Overall performance of the Safegel 1 day lens

Nick Atkins describes the results of a UK multi-centre practice-based study looking at Safegel 1 day lenses

Discontinuation from contact lens wear occurs as a result of poor comfort in as many as 72 per cent of the cases,[1] with dryness being the most commonly reported symptom.[2-4] Symptoms of discomfort and dryness with contact lens wear have been related to, among other things, dehydratation,[5] protein and lipid deposition,[6] modulus of rigidity, wettability and lubricity.[7,8]

Consequently much contact lens research and development has focused on providing even more comfortable contact lenses and specifically lenses that help eliminate dryness and other undesirable sensations. Contact lens and lens care manufacturers have spent millions working on innovative new products; from low dehydrating and more lubricious lens materials, to adding a variety of wetting and lubricating agents into multi-purpose solutions and, most recently, to lens materials. One such product to take the latter approach is Safegel 1 day, which was launched into the UK at Optrafair 2007. This patented lens material incorporates the biopolymer sodium hyaluronate (hyaluronic acid or HA) into its lens matrix, the slow release of which its manufacturer claims will improve long-term comfort.

Sodium hyaluronate

HA is currently showing great favour for its biomimetic properties and the benefits this brings to contact lens rewetting and dry eye drop formulations.[9,10] HA is a naturally occurring linear structured polysaccharide found in the aqueous and vitreous humour and the synovial fluid of joints. It is increasingly popular in dry eye preparations in differing concentrations. It is a viscoelastic, biological polymer which is pharmacologically inert, making it non-toxic. The polymer displays rheological, non-Newtonian behaviour, in that when a force is applied to a non-Newtonian liquid, viscosity decreases, unlike Newtonian liquids where viscosity remains constant. This means that HA mimics the natural tear film in becoming more elastic during the blink, increasing spreading and improving aqueous lubrication of the anterior ocular surface epithelial tissues.

HA has also been shown to have mucoadhesive properties which may help increase tear-film stability by mimicking the epithelial glycocalyx in aqueous deficient dry eyes.[11] HA has been shown to increase tear break-up time.[12,13] The all important sensations of 'burning' and 'grittiness' commonly reported in dry eye are significantly relieved when HA is used in place of hypromellose.[14] It is these properties that started the inventors' quest to see if HA could be incorporated into a hydrogel lens material to be slowly released into the pre- and post-lens tear film.

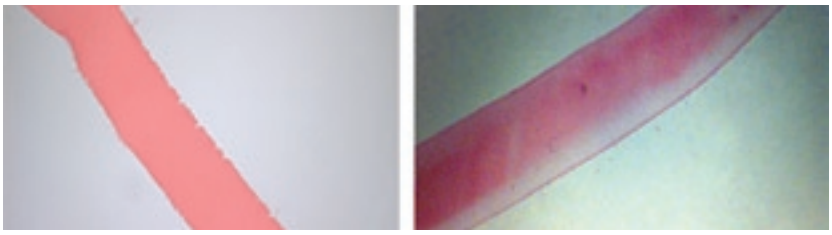


Figure 1 Safegel section stained with safranin (left). Safegel section stained with safranin after eight hours wear (right)

Safegel 1 day

The Safegel 1 day lens used in this study is composed of two polymers, the synthesised polymer Filcon 1B, constitutes the solid structure of the lens, while the watery part is enriched with the natural polymer HA, that once hydrated forms the natural hyaluronate-gel. HA supports longer lens hydration as well as the continuous lubrication and stabilisation of the pre-corneal tear film, thus improving subjective comfort while wearing the lens. Table 1 shows the parameters of Safegel 1 day although it is important to note that only the 14.10mm diameter lenses were used as part of this study.

Work at the Department of Neurosciences, Ocular Clinic, University of Padua has confirmed that HA is an integral part of the lens material and does move into the tear film during eight hours' wear.[15] Figure 1 shows an image of a lens from this study stained with safranin which binds to natural polysaccarides, as well a section after eight hours' wear which clearly shows the loss into the tear film of sodium hyaluronate from the anterior 25 per cent of the lens.

UK practitioner field study

Recent assessments have also established that regular users of soft contact lenses find that the Safegel lens can provide a greater level of tolerance and comfort than lenses hydrated in saline solution.[16] However, until now there has been no UK generated data.

During 2007 several UK-based practitioners were invited to participate in a practice-based study to evaluate the Safegel 1 day lens. This was not a true clinical trial, more a real-world evaluation by both patient and practitioner, where the practitioner was free to select which patients were fitted, albeit within the acceptance criteria of the study. Simple practitioner and patient questionnaires were used to gather data on lens performance. Apart from the obligatory discrete data – for ease of completion by

TABLE 1
Safegel 1day parameters

Water content	60%	
Tint	light blue with UV protection	
BOZR	8.60mm	
Diameter	**14.10mm**	**13.80mm**
Power range	-0.50 to -6.00 (0.25 steps) -6.00 to -8.00 (0.50 steps) -8.50 to -10.00 (0.50 steps) +0.50 to +4.00 (0.25 steps)	-0.50 to -6.00 (0.25 steps) -6.00 to -12.50 (0.50 steps) +0.50 to +4.00 (0.25 steps) +4.50 to +7.00 (0.50 steps)
Centre thickness	0.08mm (centre -3.00)	
Front curve	Aspheric (dioptric power control)	

both patient and practitioner – the forms were largely made up of statements with which the completer had to simply rate their level of agreement or disagreement on a five-point scale.

Eight practices participated, supplying completed paperwork for a total of 37 patients' fittings (74 eyes). Thirty-one patient and 29 practitioner follow-up forms were returned for analysis. There was no financial incentive to participate in the study although the lenses that the patient used were supplied without charge.

Each practitioner was asked to enter up to five subjects into this study. Each subject was examined at the initial visit to determine eligibility and to be eligible none of the exclusion criteria could be present. The key exclusion criteria included:

- Any anterior membrane dystrophy or other corneal dystrophy, corneal vascularisation or neovascularisation, ocular disease, lid or conjunctival abnormality or evidence of infection
- Any oedema, staining, corneal opacity or iritis as viewed by slit lamp (mild staining or mild limbal or bulbar injection were permissible in existing lens wearers at the discretion of the practitioner)
- Dry eye disease or a chronic level of ocular dryness that has previously caused discontinuation of contact lens wear or currently makes regular contact lens wear (≤eight hours/day) impossible

The third criterion was important as Safegel is designed for the alleviation of dry eye sensations in relatively successful lens wearers with a view to extending wearing times and not to be worn by patients with ocular dryness that was previously a contraindication to or had previously prevented contact lens wear.

The lenses were fitted by simply selecting the appropriate power and assessing the fit in accordance with soft contact lens fitting criteria. Enough lenses were supplied, depending on patient usage, to get the wearer through to the next aftercare visit when used on their usual schedule. Only one follow-up visit was required and this was scheduled at an interval of two to four weeks after initial dispensing. Classification of clinical findings followed the Efron Grading Scale, but on a simple one to four numerical scale.

Two documents, the practitioner report form and the patient questionnaire, were requested to be completed at both the initial (dispensing) and the follow-up visit. If a patient had to be seen at a time other than the scheduled visit, the investigator was asked to complete the follow up documentation as an unscheduled visit. No patients returned for an unscheduled visit in this study.

Results

The average age of the study participants was 37 years with the youngest recorded being 18 and the oldest 60. With the exception of three hypermetropes all the patients were myopic from -0.75D to -6.00D, the mean myopic powers of the Safegel 1 day lenses dispensed being -2.76D right and -2.89D for the left eye. The mean K readings for the right eye were 7.82 x 7.76 and for the left eye 7.79 x 7.71, with the steepest cornea being 7.25 x 7.30 and the flattest 8.65 x 8.50.

The type of lenses worn immediately prior to refitting as well as their prevalence can be seen in Figure 2. Figure 3 shows the clinical grading levels of five clinical signs, namely corneal oedema, corneal staining, conjunctival staining, limbal redness and lid changes. It can be seen that all patients demonstrated no or low levels of these signs, typically no more than grade one on the Efron scale both at dispensing and at the follow-up visit. There were, however, a range of minor symptoms reported by patients at both dispensing and follow-up. Figure 4 shows the incidence of symptoms reported at the follow-up appointment, with dryness being most prevalent, particularly later in the day.

Wearing times

Patients' lens wearing experience ranged from less than a year to more than 10 years, with one patient having never worn lenses before. The mean number of years was between eight and nine with wear being relatively full-time with the mean number of days' wear per week being six. Wearing times recorded for patients with their existing lenses averaged a minimum of nine hours and a maximum of 11 hours with previous lenses at the dispensing visit. Interestingly both minimum and maximum wearing times increased by two hours by the follow-up visit, with the mean maximum wearing time reported with Safegel 1 day as 13 hours.

Lens fit and vision

Practitioners were simply asked to assess lens fit based on whether the movement and centration met with their expectations for a well fitting soft lens. Figure 5 shows that 92 per cent of practitioners strongly agreed or agreed

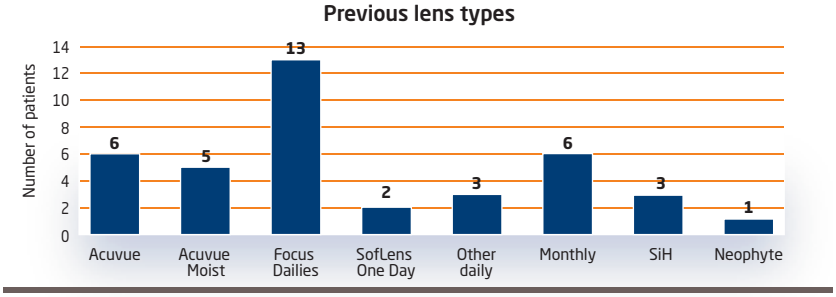
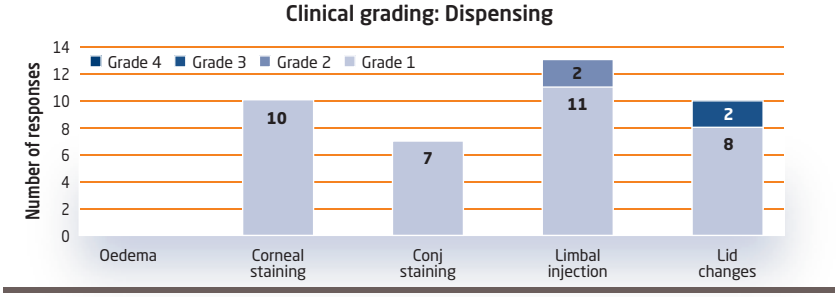


Figure 2 Previous lens types worn



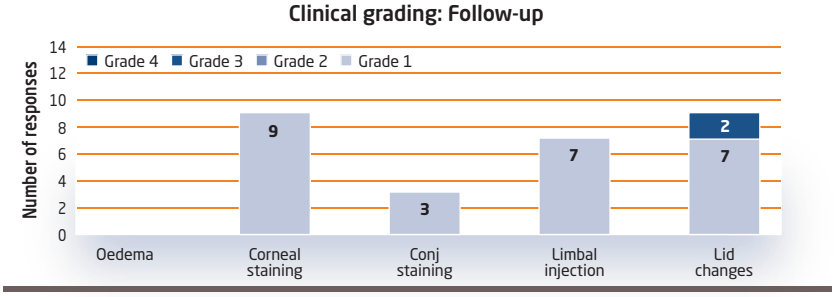


Figure 3 Clinical signs pre and post fitting

(top 2 box) with the statement that the movement of the lenses fitted met their expectations and that 88 per cent were also top 2 box in agreeing that the lens centration met their expectations. Importantly, no practitioner felt the fit unacceptable by disagreeing with these statements. Ninety-four per cent of practitioners strongly agreed or agreed with the statement that the vision with the lenses met their expectations. Only one patient had disappointing visual performance, with the practitioner disagreeing with this statement.

Lens comfort

Patient comfort was rated on insertion, in the middle of the day and at the end of the day on a five-point scale from very comfortable to intolerable. Patients who had previously worn lenses were asked to rate the comfort compared to their previous lenses. At dispensing all patients rated the comfort on insertion either very comfortable (70 per cent) or comfortable (30 per cent) and this was either better than (62.5 per cent) or the same (37.5 per cent) as their previous lenses.

Figure 6 shows the middle and end of day comfort at the follow-up visit and shows how this compared with the lenses the patients were wearing prior to the refit. Interestingly it can be seen that the number of patients who rated the comfort as better than their previous lenses increased as the day went on, with 62 per cent of patients rating the comfort of Safegel 1 day as better than their previous lenses at the end of the day.

As the lenses claim to slowly release sodium hyaluronate during the day, patients were also asked to rate how wet the lenses felt upon removal and how this compared with their previous lenses. It can be seen from Figure 7 that 63 per cent of patients agreed that the lenses felt wet to the touch and almost half felt that they were better than their previous lenses.

Finally, patients were asked their level of agreement with statements about wearing Safegel 1 day. Seventy-five per cent of wearers strongly agreed or agreed that Safegel 1 day provided them with all-day comfort (Figure 8). Figure 8 also shows that almost half (49 per cent) strongly agreed or agreed they could wear Safegel 1 day longer than other disposable lenses they had tried.

The ultimate test is perhaps whether the patient would agree to buy the new lenses their practitioner has fitted them with and 81 per cent of respondents strongly agreed or agreed that they would like to continue with Safegel 1 day lenses (Figure 9). For many practitioners, another final proof as to whether a lens lives up to its manufacturer's claims is how much the patient is prepared to pay for the claimed performance improvement. In the case of Safegel, Figure 10 also shows that just under half (47 per cent) actually agreed to the statement that Safegel 1 day are worth paying more to wear.

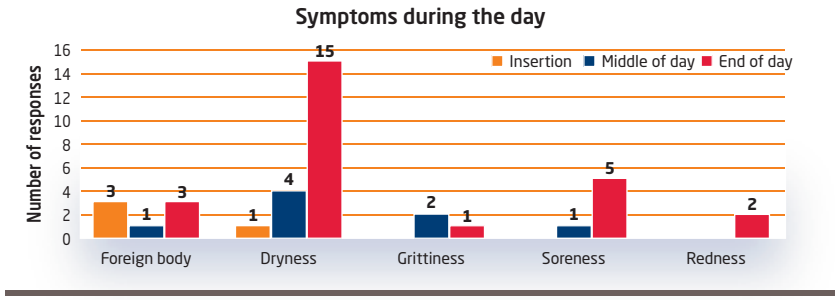


Figure 4 Patient discomfort symptoms at follow-up visit

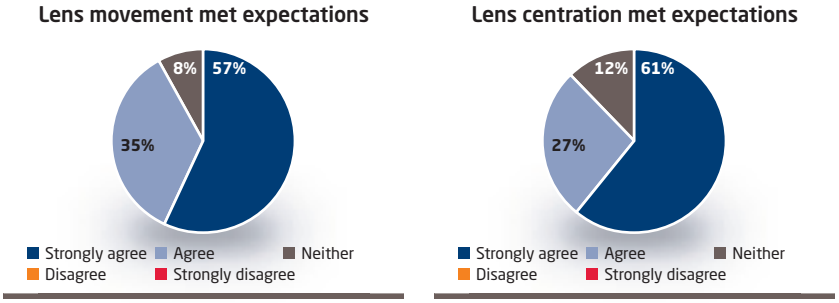


Figure 5 Lens movement and centration

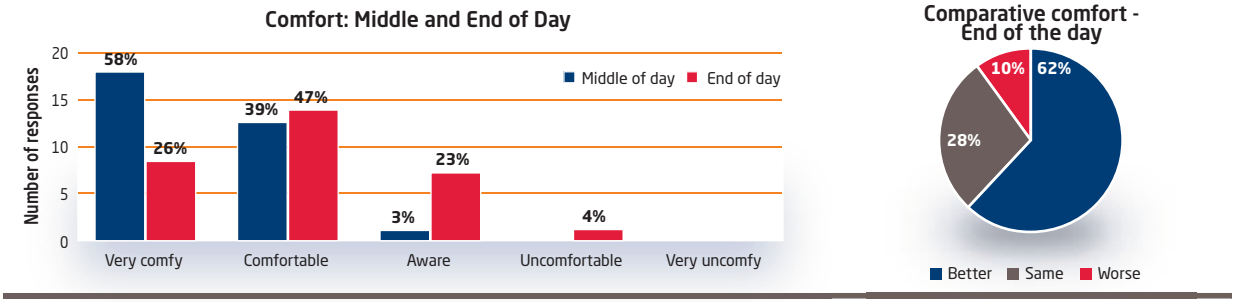


Figure 6 Comfort at middle and end of day

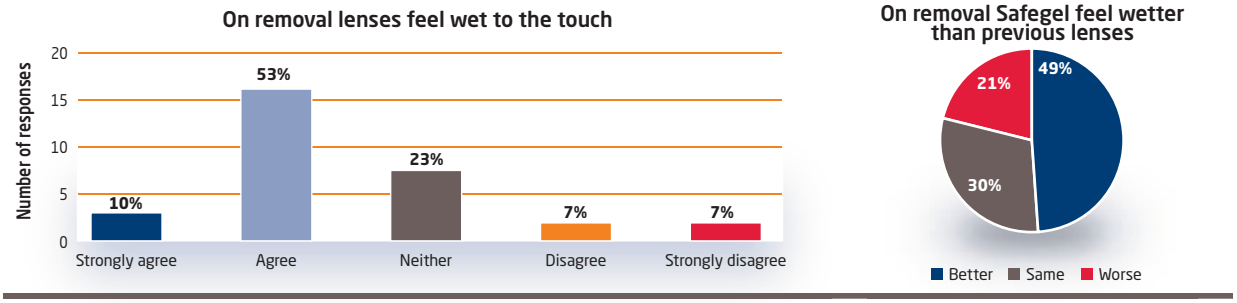


Figure 7 Patient agreement that lenses feel wet to the touch

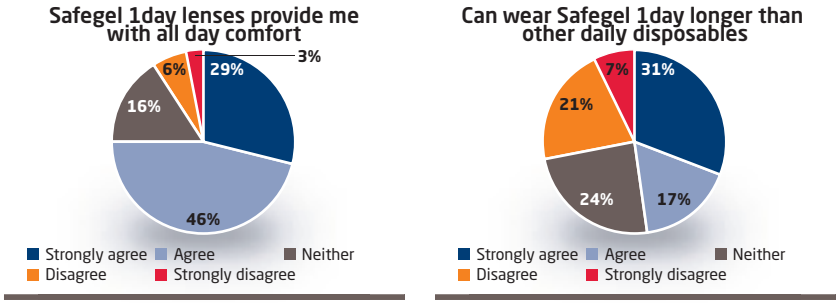


Figure 8 Patient agreement with statements about wearing Safegel 1 day

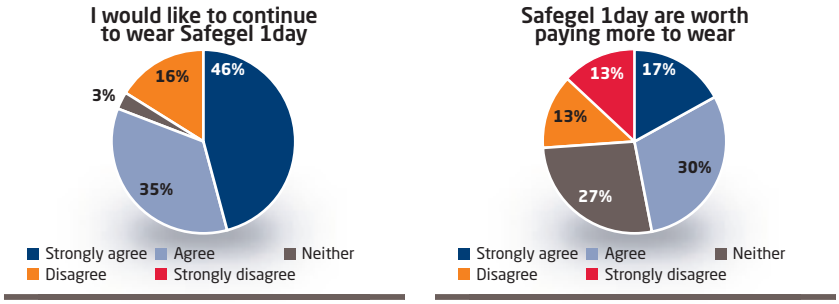


Figure 9 Patient agreement with statement about Safegel 1 day

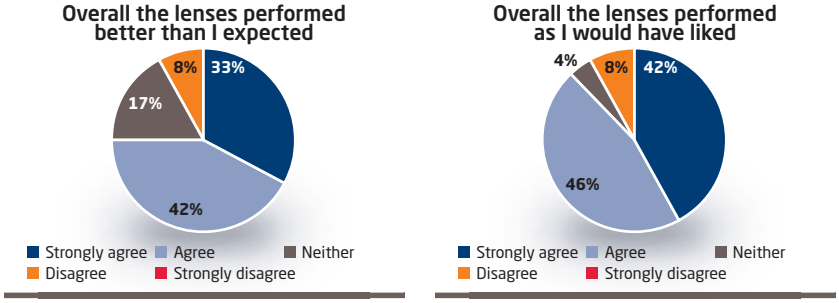


Figure 10 Practitioner assessment of overall Safegel 1 day performance

Overall performance

Eighty per cent of the practitioners strongly agreed or agreed that the patients' wearing times were better than expected, with 92 per cent also strongly agreeing/agreeing that patient acceptance of the lens met their expectations. Figure 11 shows that 75 per cent of practitioners agreed that 'overall the lenses performed better than I expected'. As practitioner expectations of a new product will vary, it is just as important to note that the top 2 box of strong agreement and agreement with the statement that 'overall the lenses performed as I would have liked', was even higher at 88 per cent (Figure 10).

Conclusions

It appears from new product development that there are two principal approaches to improving lens comfort and the symptoms associated with dryness. One is the more passive approach of maintaining hydration and making the lens as lubricious as possible. A second approach is to use additives in the lens blister or ideally within the lens matrix in order to achieve similar goals, but also to actively release wetting, and thus comfort enhancing, agents into the tear film during wear to promote improved comfort for longer wearing periods. The range of Safegel lenses takes the latter approach with the slow release of sodium hyaluronate into the tear film during wear.

While this study did not take a highly scientific approach to assessing the lenses, it reports back on the typical approach an everyday practitioner will follow when introducing new lenses into his or her practice. And from the data it can be seen that the response of both practitioners and their patients to the comfort enhancing claims of this unique lens material is generally very positive. This supports the author's own experiences and suggests that this lens technology has a definite place in helping practitioners in their ongoing battle to prevent symptoms associated with lens dryness and improving patients' wearing times, particularly in the increasingly harsh modern environments in which contact lenses commonly need to be worn.

References

1 Schlanger JL, Schwartz CA, Leser E. Happy patients: connecting comfort and compliance. *Spectrum,* 1993;8:45-7.
2 Riley C, Young G, Chalmers R. Prevalence of ocular surface symptoms, signs, and uncomfortable hours of wear in contact lens wearers: the effect of refitting with daily-wear silicone hydrogel lenses (senofilcon). *Eye Contact Lens,* 2006;32:281-6.
3 Begley CG, Caffery B, Nichols KK, *et al.* Responses of contact lens wearers to a dry eye survey. *Optom Vis Sci,* 2000;77:40-6.
4 Santodomingo-Rubido J, Wolffsohn JS, Gilmartin B. Conjunctival epithelial flaps with 18 months' silicone hydrogel contact lens wear. *Eye Contact Lens,* 2007 (in press).
5 Morgan PB, Efron N. *In vivo* dehydration of silicone hydrogel contact lenses. *Eye Contact Lens,* 2003;29:173-6.
6 Jones L, Senchyna M, Glasier MA, Schickler J, Forbes I, Louie D, May C. Lysozyme and lipid deposition on silicone hydrogel contact lens materials. *Eye Contact Lens,* 2003;29:S75-9.
7 Tighe B. Silicone hygrogel materials: how do they work? In: Sweeney DF, ed. *Silicone Hydrogels: the rebirth of Continuous Wear Contact Lenses.* Oxford: Butterworth-Heinemann, 2000:1-21.
8 Steffen R, Schnider C. A next-generation silicone hydrogel lens for daily wear. *Optician,* 2004;227:10-13.
9 Atkins N. Hycosan and its new delivery system. *Optician,* 2006; 231: 16-18.
10 Atkins N. Clinitas: A targeted approach to the management of dry eye disease. *Optician,* 2008; 235; 26-30.
11 Saettone MF, Chetoni P, Torracca MT, Burgalassi S and Giannaccini B. Evaluation of muco-adhesive properties and in *in vivo* activity of ophthalmic vehicles based on hyaluronic acid. *Int J Pharmaceutics*, 1989; 51: 202-212.
12 Limberg MB, McCaa C, Kissling GE and Kaufmann HE. Topical application of Hyaluronic acid and chondroitin sulphate in the treatment of dry eyes. *Am J Ophthalmol*, 1983; 103: 194-197.
13 Mengher LS, Pandher KS, Bron AJ and Davey CC. Effect of sodium hylaluronate (0.1%) on break-up time (NIBUT) in patients with dry eyes. *Br J Ophthalmol*, 1986; 70: 442-447.
14 Bron AJ and Tiffany JM. Pseudoplastic materials as tear substitutes. In: The Lacrimal System, (Ed. Van Bijsterveld OP, Lemp MA and Spinnelli), Kruger & Ghedini Publications, Amsterdam, 1991: 23-27
15 Atkins N. Lens approach to dry eye. *Optician,* 2006;232;37-38.
16 de Martin G. A new lens for dry eye – a comparative trial. *Optician,* 2006; 232; 30-31.

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