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Short title: Hybrid lenses in keratoconus

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Abstract

Objectives

To report the clinical outcome of hybrid contact lens fitting in keratoconus.

Methods

A retrospective chart review was performed of keratoconus patients who had been fitted with hybrid contact lenses in one or both eyes. Patients with a history of previous intraocular surgery (except for corneal crosslinking) and relevant concurrent ocular disease limiting visual outcome were excluded. The outcome data at 6-month follow-up included hybrid lens corrected visual acuity, wearing time and lens discontinuation.

Results

Fifty-four keratoconus patients (102 eyes) were included. Mean visual acuity with habitual correction prior to hybrid lens fitting was 0.63 ± 0.29 (decimal Snellen). Eyes were fitted with Eyebrid lenses (LCS Laboratories, Caen, France) and SynergEyes lenses (SynergEyes Inc, Carlsbad, CA). Refits were necessary in 13 eyes, either because of poor fitting (76.9%) or suboptimal refraction (23.1%). Visual acuity had significantly improved with hybrid lenses (0.93 ± 0.14; $p<0.0001$). In 37 eyes (37.8%), hybrid lens wear was discontinued within 6 months following lens fitting. Reported issues were discomfort in 27 eyes (73%), handling difficulties in 14 eyes (37.8%) and poor vision in 1 eye (2.7%). Success rate of lens fitting was significantly correlated to cone morphology ($p=0.01$).

Conclusions

New generation hybrid lenses are an appropriate, safe therapeutic option for keratoconus patients. Excellent visual outcomes are achieved in successful fittings, yet a dropout rate of 37.8% - mainly occurring in sagging, more peripheral, cones - still limit their clinical success.

Key words:

Keratoconus; hybrid lenses; contact lenses

Optical correction in keratoconus classically involves fitting of corneal rigid gas permeable (RGP) contact lenses.[1] The shape-retaining nature of these lenses allows the tears to pool in the precorneal space, effectively masking the irregular surface. However, lens tolerance varies significantly among individuals, and especially in highly ectatic eyes, lens instability and loss of the lens can limit the effectiveness of corneal RGP lenses.[1] The range of other available lens types for irregular corneas has expanded, especially over the past two decades.[2] Published reports have mainly focused on modern scleral lenses and their ability to postpone transplant surgery.[3,4] Few reports have been published on the newer generation hybrid contact lenses and their clinical performance.[5-8] Hybrid lenses were originally developed in the 1980s based on the practice of "piggybacking", wearing a soft lens under an RGP lens.[1] The piggyback system has the drawback of a double lens system, which is cumbersome for patients and has an increased risk of corneal hypoxia. In hybrid lenses, a center-zone RGP lens is fused to a soft peripheral skirt in a one-piece construction. The optical qualities of RGP material are thus combined with the comfort and stability of a soft contact lens. The first designs, the Saturn II (launched in 1985) and the SoftPerm (1989), were troubled with complications, ranging from a tight fit in the peripheral segment, poor oxygen permeability and deposit formation ~~and tearing at the interface~~.[9-10] Breakage at the RGP/hydrogel junction was reported to be as high as 48.5% of cases fitted with SoftPerm lenses.[6] Since 2005, SynergEyes (SynergEyes Inc., Carlsbad, CA) have sequentially launched their first-generation hybrid lenses with a patented hyperbond junction (SynergEyes A, multifocal (M), keratoconus (KC), post-surgical (PS) and ClearKone). Second generation SynergEyes lenses (Duette and Ultrahealth) were launched from 2010 onwards, and included a silicone hydrogel skirt (Dk of 84), as opposed to the hemiberfilcon A skirt (Dk of 9.3) incorporated in the first designs.[2] The EyeBrid hybrid lenses (LCS Laboratories, Caen, France) were introduced later (2012 in France, from 2014 onwards distribution in several countries worldwide). These lenses also feature a silicone hydrogel skirt and an increased range of fitting options and possibilities of a toric RGP center. The difference in junction design between SynergEyes and Eyebrid lenses is depicted in Figure 1. Lens removal of Eyebrids is facilitated by a removal plunger, to be placed on the soft peripheral zone, rather than the manual removal of other hybrid designs.

We aimed to investigate the clinical outcome of hybrid lens fitting in keratoconus patients with current designs (second-generation SynergEyes and Eyebrids) in a corneal referral hospital with special interest in the treatment of corneal ectasia.

Methods

We performed a retrospective chart review of patients with clinically diagnosed keratoconus who had been fitted with hybrid contact lenses in one or both eyes at the Department of Ophthalmology of Antwerp University Hospital (Belgium) between January 2014 and December 2018. This study was approved by the Ethics Committee of Antwerp University Hospital, Belgium. Billing records of all patients who had been fitted with hybrid lenses were identified (n=122). Subsequently, patient charts were reviewed and patients with a diagnosis of keratoconus were selected, based on characteristic slit-lamp findings and Scheimpflug tomographic features (Pentacam HR; Oculus Optikgeräte GmbH, Wetzlar, Germany) of a localized area of steepening in the anterior curvature, corneal thinning and increased posterior elevation. Exclusion criteria included patients with a history of previous intraocular surgery with the exception of corneal crosslinking and relevant concurrent ocular disease (such as retinal disease or significant cataracts). A total of 54 keratoconus patients (102 eyes) were eligible for further analysis. Contact lens fitting was performed by specialist optometrists in collaboration with an ophthalmologist with the use of trial sets. The cohort included both specialty lens naïve patients (n=23; 42.6%) and patients intolerant to other types of specialty contact lenses (n=31; 57.4%). In our center, specialty lens naïve keratoconus patients are first fitted with corneal RGP lenses. If no adequate fit can be achieved during the first lens fitting session, then fitting of a hybrid or mini-scleral lens is subsequently attempted. Lens characteristics of the hybrid lens designs included in this study are provided in Table 1, as well as the characteristics of the SynergEyes KC and ClearKone lenses. Medical records of eligible patients were reviewed, and the relevant demographic and clinical data were collected. Tomographic findings, obtained with the Pentacam HR, including maximal anterior keratometry (K_{max}) and thinnest corneal thickness (TCT) were also documented. Severity of keratoconus was classified based on K_{max} using the following definition: mild = K_{max} ≤50D; moderate = K_{max} >50D and ≤58D; severe = K_{max} >58D. The morphological pattern of the cone was classified using the axial curvature map into three categories: nipple, oval (or sagging) and globus cone. A nipple cone was defined as a small, near-central cone of 5 mm or less in diameter. In oval (or sagging) cones, the

apex was displaced below the midline, with a diameter > 5 mm, located in the mid-periphery. A globus cone had a diameter greater or equal to 75% of the diameter of the cornea. The cohort did not include pellucid-like, very peripheral cones as these are typically fitted with scleral lenses in our center. Criteria for successful wear of the hybrid lens included adequate comfort and wearing time (>8 hours per day) without significant induced corneal changes (such as corneal staining). Partial success was defined as lens wear limited to <8 hours per day or a few days per week due to moderate tolerance. The outcome data at 6-month follow-up included hybrid lens corrected visual acuity, duration of lens wear, and lens discontinuation. Results were tabulated in Excel (version 16.16.10, Microsoft Corp, Redmond, WA, USA) and statistical analysis was performed using XLSTAT (Version 2019.1.3, Addinsoft, Paris, France). Normality of data was tested with Shapiro-Wilks test. Non-normally distributed data were evaluated with the Wilcoxon signed-ranks test. Subgroup analysis was performed using the Mann-Whitney U test and Fisher's exact test. A p-value less than 0.05 was considered statistically significant.

Results

The charts of 54 keratoconus patients (102 fitted eyes) were reviewed. Six patients had 1 eye fit, and 48 had bilateral fitting. Patient characteristics are listed in Table 2. Visual acuity with habitual correction prior to hybrid lens fitting (mean ± standard deviation (SD)) was 0.63 ± 0.29 (range 0.05 – 1; decimal Snellen). Indications for hybrid lens fitting were insufficient visual acuity with habitual correction in 76 eyes (74.5%) and intolerance to other types of specialty contact lenses in 26 eyes (25.5%). The majority of eyes were fitted with Eyebrid lenses (78/102; 76.5%) (Table 3). Eyes fitted with SynergEyes Duette (n=11) and A (n=2) were predominantly mild cones. During the initial 6 months of hybrid lens wear, 18 lenses were reordered due to a tear in the junction (10 SynergEyes and 8 Eyebrids). Refits were necessary in 13 eyes (typically performed at the visit 4-6 weeks following lens dispensing), either because of poor fitting (10/13; 76.9%) or suboptimal visual acuity (3/13; 23.1%). Refits were predominantly adjustments of the same lens (11/13; 84.6%) rather than refits to different designs or brand (2/13; 15.4%). In 9 out of 13 eyes, hybrid lens wear was continued following refit. Visual acuity – as obtained with the final hybrid lens following refit when applicable - improved significantly with hybrid contact lens correction to 0.93 ± 0.14 ($p<0.0001$; Wilcoxon signed-rank test). An average of 1.3 visits per patient and 1.2 lenses per eye were needed to achieve a good fit. At 6-

month follow-up, hybrid lenses were worn successfully in 52 (51%) eyes and with partial success in 9 (8.8%). Two patients (4 eyes) were lost to follow-up (3.8%). In 37 eyes (37.8%), hybrid lens wear was discontinued within 6 months following fitting. Issues reported by patients were discomfort in 27 eyes (73%), handling difficulties in 14 eyes (37.8%) and poor vision in 1 eye (2.7%). The group of continued lens wear did not differ significantly from lens dropouts in terms of age (p=0.86) or history of crosslinking (p=0.81; Fisher's exact test). Outcome of fitting did not differ significantly by severity of disease (as defined by K_{max}) (p=0.2; Fisher's exact test). SynergEyes and Eyebrid lenses had similar dropout rates (p=0.64; Fisher's exact test) (Table 4). The morphology of the cone was significantly associated with treatment success, whereby sagging, more peripheral, cones yielded lower treatment success (p=0.02; Fisher's exact test) (Figure 2). Visual outcome in the 3 morphological types of keratoconus was similar: 0.92 ± 0.15, 0.93 ± 0.13 and 0.96 ± 0.09 for sagging, nipple and globus cones respectively (mean ± SD decimal Snellen acuity). The proportion of eyes not obtaining a hybrid-corrected visual acuity of 0.8 was higher among sagging cones (5/47; 10.6%) compared to nipple (2/50; 4%) and globus cones (0/5; 0%). Eyes that failed hybrid lens wear were refitted to soft contact lenses (9/37; 24.3%), scleral lenses (16/37; 43.2%) and corneal RGP lenses (4/37; 10.8%). Four patients returned to wearing glasses (8 eyes; 21.6%). Specialty lens refit was successful in 15 of 20 eyes (75%) (scleral lenses 11/16 (68.8%) successful, corneal lenses 4/4 (100%) success). Reasons for partial success (9 eyes) were discomfort (7/9; 77.8%) and handling issues (2/9; 22.2%). No severe complications (such as infectious keratitis or significant corneal neovascularization) occurred during follow-up.

Discussion

Specialty contact lens correction remains the cornerstone of visual rehabilitation in keratoconus patients.[11] Finding the optimal contact lens for an individual patient is often challenging, both for the patient and fitter. Corneal RGP lenses remain the gold standard first choice specialty lens in keratoconus, although recent reports on scleral lenses suggest a potential role for these lenses as a first choice.[12-13] Hybrid lens designs have undergone major changes since the limited success of the Saturn II and SoftPerm lenses, with the introduction of high Dk materials, newer types of RGP-skirt bonds and a wider range of fitting options. Few reports in peer-reviewed literature have since

elaborated on the clinical performance of these newer generation hybrid lenses and how they compare with other types of contact lens correction.[5-8] Initial clinical results with the first generation of SynergEyes lenses were published by Abdalla et al in 2010.[5] In their cohort of 61 eyes (44 patients) with keratoconus (58 eyes) or pellucid marginal degeneration (3 eyes) with a mean follow-up of 7.8 ± 4.6 months, they encountered a success rate of 86.9%. Saraç et al reported on 44 keratoconus patients fitted with hybrid lenses (Airflex (SwissLens) and Eyebrid lenses) in their analysis of contact lens fitting in lens-naïve patients.[6] Visual outcome was excellent but no further details on the clinical outcome of hybrids were offered. Another short-term outcome study was performed in 33 eyes of 18 patients fitted with SynergEyes ClearKone lenses.[7] A successful fitting was obtained in 83% of patients at 1-month follow-up, as compared to 61.1% in our cohort (60% of eyes). In the above-mentioned reports, patients previously successfully wearing SoftPerm hybrids[5] or other lens modalities including corneal RGP lenses[7] were included. These inclusion criteria, along with a shorter follow-up period, may have skewed the results towards a higher success rate of the first generation SynergEyes lenses. Uçakhan and associates recently reported on the outcome of hybrid lens fitting (Eyebrid and Airflex, SwissLens, Prilly, Switzerland) in a cohort of 33 patients with irregular astigmatism.[8] Nine patients (11 eyes; 27.5%) discontinued lens wear within follow-up of 2 months. No specific outcome results were provided for the subgroup of keratoconus eyes (37 of 47 eyes (78.7%) had keratoconus). Our success rate (60% of eyes) – with a mixture of lens naïve patients and patients intolerant to other specialty lenses - likely reflects the real-life clinical outcome of hybrid lens fitting in keratoconus patients. In those eyes achieving successful fitting, visual outcome is generally excellent. Hybrid lens-corrected visual acuity was 0.93 ± 0.14 in our cohort, which corresponds to the excellent visual outcomes in previous reports.[6,8] An important observation in our cohort, was the association between the success rate and cone morphology (Figure 2). Oval (sagging) cones, with a more decentered apex, had particularly worse success rates than nipple and globus cones. These latter two types likely allow better centration and adequate movement of the lens, thereby improving the overall fit of the hybrid lens. More peripheral cones will likely achieve more favorable results with scleral lenses, as these lenses vault over the cornea.

Discomfort was a major issue with SoftPerm lenses, occurring in 40% of the cases.[9] In the SynergEyes study of Abdalla et al, in which the first generation SynergEyes lenses with the

hemiberfilcon A skirt were fitted, discomfort occurred in 16 of 61 eyes (26.2%), and in most cases, this issue could be resolved. In the report of Ucakhan et al, 11 eyes (27.5%) discontinued hybrid lens wear within follow-up of 2 months, in which discomfort was the primary reason (5 eyes; 10.6%).[8] Discomfort was the main reason for abandoning hybrid lens wear in this study (27 of 37 eyes; 73%), despite the predominant use of second generation SynergEyes and Eyebrids (which both include a high Dk silicone hydrogel skirt). Hashemi et al performed a comparative (non-randomized) study in keratoconus patients, including 20 patients fitted with SynergEyes ClearKone hybrids and 20 with corneal rigid gas-permeable lenses.[14] Visual outcome results were similar in both groups, but the mean score of tolerance in the hybrid lens group was significantly higher than the RGP group at 2-month follow-up. Nau et al (2008) also compared wearing comfort of SynergEyes and corneal RGP in irregular corneas and reported on 54 patients fitted with first generation SynergEyes (2005-2006) for irregular astigmatism (57% keratoconus).[15] Improved comfort with hybrid lenses was reported in 79.5% of patients compared with rigid lens designs at 3-month follow-up. The short follow-up period in both comparative studies may not fully reflect the difference in tolerance on the longer term, as corneal RGP lenses typically require an adaptation period within the first weeks. Previous hybrid designs with low Dk values and poor lens mobility suffered from manifestations of corneal hypoxia, such as corneal neovascularization.[5,6,16] Cases of severe epithelial edema occurring in SynergEyes Clearkone wearers have also been described.[17] We did not encounter any hypoxia-related complications such as epithelial edema or corneal neovascularization in our cohort. With the exception of 1 patient fitted with SynergEyes A, we have largely abandoned the first generation SynergEyes hybrids (including KC and ClearKone) due to issues with the design and skirt (Dk of 9.3 compared to 84 in the Ultrahealth and Duette design), which - in our experience - resulted in circumferential tightening and peripheral corneal staining. In our cohort, the majority (76.9%) of eyes was fitted with Eyebrid lenses. These hybrids offer the advantage of more fitting options, a silicone hydrogel skirt and an easier removal system. Our data shows that despite improved designs with higher oxygen permeability of the skirt, discomfort still remains an important reason for abandoning hybrid lens wear, especially in sagging cones.

Difficulty with lens handling and breakage was a common issue with older-generation hybrids and newer-generation hybrids are claimed to have improved RGP/hydrogel junctions.[6,18] Even though our

rate of torn contacts was significantly lower (18 reorders in 6 months, out of 104 originally dispensed lenses; 17.3%), it remains a bothersome issue in clinical practice, typically occurring when cleaning the lenses. Handling difficulties in hybrid lenses have been suggested to be more prevalent in post-graft contact lens wearers due to them generally being in an older age group.[16] We found no statistically significant difference in age between the success and failure group, and despite the young overall age in our group, handling issues (lens insertion and removal) were a significant reason for discontinuation of lens wear (14 eyes of 7 patients). Studies are lacking on the direct comparison of lens handling in hybrids versus scleral and corneal lenses. In keratoconus patients successfully wearing scleral or corneal lenses, scleral lens wearers have reported more difficulty with application and removal and spending more time daily time handling the lenses compared to corneal lens wearers.[19] Lens handling is typically reported to be the main reason for scleral lens discontinuation.[20] This study indicates that discomfort is the principal reason for discontinuation of hybrid lenses in keratoconus patients.

This study has some limitations, primarily its retrospective design which prohibited us from investigating vision-related quality of life in these patients. Data on corneal staining and lens motility at follow-up was also fairly incomplete and could therefore not be adequately analyzed. Similarly, the lower success rate compared to other studies may be related to baseline characteristics (dry eye, allergies etc) or differences in lens care systems, but the incomplete information available in the case notes on these aspects did not allow reliable analysis of these aspects. A prospective study on the outcome of hybrid lens fitting with analysis of corneal staining and motility patterns of the lenses would offer more insight in the interaction of hybrids lenses with the anterior eye. It would be of particular interest to investigate whether the state of dry eye influences the clinical success of hybrid lens fitting. A follow-up of 6 months may also be insufficient to adequately assess complications such as chronic limbal hypoxia leading to corneal neovascularization and giant papillary conjunctivitis, especially in keratoconus patients with atopy.

In conclusion, new generation hybrid lenses represent an appropriate, safe therapeutic option for keratoconus patients. Excellent visual outcomes are achieved in successful fittings, yet a dropout rate of 37% - mainly occurring in sagging, cones - still limit their clinical success.

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Figures

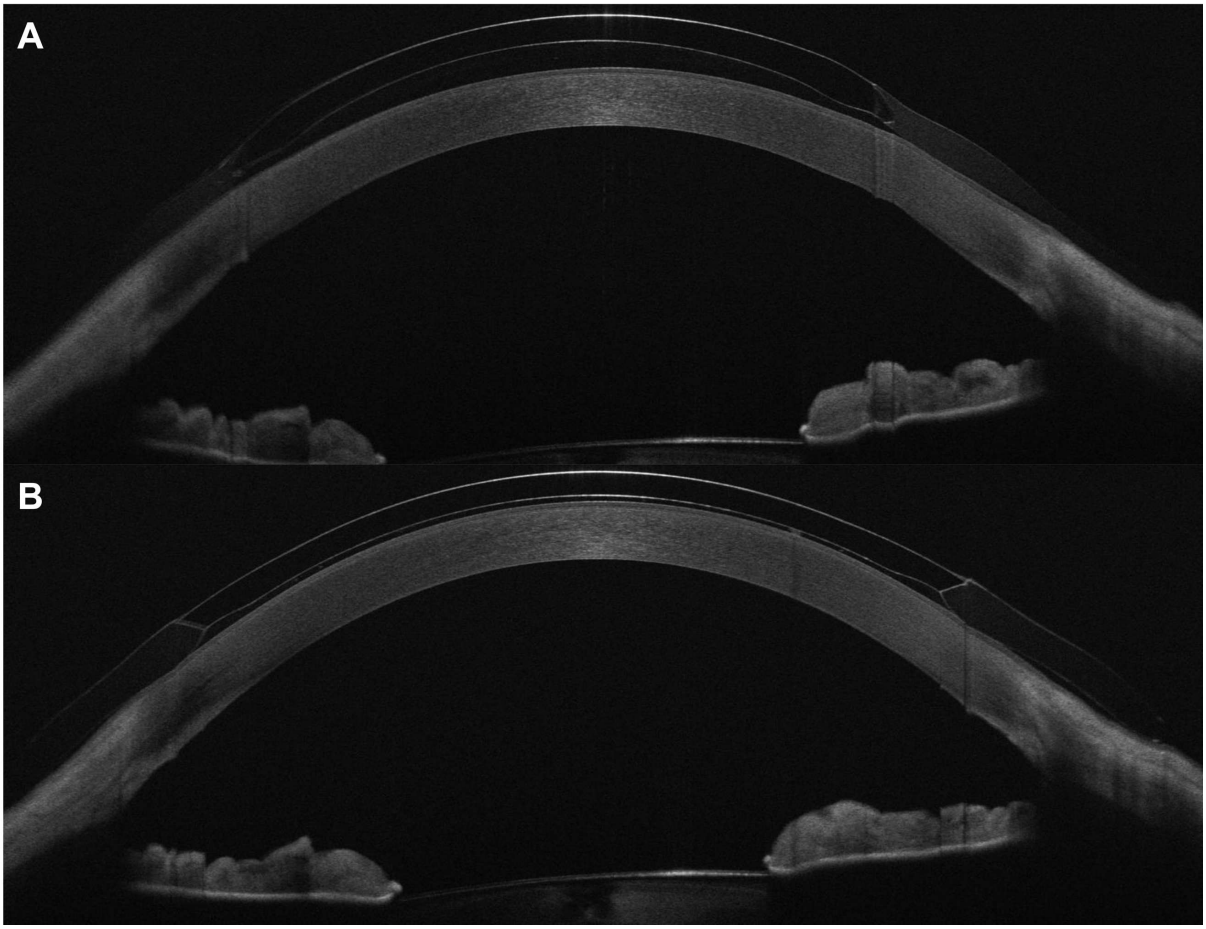

Figure 1: (A) Anterior segment OCT image (MS-39, CSO, Firenze, Italy) of SynergEyes Ultrahealth on the right eye of a normal cornea. Note the Hyperbond® junction, a patented ‘chemical bond’ of the center RGP to the soft skirt. (B) OCT image of Eyebrid lens on the same eye, highlighting the different shape of the polymeric suture between the soft and RGP materials. (Images courtesy of Jan Pauwels, Lens Optical)

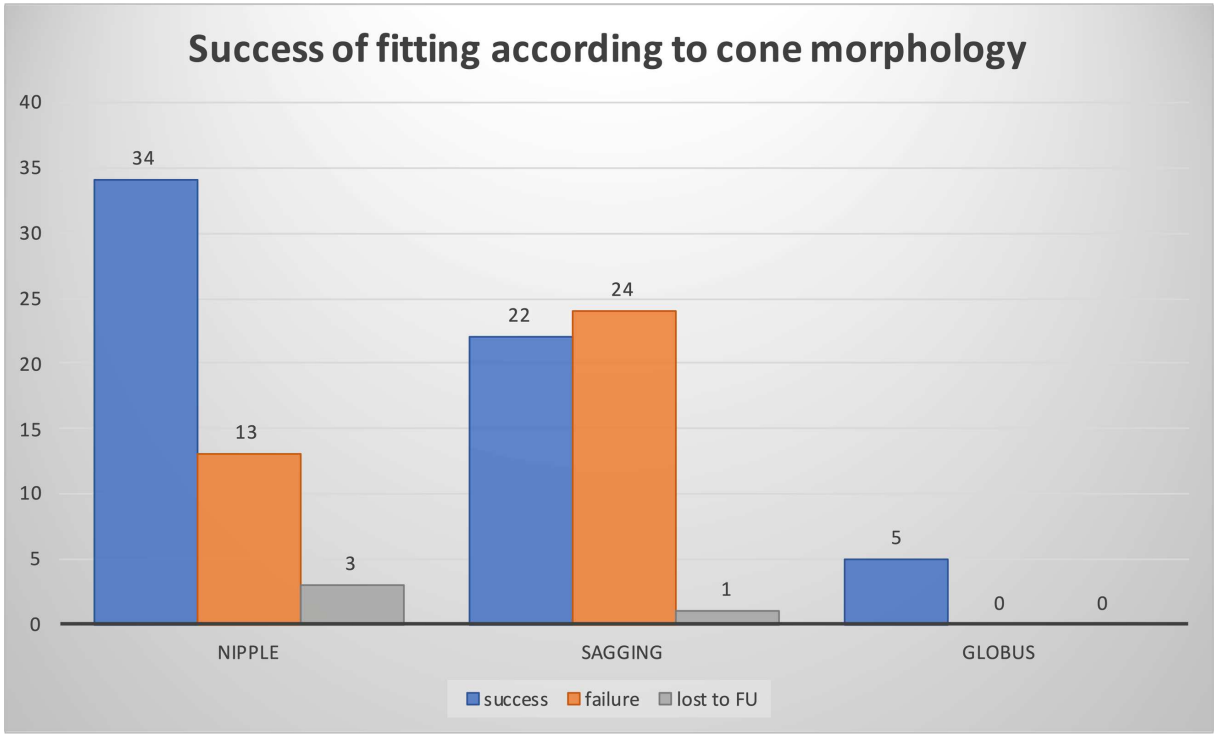

Figure 2: Distribution of hybrid lens fitting according to the cone morphology (Y axis represents the number of eyes).