procedure assures the highest reproducibility in the contact lens industry". Unfortunately it is near impossible to test this claim as the contact lens industry related to hydrophilic lenses is too large and expanding too rapidly. It is, however, possible to test just how high the reproducibility of Bausch & Lomb Soflens is, and this then was the aim of this study.

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## METHODS

### Selection Of Test Patients and Lenses

Ten patients were selected who were successfully wearing Soflens contact lenses for average daily wearing times in excess of 12 hours and achieving monocular acuities of 6/6 or better. Fitting of these test patients utilised conventional fitting relationships and dispensed lenses fell within the Soflens "Best Fit" concepts. As shown in Table 1, these patients came from a reasonable cross section, there being both myopes and hyperopes, males and females, a range of ages and both heat and chemical ascepticization methods. The lens maintenance systems used were in accordance with Bausch & Lomb's own recommendations (Bausch & Lomb, 1975). Individual prescriptions of the dispensed lenses are shown later as part of the results table.

**TABLE 1**

**PROFILE OF TEST PATIENTS**

| |
|---|
| Sex: 2 male, 8 female |
| Age: 14 years to 52 years (Av: 22) |
| Refractive Error: 8 myopes, 2 hyperopes |
| Lens maintenance system: |
| * Heat: 7 (with Protein tabs. 6) |
| * Chemical: 3 (with Protein tabs. 3) |

The necessary lenses required for these patients were then selected at random from the stock held by Bausch & Lomb Soflens. Because of the distance involved, the investigator requested a nominee to make the selection on his behalf. In all cases this selection included at least 3 different lot numbers for each lens label specification required.

**Reproducibility**

It is important to note that for the purpose of this study the term "reproducibility" was used to refer to clinical lens performance rather than to the accuracy of individual lens specifications.

Once underway, the study involved the supplying to each of the ten patients a new pair of identical label specification lenses each week for a period of 10 weeks. At each of the regular weekly visits performance of the old lenses was considered both subjectively by the patient and objectively by the investigator prior to them being replaced by the new lenses to be worn for the following week.

As mentioned earlier, consideration was on the basis of clinical performance rather than actual individual lens specifications. Thus the objective assessment was made as follows:—

(1) Centration
(2) Post Blink movement
(3) Retinoscopic reflex
(4) V. A. with contact lens
(5) Over refraction
(6) Visual acuity
(7) Clear end point of refraction
(8) Stability of V. A.
(9) Slit lamp examination
(10) Lens inspection.

Similar areas were also considered by the patient in his subjective assessments. A shortened copy of the subjective report form used is shown in figure 1.

The patient's own subjective consideration was made first so that his judgement would not be influenced by the investigator, and this was done in private and in writing so that the objective assessment would not be influenced by the patient's remarks. In this way when figures for reproducibility to objective and subjective satisfaction were finally reached a comparison and correlation between the two methods of assessment could be viewed in the knowledge that each judgement had been reached independently.

**FIGURE 1**

**SUMMARISED SUBJECTIVE REPORT FORM**

Patient ..... Week No..... Date .....

**REPORT:** **Right Lens** (....hrs worn)

*Location: Central/Fair/Poor

*Vision: Normal/Improved/Worse

*Comfort: Good/Fair/Poor

*Lens Inspection: Surface: Good/Poor
Edge: Good/Poor

Would you accept that the performance of this lens is the same as your original? YES/NO

**Other Comments:**

**Reliability**

Since the study was to test the reproducibility of the lenses, it was significant and of interest to also test the reliability of each of the 2 forms of lens performance assessment being used; subjective and objective. This was achieved by incorporating a "double blind" feature into the study technique being used.

As mentioned earlier, each patient was supplied with a pair of lenses each week for a period of 10 weeks. The patients were all led to believe that each of the lenses supplied to them was new. In actual fact, for each eye over the 10 weeks only 5 new lenses were used and each was presented on 2 occasions. This enabled a very interesting test to be made of the reliability of patient assessment of their own lenses.

The "double blind" feature was added by introducing a third party assistant who handled the random selection of lenses for weekly presentation to the patients via the investigator, already in the patient's own storage case. Accurate records of which lens was presented each week were

kept by the assistant for later comparisons of the assessments and observations made on the same lens. This then enabled a test to be made of reliability of the investigator's objective clinical assessments.

### Quality Control

Problems of a "quality control" nature were not considered as an error in reproducibility. For example, if a split lens was found to have slipped through Bausch & Lomb's quality control, this was recorded as a failing in their checking methods but not as a reproducibility problem since a lens with such an obvious fault would never be dispensed to a patient.

### Shipping Distortions

Following the work of Dr. B. Holden reported by Bausch & Lomb (ref: b), only those lenses found to be floating freely — concave side up — were used. Those lenses which adhered to the vial or stopper were boiled and then only used when they did float freely and were concave side up. The number of lenses which this was found to be necessary was also recorded.

## RESULTS

### Reproducibility

Standards for satisfactory reproducibility of objective lens performance were laid down as shown in Table 2. These were decided upon as being the signs of a well fitting hydrophilic lens (Masnick & Holden, 1975) and as being within the published Soflens tolerances for power.

**TABLE 2**

**SATISFACTORY OBJECTIVE PERFORMANCE CRITERIA**

| | |
|---|---|
| (1) Centration . . . | No more than 1.0 mm decentration in primary position. |
| (2) Post Blink Movement . . . | Slight movement only (0.5 to 1.0 mm). |
| (3) Retinoscopic Reflex . . . | Crisp. |
| (4) V.A. with contact lens . . . | No reduction when compared to original. |
| (5) Over Refraction . . . | ± 0.12 (B.V.P. to ± 5.00)<br>± 0.25 (± 5.25 to ± 20.00) |
| (6) Visual Acuity . . . | No reduction when compared to original. |
| (7) End Point of Refraction . . . | Definitive end point resulting from good apical touch. |
| (8) Stability of V.A. . . . | Perceived as non-fluctuating by patient. |
| (9) Slit Lamp Examination . . . | No oedema or injection. Indentation (if any) clears in 5 minutes. |
| (10) Lens Inspection . . . | No imperfections, distortions, etc. |

A failure to achieve the standard in any of these areas was recorded as an overall failure of the lens to achieve complete reproducibility to objective satisfaction. Results for each of the patients, right and left eyes and an overall average are shown in the first column of the results table, Table 3.

In assessing lenses for subjective impression of performance, patients classified each lens as either accepted or rejected. An accepted lens indicated reproducibility to complete subjective satisfaction while a rejected lens indicated that the patient did not feel that the performance of the original lens had been reproduced successfully, and would not accept it as a satisfactory lens replacement.

Using this system, results were again calculated for each of the patients, right and left eyes, together with an overall average. These are shown in the second column of the results table.

### Correlation

An attempt was then made to arrive at a co-efficient of correlation between the two forms of lens performance assessment already discussed. This figure is important as it gives an indication of the

**TABLE 3**

**OVERALL RESULTS**

| Patient | Lens | REPRODUCIBILITY Objective Satisfaction | REPRODUCIBILITY Subjective Satisfaction | Correlation between Obj & Subj Assessments | RELIABILITY Objective Assessment | RELIABILITY Subjective Assessment |
|---|---|---|---|---|---|---|
| 1 | R (—1.25) | 100 | 90 | 0.9 | 100 | 80 |
| | L (—1.50J) | 80 | 80 | 1.0 | 100 | 100 |
| 2 | R (—3.25F3) | 90 | 100 | 0.9 | 80 | 100 |
| | L (—3.00F3) | 80 | 100 | 0.8 | 100 | 100 |
| 3 | R (+0.75N) | 100 | 90 | 0.9 | 100 | 80 |
| | L (+0.75N) | 100 | 90 | 0.9 | 100 | 80 |
| 4 | R (—2.25B) | 100 | 100 | 1.0 | 100 | 100 |
| | L (—2.75B) | 78* | 100 | 0.78* | 100* | 100 |
| 5 | R (—1.75F3) | 100 | 50 | 0.5 | 100 | 40 |
| | L (—1.75F3) | 100 | 70 | 0.7 | 100 | 40 |
| 6 | R (—6.50F3) | 100 | 100 | 1.0 | 100 | 100 |
| | L (—6.50F3) | 100 | 100 | 1.0 | 100 | 100 |
| 7 | R (—3.00F) | 90 | 100 | 0.9 | 80 | 100 |
| | L (—2.50F) | 100 | 90 | 0.9 | 100 | 80 |
| 8 | R (+2.00N) | 78* | 50 | 0.33* | 100* | 40 |
| | L (+2.00N) | 80 | 100 | 0.8 | 100 | 100 |
| 9 | R (—3.75F) | 90 | 100 | 0.9 | 80 | 100 |
| | L (—2.00F) | 100 | 100 | 1.0 | 100 | 100 |
| 10 | R (—6.00B) | 100 | 100 | 1.0 | 100 | 100 |
| | L (—1.50J) | 100* | 90 | 0.88* | 100* | 80 |
| AVERAGE | | 93.3% | 90.0% | 0.854 | 97.0% | 86.0% |

Sample: 10 weekly lens changes per patient (Total: 200 lenses)

* Only 9 lenses objectively assessed (1 lens lost each)

relevance to one another of subjective patient satisfaction and the objective clinical assessments by the practitioner.

Where, for the same lens, the objective and subjective assessments agreed a correlation co-efficient of 1.0 was assigned. In the case of a disagreement, the correlation of 0 applied. In this way the co-efficient of correlation figure calculated for the 10 week period.

Correlations between subjective patient satisfaction and objective clinical practitioner assessment for each of the individual patients are shown in column 3 of the results table, along with the overall average.

**Reliability**

As outlined earlier, reliability percentages were arrived at after comparison of assessments made on the same lenses when observed on 2 occasions unknown to either the patient or the investigator. These figures for objective investigator reliability and subjective patient reliability of assessment are shown in columns 4 and 5 of the table, Table 3.

It is especially interesting to note the reliability of some of the patients who

reported particularly poor reproducibilities. For example, patient "8 Right" assessed only 50% of her lenses as having been reproduced to her satisfaction. However her reliability in making these assessments was only 40% — in other words, of the 5 lenses worn for 2 separate weeks she was only in agreement with herself for 2 out of the 5 lenses. One could argue that with such poor reliability of patient assessment, her resultant figure for reproducibility should be ignored. This however is not a valid point as this patient in clinical practice would still be dissatisfied with 50% of the lenses supplied to her. It is agreed that this dissatisfaction is not all due to the lenses and that individual patient personalities are involved. Nevertheless these patients exist and their subjective assessment of reproducibility to their own satisfaction (regardless of reason) must still be considered.

**Reasons for Lens Rejection**

Having assessed objective and subjective reproducibility at 93.3% and 90.0% respectively it is relevant to examine the reasons why the remaining lenses were rejected.

Using the standards already discussed in Table 2, objective practitioner assessment rejected a total of 13 lenses from the 197 seen during the course of the study. These rejections fell into 4 groupings of standards which failed to be met. See Table 4.

The inter-relationship between one failed standard and another is easily understood when considered in the clinical sense. For example, group 2 clearly represents a substantially steep fitting lens, decentring probably inferior and temporal, showing a distorted retinoscopic reflex after each blink, a varied and widely fluctuating visual acuity and a non repeatable end point of refraction.

Subjective patient assessment rejected a total of 20 lenses from the 200 worn during the study. The principal reasons for rejection given by the test patients are shown in Table 5. Where this was a split decision between more than one area, the rejection reasons shown in the table was also distributed accordingly. This explains the appearance of fractions.

**TABLE 4**

**REASONS FOR OBJECTIVE LENS REJECTION**

| | |
|---|---|
| Group 1 | |
| ★ Centration | |
| ★ Post Blink Movement | |
| ★ Stability of V.A. | |
| (INTERPRETATION: Flat Fitting) | 2 rejected |
| Group 2 | |
| ★ Centration | |
| ★ Retinoscopic Reflex | |
| ★ V.A. with contact lens | |
| ★ End Point of Refraction | |
| ★ Stability of V.A. | |
| (INTERPRETATION: Steep Fitting) | 4 rejected |
| Group 3 | |
| ★ V.A. with contact lens | |
| ★ Over refraction | |
| (INTERPRETATION: Incorrect Power) | 6 rejected |
| Group 4 | |
| ★ V.A. with contact lens | |
| ★ V.A. with over refraction | |
| ★ Lens inspection | |
| (INTERPRETATION: Soiled Lens Surface) | 1 rejected |
| TOTAL: | 13 lenses |

**TABLE 5**

**REASONS FOR SUBJECTIVE LENS REJECTION**

| | | |
|---|---|---|
| Location ..... | 4 | lenses rejected |
| Vision ..... | 4 | lenses rejected |
| Comfort ..... | 11.5 | lenses rejected |
| Lens Integrity ..... | 0.5 | lenses rejected |
| TOTAL: | 20.0 | |

### Quality Control

During the course of the study, it was not found necessary to reject any of the lenses used on the basis of a failure in quality control.

### Shipping Distortions

Of the 100 new lenses used during the study, 83 were found to be shipped as preferred — i.e. floating freely, and concave side up. Thus the lenses which adhered to the vial or stopper and needed to be boiled free represented 17% of the sample. This compares to the figure of 30% attributed to Holden (Bausch & Lomb, ref: b) for the proportion of unopened lenses having distortions and requiring boiling to improve them.

### Lost Lenses

Bausch & Lomb (ref: c) quotes a lost lens expectation figure of 1 lens per pair-wearing patient per annum. This study covered a period of 10 weeks for 10 patients, giving a total of 100 "patient weeks" or 1.92 "patient years". During the period of the study the test patients lost a total of 3 single lenses. This then represents a single lens loss rate of 1.56 lenses per pair wearing patient per annum. There were no lenses split or damaged due to patient mishandling during the course of the study.

## DISCUSSION & CONCLUSION

After viewing the results of this study (Table 6) there is no doubt that the spin cast hydrophilic lens manufactured by Bausch & Lomb Soflens is indeed "highly reproducible". Coombes (1971) claims that this "inherent reproducibility" is the result of the spin casting method and the exacting quality assurance measures taken in manufacturing "uniform quality, interchangeable lenses".

We are offered two basic methods of hydrophilic lens manufacture; spin casting and lathe cutting. While the spin casting method has the disadvantage of a limited range of lens specifications available, it must be conceded that its reproducibility of 90 to 93.3% is high. Whether it is the highest in the contact lens industry, as mentioned earlier, is impossible to gauge, but it is certainly impressive.

A summary of overall results is shown in Table 6. In addition to the figures for reproducibility, those for the assessment reliabilities and the correlation between patient satisfaction and practitioner assessment are also interesting.

**TABLE 6**

**SUMMARY OF RESULTS**

**BAUSCH & LOMB SOFLENS (SPUN CAST)**

| | |
|---|---|
| **Reproducibility** to Objective Practitioner Satisfaction: | 93.3% |
| **Reproducibility** to Subjective Patient Satisfaction: | 90.0% |
| **Correlation** between Practitioner Assessment and Patient Satisfaction: | Co-eff = 0.854 |
| **Reliability** of Practitioner Assessment: | 97.0% |
| **Reliability** of Patient Assessment: | 86.0% |

The correlation figure of 0.854 is explained largely by the poor figure for patient assessment reliability. This reliability is not surprising when the range of personalities in the community is considered. In fact, it is perhaps more surprising to some readers that there were patients who achieved 100% reliability while still rejecting some lenses. Another explanation for the correlation result is contained in the table showing principal reasons for subjective lens rejection (Table 5). The majority of patients rejected lenses on the basis of comfort. As this is a difficult symptom for the practitioner to measure objectively, correlation would certainly have been improved in the clinical situation where practitioner-patient communication regarding the lenses is permitted.

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