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Quality of Life in Patients with Dohlman-Doane Type 1 Keratoprosthesis (Boston Kpro)

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Abstract

Introduction: The aim of this study was to assess quality of life in patients undergoing implantation of a Dohlman keratoprosthesis.

Materials and methods: Cross-sectional controlled, with patients undergoing implant Dohlman keratoprosthesis type I at the Hospital de Clinicas de Porto Alegre between September 2005 and May 2013. Two questionnaires of quality of life were administered in these patients SF-36 and VF-14. Furthermore, a retrospective patient charts analysis was performed.

Results: Keratoprosthesis implant surgery was performed in 33 eyes of 26 patients. A statistically significant difference was found between groups (separated by visual acuity) for the questionnaire of visual acuity (p=0.01). In SF-36 domains, there were difference in general health (p=0.036), vitality (p=0.028) and mental health (p=0.037). On the Spearman correlation analysis, 5 of the 8 domains of the SF-36, correlated with visual questionnaire (VF-14), when analyzed for the entire sample. When we separated the analysis by subgroups (according to visual acuity), in the group of lowest visual acuity had only one domain correlation (mental health). In the group of best vision, the 5 domains remained with a positive association.

Conclusion: Patients with greater visual acuity showed better results in the VF-14 responses, with a statistically significant difference between groups.

Keywords: Boston keratoprosthesis; Cornea; Quality of life; Questionnaires

Introduction

According to the World Health Organization (WHO), it has been estimated that 285 million people worldwide have some visual loss - 39 million bilaterally blind. Of these, 8 million are due to corneal causes [1]. Diseases affecting the cornea are a major cause of blindness worldwide, behind only to cataract in overall importance. In developing countries, there is a disproportionate prevalence of corneal diseases as a leading cause of blindness [2]. In Brazil, this statistic points to more than two million people with some level of visual disability. Also according to the WHO, this number is expected to grow in proportion in the near future, due to factors such as the gradual increase in average life expectancy [1].

In this context, corneal blindness is treated primarily with corneal transplantation. For many patients, a corneal graft could offer a second chance of sight. However, in some cases (eg, in patients with multiple graft failures, limbal stem cell failure, severe chemical burns and autoimmune diseases such as Stevens Johnson syndrome) keratoprostheses offer these patients hope and prospect of visual rehabilitation [3]. A keratoprosthesis that is widely used today is the Dohlman-Doane keratoprosthesis (Boston type I – Kpro), which has retention rate of 90% in cases of non-immune diseases and 50% in cases of autoimmune diseases of mucous membranes [4]. This has become the most common procedure for handling cases where penetrating keratoplasty has failed. It is being used at a rate of approximately 1,200 per year worldwide [4,5].

Significant improvement in visual acuity (VA) has been reported after keratoprosthesis implantation. At 1 year postoperatively, 57% to 83% achieve 20/200 or better of VA [6,7]. Based on this visual gain, we can deduce that a significant improvement in quality of life is achieved in these patients. Thus, the aim of this study was to assess the quality of life in patients that had undergone implantation of Dohlman-Doane keratoprosthesis.

Materials and Methods

This project was approved by the Research Ethics Committee of the Hospital de Clinicas de Porto Alegre, and conducted in accordance with the Helsinki Declaration (protocol number 13-0369). Patients were instructed about the study and asked permission to record the consent via telephone. Informed consent was obtained from all individual participants included in the study. The entire questionnaire was recorded. Phone calls were made by staff of the researcher responsible, lasting about 30 minutes, digitally archived, and questionnaires were completed immediately during the interview, presenting a minimal risk to the patient.

A cross-sectional study, conducted with all patients submitted to implant of Dohlman-Doane keratoprosthesis type I at the Hospital de Clinicas de Porto Alegre between September 2005 and May 2013.

Patients unable to answer questions, or with less than one year of postoperative follow-up were excluded.

A generic scale (SF-36) and other scale related to vision (VF-14) were applied in these patients. The SF-36 has eight domains, the final score ranging from 0 (worst capacity) and 100 (best level of function). High scores show a better health condition. The VF-14 gives a measure of vision-related functional capacity, based on 14 activities related to this sense. The score also ranges from 0 to 100. These questionnaires have been translated and validated to Portuguese language [8]. Furthermore, an analysis of the charts of these patients was performed, assessing visual acuity and complications.

Patients were divided into two groups, separated by your current visual acuity (cutoff 1.0 LogMar or 20/200 Snellen) at the time of interview, considering their last follow-up. In both groups, the two questionnaires were compared and the results applied. The primary outcome was to assess the quality of life in these patients. Secondary outcomes were post-operative visual acuity and complication rates.

The unit of study was the patient. Sample distribution was considered non-parametric on analysis by the Shapiro-Wilk test. Then, the variables were analyzed with the Mann-Whitney U test and Spearman correlation coefficient. Effect were considered statistically significant at $p<0.05$. Data were analyzed using the statistical package SPSS version 18 (IBM®). Complication rates and visual acuity were described as percentages, averages and standard-deviation.

Results

During the analyzed period, type I Boston K-Pro implantation was performed in 33 eyes of 26 patients. No patients refused participation in the study. Five patients were lost to follow-up (19.23%) – one patient passed away and four patients had less than 1 year follow-up. Questionnaires were then applied in 21 patients, analyzing their results, visual acuity and rate of complications.

The average follow-up time was 56.1 ± 42.4 months (12 to 102 months). Retention percentage of keratoprosthesis in this sample was 85.71%. All 33 eyes received a type I Boston KPro. Pseudophakic type 1 Boston KPro was implanted in 30 eyes, and aphakic type 1 Boston KPro in 3 eyes

The underlying pathologies were multiple graft failure in 15 eyes (keratoconus, bullous keratopathy, acute glaucoma, aniridia, Acanthamoeba keratitis), alkaline burn eyes in 8, Stevens-Johnson syndrome (SJS) in 3, thermal burn in one. All eyes had a preoperative visual acuity (VA) preoperatively worse or equal to 1.0 (LogMar) and have had several surgeries prior to K-Pro implantation. All eyes with limbal stem cell deficiency (burns, aniridia and SJS) were previously submitted to a conjunctival limbal transplantation with a living donor HLA compatibility >50% and/or to an allogeneic limbal cadaver transplantation with systemic immunosuppression.

Quality of Life

The analysis of the questionnaires is presented in Table 1. The first eight fields represent the values obtained in the SF-36. The latter refers to the VF-14. The analysis of these results was made with the Mann-Whitney U test and revealed a statistically significant difference between groups for the VF-14 ($p=0.01$) (Figure 1). For the domains of the SF-36, only 3 had differences between the groups, which were general health ($p=0.036$), vitality ($p=0.028$) and mental health ($p=0.037$). It is prudent to emphasize that the analysis of the SF-36 cannot gather all the fields in a result; it should only be done individually.

Groups		Physical Functioning (SF-36)	Role-Physical (SF-36)	Bodily Pain (SF-36)	General Health (SF-36)	Vitality (SF-36)	Social Functioning (SF-36)	Role-Emotional (SF-36)	Mental Health (SF-36)	VF14
≤ 1,0	N=9									
	Average	65.00	44.44	70.89	46.78	57.22	47.9167	59.2589	65.33	31.9422
	Standard Deviation	38.406	48.052	25.867	18.853	20.480	15.93444	49.37908	13.115	8.20248
>1,0	N=12									
	Average	85.42	72.92	84.83	67.42	74.17	56.7500	77.7767	78.00	68.1517
	Standard Deviation	16.984	37.626	22.457	22.889	13.114	6.20575	38.49037	8.780	21.9326
	p value	0.221	0.129	0.124	0.036	0.028	0.398	0.460	0.037	0.001

Table 1: Questionnaires analysis.

In Table 2, according to the Spearman correlation analysis, we can see that of the 8 domains of the SF-36, five had a statistically significant correlation with the VF-14, when analyzed for the entire sample. When we separate the analysis by subgroups (according to visual acuity), as seen in Table 3, in the lowest visual acuity had only one domain correlation (mental health). In the group of best vision, the 5 domains remained with a positive association.

Visual acuity

The best postoperative corrected VA was better than or equal to 1.0 (LogMar) in 12 patients (57.14%). The nine remaining eyes did not reach ambulatory VA (20/200) (42, 85%). Postoperative refractive error ranged from -2.00D to +9,50D. Astigmatism did not exceed -2.00D.

Postoperative complications

Postoperative complications are shown in Table 4. Eighteen of the twenty-one patients (85.71%) had a postoperative complication, and 9 patients had severe complications (42.85%).

Among minor complications, nine patients (42.85%) showed retro-prosthetic membrane, each being treated with YAG laser capsulotomy between the third and fifth postoperative month and two eyes required anterior vitrectomy. Nine patients (42.85%) developed cystoid macular edema confirmed by angiography or optical coherence tomography, treated with intravitreal or sub-Tenon triamcinolone, intravitreal injection of Avastin, or medical treatment. Three patients (14.28%) showed fibrin in the anterior chamber, two in the first month after surgery and one in the fourth month, treated with injection of tissue plasminogen activator (tPA) and corticosteroids. Increased intraocular pressure was identified to the third postoperative month in four patients (19.04%), being controlled with medication. Eight patients (38.09%) had preoperative glaucoma. Ahmed valve was implanted in 4 eyes (one previously and three simultaneously with the KPro surgery). Seven eyes had a stable visual field, at least 30°, and one eye had stable tubular field, during the follow-up period. Two eyes with preoperative terminal glaucoma experienced postoperative visual acuity insufficient to perform the examination.

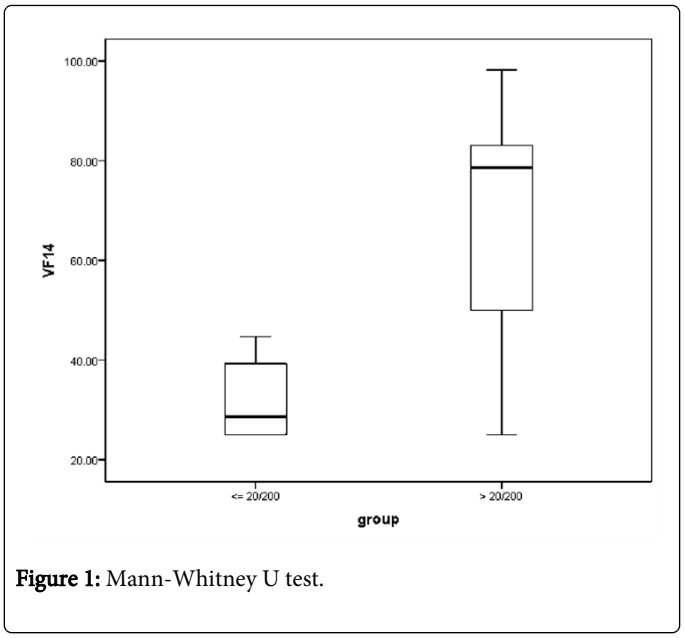

Figure 1: Mann-Whitney U test.

Spearman's rho		Physical Functioning (SF-36)	Role-Physical (SF-36)	Bodily Pain (SF-36)	General Health (SF-36)	Vitality (SF-36)	Social Functioning (SF-36)	Role-Emotional (SF-36)	Mental Health (SF-36)
VF14	Correlation Coefficient	0.513	0.477	0.183	0.663	0.639	0.337	0.423	0.774
	Sig. (2-tailed)	0.017	0.029	0.427	0.001	0.002	.135	.056	.000
	N	21	21	21	21	21	21	21	21

Table 2: Spearman correlation analysis between SF-36 and VF-14.

Spearman's rho			Physical Functioning (SF-36)	Role-Physical (SF-36)	Bodily Pain(SF-36)	General Health (SF-36)	Vitality (SF-36)	Social Functioning (SF-36)	Role-Emotional (SF-36)	Mental Health (SF-36)
≤ 1,0	VF14	Correlation Coefficient	0.083	-0.222	-0.207	0.358	0.335	0.324	0.389	0.772
		Sig. (2-tailed)	0.831	0.565	0.593	0.344	0.378	0.395	0.300	0.015
		N=9								
> 1,0	VF14	Correlation Coefficient	0.773	0.639	-0.078	0.621	0.434	0.363	0.621	0.746
		Sig. (2-tailed)	0.003	0.025	0.810	0.031	0.159	0.247	0.031	0.005
		N=12								

Table 3: Spearman correlation subgroups analysis.

Complications	Patients (%)
Retro-prosthetic membrane	9 (42.85)
Cystoid macular edema	9 (42.85)
Corneal necrosis	8 (38.09)
Glaucoma	4 (19.04)
None	3 (14.28)
Retroprosthetic fibrin	3 (14.28)
Endophtalmitis	2 (9.52)
Retinal detachment	2 (9.52)

Table 4: Postoperative complications.

We considered keratolysis, endophthalmitis and retinal detachment as major complications. Eight patients (38.09%) had keratolysis. Four of these needed to undergo a donor cornea exchange, one eye a sclera patch and conjunctival graft and the other eye medical treatment was required. All these 4 cases had preoperative limbal stem cell deficiency treated with limbal transplantation. Four patients (19.04%) presented clinical symptoms of infectious keratitis, two of which developed *Candida albicans* endophthalmitis, treated with corneal transplantation, K-Pro and IOL explantation, anterior vitrectomy, intravitreal and endovenous voriconazole. This eye received a new Boston K-Pro two months later. Two patients (9.52%) developed retinal detachment, having been treated with pars plana vitrectomy and retinopexy. K-Pro explantation was necessary in 3 eyes, and one eye developed phthisis bulbi.

Discussion

Boston type I keratoprosthesis is currently an important alternative in cases of corneal blindness for which penetrating keratoplasty does not offer a good prognosis [8-10]. An important advantage of Boston K-Pro is that there is no need of systemic immunosuppression [11]. Ma et al. has, however, recently proposed systemic immunosuppression for patients with immune mucous membrane diseases [12]. Cases of alkali burn and multiple previous corneal grafts have a better prognosis than patients with immune mucous membrane diseases, such as SJS, Lyell syndrome and ocular cicatricial pemphigoid [7].

In cases of multiples corneal transplantation, each new transplant increase the risk of graft rejection, as well as other complications, such as cystoid macular edema and glaucoma, decreasing the median graft survival time decrease [7]. Furthermore, in cases of severe ocular surface diseases, such as severe bilateral alkali burns and immune diseases of mucous membranes, the prognosis for corneal transplantation is poor, even with systemic immunosuppression [12].

In our sample, all patients received keratoprosthesis type I. During the follow-up period, similar to other published series [6]. Despite the high incidence of postoperative complications (85.17%), the retention rate was 85.71% in our series, during the follow-up period, consistent with previous studies [6].

Currently, there are studies that indicate the validity of questionnaires to determine the quality of life in patients with visual impairment or undergoing to ophthalmological procedures, one of the most used is the VF-14 [13]. This tool becomes valid to measure the visual function in patients with corneal disease [8,14-16], except for patients with keratoconus [17]. Also, the use of questionnaires to assess quality of life is well established in patients undergoing cataract surgery [18,19]. According to Bilbao, this instrument has a high accuracy in determining the quality of life after cataract surgery, in contrast with generic scales like SF-36, which did not obtain good effectiveness in these patients [20]. Furthermore, there are studies that use these tools to evaluate corneal transplantation patients, with an excellent response rate [8,14].

Boisjoly et al. demonstrated a positive correlation of the VF-14 visual scale with the scale of general health SF-36 in patients undergoing corneal transplantation [15]. Recently, Cortina and Hallak show the impact of Boston keratoprosthesis (KPro) implantation on patient using the National Eye Institute Visual Function Questionnaire 25 (NEI VFQ-25) [21]. The quality of life of these patients significantly improved postoperatively compared with their preoperative status [21].

In our sample, we decided to use the VF-14 and SF-36 questionnaires because they are already well established in the assessment of quality of life in patients with visual disability [15]. It is known that the improvement of corneal transparency is not synonymous with functional improvement in these patients. In some cases, a good visual acuity after the procedure is not correlated with a better quality of life. In our series of cases there was, however, a strong positive correlation between the results of postoperative VA with the VF-14. Patients with better postoperative VA had better results in the VF-14 responses, with a statistically significant difference between groups. When the SF-36 results were analyzed, which is an index of perception of general health, we found, however, a statistically significant correlation with VA only in only three of the eight domains, for the whole sample.

When we correlated both the questionnaires, we observed a positive correlation with the VF-14 in five of the eight domains of SF-36, when analyzed for the entire sample. When we separated the analysis for VA, in the group of best vision, the five domains remained with a positive association; in the lowest VA group only one domain had a positive correlation (mental health).

Although the general health questionnaires such as the SF-36 did not show a good discriminative ability to measure the functional outcome of ocular interventions, in our sample there was a good correlation with the SF-36 in patients that had a good postoperative VA in comparison to the VF-14. Thus, beyond the specific questionnaires for visual function, in some cases, the general health questionnaires can be availed for a more comprehensive analysis of general patient health.

The main limitation of this study arises from methodological concerns regarding a "before and after". For a strong conclusion, a cohort study delineation would be more appropriated, comparing scores before and after surgery, as Cortina and Hallek's paper.[21] However, this was not possible because our first surgeries were ten years ago and questionnaires were not applied in that time. Because of that, we decide to divide our patients in two groups based on visual acuity and to compare score results of both groups - a cross sectional study. In despite of, our interpretation is that the observed differences were clinically important.

In conclusion, we observed that in our sample Boston KPro implantation has the potential of significantly improving the vision-

related quality of life in patients with poor prognosis. Patients who achieve a better visual acuity have better measures on quality of life scales, as compared to those with worse visual outcomes.

Conflict of Interest

All authors certify that they have NO affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speaker's bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patient-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

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