

Corneal Collagen Crosslinking for Keratoconus: Experience of the Ophthalmology Department at CHU Hassan II in Fez (About 65 Cases)

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| Received: 22.02.2026 | Accepted: 02.04.2026 | Published: 11.04.2026

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Abstract

Case Report

Keratoconus is an idiopathic corneal dystrophy characterized by ectasia and progressive non-inflammatory thinning of the cornea. It affects young individuals and has considerable progressive potential, thus constituting a source of visual impairment for children and young adults. Collagen crosslinking (CXL) is currently the only treatment that can slow its progression. We conducted a prospective study at the Ophthalmology Department of CHU Hassan II in Fez, where we collected epidemiological and clinical data over two years with a 12-month follow-up period. The study included 57 patients (65 eyes). Our patients benefited from a modified accelerated protocol (9 mW/cm², 14 minutes). Our results demonstrated a decrease in maximum keratometry (kmax) from 57,54 diopters to 54,68 diopters at 6 months (p=0,009) and 54,32 diopters at 12 months (p=0,128). The average pachymetry was 448 μm, and it decreased by 32 μm after a 6-month period. Corneal OCT was performed on 24 eyes and showed a continuous and regular demarcation line in 50% of cases. The main complication was corneal haze. An improvement in the topographic profile and visual acuity (VA) is observed, especially when the management is early. We quantified the rates of stabilization, improvement and progression following corneal cross-linking according to predefined criteria: 29% of eyes were stable, 66% improved and 5% showed progression following CXL. Corneal crosslinking represents a promising procedure in stabilizing and regressing the progression of this potentially blinding corneal dystrophy.

Keywords: Keratoconus; crosslinking; corneal graft; corneal dystrophy.

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INTRODUCTION

Keratoconus (from the Greek keras, "horn," "cornea" and konos, "cone") was first described by Nottingham in 1854 [1]. It is a non-inflammatory, progressive, bilateral, and often asymmetric pathology of the cornea. It is accompanied by thinning of the cornea, which primarily affects the collagenous stroma. It generally begins in adolescence, progresses during the first decades, and stabilizes during the third or fourth decade. There are various stages of progression, depending on corneal deformation, with a significant decrease in visual acuity, which can lead to corneal blindness, as in the terminal stages visual acuity can drop below 1/20, in which case the only viable treatment remains corneal transplantation. Stages of visual impairment between 1/20 and 4/10 are extremely common, with an impact on social life. The rate of progression varies from one patient to another, ranging from several months to several years, but it can be very rapid over a few months. Therefore, stabilizing this disease before it reaches advanced stages is an important

therapeutic challenge. The only treatment currently shown to be effective in stiffening the corneal stroma and thus slowing the progression of keratoconus is corneal collagen crosslinking (CXL), developed by Théo Seiler (Zurich, Switzerland), which combines UVA and riboflavin as a photosensitizing substance. Corneal cross-linking (CXL) has evolved considerably since its introduction. The original Dresden protocol involved epithelium-off (epi-off) treatment with 3 mW/cm² UV-A irradiation for 30 minutes after applying riboflavin. This approach was associated with postoperative discomfort and a longer recovery period. To improve patient comfort and reduce complications, several modifications have been proposed, including: Transepithelial (epi-on) CXL, which preserves the epithelium but may reduce riboflavin penetration and biomechanical effect ; Accelerated protocols, using higher UV-A intensity for a shorter duration, aiming to achieve the same total energy while shortening treatment time; Customized and pulsed protocols, which adjust irradiation patterns to enhance safety and efficacy, particularly in thinner corneas. These protocol adaptations have expanded the indications of

Citation: Meryem Mouajab, Hassan Moutei, Fouad Chraibi, Meriem Abdellaoui, Idriss Benatiya. Corneal Collagen Crosslinking for Keratoconus: Experience of the Ophthalmology Department at CHU Hassan II in Fez (ABOUT 65 CASES). Sch J Med Case Rep, 2026 Apr 14(4): 671-677.

CXL, improved patient tolerance, and maintained its effectiveness in stabilizing or improving keratoconus [2]. In our study we report the results of a prospective study, the aim of which is to evaluate the effectiveness of corneal crosslinking (CXL) on the progression of keratoconus in our context and to demonstrate whether the modified accelerated protocol allows for stabilization or improvement comparable to standard protocols with potentially fewer side effects.

MATERIALS AND METHODS

This is a prospective non-randomized interventional study including patients with keratoconus who received corneal collagen crosslinking treatment over a period of 2 years between September 2014 and September 2016 at the ophthalmology department of Hassan II University Hospital Center in Fez.

Inclusion Criteria: All patients presenting with progressive keratoconus with disease progression over 6 months, defined by:

- ✓ an increase in maximum keratometry of more than one diopter (1D).
- ✓ an increase in cylinder \geq 1D.
- ✓ an increase in spherical correction \geq 0.5 D.
- ✓ Young patients \leq 20 years old.
- ✓ Pachymetry \geq 400 μ m.
- ✓ Transparent cornea.

Exclusion Criteria: Patients were excluded from our study if they had:

- ✓ a history of herpetic keratitis.
- ✓ corneal opacity.
- ✓ patients lost to follow-up.

Patients were staged according to the Krumeich classification. Patient interviews or interviews with the parents of children, a complete ophthalmological examination including a rigid lens trial, and corneal topography (Pentacam, Oculus, Inc.) were performed for all patients, and the results were recorded on a common data collection form. All patients received a modified accelerated epi-off protocol: 9 mW/cm² - 14 min which delivers a total of 7.5 J/cm² instead of 5.4 J/cm² in the standard protocol (3 mW/cm² - 30 min). The device used in our department is the Lightmed Lightlink-CXL. The course of the CXL was as follows:

- **1st step:** Epithelial debridement using a scraper over an 8 mm diameter.
- **2nd step:** Soaking with the instillation of 0.1% isotonic riboflavin (Vibex Rapid®), 1 drop every 3 minutes.
- **3rd step:** UVA irradiation for 14 minutes while maintaining riboflavin instillation every 3 minutes.
- **4th step:** Placement of a therapeutic soft contact lens.

The entire protocol is carried out in the operating room under optimal aseptic conditions. The evaluation of the effects of CXL after 6 months defines three situations:

- Progression when the maximum keratometry increases by more than 1D.
- Stabilization when the difference between the two maximum keratometries is between 0 and 1D.
- Improvement when the maximum keratometry decreases by more than 1D.

Statistical analysis:

The statistical analysis of the various parameters studied was carried out at the epidemiology department of CHU Hassan II in Fez using SPSS software version 19 (SPSS Inc., Chicago, IL, USA). Continuous variables were expressed as mean \pm standard deviation (SD), and categorical variables as frequencies and percentages. Comparisons between preoperative and postoperative measurements were performed using the paired t-test for normally distributed variables, and the Wilcoxon signed-rank test for non-normally distributed variables. Categorical outcomes (rates of stabilization, improvement, and progression) were analyzed using the chi-square test or Fisher's exact test as appropriate. A p-value \leq 0.05 was considered statistically significant.

RESULTS

Our study includes 57 patients, totaling 65 eyes, with an average age of 19 years \pm 5,7 [8 years, 35 years], without a predominance of sex (Sexe ratio H/F: 1,03). The main medical histories are represented by the presence of a history of chronic eye rubbing in 35 patients (64%) and occasional in 12%. An atopic background was found in 22 patients. The search for similar cases identified 3 cases of keratoconus among the siblings of patients followed in our center. One case of lupus in remission and two pregnant women were included in our series. The main functional signs reported by patients or their families are decreased visual acuity, blurred vision, allergic conjunctivitis, or chronic eye rubbing. These functional signs may occur in isolation or in combination. Uncorrected visual acuity is less than or equal to 1 LogMAR in 25 eyes, and between 1 and 0,4 LogMAR in 26 patients. After optical correction, 18 patients experienced an increase in visual acuity to 10/10 (0 LogMAR), and 25 patients to greater than 7/10 (0,16 Log MAR). The average visual acuity is 0,16 Log MAR. The main clinical signs observed during the ophthalmological examination are those of allergic conjunctivitis and Munson's sign. Other clinical signs include corticosteroid-induced cataract in one patient; strabismus of the fellow eye in one patient; and amblyopia in three children. The Krumeich classification was adopted to stratify patients according to different degrees of severity. Stage III being the most common among our patients. The different topographic parameters studied are summarized in Table 1. The main indications for corneal crosslinking were made in

children or young adults under the age of 20, or in cases of progressive keratoconus, including 2 pregnant women. Patients with progressive keratoconus account for 69% of the patients. Young patients aged 20 or younger are included from the first consultation; they represent 31% of the patients. All patients received the following therapeutic protocol: The modified accelerated protocol (9 mW/cm², 14 minutes): 30 minutes of riboflavin instillation (1 drop every 3 minutes) followed by 14 minutes of UVA irradiation. The main operative incidents are intraoperative ocular revulsion during irradiation, which is explained by pain at the end of the procedure; most patients poorly tolerate the supine operative position. Postoperative follow-ups showed stable corrected visual acuity during the 6 months following the crosslinking. The final average visual acuity is 0,16 Log MAR. The postoperative complications are: Ocular pain in all patients; sterile infiltrates in one patient; delayed epithelial healing; healing after 72 hours in one patient; infectious keratitis in 2 patients, with one case of para-axial keratitis in a lupus patient in remission, and one case of peripheral keratitis measuring 1 mm, related to the non-application of postoperative treatment. In both cases, functional recovery was good. One case of corneal edema, which regressed after 4 days of symptomatic treatment (Figure 1). Corneal haze is the most common complication in our patients, with 7 patients presenting transient haze graded at 0.5+ (barely detectable trace of haze); 6 patients

presented haze graded at 1+ (mild haze not affecting refraction). In all cases, this haze disappeared by the 3-month follow-up visit. Crosslinking failure is defined by a progression of keratometry of more than 1 D in 6 months or more than 2 D in one year: observed in 3 patients, representing 5% of our series. The control corneal topography performed at one month, at three months, and then every six months was conducted for all patients. The following were noted: Stabilization of the disease in 19 eyes (29%); Progression in 3 eyes (5%); Improvement in 43 eyes (66%) (table 2). A statistically significant improvement in keratometry over time was observed (at 3 months p=0.024 and at 6 months p=0.009). This decrease is not significant at 1 year and 2 years (p=0.128 and p=0.094, respectively), probably due to the size of our sample. A decrease in mean pachymetry of 26 μm was noted after CXL; nevertheless, pachymetric changes are significant at 6 and 24 months, respectively. The progression of mean astigmatism shows an improvement that is statistically significant at 6 months and one year (p=0.018 and 0.042, respectively). Some patients underwent anterior segment OCT after 15 days; it was performed on 24 eyes. The demarcation line was studied. It was continuous in 11 eyes (Figure 2); discontinuous in 6 eyes (Figure 3); absent in 7 eyes (Figure 4). The study of the relationship between CXL effectiveness and the quality of this line could not be established due to the insufficient number of patients who underwent this examination.

Table 1: The topographic data collected from the study

K max	Pachymetry	Corneal astigmatism	Average K	Optical R
57,5+/-6,4	448+/-34	4,68+/-3	48+/-3,6	7,02+/-0,4

Table 2: Comparison of clinical characteristics according to outcomes after CXL (n=65 eyes)

Parameter	Improvement (n=43)	Stabilization (n=19)	Progression (n=3)
Mean age (years)	24.7 ± 3.2	25.5 ± 4.1	23.2 ± 2.9
Pre-op K max(D)	55.6 ± 2.3	54.3 ± 3.4	57.6 ± 4.9
Post-op K max(D)	53.5 ± 4.4	53.6 ± 2.5	58.6 ± 3.4
Kmax change (D)	-3.4± 2.4	-1.4± 0.4	+1.9± 1.4
Pre-op VA (log MAR)	0.58± 0.22	0.55± 0.25	0.62± 0.28
Post-op VA (log MAR)	0.32± 0.18	0.52± 0.30	0.78± 0.3
Pachymetric changes (μm)	+9± 10	+1± 6	-19± 12

Table 3: Evolution of maximum keratometry after CXL in different published studies

Authors	Pre-op Kmax (diopters)	1 months	3 months	6 months	12 months	24 months
Asri <i>et al.</i> , [11]	54.09 ±6.07	53.39 ±5.26	52.62 ±5.66	52.96 ± 5.45 p= 0.001	53.60 ± 5.47 p=0.045	-
Guber <i>et al.</i> , [21]	52.69 (50.93 à 54.45)	-	52,83 p=0.858	-	52,53 p=0.855	-
Viswanathan <i>et al.</i> , [18]	49.65±4.91	-	-	-1,1D p = 0.009	1.18 ±1.83 D p= 0.005	2.4 ±4.41 P = 0.14
Mazzotta <i>et al.</i> , [20] (accelerated)	Continuous Cxl 56.84, Pulsed Cxl 55.40	-	-	-	+0.15 p>0,05 -1.39 p<0,05	-
Koc <i>et al.</i> , [12] (accelerated)	58.06± 6.86	-	-	-	56.21± 6.21 p<0.001	-
Chan [19] (accelerated)	62.1 ± 10.4	-	-	-	61.5± 9.4 p=0.184	-
Our series	57,54 ±6,44	56,44 ±6,49 p=0,066	55,82 ±6,70 p=0,024	54,68 ±6,09 p=0,009	54,32 ±5,62 p=0,128	52,39 ±5,03 p=0,094

Table 4: Evolution of Postoperative pachymetry

Authors	Pre-op pachymetry (µm)	3 months	6 months	12 months	24 months
Asri <i>et al.</i> , [11]	482 ±59	491 ±69	444 ±42	471 ±47	-
Viswanathan <i>et al.</i> , [18]	470,35±39,26	-	-	467,64±43,53 p=0,60	-
Koc <i>et al.</i> , [19]	451,7 ±45,1	-	-	419,2 ±46,2 p=0,001	-
Our series	448,59± 34,87	414,76±40,2 p=0,650	416,75±44,48 p=0,007	425,03±32,72 p=0,063	412,77±34,81 p=0,009

Table 5: The different protocols published in the literature

Authors	Years	Number of patients	Protocols
Mazzotta <i>et al.</i> , [11]	2014	20	Accelerated protocol 30 mW/cm ² / 4 min
Kymionis <i>et al.</i> , [10]	2014	52	Modified accelerated protocol (9 mW/cm ² 14 min)
Koc <i>et al.</i> , [12]	2016	146	Accélérâtes protocol (9 mW/cm ² 10 min)
Wollensak [16]	2003	22 (33 eyes)	Standard 3 mW/cm ² , 30 min
Guber [21]	2013	28	Standard 3 mW/cm ² , 30 min
Chan [19]	2015	25	Accelerated 18 W/cm, 5 minutes
Our study	2016	57 (65 eyes)	Modified accelerated protocol (9 mW/cm ² 14 min)

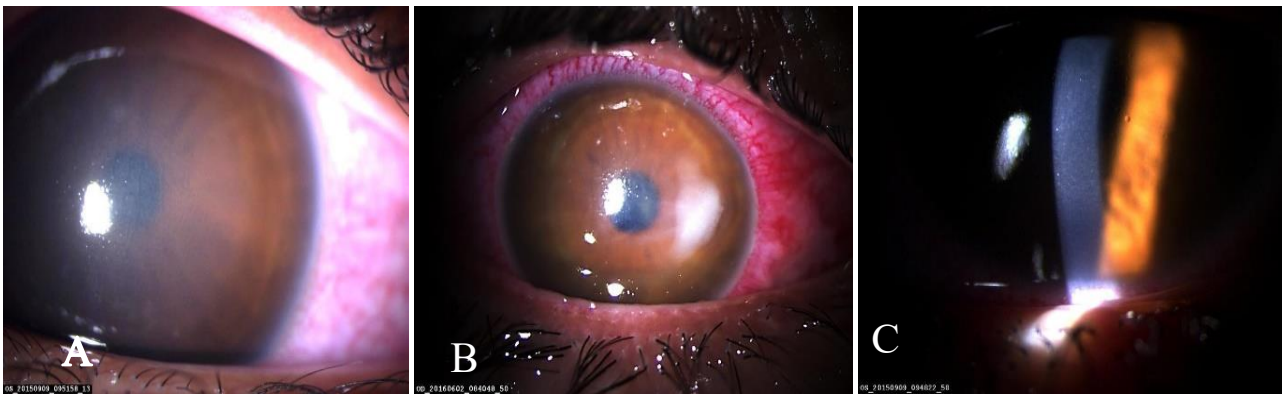


Figure 1: Image of the anterior segment illustrating the various post-CXL complications. A: corneal edema; B: corneal infiltrate related to keratitis; C: corneal haze

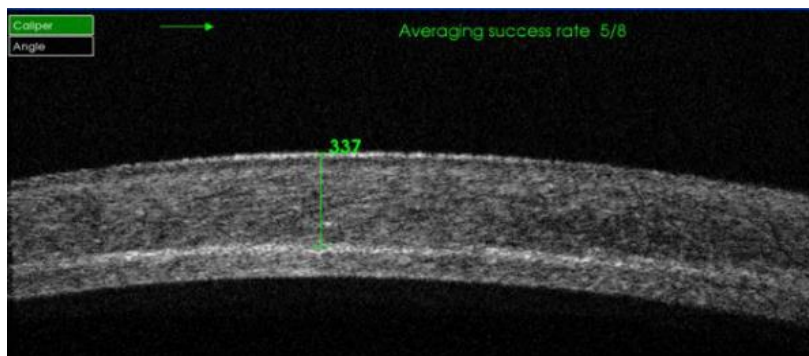


Figure 2: Continuous demarcation line located at 337 µm in the stroma.

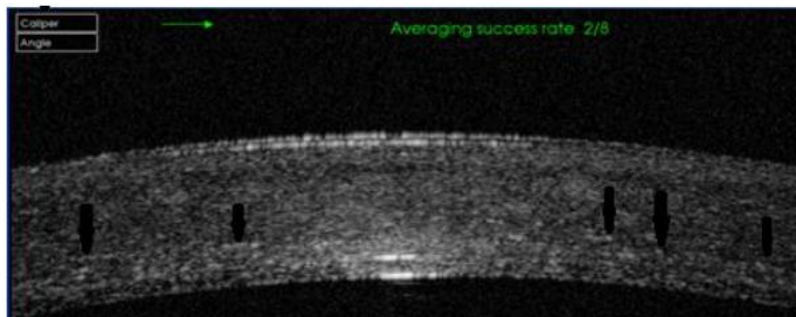


Figure 3: Discontinuous demarcation line in the stroma

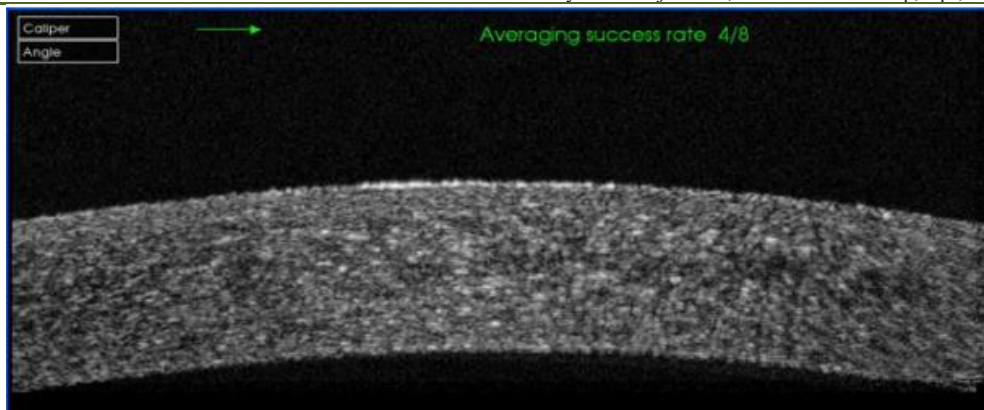


Figure 4: No demarcation line was observed in the stroma

DISCUSSION

Keratoconus is a bilateral, non-inflammatory corneal dystrophy that is often progressive, manifesting as a protrusion of the cornea that generally begins during adolescence. This deformation is accompanied by a progressive thinning of the cornea. The progression leads to a decrease in visual acuity related to the severity of irregular astigmatism and the frequent occurrence of corneal opacities. Its pathophysiology is still poorly understood, but genetic, environmental, familial, mechanical, and even inflammatory factors are implicated in its development. The main hypothesis explaining its etiopathogenesis is related to the defective interaction between collagen fibers and glycosaminoglycans, which renders the spaces between the collagen lamellae uneven and unstable, leading to a displacement of the collagen lamellae relative to each other, thereby causing corneal thinning and protrusion [3,4]. CXL is a physical treatment for keratoconus that involves the application of riboflavin with UVA irradiation, which strengthens the ectatic cornea by creating cross-links between collagen fibers, thereby halting the progression of the dystrophy [5,6]. In our study, the age at diagnosis of keratoconus is often during the second decade of life. This finding is comparable to that of the study by Sharma R in India [7]. Several studies have described a predominance of males in keratoconus involvement [8,9], which was not observed in our study. The protocol adopted by our department was proposed by Kymionis *et al.*, [10] in 2014 (modified accelerated protocol 14 min 9mW/cm²). They concluded that the demarcation line is located at the same depth level as with the standard protocol (30 min 3mW/cm²) and suggested that it may replace the latter. It should be noted that the protocol delivers an energy of 7.5 J/cm² compared to 5.4 J/cm² delivered by the standard protocol. Nevertheless, in our study, this protocol did not cause severe corneal edema or corneal burns, as reported in a study where patients received standard treatment [11]. Accelerated protocols are proposed to shorten treatment time in order to ensure patient comfort and to increase patient and physician compliance. Results from experimental and clinical studies suggest that the accelerated protocol has biomechanical effects and

safety similar to the conventional protocol [12]. All studies agree on the positive effect of corneal collagen cross-linking in stabilizing and reducing maximum keratometry, regardless of the protocol used, although the timing of treatment effectiveness varies from one study to another (Table 3). In our study, the change in Kmax is statistically significant at 6 months, but it is not at 1 year and 2 years. The same observation was found in Chan's study and in a subgroup of Mazzotta. We observed a significant improvement in astigmatism in the 6 months and 12 months. This is not the case for the other two studies. Pachymetry is calculated by the Scheimpflug rotating topographer. Pachymetric changes are significant in our study (-23 μm at 1 year) unlike in other published studies, as shown in Table 4. Since the advent of CXL for keratoconus by Wollensak *et al.*, in 2003, several centers have focused on this therapy. Numerous clinical studies have confirmed the efficacy and safety of the procedure. The objective of our study was to demonstrate the success rate and complications of an accelerated protocol that is still rarely used. In Germany, the first CXL study on human eyes included 23 eyes with a follow-up of 3 to 4 years [16]. The authors reported an average decrease of 2.01 D in Kmax and 1.14 D in refraction in a group of 16 eyes (70%). A longer follow-up of 5 years, including 60 eyes, showed an average reduction of 2.87 D in Kmax and an improvement in visual acuity of 1.14 lines. In Italy, Vinciguerra *et al.*, [17] compared in a prospective non-randomized study the effect of CXL on keratoconic eyes against an untreated control group in 28 patients. They reported a decrease of 6.16 D in K max (p=0.0011) and an improvement of BCVA by 0.14 (equivalent to 1.4 lines) (p=0.0001). In our study, crosslinking resulted in an average reduction of maximum keratometry of 2.86 D, 3 D, and 5.15 D at 6, 12, and 24 months, respectively, with stabilization of visual acuity (gain of one line of visual acuity); we even observed a significant regression of the mean astigmatism. Authors have shown that the best response to CXL was observed in patients under 26 years of age with a clear cornea, excluding cases of rapidly progressing keratoconus. This would be explained by a better "plasticity" of collagenous tissues in young adults. The factors of poor prognosis are female

sex and preoperative keratometry > 58D [11]. Another study concluded that patients with a lower preoperative corrected visual acuity and higher maximum keratometry are the most likely to experience improvement after accelerated CXL. The complication rate is approximately 3% (ranging from 1 to 10% according to studies) [11,13], with the most common being corneal haze, which decreases between 3 and 12 months. Herrmann *et al.*, discussed that post-CXL haze is not a complication but rather a usual observation following this procedure, and that riboflavin saturation before UVA exposure would protect against haze. Once installed, corticosteroids can be an effective treatment [14]. Two eyes presented a serious complication: two cases of infectious keratitis, both of which had a good outcome. This is a rare complication, with 10 cases reported in the literature [15]. Due to the negligible number of cases of keratoconus progression after CXL, there is no consensus defining progression or a management strategy. The most accepted definition is an increase of more than one diopter in maximum keratometry over one year, or a loss of 2 lines of visual acuity; this failure rate is on average 8 to 10%. In our study, it is 6% [12]. The protocol adopted by our department was proposed by Kymionis *et al.*, [10] in 2014 (modified accelerated protocol 14 min 9 mW/cm²). They concluded that the demarcation line is located at the same depth as with the standard protocol (30 min 3 mW/cm²) and suggest that it can replace the latter (Table 5). The strength of our study is the prospective nature; the large sample size of our series; the long follow-up period. However, the limit of our study is not a randomized study, which leads us to conduct a new study comparing this protocol with the conventional protocol in a randomized manner.

CONCLUSION

In conclusion, the effect of accelerated CXL on the improvement of VA and the cessation of keratoconus progression has been demonstrated by several studies. Accelerated crosslinking is a technique that aims to simplify the operative protocol for both the patient and the surgeon, and its effectiveness is comparable to that of the conventional technique with fewer side effects. However, the challenge remains the stabilization of the disease and the preservation of good long-term visual acuity, as there is currently no truly validated accelerated treatment protocol. It seems reasonable to advise against the use of fluences higher than 9 mW/cm².

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