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**4   Visual and refractive outcomes of 100 small incision lenticule extractions (SMILE) in moderate and high myopia: a 24-month follow-up study**

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*Abstract*

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7   **Purpose**: We aimed to present the visual results obtained in 100 small incision lenticule extraction (SMILE)
8   refractive surgeries; demonstrate whether the technique is effective in the treatment of moderate and high myopia;
9
10  and observe the follow-up of these patients over 24-month period.
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12  **Methods**: One hundred eyes of 50 consecutive patients were treated with SMILE. The preoperative spherical
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14  equivalent refraction was $-5.64 \pm 1.23$ D. During the postoperative period, patients were examined at 3, 6, 12, and
15  24 months. We analysed the efficacy, safety, predictability, and stability of the technique.
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17  **Results:** The Snellen visual acuity of 99% of the patients was 20/20 or better after 24 months of follow-up. Two
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19  eyes had a loss of two lines of visual acuity; 1% of the patients had a loss of one line of visual acuity. The
20  postoperative spherical refraction was $-0.04 \pm 0.35$ D ($-1.00$ to $0.50$ D). The postoperative spherical equivalent
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22  refraction was $-0.19 \pm 0.38$ D ($-1.25$ to $0.50$ D). Eighty-three percent of the eyes were within $\pm 0.50$ D, and 87%
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24  obtained a residual astigmatism of $0.50$ D or less.
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26  **Conclusion:** The SMILE technique was demonstrated to be an effective, predictable, safe, and stable technique
27  in the treatment of moderate-to-severe myopia during the 24-month follow-up. Long-term follow-up should be
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29  undertaken to observe possible refractive regressions.
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33  **Keywords**
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36      • Small incision lenticule extraction
37      • Visual outcomes
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39      • Femtosecond
40      • Refractive surgery

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**Introduction**

Small incision lenticule extraction (SMILE) is a minimally invasive procedure, in which no corneal flap is performed. The first results of SMILE surgery were published in 2011 by Shah[1] and Sekundo.[2] The femtosecond laser has been used In ophthalmology for corneal flaps[3], intrastromal rings or RAINDROP®, and the KAMRA® pocket. In the last decade, the femtosecond laser has obtained more accuracy and several uses.[4, 5]

The ability to make high-precision cuts in the cornea led to the birth of intrastromal surgery, which is less invasive[6] than femtosecond laser assisted in situ keratomileusis (LASIK). During SMILE, the femtosecond laser is used to create an intrastromal lenticule with a small 2-mm incision in an arched and peripheral shape. After the creation of the lenticule, the anterior and posterior tissue bridges of the lenticule are separated.[7] The lenticule is then removed with a tweezer via the small incision. This process is performed 100% with femtosecond laser.[1]

SMILE is currently a surgical technique that is only performed in subjects with myopia, although it is getting results in hyperopia.[8] A study has analysed the possibility of preserving the lenticule obtained from the surgery in a myopic patient and implanting it in a hyperopic patient.[9] Although, more recently, a study has pointed to carving the extracted lenticule with a curvature favourable to hyperopia.[10]

**Materials and Methods**

<u>Subjects</u>

This retrospective, longitudinal, and descriptive study analysed the first 100 eyes (50 patients, 32 men and 18 women) subjected to refractive surgery with SMILE at the Tecnolaser Vision® Clinic (Seville, Spain). The patients received SMILE to correct their myopia between January and September 2015. The inclusion criteria were as follows: a stable refraction, spherical equivalent between -4.00 and -10.00 D, preoperative visual acuity (VA) of 20/20 or higher, central corneal thickness of at least 500 μm, no previous ocular surgery, and understanding of informed consent. The exclusion criteria were as follows: topography suggestive of keratoconus or corneal degeneration, alteration of extrinsic motility, amblyopic eye, systemic medication, or active ocular disease.

Contact lens users were advised not to use them at least 15 days before surgery. The surgeries were performed by two surgeon's expert in the SMILE technique (FAA and JAC). Surgeons performed a twelve-months learning curve with Femtosecond Lenticule Extraction (ReLEx Flex ®) before starting on SMILE. The pre-operative study and postoperative revisions were conducted with the help of optometrists' who are experts in refractive surgery. The protocol adhered to the principles of the Helsinki declaration. Informed consent was obtained by all participants after explaining the benefits and risks of the SMILE procedure.

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## Surgical technique

The procedures were performed with the VisuMax Femtosecond Laser System (Carl Zeiss Meditec AG, Jena, Germany) using topical anaesthesia in drops. The patient was placed on the table under the cone. The laser was focused on the patient's pupil. The patient was asked to observe a green light inside the cone. The pulses of the laser were applied with a pulse energy of approximately 130 nJ. Focusing on a precise depth in the corneal tissue, the laser created a microphotodisruption in the form of a gas bubble of carbon dioxide and water to create tissue separation. The spot distance of each laser spot was 4.5 μm. The frequency of the laser was 500 KHz.  The femtosecond incisions were performed in the following order: the back surface of the lenticule, the height of lenticule´s edge, the anterior lenticule surface, and the lateral cut incision to access the lenticule. Lenticule´s diameter was fixed at 6.5 mm, and the stromal lid was terminated at the depth of 120 μm, 7.3 mm in diameter centred on the pupil. The side cut was set to the width of 3.5 mm and was located at the 12 o'clock position.

## Statistical analysis

Statistical analysis was performed with SPSS statistics 25.0 (IBM Corporation, Armonk, NY, USA). All VA data were converted into Snellen formats. The Wilcoxon test was performed for non-parametric dependent variables. All statistical tests were performed with a 95% confidence level ($P < 0.05$).

## Results

### Demographics

A total of 100 eyes belonging to 50 patients were included in this retrospective study. The age of the patients was $32.79 \pm 6.71$ years (20-48 y). The gender distribution was 64 men and 36 women. The results of preoperative and postoperative examinations (i.e., spherical refraction, cylindrical refraction, refraction in spherical equivalent, maximum keratometry, minimum keratometry, mean keratometry, and total central pachymetry) are described in the Table 1.

### Efficacy

The efficacy is shown in Figure 1A as percentage of preoperative corrected distance visual acuity (CDVA) and postoperative uncorrected visual distance acuity (UDVA). The results correspond to a 24-month follow-up period. Ninety-nine percent of the eyes obtained a VA of 20/20 or better in the postoperative period. In addition, 100% obtained a VA of 20/25 or better. Both eyes with PRK enhancement have been excluded from the statistics (UDVA and CDVA). The efficacy index was 0.97 at 24 months after SMILE surgery.

Safety

The safety results for the SMILE technique are presented in Figure 1B. After the 24-month follow-up visit, it was observed that 97% (95 eyes) did not obtain changes in VA on the Snellen test. One eye lost one line of sight on VA Snellen, and two eyes lost two lines of vision in Snellen VA. Also, there were two eyes (2%) that achieved a two- line improvement in Snellen VA.

In two of the surgeries, the lenticule did not come out complete and, thus, created an irregular astigmatism; these two cases correspond with the patients who lost two lines of Snellen VA. This residual irregular astigmatism was not correctable with ophthalmic lenses or contacts lenses. Finally, the ocular surface was adjusted by topography-guided photorefractive surgery (PRK). During the surgeries, separation of the lenticule tissue bridges was achieved for a satisfactory surgery.

Predictability

The results of predictability are shown in Figure 1C. The mean predictability was $-0.06 \pm 0.01$. The regression line value was $0.9979x + 0.18$. The spherical equivalent obtained was as follows: 83% of the eyes were within $\pm 0.50$ D range, and 97% of the eyes resulted in $\pm 1.00$ D (Figure 1D). The residual astigmatism at 24 months postoperatively was 87% 0.50 D or less and 99% 1.00 D or less (Figure 1E).

Stability

The stability outcome is shown in figure 1F. The change in the refraction manifested before and after SMILE was $-5.64 \pm 1.23$ D preoperatively and $-0.19 \pm 0.38$ D postoperatively. There were no observed statistically significant differences between the results at 3 months ($-0.15 \pm 0.64$ D) and those at 6 months ($-0.13 \pm 0.59$ D) ($P = 0.09$), nor were there statistically significant differences observed between the results at 12 months ($-0.19 \pm 0.44$ D) and those at 24 months ($-0.31 \pm 0.62$ D) ($P = 0.12$).

Patients described a satisfactory experience in relation to the surgical process, as well as postoperative results. However, patients found that the visual recovery process was slower than expected. The average visual recovery time was $3.05 \pm 1.20$ ($1.00 - 4.00$) weeks.

**Discussion**

This study reports visual outcomes obtained in 100 SMILE surgeries. We have analysed the efficacy, safety, predictability, and stability with a follow-up time of 24 months.

After observing the results, our study showed that the technique of refractive surgery with SMILE is effective in myopia treatment, predictable in refraction results, and stable over 2 years. To our knowledge, we presented the largest number of eyes with a follow-up of 24 months in the scientific literature regarding SMILE visual outcomes.

Efficacy is shown with a cumulative percentage of UDVA with 20/20 or better of 99% (Figure 1A); other authors obtained excellent results of over 90%.[11–17] These authors have shown results like those obtained in our work. In our case, a 100% of the eyes obtained a UDVA of 20/25 or better. There have been, however, critical studies in which the efficacy of the SMILE technique was below 90% of VA in 20/20 or better[18–21], and even below 60%.[22, 23] It is important to note that the follow-up period of the studies with the worst efficacy results[22, 23] was 3 months; thus, the VA of the patients included in the study was not yet stable.

In terms of safety, 1% of the eyes in our study lost one line of VA (figure 1B). In this case, other authors[11, 13, 16, 18, 19, 21, 23] had dismissed a loss of similar VA. In contrast, other studies described worse results (between 12% and 23%).[12, 14, 15, 20, 24, 25]In our work, we obtained 2 eyes with a loss of two lines, which is the same as was found by other authors who described the SMILE technique. The eyes that had a loss of two lines had an incomplete extraction of the lenticule. Fragments of the lenticule were inside the interface and were impossible to extract. These complications have been critical in a recent study published by Hamed et al.[26] and Han et al.[27] Other prevalent complications have been described by Ramirez-Miranda et al. [28] as epithelial defect, cap rupture or opaque bubble layer. It was necessary to re-treat these two eyes with topography-guided photorefractive keratectomy (PRK)[29] to regulate the unequal surface caused by the lenticule´s fragments. Six months of after re-treatment, the two eyes recovered a VA of 20/20. Other authors such as Breyer et al. [30] reported safety of SMILE even with a percent of tissue altered (PTA) more than 40%. They found 97.7% eyes (in < 40% PTA group) and 96.4% eyes (in ≥ 40% PTA group) remained unchanged or gain lines.

SMILE's predictability was also studied; after performing the linear regression, the following line was obtained: $y = 0.9977x + 0.1858$ (Figure 1C). Thus, for a calculated correction refractive of - 1.00 D, the final correction obtained was - 1.18 D. This implies a mean hypercorrection of - 0.18 D. The predictability obtained by the other authors are shown in Table 2. The results of the spherical equivalent obtained (83% ≤ ± 0.50 D and 97% ≤ ± 1.00 D) (Figure 1D) are in line with those obtained by a large number of studies.[11–16, 18, 19, 21–23] Authors such as Blum et al.[24] and Pedersen et al.[20] obtained greater variability in their results. As for the refractive astigmatism, excellent results were obtained: 87% ≤ ± 0.50 D and 99% ≤ ± 1.00 D (Figure 1E). In this case, few authors studied the refractive astigmatism obtained in SMILE.

As for stability, 3% of the eyes obtained a change $\geq \pm 0.50$ D on comparing the spherical equivalent refraction between the 12-month and 24-month visits. In contrast, in terms of refractive change, patients obtained an average refractive regression of -0.24 D on between the 3-month and 24-month visits. Other authors with follow-up periods of 5 years[24] and 4 years[11] obtained a regression of - 0.48 D in the case of Blum et al.; and, 10.6% of the eyes obtained a myopic regression $\geq \pm 0.50$ D in the case of Han et al. 5-years data reported by Blum et al. a 200kHz laser was used, not the VisuMax System used in this study. Burazovitch et al. [31] reported that four years after the surgery, 87% high myopic group eyes were within 0.50 D target. Other studies with a short follow-up period[12, 13, 15, 16, 19, 21, 23] (from 3 months to 12 months) obtained excellent stability results. Zhao et al. [32] reported that posterior corneal surface changes were stable after SMILE in long-term follow-up. The agreement of our results with those of the other authors suggests that the SMILE technique remains stable until 12 months, after which there is a slight regression up to 24 months. Although, in our study, this did not seem to impact in terms visual efficacy. In this sense, patients included in this study have shown their commitment to follow up after 10 years from SMILE surgery. The data obtained will provide us with conclusive values of myopic regression in SMILE.

In conclusion, SMILE has proved to be effective, safe, predictable, and stable in the treatment of moderate myopia with a 24-month follow-up.

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Table Legends

Table 1. Preoperative and Postoperative Refractive changes

† Values are reported as mean ± standard deviation (range) *The Wilcoxon test for dependent variables was used. SD = standard deviation; SMILE = small incision lenticule extraction; SE = spherical equivalent; D = diopters; K max = maximum keratometry; K min = minimum keratometry; K mean = mean keratometry; CCT = central corneal thickness.

Table 2. **Efficacy**. Percentage postoperative uncorrected distance visual acuity (UDVA) with 20/20 or better. (Efficacy index is also shown when percentage was not available.) **Safety**. Percentage of eyes with corrected distance visual acuity CDVA with one and two lines of loss. **Predictability**. Distribution of the difference in
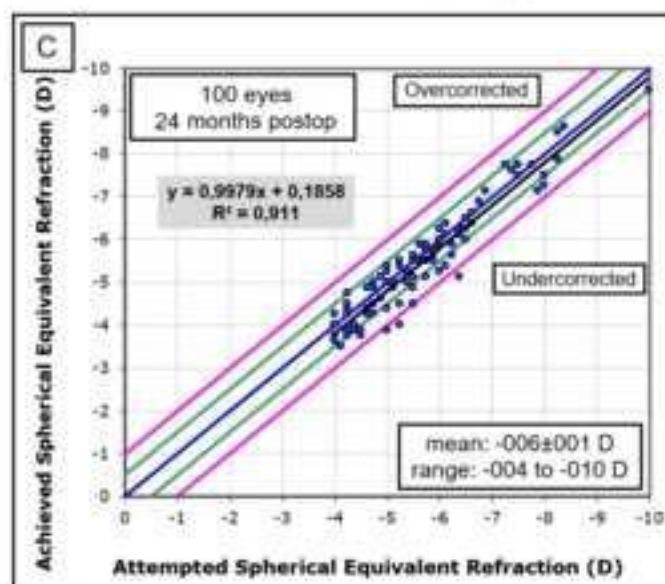
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attempted vs. achieved expressed with a line of lineal regression. **Spherical Equivalent.** Percentage of eyes within spherical equivalent (SE) $\leq 0.50$ D y $\leq 1.00$ D. **Stability.** Changes in refraction after follow-up time (expressed in percentage $> 0.50$ D and regression´s diopters).

Figure Legends

Figure 1. SMILE visual and refractive outcomes. (A) Uncorrected visual acuity (UDVA). (B) Change in corrected distance visual acuity (CDVA). (C) Spherical equivalent attempted vs. achieved. (D) Spherical equivalent accuracy. (E) Distribution of refractive astigmatism. (F) Stability of spherical equivalent refraction. D = diopters.

Figure 1

Click here to access/download;Figure;Figure 1.tif



**Uncorrected Distance Visual Acuity**
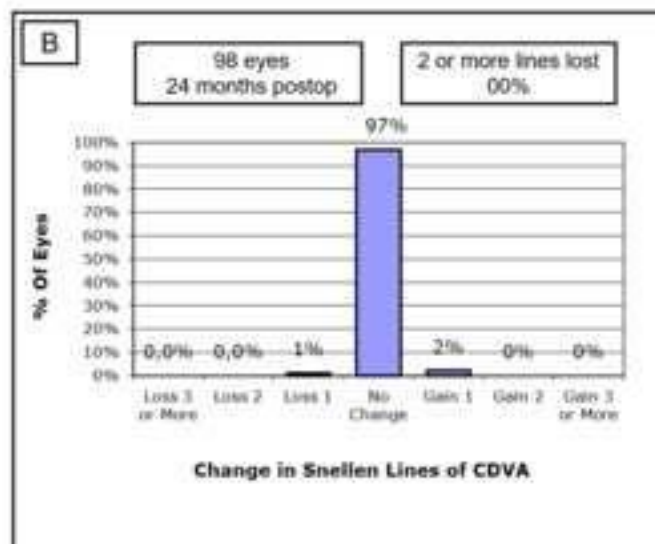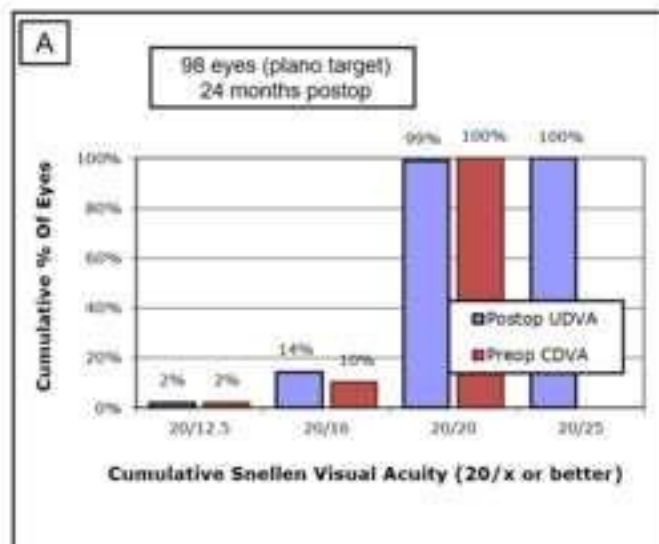
**Change in Corrected Distance Visual Acuity**

**Spherical Equivalent Attempted vs Achieved**
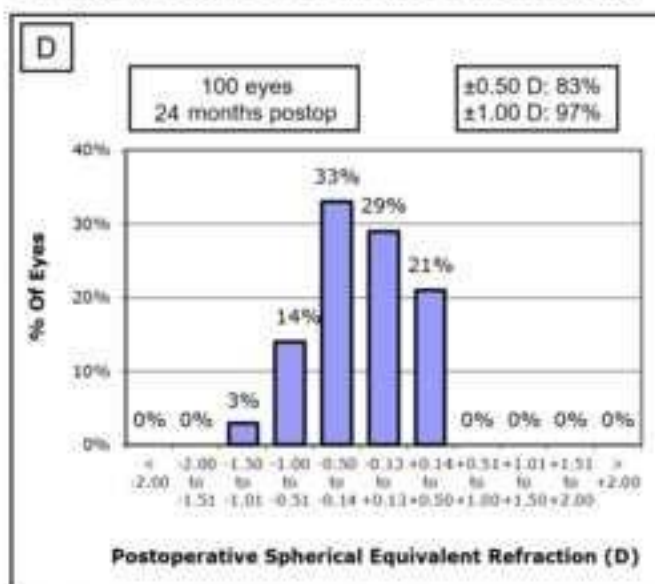
**Spherical Equivalent Refractive Accuracy**
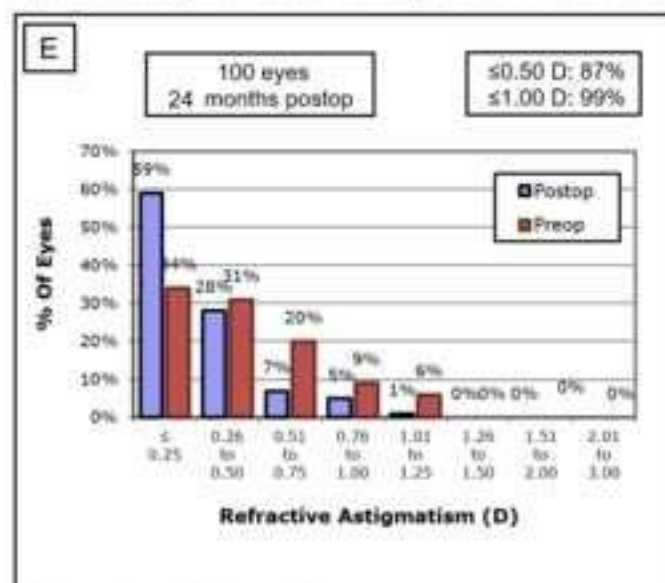
**Refractive Astigmatism**
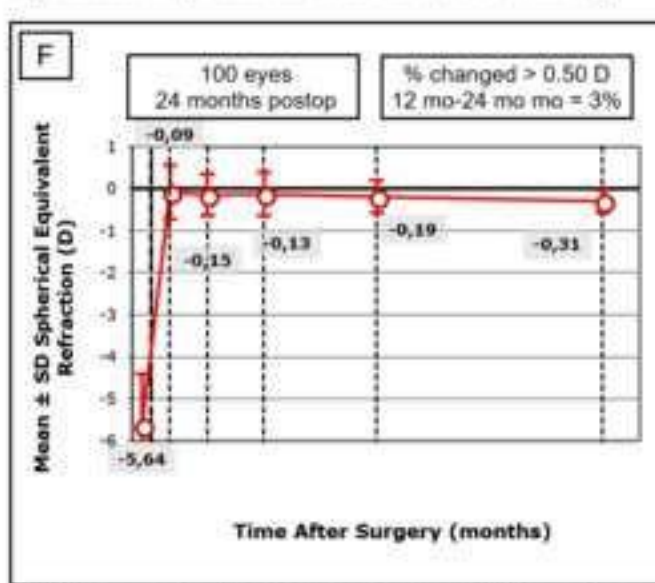
**Stability of Spherical Equivalent Refraction**

Table 1

| Parameter | Preoperative | Postoperative | P value |
|---|---|---|---|
| Manifest Sphere † (D) | -5.40 ± 1.25 (-10.00 to -3.50) | -0.04 ± 0.35 (-1.00 to 0.50) | <0.01* |
| Manifest Cylinder † (D) | -0.48 ± 0.37 (-1.25 to 0.00) | -0.31 ± 0.30 (-1.25 to 0.25) | <0.01* |
| Manifest SE † (D) | -5.64 ± 1.23 (-10.00 to -4.00) | -0.19 ± 0.38 (-1.25 to 0.50) | <0.01* |
| K max † (D) | 44.01 ± 1.39 (40.90 to 46.50) | 39.78 ± 1.80 (36.10 to 44.60) | <0.01* |
| K min † (D) | 44.82 ± 1.39 (41.80 to 47.70) | 40.51 ± 1.85 (36.30 to 45.80) | <0.01* |
| K mean † (D) | 44.42 ± 1.37 (41.45 to 47.10) | 40.14 ± 1.81 (36.20 to 45.20) | <0.01* |
| CCT † (µm) | 550.32 ± 32.15 (500.00 to 635.00) | 461.32 ± 36.05 (385.00 to 550.00) | <0.01* |

Table 2

| Author | Efficacy | Safety | Predictability | Spherical Equivalent | Stability | Follow-up |
|---|---|---|---|---|---|---|
| Blum et al. (2016) [24] | 0.9 | 10% / 0% | 1.0046x – 0.433 | 48.2% / 78.6% | - 0.48 D | 5 years |
| Fernández et al (2017) [18] | 85% | 1.4% / 2.8% | 0.9475x + 0.001 | 86% / 97% | - | 6 months |
| Han et al. (2016) [11] | 92% | 0% / 0% | 1.03x + 0.25 | 89% / 100% | 10.6 % | 4 years |
| Hansen et al. (2016) [22] | ≈60% | ≈15% / 1.6% | 1.0019x -0.045 | 88% / 98% | - | 3 months |
| Kamiya et al. (2014) [12] | 96% | 15% / 0% | 0.9833x – 0.080 | 100% / 100% | 3.8% | 6 months |
| Kim et al (2014) [19] | 79.8% | 3% / 0.3% | 0.9102x – 0.395 | 86.1% / 97.2% | - 0.03 D | 6 months |
| Kim et al. (2015) [13] | 93.1% | 3.4% / 0 % | - | 87.9% / 96.6% | - 0.02 D | 12 months |
| Kobashi et al. (2018) [14] | 100% | 13% / 3% | 1.0061x + 0.106 | 100% / 100% | - 0.05 D | 24 months |
| Lin et al. (2014) [23] | 58.3% | 1.6% / 1.6% | 0.912x – 0.362 | 98.3% / 100% | -0.04 D | 3 months |
| Liu et al. (2016) [15] | 96% | 23% / 3% | 0.97x – 0.11 | 97% / 100% | 2.65 % | 6 months |
| Pedersen et al. (2015) [20] | 72% | 12% / 0% | 0.8795x – 0.576 | 78% / 90% | - 0.08 D | 3 years |
| Torky et al. (2017) [21] | 89% | 0% / 0% | - | 89.4% / 97.8% | + 0.02 D | 6 months |
| Yildirim et al (2016) [16] | 94% | 6% / 0% | 0.9889x + 0.185 | 92% / 100% | - 0.10 D | 12 months |