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Which soft lens power is better for piggyback in keratoconus? Part II

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ABSTRACT

Purpose: To evaluate how soft lens power affects rigid gas-permeable (RGP) lens power and visual acuity (VA) in piggyback fittings for keratoconus.
Methods: Sixteen keratoconus subjects (30 eyes) were included in the study. Piggyback contact lens fittings combining Senofilcon-A soft lenses of −6.00, −3.00, +3.00 and +6.00 D with Rose K2 RGP contact lenses were performed. Corneal topography was taken on the naked eye and over each soft contact lens before fitting RGP lenses. Mean central keratometry, over-refraction, RGP back optic zone radius (BOZR) and estimated final power as well as VA were recorded and analyzed.
Results: In comparison to the naked eye, the mean central keratometry flattened with both negative lens powers ($p < 0.05$ in all cases), did not change with the +3.00 soft lens power ($p = 1.0$); and steepened with the +6.00 soft lens power ($p = 0.02$). Rigid gas-permeable over-refraction did not change significantly between different soft lens powers (all $p > 0.05$). RGP's BOZR decreased significantly with both positive in comparison with both negative soft lens powers (all $p < 0.001$), but no significant differences were found among negative- or positive-powers separately (both $p > 0.05$). Estimated RGP's final power increased significantly with positive in comparison with negative lens powers (all $p < 0.001$), but no significant differences were found among negative or positive lens powers separately (both $p > 0.05$). Visual acuity did not change significantly between the different soft lens powers assessed (all $p > 0.05$).
Conclusion: The use of negative-powered soft lenses in piggyback fitting reduces RGP lens power without impacting VA in keratoconus subjects.

Rigid gas-permeable (RGP) contact lenses represent the most common and successful management option for early to moderate cases of keratoconus [1], despite the development of surgical treatments that aim to regularize the anterior corneal surface (i.e. intrastromal corneal ring implantation) [2] or to stabilize the progression of the disease (i.e. cross-linking) [3]. Currently, a number of contact lens designs and materials are available to fit irregular corneas, particularly keratoconus as it is the most common primary ectasia [1,4]. Corneal RGP [5,6], semi-scleral [7,8], scleral [9], hybrid [10] or custom-made soft contact lenses [11,12] are commonly used to manage keratoconus patients. However, corneal RGP lenses are probably the most widely prescribed contact lens design in keratoconus subjects worldwide. Discomfort or recurrent anterior corneal surface erosions are sometimes associated with the use of these lenses leading to reduced wearing time and sometimes to discontinuation from lens wear. In cases of unbearable discomfort with RGP lens wear, a soft lens can be used as a carrier of the RGP lens; the fitting of a RGP lens onto a soft contact lens is known as piggyback system and was first described by Baldone in the early 1970s [13,14]. It is estimated that piggyback is used by about 2% of keratoconus contact lens wearers [15]. Furthermore, VA is similar with piggyback systems in comparison to RGP lens wear alone [16].

Piggyback fitting is normally recommended using a low-positive powered soft contact lens because it shifts the highest elevation of the cornea to a more centered location and hypothetically facilitates RPG lens centration, although the use of a negative-powered lens was recommended by Baldone in steeper corneas [17]. However, despite of the latter and although central keratometry is steeper in keratoconus in comparison to normal corneas, most

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practitioners continue using a low positive-powered soft lens in piggyback fittings for the keratoconic cornea [18,19]. In a previous study, we demonstrated that negative-powered soft lenses create a flatter and less powerful anterior corneal surface, which reduces coma-like aberration potentially leading to an improvement in visual acuity, thus making them more suitable for piggyback contact lens fittings [20]. However, the results of that study were devired FROM using a theoretical approach as no RGP lenses were fitted over soft contact lenses of different powers. Furthermore, as a result of the latter, we were unable to assess the impact of negative-powered soft lenses on visual acuity or RGP lens fitting (i.e. centration, movement and power). On the contrary, in a very recent study performed on regular corneas, the use of a low positive-powered soft contact lens was recommended for piggyback fitting in all cases (i.e. regular and irregular corneas) because: (1) it is believed to facilitate RGP lens centration; and (2) it does not contribute to the total power of the piggyback lens system [21].

Based in all the above, the purpose of the present study was to evaluate whether positive- or negative-powered soft lenses are better for piggyback in keratoconus with regards to RGP lens fitting and visual acuity.

1. Methods

This was a prospective non-dispensing masked study. Sixteen subjects (30 eyes) of at least 18 years of age with keratoconus were enrolled. A comprehensive optometric and ophthalmologic examination was performed in all cases which included: uncorrected and corrected visual acuity with contact lenses, biomicroscopy examination, fundus evaluation, keratometry and corneal topographic analysis (Pentacam Eye Scanner, software version 1.16.r:04, Oculus Inc, Wetzlar, Germany). The patients should be habitual RGP lens wearers to be enrolled. Exclusion criteria were previous history of acute corneal hydrops, corneal surgery or other ocular disease. All subjects were provided written informed consent to participate in the study. The study followed the Tenets of the Declaration of Helsinki and was approved by the Institutional Review Board of MGR Doctores Ophthalmology Clinic, Madrid, Spain.

The soft contact lenses used in the study were made of Senofilcon A material and all had BOZRs of 8.40 mm (Johnson & Johnson Vision Care Inc., FL, USA). RGP lens fitted in this study were Rose K2 manufactured in tisilfocon A material (Menicon Co., Ltd. Nagoya, Japan). In subjects with bilateral keratoconus, the study was performed on both eyes as it is well established keratoconus is a bilateral and asymmetric condition [22,23].

1.1. Fitting method

Corneal topography was obtained in the naked eye (i.e. without contact lens) in eligible subjects. Then, one of the soft lenses were fitted and allowed to settle down on the eye for 10 min before taking a new corneal topography with the soft lens over the cornea (Fig. 1). Then, a RGP contact lens was fitted over the soft contact lens with a BOZR equal to the mean central keratometry measured over the soft lenses minus 0.2 mm, accordingly to the manufacturer's fitting guide. Then, the BOZR was flattened or steepened in 0.10 mm steps until the first definite apical clearance lens (FDACL) was observed following previous reported methodology [5,24]. Once the FDACL was achieved, the BOZR was flattened 0.10 mm to obtain a three-point-touch fitting approach [5]. The RGP lens was allowed to settle on the eye for 30–45 min and the lens fitting was assessed using low weight molecular fluorescein (Haag-Streit, Koeniz, Switzerland). The soft lens was required to cover the entire cornea without overpassing the limbus, whereas the RGP lens must be well centered whithin the limbal area. A RGP lens was considered well centrated when the pupil was covered by the lens' optic zone without touching the limbus on primary gaze (Fig. 2). Rigid gas-permeable lens movement was required to be between 0.5 and 1.5 mm with blink. When RGP lens centration and/or movement were inappropriate, changes to the edge lift were performed to improve fitting (i.e. excessive movement or upper lens decentration was remedied by decreasing the edge lift, whereas insufficient movement or downward lens decentration was solved increasing the edge lift). Once an optimal lens fitting was achieved, an over-refraction was performed. The procedure described above was repeated with soft lenses of −6.00, −3.00, +3.00 and +6.00 D, consecutively. The same investigator (M.R.-J.) carried out all the lens fittings and assessments.

1.2. Statistical analysis

Differences in mean central keratometry, RGP over-refraction, RGP's BOZR and RGP final estimated power as well as best contact lens visual acuity (BCLVA), between the naked eye and the different soft lenses were analyzed using a repeated measures analysis of variance (ANOVA) followed by post-hoc tests, if necessary. Equality of variances and sphericity were tested using the Levene and Mauchly tests, respectively, to select appropriate p-values. Statistical analyses were performed using SPSS 15.0 software (SPSS Inc, Chicago, IL, USA). The level of statistical significance was taken as 5%.

2. Results

Eleven males (68.8%) and 5 females (31.3%) habitual corneal RGP contact lens wearers with keratoconus were included in the study. The mean age (±SD; range) of the subjects was 34.9 ± 8.8 (range 21.3–49.4) years. Thirty eyes (16 right eyes and 14 left eyes) were fitted. According to the keratoconus severity score [25], 21 eyes and 9 eyes had mild and moderate keratoconus, respectively. No subjects were previously fitted using a piggyback contact lens system.

An average of 2.55 ± 0.78 RGP trial lenses were necessary to achieve an optimal piggyback lens fit. No clinically significant differences on RGP lens centration or movement were found between different soft lens powers fitted in this study (Fig. 2).

Significant differences were found in mean central keratometry between the different conditions tested ($p < 0.001$). In comparison to the naked eye, the mean central keratometry flattened with negative-powered soft lenses ($p < 0.05$ with −3.00 and −6.00 soft lenses); did not change with the +3.00 soft lens power ($p = 1.0$); and steepened with the +6.00 soft lens power ($p = 0.02$) (Table 1).

Although RGP over-refraction difference between −6.00 and +6.00 soft lenses was 3.26 D, being higher (more negative) with both positive lenses in comparison with both negative lenses (Table 1), such differences were not statistically significant ($p = 0.91$, Table 2).

Statistically significant differences were found in RGP's BOZRs fitted on top of each of the 4 different soft contact lenses ($p < 0.001$). The BOZRs were steeper with both positive power lenses in comparison with both negative power lenses (Table 1). However, the BOZR was not statistically different among negative power (−3.00 vs −6.00 D) or positive power (+3.00 vs +6.00 D) lenses (Table 2). The more positive the soft contact lenses fitted, the smaller the differences between mean central keratometry and BOZR (Fig. 3).

Statistically significant differences were also found in estimated RGP's final powers ($p < 0.001$, Fig. 4). The estimated final power of the RGP lens increased significantly with both positive power lenses in comparison with both negative power soft lenses (all $p < 0.001$), but no significant differences were found among negative- or positive-powers separately (both $p > 0.05$).