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Corneal Tissue Consumption per Diopter Decreases with Increasing Correction in Customized Femtosecond LASIK: A Prospective Randomized Double-Blind Contralateral-Eye Study

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Abstract

Purpose

To evaluate whether corneal tissue consumption per diopter varies according to the magnitude of myopic correction in customized femtosecond laser in situ keratomileusis (FS-LASIK) and to compare tissue-consumption between topography-guided (Contoura®) and asphericity-guided (Custom-Q®) ablation profiles.

Setting

Private refractive surgery center, Recife, Pernambuco, Brazil.

Design

Prospective, randomized, double-blind, contralateral-eye clinical trial.

Methods

Sixty-one patients undergoing bilateral customized FS-LASIK for myopia with or without astigmatism were enrolled. Eyes were randomized to receive Contoura® or Custom-Q® treatment. Tissue consumption was evaluated as predicted values obtained from the WaveLight® planning software and as observed values calculated from postoperative pachymetric changes, expressed as micrometers per diopter treated (μm/D). Eyes were stratified into low (0.0 to − 2.9 D), moderate (− 3.0 to − 4.9 D), and high (≥ − 5.0 D) myopia groups.

Results

Predicted tissue consumption was analyzed in 96 eyes and observed tissue consumption in 94 eyes. Mean predicted and observed tissue consumption were 15.01 ± 1.24μm/D and 14.49 ± 1.99μm/D, respectively (*P* = .08). Tissue consumption per diopter decreased significantly with increasing myopia for both observed values (15.03 ± 2.30 μm/D in low myopia, 14.53 ± 1.79 μm/D in moderate myopia, and 13.43 ± 1.49 μm/D in high myopia (*P* = .012) and predicted values (15.67 ± 0.79, 15.23 ± 0.66, and 13.35 ± 1.47 μm/D; (*P* < .001). Predicted tissue consumption showed significant inverse correlations with refractive magnitude in both treatment groups, whereas no significant overall differences were found between ablation profiles.

Conclusions

Corneal tissue consumption per diopter in customized FS-LASIK decreases as the magnitude of myopic correction increases rather than remaining constant. These findings suggest that individualized tissue-consumption estimates may improve preoperative tissue-preservation calculations compared with the conventional assumption of a fixed value of approximately

Trial Registration

ISRCTN78153726. Registered 20 October 2022.

VALUE STATEMENT

WHAT WAS KNOWN

- Accurate estimation of corneal tissue consumption plays an important role in refractive surgery planning because it directly influences residual stromal bed calculations, Percent Tissue Altered (PTA), and the assessment of biomechanical safety.
- During preoperative planning, tissue consumption is commonly estimated using an average value of approximately 15 μm per diopter, although this assumption has not been adequately validated across different levels of myopia or customized ablation profiles.
- Whether tissue consumption per diopter remains constant as myopic correction increases in contemporary customized femtosecond LASIK had not previously been investigated in a prospective randomized contralateral-eye study.

WHAT THIS PAPER ADDS

- This study demonstrates that corneal tissue consumption per diopter decreases progressively as the magnitude of myopic correction increases in customized femtosecond LASIK performed with the WaveLight® platform.
- The findings indicate that a single average tissue-consumption value may not accurately represent tissue removal across the full spectrum of myopic corrections.
- By showing that tissue consumption varies according to refractive magnitude, this study provides evidence supporting more individualized tissue-preservation calculations during preoperative planning for customized LASIK.

INTRODUCTION

Accurate estimation of corneal tissue consumption remains a fundamental component of refractive surgery planning because it directly influences residual stromal bed (RSB) calculations, biomechanical risk assessment, and the selection of the most appropriate surgical technique for each patient. Because postoperative ectasia is thought to result from excessive biomechanical weakening of the cornea,

preserving adequate stromal tissue has become one of the cornerstones of modern refractive surgery. Consequently, reliable preoperative prediction of tissue removal is essential for optimizing both surgical efficacy and safety[1–4].

The relationship between refractive correction and tissue removal has traditionally been estimated using the Munnerlyn formula, which was originally developed for conventional spherical myopic ablations[1,4–6]. Although this model remains the basis for many contemporary planning tools, it relies on simplified assumptions of spherical corneal geometry and ablation depth. Chang et al. demonstrated that the Munnerlyn approximation systematically underestimates theoretical ablation depth and that this discrepancy increases with larger optical zones, highlighting limitations that may become increasingly relevant in modern laser refractive surgery[1].

The introduction of the Percent Tissue Altered (PTA) by Santhiago et al. represented a major advance in refractive surgery by providing a practical metric for estimating the biomechanical impact of tissue removal and identifying eyes at increased risk for postoperative ectasia[1,2–6]. Because PTA calculations depend directly on the estimated depth of tissue removal, inaccuracies in tissue consumption prediction may influence biomechanical risk assessment and surgical decision-making. Gatinel et al. emphasized that PTA is fundamentally a one-dimensional metric and may not fully reflect the true three-dimensional volume of tissue altered during refractive surgery, particularly when different optical zones and treatment profiles are considered[7]. These observations underscore the importance of improving the accuracy of tissue-consumption estimates used during preoperative planning.

At the same time, customized ablation profiles have become increasingly popular because of their ability to optimize visual quality beyond conventional refractive correction. Topography-guided and asphericity-guided treatments aim not only to correct low-order refractive errors but also to improve corneal shape, reduce optical irregularities, and minimize the induction of higher-order aberrations[5–8]. Previous studies have consistently demonstrated excellent visual and refractive outcomes with these customized approaches, contributing to their widespread adoption in contemporary refractive surgery[9–19]. Alió et al. highlighted that topography-guided treatments may require additional tissue removal[8]. Although a value of approximately 15 µm/D is frequently used during preoperative planning, the extent to which tissue consumption varies according to the magnitude of myopia remains poorly understood. Consequently, tissue consumption in customized procedures may not be entirely explained by the magnitude of refractive correction. Despite the growing use of customized ablation profiles, little is known about how tissue consumption per diopter behaves across different levels of myopia, and no prospective randomized contralateral-eye study has specifically investigated this relationship.

This question may be clinically relevant because tissue consumption is routinely incorporated into preoperative safety calculations that help determine whether a patient is a candidate for lamellar refractive surgery or should instead undergo a surface ablation procedure. If tissue consumption varies according to the magnitude of ametropia being treated, the use of a single average estimate for all refractive ranges may lead to inaccuracies in tissue-preservation calculations and biomechanical risk

assessment. We hypothesized that tissue consumption per diopter would decrease with increasing myopic correction and therefore would not remain constant across different refractive ranges.

To the best of our knowledge, the present study is the first prospective, randomized, double-blinded, contralateral-eye clinical trial designed to investigate corneal tissue consumption per diopter in customized femtosecond LASIK. In addition to directly comparing topography-guided (Contoura®) and asphericity-guided (Custom-Q®) ablation profiles, eyes were stratified according to the magnitude of myopia to determine whether tissue consumption per diopter varies across different refractive ranges. The purpose of this study was to evaluate whether tissue consumption per diopter remains constant across different levels of myopia and to assess the implications of these findings for preoperative tissue-preservation calculations using the WaveLight® platform.

METHODS

Patients and Study Design

This prospective, randomized, double-blind, contralateral-eye comparative study was approved by the Ethics and Research Committee of the Federal University of São Paulo (UNIFESP; approval number 3,245,443), complied with Resolution 466/2012 of the Brazilian National Health Council regarding research involving human subjects, and adhered to the tenets of the Declaration of Helsinki. The present study represents a prespecified secondary analysis of a broader prospective randomized clinical trial registered in the ISRCTN Registry (ISRCTN78153726; registration date: 20 October 2022). This analysis focused specifically on corneal tissue consumption per diopter in customized femtosecond LASIK. This cohort has also contributed data to a previous report focusing on refractive outcomes, higher-order aberrations, and epithelial remodeling; the present analysis, by contrast, addresses tissue consumption per diopter as a distinct, prespecified endpoint of the same trial. Written informed consent was obtained from all participants before enrollment. This study was conducted and is reported in accordance with the CONSORT 2010 Guidelines. A completed CONSORT checklist is provided as an additional file.

The primary endpoint of the study was the comparison of tissue consumption per diopter among low-, moderate- and high-myopia groups. The secondary endpoint was the comparison of tissue consumption between 2 customized femtosecond LASIK profiles: topography-guided (Contoura®) and asphericity-guided (Custom-Q®).

Sixty-one consecutive patients were initially enrolled. Of these, 48 patients completed the 3-month follow-up and had sufficient data available for the final analysis, yielding 96 eyes for the assessment of predicted tissue consumption. Thirteen patients were excluded from the final analysis because of incomplete postoperative follow-up. Eligible patients were between 20 and 35 years of age, had stable refraction for at least 1 year, myopia ranging from − 0.50 to − 8.00 diopters (D), astigmatism up to − 3.00 D, a maximum spherical equivalent of − 8.00 D, and corrected distance visual acuity of 20/20 or better. Exclusion criteria included dry eye disease, abnormalities of the anterior or posterior segment, central

corneal thickness less than 500 μm, percent tissue altered greater than 35%, suspected or established keratoconus, collagen vascular disease, diabetes mellitus, pregnancy, breastfeeding, or any intraoperative complication. Contact lens wearers were instructed to discontinue lens use at least 4 weeks before screening.

To investigate the influence of refractive magnitude on tissue consumption, eyes were stratified according to preoperative spherical equivalent into 3 groups: low myopia (0.00 to − 2.99 D), moderate myopia (− 3.00 to − 4.99 D), and high myopia (≥ − 5.00 D). This stratification was established before statistical analysis and represented the primary comparison of the study.

Sample Size

This study used a convenience sample of all consecutive eligible patients presenting for a bilateral customized femtosecond LASIK during the enrollment period; no a priori sample size calculation was performed. We recognize this is a limitation of the study.

Preoperative and Postoperative Assessment

All patients underwent a comprehensive ophthalmologic examination, including uncorrected and corrected distance visual acuity, manifest and cycloplegic refraction, corneal tomography, corneal topography, epithelial thickness mapping, corneal asphericity analysis, and higher-order aberration assessment.

Corneal tomography and asphericity measurements were obtained using the Galilei G6® tomographer (Ziemer® Ophthalmic Systems), whereas corneal topography was performed using the Topolyzer Vario® (Alcon® Laboratories). Corneal aberrations were analyzed using Zernike decomposition over a 6.0-mm pupil diameter and expressed in micrometers. Epithelial thickness maps were obtained using Fourier-domain optical coherence tomography (RTVue Avanti®; Optovue Inc.) over a 9.0-mm corneal diameter.

All preoperative and postoperative examinations were performed by the same technician under standardized lighting conditions. Postoperative examinations were conducted at 1 day, 1 week, 1 month, and 3 months after surgery. At the 3-month visit, manifest refraction, corneal tomography, and epithelial thickness mapping were repeated. Postoperative pachymetry measurements suitable for the calculation of observed tissue consumption were available in 94 eyes. Two eyes were excluded from this analysis because complete postoperative pachymetry data were unavailable at the 3-month visit. The postoperative regimen consisted of topical moxifloxacin 0.5% combined with dexamethasone 0.1% administered 4 times daily for 1 week, in addition to preservative-free lubricating drops.

Randomization and Surgical Technique

Randomization was performed on the day of surgery by an independent ophthalmologist, who was not involved in preoperative planning or postoperative assessment, using a computer-generated simple randomization sequence. The sequence was held by this independent ophthalmologist and was not accessible to the operating surgeon until the time of surgery, ensuring allocation concealment. The first treated eye was always the right eye. One eye was randomly assigned to topography-guided treatment (Contoura®), whereas the fellow eye received asphericity-guided treatment (Custom-Q®). The surgeon and surgical assistant remained masked to treatment allocation during surgical planning.

All procedures were performed by the same surgeon using the WaveLight® EX500 excimer laser platform (Alcon Laboratories) and the Z8® femtosecond laser system (Ziemer® Ophthalmic Systems). In all eyes, the flap was programmed to a thickness of 110 µm and a diameter of 9.0 mm, and treatments were performed using a 6.5-mm optical zone. Emmetropia was targeted in all cases.

For Contoura® treatments, 8 high-quality topographic images were obtained and transferred to the WaveLight® planning software. Only examinations with a Quality Dynamic Link Library score of 3 or higher were accepted. Treatment planning followed the manufacturer's updated recommendations, including adjustments between manifest and topographic astigmatism. Eyes with differences greater than 1.25 D between manifest and topographic cylinder or with significant axis discrepancies were excluded from topography-guided planning. For Custom-Q® treatments, the sphero-cylindrical correction was adjusted according to the WaveLight® nomogram using the preoperative Target-Q value obtained from the Topolyzer Vario.

Outcome Measures

Tissue consumption was evaluated using 2 different approaches. Predicted tissue consumption was obtained directly from the WaveLight® planning software. Observed tissue consumption was calculated as the difference between preoperative and postoperative central corneal thickness measured at 3-month visit and divided by the attempted spherical equivalent correction, yielding a value expressed in micrometers per diopter treated (µm/D). The primary outcome measure was the comparison of tissue consumption among low, moderate, and high myopia groups. The secondary outcome measure was the comparison of tissue consumption between Custom-Q® and Contoura® treatments.

Statistical Analysis

Descriptive statistics were calculated for all variables and reported as mean ± standard deviation, minimum, maximum, and sample size when appropriate. Data distribution was assessed using the Kolmogorov-Smirnov test. Because most variables showed a non-Gaussian distribution, nonparametric methods were used throughout the analysis.

Paired comparisons between predicted and observed tissue consumption were performed using the Wilcoxon signed-rank test.

Comparisons between treatment profiles were performed using the Mann-Whitney U test. Comparisons among low-, moderate-, and high-myopia groups were performed using the Kruskal-Wallis test, followed by Dunn multiple-comparison testing when appropriate.

Correlations between ametropia group and tissue consumption were assessed using Spearman rank correlation coefficients. Statistical analyses were performed by an independent biostatistician. All tests were two-sided, and P values less than .05 were considered statistically significant.

RESULTS

A total of 96 eyes were included in the analysis of predicted tissue consumption, whereas postoperative pachymetric data suitable for the calculation of observed tissue consumption were available in 94 eyes. Baseline clinical, refractive, and tomographic parameters were comparable between the Custom-Q® and Contoura® groups, with no significant differences detected in any preoperative parameter (Table 1).

Table 1
Baseline Preoperative, Clinical Refractive, and Tomographic Characteristics of Eyes Treated With Custom-Q® and Contoura®

Variable	Custom-Q® (n = 38)		Contoura® (n = 38)		Mann-Whitney U (p)
	Mean	SD	Mean	SD	
Preop. UDVA	1.11	0.301	1.12	0.313	1.00
Preop. CDVA	-0.08	0.059	-0.09	0.060	0.48
Preop. Visual Acuity Lines	-0.11	0.509	-0.21	0.528	0.59
Preop. Spher. Equivalent	-3.39	1.600	-3.33	1.615	0.76
Preop. Sphere	-2.98	1.547	-2.87	1.536	0.66
Preop. Cylinder	-0.82	0.665	-0.93	0.788	0.65
Preop. Spher. Equiv. Axis	106.91	68.590	113.88	72.364	0.77
Preop. Simulated K	44.10	1.396	44.07	1.418	0.93
Preop. Simulated Keratom. Astigmatism	-1.04	0.689	-1.17	0.671	0.37
Preop. Astigmatism Axis	102.84	73.026	105.29	76.733	0.72
Preop. Total Corneal Astigmatism	-0.97	0.681	-1.07	0.659	0.50
Preop. TCP Astig. Axis	88.84	66.841	95.13	75.409	0.59
Preop. Pachymetry	543.39	29.935	542.42	28.581	0.86
Preop. Total RMS	1.23	0.572	1.34	0.557	0.29
Preop. Topolyzer Aspheric. Factor	-0.27	0.102	-0.28	0.116	0.99

Preop.= preoperative; UDVA= uncorrected distance visual acuity; CDVA = Corrected distance visual acuity; Spher. Equivalent= spherical equivalent; Sphere= spherical refractive error; Cylinder= refractive cylinder; Spher. Equiv. Axis = spherical equivalent axis; Simulated K= simulated keratometry; Simulated Keratom. Astigmatism = simulated keratometric astigmatism; TCP Astig. Axis = total corneal power astigmatism axis; Pachymetry = central corneal thickness; RMS= root mean square; Topolyzer Aspheric. Factor = Topolyzer asphericity factor.

The primary analysis demonstrated that tissue consumption per diopter varied according to the magnitude of myopic correction (Table 2). Mean observed tissue consumption progressively decreased from 15.03 ± 2.30 µm/D in the low-myopia group to 14.53 ± 1.79 µm/D in the moderate-myopia group and 13.43 ± 1.49 µm/D in the high-myopia group. Comparison among the three refractive groups revealed a statistically significant difference

Table 2
Tissue Consumption per Diopter According to Myopia Group

Myopia Group	Predicted			Observed			Wilcoxon (p) Test
	M	SD	N	M	SD	N	
Low Myopia (0- 2.9D)	15.67	0.789	33	15.03	2.298	33	0.18
Moderate Myopia (3- 4.9D)	15.23	0.663	44	14.53	1.790	42	0.08
High Myopia (>-5D)	13.35	1.473	19	13.43	1.487	19	0.53

(Kruskal-Wallis, P = .012). Post hoc analysis demonstrated significantly lower tissue consumption in eyes with high myopia compared with both low-myopia eyes (P = .009) and moderate-myopia eyes (P = .009), whereas no significant difference was observed between low and moderate myopia (P = .348).

Overall, mean predicted tissue consumption was 15.01 ± 1.24 µm/D (range, 11.40–18.41 µm/D), whereas mean observed tissue consumption was 14.49 ± 1.99 µm/D (range, 8.28–18.95 µm/D). Although observed values tended to be lower than predicted values, the difference did not reach statistical significance (Wilcoxon test, P = .08) (Table 3).

Table 3
Comparison of Predicted and Observed Tissue Consumption in the Overall Sample

Tissue Consumption	Mean	SD	Min	Max	N
Predicted	15.01	1.242	11.40	18.41	96
Observed	14.49	1.998	8.28	18.95	94
Observed tissue consumption tented to be lower than predicted tissue consumption; however, the difference did not reach statistical significance					
(Wilcoxon signed-rank test, P = .08).					

A similar pattern was observed for predicted tissue consumption. Mean predicted values decreased from 15.67 ± 0.79 µm/D in the low-myopia group to 15.23 ± 0.66 µm/D in the moderate-myopia group and 13.35 ± 1.47 µm/D in the high-myopia group. The overall difference among groups was highly significant (Kruskal-Wallis, P < .001). Post hoc analysis demonstrated significant differences between low and moderate myopia (P = .004), low and high myopia

(P < .001), and moderate and high myopia (P < .001), indicating a progressive reduction in predicted tissue consumption with increasing refractive correction (Table 2).

When predicted and observed values were compared within each ametropia group, no statistically significant differences were identified. In the low-myopia group, predicted and observed tissue consumption averaged 15.67 ± 0.79 µm/D and 15.03 ± 2.30 µm/D, respectively (P = .18). Corresponding values in the moderate-myopia group were 15.23 ± 0.66 µm/D and 14.53 ± 1.79 µm/D, respectively (P = .08), whereas in high myopia they were 13.35 ± 1.47 µm/D and 13.43 ± 1.49 µm/D (P = .53) (Table 2).

Subgroup analysis according to treatment profile demonstrated a similar reduction in tissue consumption with increasing ametropia in both customized ablation profiles (Table 4).

Table 4
Predicted and Observed Tissue Consumption Stratified by Myopia Group and Treatment Profile

Treatment Profile	Refractive Error	Predicted			Observed			Wilcoxon (p) test
		M	SD	N	M	SD	N	
Custom Q®	0-2.9D	15.33	0.489	18	14.84	2.024	18	0.45
	3-4.9D	14.93	0.328	22	14.33	2.134	21	0.48
	5D	12.89	1.432	9	13.71	1.539	9	0.04
Contoura®	0-2.9D	16.08	0.899	15	15.26	2.644	15	0.31
	3-4.9D	15.52	0.783	22	14.74	1.387	21	0.07
	5D	13.77	1.450	10	13.17	1.470	10	0.28

In the Custom-Q® group, predicted tissue consumption decreased from 15.33 ± 0.49 µm/D in low myopia to 12.89 ± 1.43 µm/D in high myopia, whereas observed tissue consumption ranged from 14.84 ± 2.02 µm/D to 13.71 ± 1.54 µm/D. A statistically significant difference between predicted and observed values was detected only in the high-myopia subgroup, in which observed tissue consumption exceeded the predicted value (13.71 ± 1.54 µm/D versus 12.89 ± 1.43 µm/D; P = .04). No significant differences were observed in the low- or moderate-myopia groups (P = .45 and P = .48, respectively).

In the Contoura® group, predicted tissue consumption decreased from 16.08 ± 0.90 µm/D in low myopia to 13.77 ± 1.45 µm/D in high myopia, whereas observed tissue consumption decreased from 15.26 ± 2.64 µm/D to 13.17 ± 1.47 µm/D across the same refractive intervals. No statistically significant differences were found between predicted and observed values within any ametropia subgroup, although a trend toward lower observed consumption was observed in the moderate-myopia group (P = .07) (Table 4).

The relationship between refractive magnitude and tissue consumption was further explored using Spearman correlation analysis (Table 5). Predicted tissue consumption demonstrated a significant inverse correlation with ametropia in both treatment groups. The correlation coefficient was ρ = −0.68 for Custom-Q® (P < .01) and − 0.55 for Contoura® (P < .01). When all eyes were analyzed together, the inverse correlation remained significant (ρ = −0.54, P < .01), indicating that predicted tissue consumption per diopter decreased as the magnitude of myopia increased.

Table 5: Spearman Correlation Between Myopia Group and Predicted and Observed Tissue Consumption

Treatment	Correlation With Refractive Error Group					
	Predicted Tissue Consumption			Observed Tissue Consumption		
	Rho	p	N	Rho	p	N
Custom Q®	-0.68	<.01	49	-0.19	0.21	48
Contoura®	-0.55	<.01	47	-0.40	0.01	46
All Eyes	-0.54	<.01	96	-0.28	0.01	94

Observed tissue consumption showed a weaker association with refractive magnitude. No significant correlation was identified in the Custom-Q® group (ρ = −0.19, P = .21), whereas a significant inverse correlation was observed in the Contoura® group (ρ = −0.40, P = .01). In the pooled analysis, observed tissue consumption also demonstrated a significant, although weaker, inverse correlation with ametropia (ρ = −0.28, P = .01) (Table 5).

Scatterplot analysis showed a similar overall distribution of predicted and observed tissue consumption across refractive ranges. However, a greater dispersion of postoperative measurements was observed with increasing myopic correction. Regression analysis confirmed the inverse relationship between refractive magnitude and tissue consumption, with a steeper decline observed for predicted values than for observed values (Fig. 1).

Overall, these findings demonstrate that tissue consumption per diopter is not constant across different levels of myopia and decreases significantly with increasing refractive correction in both topography-guided (Contoura®) and asphericity-guided (Custom-Q®) femtosecond LASIK treatments.

DISCUSSION

The principal finding of the present study is that corneal tissue consumption per diopter was not constant across different levels of myopic correction in customized femtosecond LASIK performed with the WaveLight® platform. Instead, both predicted and observed tissue consumption decreased as the

magnitude of myopia increased. This finding challenges the common assumption that myopic LASIK consumes a fixed average of approximately 15 μm/D of tissue per diopter, regardless of treatment magnitude or ablation profile. In routine clinical practice, this simplified estimate is often used to calculate residual stromal thickness and PTA; therefore, inaccuracies in tissue-consumption prediction may influence biomechanical risk assessment and surgical decision-making[1,2,4].

Customized ablation profiles have become increasingly popular because of their ability to optimize optical quality while maintaining excellent refractive outcomes[5,7–10]. Recent studies evaluating contemporary customized ablation strategies have consistently reported excellent refractive accuracy, visual outcomes, and patient satisfaction[5,13–19]. However, most of these studies focused primarily on visual performance and refractive predictability rather than on tissue-consumption behavior. To our knowledge, no previous prospective randomized contralateral-eye study has specifically evaluated whether tissue consumption per diopter varies across different ranges of myopia.

The literature specifically addressing corneal tissue consumption in contemporary customized laser refractive surgery remains limited. Most available studies have evaluated visual outcomes, refractive accuracy, optical quality, or biomechanical risk metrics rather than the relationship between refractive magnitude and tissue consumption per diopter. This relative scarcity of data limits direct comparison with the present findings and underscores the need for further investigation in this area.

The clinical relevance of this finding becomes particularly important in borderline cases. For example, in an eye with a central corneal thickness of 530 μm, a planned flap thickness of 110 μm, and a 7.00 D myopic correction, assuming a fixed tissue consumption of 15 μm/D would result in an estimated PTA of approximately 40.6%. If tissue consumption is instead estimated at 13 μm/D, as observed in higher myopic corrections in the present customized ablation cohort, the estimated PTA would decrease to approximately 37.9%. Although such calculations should not be used in isolation, this example illustrates how individualized tissue-consumption estimates may influence surgical planning and the choice between lamellar and surface ablation procedures.

The nonlinearity observed in the present study is consistent with the known limitations of traditional ablation models. The Munnerlyn formula remains historically important, but Chang et al. demonstrated that it systematically underestimates theoretical ablation depth and that this error increases with optical zone diameter and correction magnitude[1]. This is particularly relevant in modern refractive surgery, in which treatment planning no longer relies exclusively on simple spherical ablation profiles. Larger optical zones, blend zones, customized asphericity, and topography-guided corrections may all modify the relationship between refractive treatment and tissue removal.

The discrepancy between predicted and observed tissue consumption also agrees with the findings of Savini et al., who reported only moderate agreement between EX500®-predicted and Scheimpflug-measured ablation depth after femtosecond LASIK[6]. Their study suggested that predicted ablation depth may be overestimated in lower corrections and underestimated in higher corrections. Our results

similarly show that predicted and observed values do not behave identically across ametropia groups, reinforcing the need for caution when using software-derived predictions as absolute values.

The introduction of the Percent Tissue Altered (PTA) by Santhiago et al. represented a major contribution to refractive surgery, providing a practical method for estimating the biomechanical impact of tissue removal and identifying eyes at increased risk for postoperative ectasia[2]. The present findings should not be interpreted as a limitation of the PTA concept itself. Rather, they suggest that one of the variables used in PTA calculation – the estimated ablation depth – may benefit from refinement according to the magnitude of ametropia and the ablation profile being planned. Individualizing tissue-consumption estimates may therefore provide a more precise assessment of residual stromal tissue and improve the interpretation of PTA in borderline cases.

Gatinel et al. demonstrated that the PTA is a one-dimensional metric and does not represent the true volume of surgically altered corneal tissue[7]. Their analysis showed that the volume varies with flap thickness and the square of flap diameter, whereas ablated tissue volume is proportional to myopic correction and to the fourth power of treatment diameter[7]. This distinction is highly relevant to our findings. If tissue consumption per diopter varies according to ametropia, and if tissue removal is influenced by optical zone and customized ablation profile, then any safety index based only on linear tissue depth may fail to capture the real biomechanical impact of surgery. In this context, our results support the need for more individualized and, potentially, more volumetric approaches to preoperative planning[2,7].

The comparison between Custom-Q® and Contoura® further reinforces this concept. Customized ablations are not purely refractive treatments; they also modify corneal shape, asphericity, and higher-order aberration profiles. In this present study, the high-myopia Custom-Q® subgroup showed a significant difference between predicted and observed consumption, whereas the moderate-myopia Contoura® subgroup approached significance. These findings should not be interpreted as evidence that one technique is universally more tissue-saving than the other. Rather, they suggest that tissue behavior depends on the interaction among ametropia magnitude, ablation profile, and treatment planning algorithm.

A particularly important observation of the present study was that predicted tissue-consumption values demonstrated a stronger inverse correlation with ametropia and observed values. This finding suggests that the treatment-planning software imposes a more consistent mathematical relationship between refractive correction and tissue consumption than is ultimately observed clinically. In actual surgical conditions, factors such as laser-tissue interaction, stromal hydration, epithelial remodeling, wound healing, and measurement variability may influence postoperative corneal thickness and contribute to the weaker association observed for measured tissue consumption. Consequently, software-derived estimates should be regarded as useful planning tools rather than exact representations of tissue removal.

These findings may also have implications for future refinements of preoperative tissue-preservation calculations. Contemporary planning strategies frequently rely on simplified assumptions regarding tissue consumption, yet our results indicate that tissue removal does not behave uniformly across different refractive ranges. Incorporating refractive magnitude into tissue-consumption estimates may improve the precision of residual stromal tissue calculations and enhance individualized surgical planning, particularly in eyes approaching commonly accepted biomechanical safety thresholds.

It should be emphasized that the present study evaluated only customized ablation profiles using the WaveLight® platform. Therefore, the extent to which these findings can be extrapolated to wavefront-optimized (WFO) treatments remains uncertain. Recent comparisons between topography-guided and wavefront-optimized treatments have focused primarily on visual and refractive outcomes rather than tissue-consumption behavior [15,18]. This distinction is clinically relevant because many of the assumptions currently used in tissue-preservation calculations originated from conventional ablation models that are conceptually closer to WFO treatments than to contemporary customized procedures. Additional studies are warranted to determine whether the progressive reduction in tissue consumption per diopter observed in the present series is specific to customized treatments or represents a more universal characteristic of corneal laser ablation.

To our knowledge, no previous prospective randomized contralateral-eye study has specifically investigated the relationship between refractive magnitude and tissue consumption per diopter in customized femtosecond LASIK.

This study has several limitations that should be considered when interpreting the findings. Although the randomized contralateral-eye design minimized interindividual variability, the number of eyes within each myopia subgroup, particularly the high-myopia group, was relatively small and may have limited the ability to detect more subtle differences between treatment profiles. This reflects the use of a convenience sample rather than a sample size determined by a priori power calculation, which may have limited the ability to detect smaller differences, particularly within the high-myopia subgroup. In addition, observed tissue consumption was estimated from postoperative pachymetric changes, which may have been influenced by factors such as epithelial remodeling, stromal hydration, wound healing, and measurement variability. Finally, because this study evaluated only customized ablation profiles performed with the WaveLight® platform, the results may not be directly applicable to other excimer laser systems, treatment algorithms, or wavefront-optimized procedures.

Using the WaveLight® platform, corneal tissue consumption per diopter in customized femtosecond LASIK was found to decrease progressively with increasing myopic correction rather than remain constant. These findings suggest that the commonly adopted assumption of an average tissue consumption of approximately 15 μm/D may not accurately reflect tissue removal across the full spectrum of myopic treatments. Predicted and observed tissue consumption showed similar overall trends but only partial agreement across refractive ranges. These results support the need for more

individualized surgical planning models that account for refractive magnitude, optical zone, ablation profile, and volumetric tissue alteration.

Declarations

Ethics approval and consent to participate

This study was approved by the Research Ethics Committee of the Federal University of São Paulo (UNIFESP), approval number 3,245,443, and was conducted in accordance with the Declaration of Helsinki and Resolution 466/2012 of the Brazilian National Health Council. Written informed consent was obtained from all participants prior to enrollment.

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare no competing interests.

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Author Contribution

A.F.V.L conceived and designed the study, coordinated patient recruitment and data collection, performed the data analysis, interpreted the results, and wrote the manuscript. E.M.A performed all surgical procedures and contributed to the clinical conduct of the study, contributed to data collection and reviewed the manuscript.P.R.A.M and R.M.V contributed with data collection and reviewed the manuscript. All authors read and approved the final manuscript.

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Figures

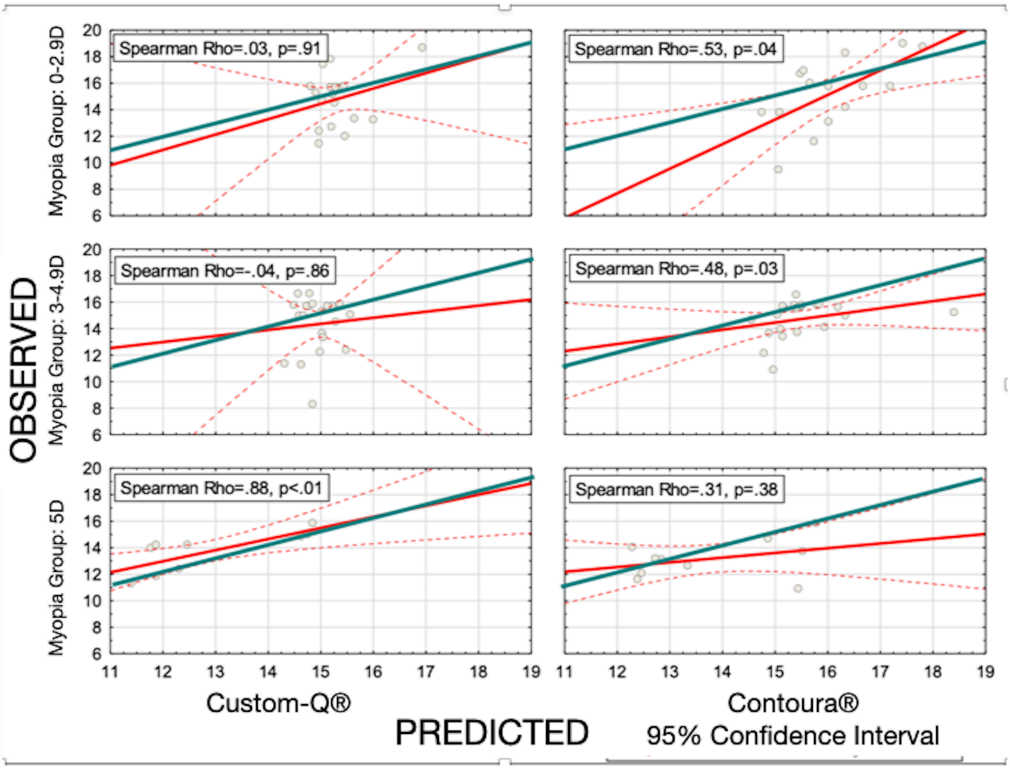


Figure 1

Scatterplots showing the relationship between refractive magnitude and corneal tissue consumption per diopter. Predicted (A) and observed (B) tissue consumption are shown for Custom-Q and Contoura treatments. Regression analysis demonstrates a progressive decrease in tissue consumption per diopter as the magnitude of myopic correction increases.

Supplementary Files

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