# ANALYSIS OF VAULT PREDICTION IN PHAKIC IMPLANTABLE PHAKIC COLLAMER LENSES: MANUFACTURER'S CALCULATOR vs THEORETICAL FORMULAE VS CLINICAL PRACTICE.

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Highlights/Key Messages

1. Sizing calculation with OCOS according to WTW and ACD is a good indicator, with a high success rate.
2. Sometimes it is necessary to use the ACW and CLR variables as accessory measures to adjust the size of the lens to be implanted according to the ocular anatomy.
3. Calculation of ICL sizing with Nakamura2 suggests larger sizes in 32.5% of cases, and smaller sizes in 18.6% of cases.

**Statements and Declarations**

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All procedures performed in studies involving human participants were inaccordance with the ethical standards of the institutional and/or national researchcommittee and with the 1964 Helsinki Declaration and its later amendments orcomparable ethical standards. The study was approved by the Bioethics Committee of the Hospital Clínico San Carlos (Madrid)

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# ANALYSIS OF VAULT PREDICTION IN PHAKIC IMPLANTABLE PHAKIC COLLAMER LENSES: MANUFACTURER'S CALCULATOR vs THEORETICAL FORMULAE VS CLINICAL PRACTICE.


## ABSTRACT

**BACKGROUND:** Implantable Collamer Phakic (ICL) intraocular lens sizing calculations are necessary to avoid complications associated to inadequate sizing. Historically Holladay R, Dougherty, Hernández-Matamoros and other authors have tried to create new formulas that solve calculation problems and provide higher reliability. In addition, in recent years the appearance of new equipments, parameters and formulas have led to significant progress. This paper compares the sizing according to manufacturer's method and other methods.

**METHODS:** Forty-three eyes of 24 patients with EVO ICL implanted, with at least 1 year of follow-up, were analysed. The analysed variables were: WTW, ACD, ACW (ATA), CLR, ICL size, vault measured at 1 week and 1 year after surgery, ICL size and vault predicted by Nakamura-2 as well as vault size predicted by Igarashi.

**RESULTS:** Sizing calculation with OCOS according to WTW and ACD is a good indicator with 86% success rate. The calculation with Nakamura 2 suggests larger ICL sizes in 32.5% of cases and smaller in 18.6% of cases, while the resulting Vault according to Igarashi obtains better results without significant differences.

**CONCLUSIONS**: ICL Sizing according WTW and ACD, using the manufacturer's algorithm seems to be the most predictable method compared to other algorithms using other variables. The surgeon's expertise also have a high importance in the final ICL size election.



**KEYWORDS :** Implantable Collamer Phakic (ICL), Sizing, vault,calculator.


## INTRODUCTION

Refractive surgery techniques have evolved greatly in recent decades, with the emergence of a wide range of techniques to correct a variety of ametropia. Among these techniques, the implantation of posterior chamber phakic lenses should be highlighted, with the Visian ICL (Implantable Collamer Lenses – STAAR Surgical, Mopnrovia, CA) occupying an important place among them, which is a safe, effective and predictable technique, as has been demonstrated in many studies (Packer 2016, Frost, Ritter et al. 2019).

Currently the ICL lens is manufactured in 4 sizes for hyperopia between 11.6 and 13.2mm and another 4 for myopia, between 12.1 and 13.7 mm, so the lens size calculation to be implanted should be as accurate as possible being key to avoid potential associated problems. Larger lenses could be associated to acute glaucoma and iridocorneal angle closure (Frost, Ritter et al. 2019). Otherwise, smaller lenses than ideal size increase the risk of anterior subcapsular cataract, especially with the previous lens model presented before 2011 (Visian ICL V4c)(Fernandes, González-Méijome et al. 2011) due to the proximity of the lens to the anterior surface of the crystalline lens, which hinders the flow of aqueous humour between the lens and the crystalline capsule. Since the lunch of the model (Visian ICL V4c with Ks-Aquaport) in 2011, recent studies have shown that the introduction of the central hole (Aquaport®) in ICL designs significantly reduces the prevalence of cataracts, with the latest published meta-analysis placing the prevalence of cataracts at 0%(Packer 2016). Typically, it was considered that the appropriate lens size was the one whose distance from its the posterior surface to the anterior surface of the crystalline lens (vault) was between 250-750 microns, therefore, the manufacturer's online calculator (Online Calculation and Ordering System – OCOS) tends to estimate the ICL Size for an achieved vault close to 500 microns. Thanks to the development of anterior chamber imaging techniques such as anterior segment optical coherence tomography (AS-OCT) or ultrasonic biomicroscopy (UBM), magnified images of the anterior chamber can be obtained. This makes possible to assess the effect of the lens with the adjacent structures of the eye. It will also helpful measuring distances that provide information about the anatomical safety of the surgery. Thus, in the postop, the visualization of the positioning of the lens and its relationship with the surrounding structures (crystalline lens, IA) have become a very important variable to take into account in addition to the numerical value.(Gonzalez-Lopez, Bilbao-Calabuig et al. 2019) Therefore, vault seems to be a variable related and affected by multiple factors such as the crystalline lens movement, and the safety of the procedure should take in account the position of the lens, the anterior chamber depth, irido-corneal angles and pupillary function.

To obtain the most suitable lens size for implantation in each case, there are two factors: adequate knowledge of the morphology of the anterior chamber and the development of appropriate calculation formulas based on these anatomical variables. At this moment, the ICL size calculation according to OCOS is based on the horizontal

corneal diameter distance (WTW) and the anterior chamber depth, measured from the corneal endothelium to the anterior lens capsule (ACD). To improve the precision on these calculations, using imaging techniques has also become important during the preoperative period. These techniques make possible to define the crystalline lens rise (CLR) as the elevation of the crystalline lens over the line between iridocorneal angles (Qi, Chen et al. 2017, Gonzalez-Lopez, Mompean et al. 2018), iris-crystalline convexity, angle-angle distance (ATA), anterior chamber horizontal diameter defined as the distance between sclero-corneal spurs (ACW), pupillary diameter, and other factors that have been described that affect vault value(Baïkoff 2006). In any case, it is important to remind that vault has been described as a dynamic measurement, influenced by accommodation, pupil dynamics and light conditions (Gonzalez-Lopez, Mompean et al. 2018, Kato, Shimizu et al. 2019); so for that reason, to predict an unique value of vault with static measures does not seem to make much sense (Gonzalez-Lopez, Mompean et al. 2020).

Nowadays, the most used formula is the one developed by the lens manufacturer STAAR Surgical through its online calculator OCOS, which uses the parameters of date of birth (age), refraction, keratometry (K), vertex distance (DVI), pachymetry (CCT), anterior chamber depth measure from endothelium and white-white measurement, being the last two the most important parameters in sizing calculations. Some authors consider that this formula has associated an implicit error when introducing the WTW data due to the fact that the lens is located in the ciliary sulcus, and it is also known that there is no fixed equivalence between both parameters, but rather it depends on other parameters of each eyeball (Córdoba, Graue-Hernández et al. 2019). On the other hand, there have been several attempts to develop ICL size calculation formulas that also predict vault before implanting the lens: for the first approaches the size was selected by adding a correction factor to the WTW, depending on the ACW, later, pupil diameter was also introduced by other authors (Lee, Kang et al. 2018). Nakamura et al described their own formula according ACW in 2018(Nakamura, Isogai et al. 2018) and 2 years later described a new formula with better predictability (NK-2)(Gonzalez-Lopez, Mompean et al. 2018, Nakamura, Isogai et al. 2020). Igarashi (7, 8) developed another formula that predicts the resulting vault after surgery according to ICL compression, defined as the difference between ICL size and ATA measure (Igarashi, Shimizu et al. 2019). In his latest work, Igarashi (Igarashi, Shimizu et al. 2021) showed the high correlation between the results obtained with the OCOS manufacturer calculator and the formulas implemented and included in the software of the CASIA-2 equipment(TOMEY Inc, Nagoya, Japan) which is an Anterior Segment Optical Coherence Tomograph.

Expert surgeons usually select the size of the lens based on the initial calculation provided by the manufacturer's website and modify it according to other intraocular anatomical variables not considered by the calculator, based on their own experience.

Therefore, the aim of this study is to analyse the accuracy of the calculation of the ICL lens size to be implanted according to the manufacturer's calculator, the lens finally implanted by the surgeon and the vault obtained one month after surgery. All this is compared with the formulas developed by Nakamura and Igarashi, and with the vault predicted in the same way.

## OBJECTIVE

The main objective of this analysis is to study the differences between the ICL sizes implanted according to manufacturer's calculator (OCOS) and the ICL size calculation according to other authors' published formulas, as well as to study the vault achieved one week and one year after surgery and compare it with the prediction made by these authors, in order to quantify the accuracy of the calculations and to establish the best method for calculating ICL sizing and estimating the achieved vault.

## METHODS

Eyes of patients with EVO Visian ICL implanted at Rementería Clinic (Madrid, Spain) between 2018 and 2020, with at least 1 year of follow-up, were analysed. Inclusion criteria included age between 21 and 45 years, myope or myopic astigmatism, with stable refraction at least for last 12 months (0.50D change in last 12 months), with minimum anterior chamber depth (ACD) of 2.80 mm measured from corneal endothelium to anterior capsule of crystalline lens, with no corneal alterations, keratoconus, or ecstatic profile on topography, and without any previous ophthalmic surgery or ocular pathology contraindicating surgery. All subjects were operated by the same expert surgeon (L.A.R.).

Subjective refraction was obtained by one experienced clinical optometrist (V.B.S.) under physiological and cycloplegic conditions, at 12 mm of corneal vertex distance. Previous cycloplegic instillation, corneal topography

was acquired with a Scheimpflug image-based topography (PENTACAM HR. Oculus Optikgeräte GmbH, Wetzlar, Germany) and anterior chamber optical coherence tomography (AS-OCT) was acquired with VISANTE OCT (Zeiss, Jena, Germany). White-to-white (WTW) distance was obtained with corneal topography (Pentacam HR), and angle-to-angle (ACW), Cristalline lens rise (CLR) and ACD was obtained with AS-OCT (Visante).

- ICL CALCULATION

ICL size and power was calculated with manufacturer's webpage (Online Calculating and Ordering System – OCOS), selecting the lens that provides a refractive calculation closest to emmetropia. Final ICL size was decided by surgeon, according OCOS ICL calculation and the relationship between ACD, ATA and CLR, based on his own experience. ICL implantation surgery was performed without any intra- or postoperative complications.

Post-op revisions were performed at 24h, 1 week, 1 month and 1 year after surgery, obtaining subjective refraction, uncorrected and corrected distance visual acuity, ACD, Vault (measured in microns), intraocular pressure (in mmHg).

On the other hand, Nakamura's ICL sizing calculation and vault prediction, and Igarashi's vault prediction were also calculated using an Excel spreadsheet, according to their own published formulas.

STATISTICAL ANALYSIS

All data were included on a database created for this analysis and analysed using SPSS software (IBM corp, Ver. 21.0). Statistical demography and the relationship between vault predictions and differences was performed.

**RESULTS**

43 eyes from 24 subjects were analysed. Pre-op anatomical and refractive data is described in table 1. Toric ICL were implanted in 26 of 43 (60.5%) cases, when refractive astigmatism was higher than 1.00 D.

- SIZING

OCOS established a 13.2mm sized ICL in 46.51% of cases, and 12.6 mm in 44.19% of cases, only 4.65% of cases were indicated with both 12.1 and 13.7 mm ICL. Implanted ICL size was according to figure 1, with 12.6 mm size in 53.49% of cases and 13.2 mm in 41.86% of cases, 12.1 mm ICL was implanted only in 4.65% of cases and 13.7mm (0.00%). There was agreement in 86.05% of cases between the lens size calculated by OCOS and the one finally implanted lens according to the surgeon's clinical criteria. In the 13.95% of cases (6/43) the implanted lens was one size smaller than the OCOS calculation.

*Table 1. Demographical statistics. white-to-white acquired with Pentacam HR. ACD, ATA and CLR were acquired with Visante OCT.*

***Figure 1*** *OCOS calculated ICL size, final implanted ICL size and Nakamura's adjusted ICL size distribution.*

- THEORETICAL FORMULAE

ICL Size calculation distribution according to Nakamura's formula 2 is described in figure 1. 13.2mm ICL was the most suggested size, in 67.44% of cases, and 12.6 mm size was suggested in 27.91 % of cases. This showed an agreement with OCOS calculation in 48.84% of cases, the rest of cases Nakamura's formula indicated a bigger ICL size in 32.56% of cases, and a smaller size in 18.60% of cases.

- VAULT.

Mean achieved vault one week and one year after surgery is described on table 2. There was a reduction of central vault of 85.44 microns during the first year. The mean vault achieved in lenses with agreement between OCOS and the surgeon's final decision was 562.19 ± 222.15 μm (Range 160 to 1060), on the other hand, mean vault achieved in cases that surgeons decided to implant one size smaller that the OCOS calculation was 356.83 ± 146.27 μm (Range 220 to 644).

Regarding theoretical vault prediction, Nakamura's formula 2 vault prediction is described in table 2. There was statistical difference between theoretical vault prediction and achieved vault ($p<0.001$), and between the theoretical vault prediction for optimal ICL size and achieved vault ($p=0.038$).

*Table 2. Mean central Vault achieved one week and one year after surgery. Reduction of vault in 12 months. Theoretical vault predictions according Nakamura 2 (NK2) and Igarashi's (IG) formulas. P-values are described for mean differences at 1 week (w) and 1 year (y).*

Regarding Igarashi's vault prediction formula, mean vault prediction was similar and non statistically different from the achieved vault at one week (p=0.530 for one week and 0.184 for one year).

***Figure 2*** *Vault prediction according to theoretical formulas (NK left – IG right) and achieved vault 1 week after surgery.*

Correlations between Theoretical vault prediction according to NK2 and IG, and achieved vault at 1 week are described in figure 2. NK2 prediction showed a very poor correlationship with achieved vault (R=0.355; $R^2$=0.126; p=0.020), and IG vault prediction showed a positive and statistically significant correlationship with achieved vault, but also with low predictability (R=0.354; R2=0.125; p= 0.020).

## DISCUSSION

Calculating ICL size is essential for the success of the surgery, as miscalculations can lead to complications such as cataract, angular closure, etc. According to the results reported by Parker(Packer, Alfonso et al. 2020) in his work, there is still no definitive method for determining the size of the ICL, which is why it is considered necessary to analyse the current formulas available and compare them with clinical outcomes. In another literature review recently published, Montés-Micó et al concluded that anterior segment anatomy should be carefully studied to obtain good results and avoid complications(Ando, Kamiya et al. 2020, Montés-Micó, Ruiz-Mesa et al. 2021).

It's well known that the manufacturer's calculator is based on WTW and ACD variables. Development of new calculation formulas and vault prediction show up in a moment in which new equipments allow the visualisation and measurement of internal structures that could affect the vault's prediction, such as the CLR.

An important factor is that the lens is only available in 4 sizes (12.1, 12.6, 13.2 and 13.7 mm for myopic subjects). A high-vault related problem, that in spherical lenses can be solved by implanting the lens vertically which offers an intermediate solution in some cases (Gonzalez-Lopez, Mompean et al. 2018, Matarazzo, Day et al. 2018) but in the case of toric ICLs this is not possible.

Also, as described by Ando(Ando, Kamiya et al. 2020)(2), the results obtained using the calculation formula included in the CASIA 2( Tomey, Nagoya, Japan) kit, the Nakamura formula, showed a concordance in the results obtained of 57.5% and 62. 5% respectively compared to OCOS formula. When the 3 formulas were compared simultaneously, it was observed that in 50% of the cases studied, the 3 formulas gave the same result. This is contrary to what was indicated by Igarashi (Igarashi, Shimizu et al. 2021)(3) in his work, who established that in most of the cases studied, OCOS provided a higher size than that obtained with the formula he designed. In our study, OCOS calculated lower ICL Sizes than Nakamura suggested in 32.56% of cases, with an agreement of 48.84% between them.

On the other hand, Ando(Ando, Kamiya et al. 2020) found that in cases in which Nakamura and Casia2 did not provide values in agreement, the first formula provided higher vault values. Both this study and our study have shown that the new formulae give lower values for size than OCOS, although in more than 30% of the cases this vault would be calculated with a larger lens size, which seems to be incorrect.

In our work, considering the mean vault achieved in the clinic as a good result since surgeon didn't have to do any exchange of the lens due to vault-related complications, sizing with OCOS according to WTW and ACD was a good indicator, with agreement rate of 86%. In 14% (6/43) a lens was implanted at a size smaller than suggested by the OCOS. Only one case had a vault larger than 1000 µm, but with no angle compromise or intraocular pressure elevation.

Another noteworthy aspect of Ando's work(2), and which establishes a difference with ours, is that his work analysed results obtained with the V4c and V5 ICL models, while all the patients in our work were implanted with a V4c ICL lens. Thanks to his model differentiation, he was able to observe that NK formula provided more accurate results in eyes implanted in V5, while similar results were obtain with the KS formula in eyes implanted with V4c and V5. Then, should the difference between V4c and V5 is only the optical zone diameter (increased in the V5 version), the vault achieved should not be different for each lens but this is not the case. So future studies analizing V5 model must be developed to explain this fact.

As mentioned above, the Nakamura2 calculation suggests larger ICL sizes in 32.56% of cases, and smaller in 18.6%. Its ability to predict the vault was not good, with a difference of +284.23 ±417.87µm at one week compared to the clinically achieved vault. The resulting vault calculation according to Igarashi gives better results, with no significant differences at 1 week and 1 year. The mean difference between the Igarashi's vault and the actual vault was -25.80±267.12 µm at one week after surgery. Even so, there is considerable scatter in data, which reduces the correlation between calculated/actual vault to 12.5% accuracy. It should be noted that these errors in vault calculation vary with ICL size, with Igarashi et al (Igarashi, Shimizu et al. 2021) stating that the vault calculation error was approximately -20% for an ICL size of 12.1 mm and approximately +30% for ICL sizes of 13.2 and 13.7 mm.

## CONCLUSION

Based on these results, the best results in Sizing and Vault ICL calculation are obtained using online calculator (OCOS) with the measurements of WTW and ACD, using the ACW and CLR variables as accessory measurements advising the surgeon to reduce the size of the lens to be implanted by one size according to the ocular anatomy.

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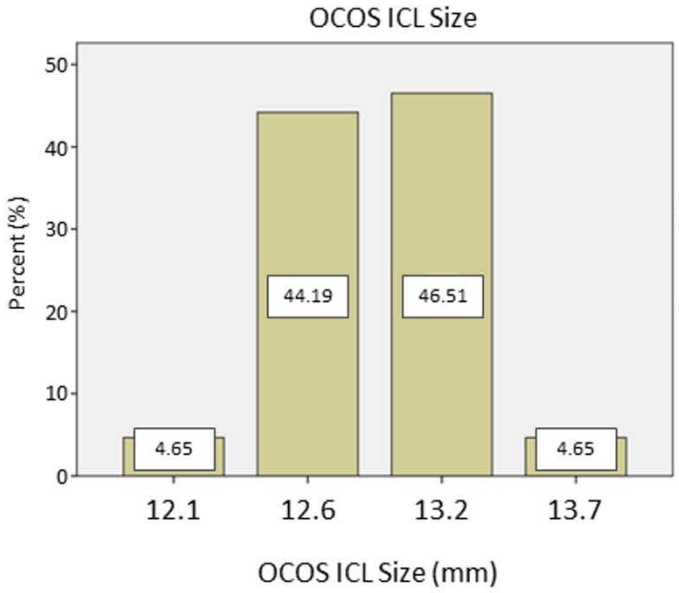
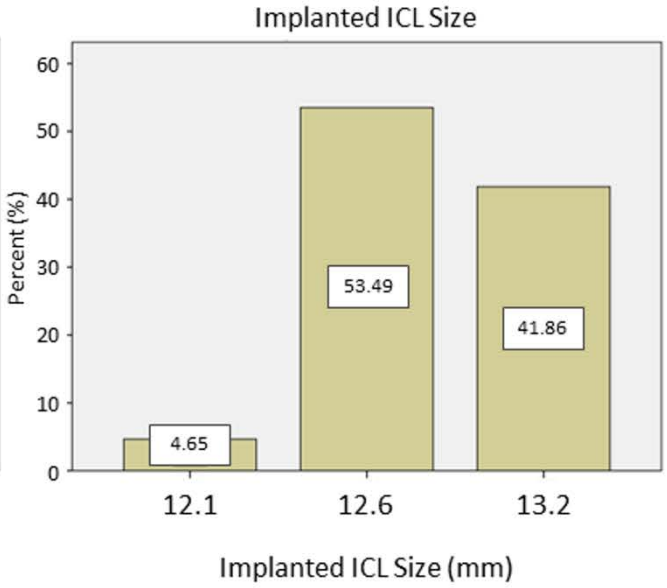
*Table 1. Demographical statistics. white-to-white acquired with Pentacam HR. ACD, ATA and CLR were acquired with Visante OCT.*

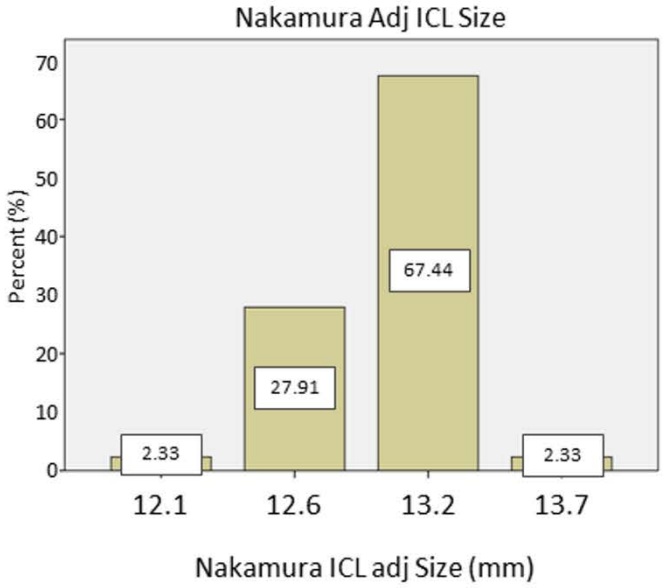
| N=43 | Mean ± SD | Range |
|---|---|---|
| Sphere (D) | -8.57 ± 3.06 | -4.75 to -20.50 |
| Cylinder (D) | -1.45 ± 0.82 | -0.25 to -3.50 |
| Spherical equivalent (D) | -9.36 ± 3.24 | -5.50 to -21.25 |
| White to White (mm) | 11.83 ± 0.29 | 11.30 to 12.70 |
| Anterior Chamber Depth (mm) | 3.35 ± 0.20 | 2.95 to 3.87 |
| Angle to angle (mm) | 12.18 ± 0.35 | 10.95 to 13.00 |
| Cristalline Lens Rise (μm) | 104.95 ± 186.89 | -339 to 400 |

*Table 1. Mean central Vault achieved one week and one year after surgery. Reduction of vault in 12 months. Theoretical vault predictions according Nakamura (NK) and Igarashi's (IG) formulas. P-values are described for mean differences at 1 week (w) and 1 year (y).*

| N=43 | Mean ± SD | Range | p value |
|---|---|---|---|
| Vault 1 Week (μm) | 533.53 ± 223.93 | 160 to 1060 | - |
| Vault 1 Year (μm) | 448.09 ± 203.61 | 110 to 1040 | - |
| Vault reduction at first year (μm) | 85.44 ± 102.61 | -5 to 370 | <0.001 |
| Theoretical NK vault prediction (μm) | 328,83 ± 361,30 | 0 to 1160 | (w)<0.001<br>(y)<0.001 |
| Theoretical NK vault prediction for optimal size (μm) | 514,66 ± 254,13 | 66 to 1060 | 0.038 |
| Theoretical IG vault prediction (μm) | 507,73 ± 245,01 | 153 to 919 | (w)0.530<br>(y)0.184 |
| Difference achieved vs theoretical NK 1 week (μm) | 284,23 ± 417,87 | -750 to 1130 | <0.001 |
| Difference achieved vs theoretical NK 1 year (μm) | 198,79 ± 452,25 | -960 to 950 | 0.006 |
| Difference achieved vs theoretical IG 1 week (μm) | -25,80 ± 267,12 | -439 to 656 | 0.530 |
| Difference achieved vs theoretical IG 1 year (μm) | 59,64 ± 289,74 | -439 to 656 | 0.184 |



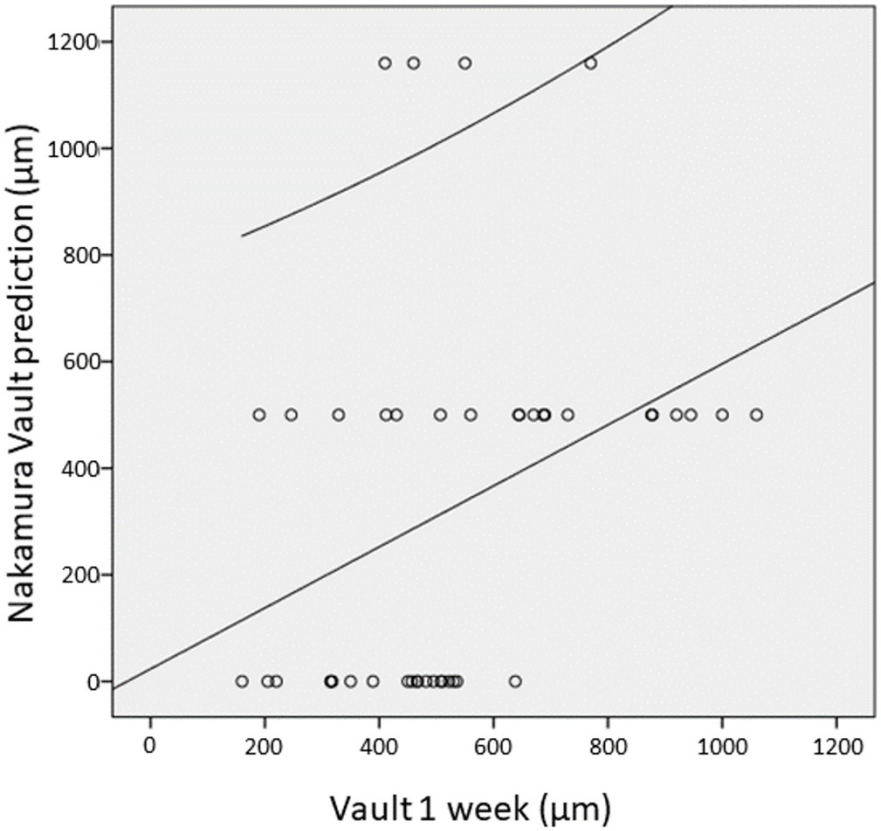



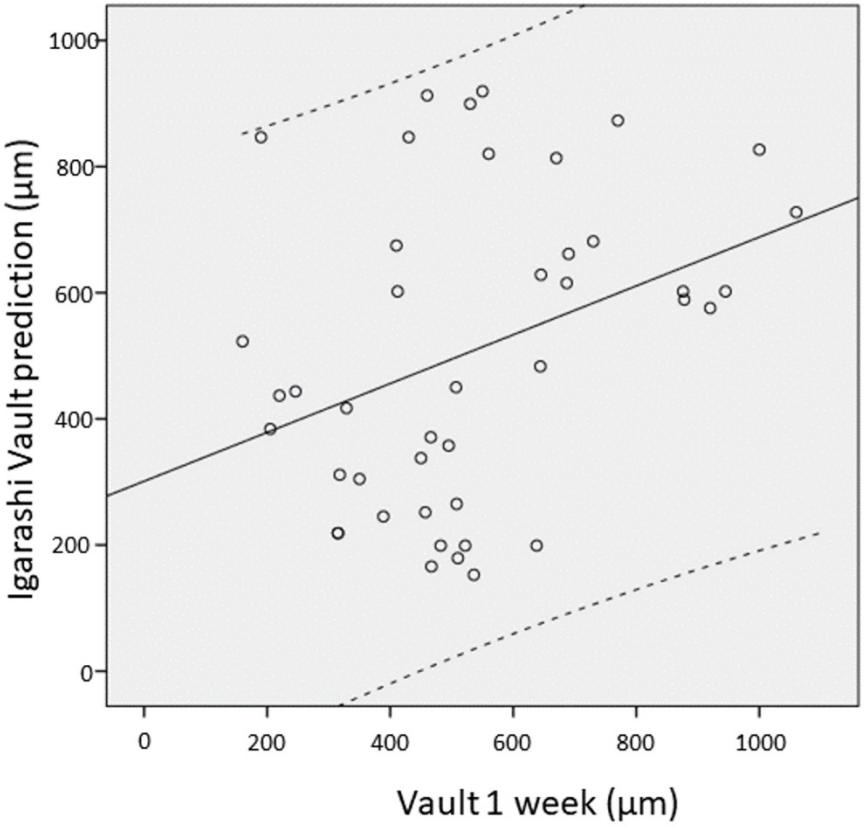

12.6 mm → 44,19%
13.2 mm → 46,51%

12.6 mm → 53,49%
13.2 mm → 41,86%

12.6 mm → 27,91%
13.2 mm → 67,44%




R = 0,355, $R^2$=0,126; p=0,02




R = 0,354, $R^2$=0,125; p=0,020