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Outcomes of Boston keratoprosthesis type 1 reimplantation – multicenter study results

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Abstract

Purpose: To investigate the visual and anatomical outcomes of Boston keratoprosthesis type 1 reimplantation.

Design: Subgroup analysis of multicenter prospective cohort study.

Participants: Of 303 eyes who underwent keratoprosthesis implantation between January 2003 and July 2008 by one of 19 surgeons at 18 medical centers, 13 eyes of 13 patients who underwent reimplantation of Boston keratoprosthesis type 1 were compared to 13 eyes of 13 diagnosis-matched patients who underwent initial implantation.

Methods: Forms reporting preoperative, intraoperative, and postoperative parameters were prospectively collected and analyzed. Main outcome measures were keratoprosthesis retention and logMAR visual acuity.

Results: After a mean follow-up time of 17.1 ± 17.6 months, the retention of both initial and repeat keratoprosthesis implantation was 92.3% (12/13 in both groups). 62% of initial implantation and 58% of repeat implantation eyes achieved visual acuity better than 20/200. Vision worse than 20/200 was often due to glaucoma or posterior segment pathology. Best-recorded logMAR visual acuity was significantly improved postoperatively in both groups ($p < 0.001$), and there was no statistically significant difference in final logMAR visual acuity between the two groups ($p = 0.89$). Sterile keratolysis ($n=4$) and fungal infection ($n=5$) were the most common causes of initial keratoprosthesis failure in the repeat Kpro group. The single failure

*Group members listed in Appendix 1.

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in the repeat keratoprosthesis implantation group was due to fungal keratitis, and in the control group, was related to keratoprosthesis extrusion.

Conclusions: Repeat keratoprosthesis implantation is a viable option after failed initial keratoprosthesis, with visual and anatomical outcomes comparable to those of initial procedures.

Keywords

Keratoprosthesis; outcomes; reimplantation

Introduction

Since its approval by the FDA in 1992, the Boston keratoprosthesis (Kpro) has emerged as a viable alternative to penetrating keratoplasty (PK) in patients with prior history of failed grafts for conditions including chemical and thermal injury, congenital aniridia, Stevens-Johnson Syndrome (SJS), ocular cicatricial pemphigoid (OCP), bullous keratopathy, and Fuchs dystrophy.

Outcomes of Boston Kpro implantation are generally favorable, with visual acuities improving significantly post-operatively and reaching 20/200 or better in more than 40% of patients^{1–5} and sustaining this visual acuity for an average of 47.8 months⁶. Retention rates are also high, previously reported at 94% after 1 year⁷, 89% after 2 years⁷, and 67% at 7 years².

Despite these favorable outcomes, significant challenges in the management of Kpros remain. For instance, the monitoring and treatment of glaucoma is difficult and can lead to progressive loss of vision⁸. Despite close follow-up and careful monitoring, some patients may require explantation or replacement of the Kpro. Common causes of Kpro failure include infectious keratitis, endophthalmitis, sterile keratolysis, and extrusion⁷.

Eyes that fail initial Kpro implantation may either be rehabilitated with a tectonic keratoplasty or undergo repeat Kpro implantation. While much research has focused on the outcomes of initial Kpro implantation, there exists little insight into outcomes of repeat Kpro implantation. One recent study reported that eyes with ocular surface disease, defined as SJS, OCP, atopic disease, severe keratoconjunctivitis sicca, or cicatrizing conjunctivitis from chemical or thermal injury, were more likely to require repeat Kpro implantation. In the study, eyes that achieved 20/200 vision after the first Kpro were statistically more likely to achieve greater than 20/200 vision after the repeat Kpro implantation⁹.

In this multicenter study, we report a matched case-control comparison of the visual and anatomical outcomes of 13 eyes that underwent repeat Kpro implantation to 13 eyes that underwent their first Kpro implantation, and report notable trends for causes of KPro failure.

Methods

The Boston Keratoprosthesis Type 1 is obtained from the Massachusetts Eye and Ear Infirmary. The technique for implanting the Boston Keratoprosthesis has been previously described and all surgeons reported using a similar technique¹.

Data Collection:

The Boston Keratoprosthesis Multicenter Study is a large prospective cohort study of patients undergoing Boston Keratoprosthesis Type I implantation since January 1, 2003. It is approved by the institutional review board at the Albany Medical Center. Because this study began 2 years before the public launch of the clinicaltrials.gov website, it is not registered on the site. Data collection was performed using a mail-in Case Report Form consisting of approximately 70 perioperative variables that was sent to all surgeons known to be performing multiple procedures at the time of study initiation. After each patient was assigned a unique study number in accordance with Health Insurance Portability and Accountability Act regulations, the data forms were sent to a data coordinating center approved by the institutional review board. Follow-up data was reported by the participating surgeons at intervals of one month, six months, twelve months, and annually thereafter.

In patients with bilateral Kpro implantation, only the first eye was included because the eyes are not independent data points. However, in some patients, it was their second eye that required repeat KPro, so for this report, the other eye was removed from the database.

Based on previously published prognostic categories¹⁰, the patients were categorized into the following pathologic groups: severe autoimmune disease (ocular cicatricial pemphigoid [OCP] and Stevens Johnson Syndrome [SJS]), chemical injuries, herpes simplex (HSV) keratitis, Fuchs endothelial dystrophy, keratoconus, infectious keratitis, neurotrophic ulcers, limbal stem cell deficiency (LSCD), pseudophakic bullous keratopathy (PBK), trauma, aniridia, miscellaneous, failed penetrating keratoplasty (PK) and unknown.

Cases were defined as those eyes that underwent repeat Kpro implantation. Eyes missing basic demographic data (ie. age, sex) were not considered for control selection. Controls were matched by diagnosis and failure status and were randomly selected using a random number generator (<https://www.random.org/>; accessed September 16, 2016).

Analysis:

A Microsoft Excel spreadsheet was used to compile the data and SAS version 9.3 (SAS Institute Inc., Cary NC, USA) was used for all data analyses. Because some surgeons provided data at follow-up time points (e.g. 6 months, 1 year, etc.) without a specific date, a follow-up date was imputed for these patients. Association between categorical variables was examined using Chi-square test. For comparisons of continuous variables between two groups, Wilcoxon rank-sum was utilized because of a non-normal distribution of data in the repeat KPro group.

Visual acuity measurements were obtained using a standard Snellen chart viewed from a distance of 6 meters and were converted to logarithm of the minimum angle of resolution (logMAR) units for the analysis, which was the primary outcome of interest. Visual acuity measurements that were recorded as counting fingers were converted to a Snellen equivalent using the conversion algorithm described by Holladay¹¹, although a lower limit of 20/2000 was utilized. When a distance at which finger counting was measured was not recorded, the distance was assumed to be 2 feet, which is equivalent to 20/2000. One research group^{12,13} has calculated that hand motions acuity ranges between 2.28 and 3.60 logMAR units; the

upper limit was used for this study. Pairwise comparisons of baseline and final visual acuity measurements in the same eye were compared using the Wilcoxon signed-rank test.

Eyes with light perception (LP) and no light perception (NLP) visual acuity were excluded in initial analyses of visual acuity, although they were summarized in the figures using the format previously published for Boston keratoprotheses^{4,14}. In addition, the same analysis was performed by assigning Snellen values of 20/40000 for LP and 20/60000 for NLP. Results for these analyses are presented only when they differed from the primary approach.

Based on the recommendations by Jabs¹⁵, the time to achieve 20/200 vision was analyzed using Kaplan-Meier curves with 95% Hall-Welner Bands¹⁶ and the log-rank test was used for group comparisons. Time to achieve 20/200 visual acuity was defined as from the date of surgery to the first follow-up visit at which 20/200 visual acuity was observed, including preoperatively. As such, eyes with better than 20/200 visual acuity prior to KPro placement were censored at time zero. For those eyes, time to loss of 20/200 visual acuity was analyzed as well. For the latter analysis, fluctuation in vision was discounted such that, for example, an eye that had hand motions vision preoperatively, 20/50 vision at 1 week, 20/200 at one month, 20/400 at 6 months, 20/100 at 1 year, and hand motions at 2 years would be recorded as having lost 20/200 vision after 22.77 months.

Results

Between January 2003 and July 2008, information on 321 Boston Keratoprotheses Type I implants placed in 303 patients by 19 surgeons at 18 medical centers was collected. Eight eyes of 8 patients that underwent sequential bilateral keratoprosthesis implantation were also excluded. There were 13 repeat Kpro eyes, and controls matched by diagnosis were randomly selected from 149 eyes with complete demographic data.

There was no difference in age between repeat Kpros and controls ($p=0.562$; Table 1); the mean age of patients in this cohort was 64.7 ± 14.8 and ranged from 38.5 – 89.0 years. There were more women and right eyes in the control group, but these differences were not statistically significant ($p=0.562$ and $p=0.420$, respectively). Preoperative visual acuity was better in repeat Kpro eyes (1.23 ± 0.61 logMAR units) than control eyes (2.02 ± 0.46 logMAR units) but, again, this difference wasn't statistically significant ($p=0.127$). The average time from initial Kpro to repeat Kpro was 14.2 months (range 2–35 months). Detailed baseline clinical characteristics of both repeat Kpro and control groups are shown in Table 1.

There was no difference in mean follow-up time between repeat Kpros (18.7 ± 19.3 months) and controls (15.4 ± 15.8 months; $p=0.723$). The overall Kpro retention rate was the same for both groups: 92.7%; there was one failure in each group.

Visual acuities before and after Kpro implantation for both groups are shown in Figure 1. There was a statistically significant improvement in logMAR visual acuity in both control and repeat Kpro eyes ($p<0.0001$). Eight patients achieved a final visual acuity of 20/200 or better in both the control group and the repeat Kpros group. There was no statistical difference in final logMAR visual acuity between groups ($p = 0.486$), and a

similar proportion in each group achieved 20/200 vision (61.5% in controls, 58.3% in repeat Kpro; $p=0.870$). There was no difference in the time to achieve 20/200 between groups ($p=0.373$), with a median overall time of 0.62 months. However, after having achieved 20/200 visual acuity, 2 eyes in the repeat Kpro group lost it, in comparison to none of the controls ($p=0.182$). Four out of 13 eyes in the repeat Kpro group had final visual acuities of HM or worse compared to three in the control group.

Within the repeat Kpro group, one patient improved beyond 20/200 before it was lost due to a retinal detachment and suprachoroidal hemorrhage. The visual acuities in the other 3 cases were limited by advanced glaucoma, suprachoroidal hemorrhage, and retinal detachment. In all 4 of these cases, preoperative visual acuities were CF or worse. Within the control group, all three patients who had final visual acuities of HM or worse had preoperative visual acuities of LP. One patient's vision was limited by a pre-existing retinal detachment, another's was limited by advanced glaucoma, and the third patient suffered Kpro extrusion.

Both groups developed retroprosthetic membranes at a similar rate, with 30.8% in the control group and 25.0% in the repeat Kpro group ($p=0.748$). The majority of patients (17 out of 26) had a polymethyl methacrylate (PMMA) backplate, three had a titanium backplate, and the remaining six were unknown.

There was no difference in the time to achieve 20/200 vision (Figure 2) between initial (6 months) and repeat Kpro groups (0.6 months; $p=0.373$). Figure 3 shows the time to loss of 20/200 visual acuity; none of the initial Kpro eyes lost 20/200 vision after having achieved it at some point during follow-up. However, a quartile time to loss of 20/200 for repeat Kpro eyes was 11.8 months, although this was not statistically significant ($p=0.133$).

The overall clinical course for patients receiving initial and repeat Kpro implantation is detailed in Tables 2 and 3, respectively. The reasons for failure of initial Kpro in the repeat Kpro group are listed in Table 3. They include bacterial and fungal endophthalmitis, fungal keratitis, wound leak, Kpro extrusion, corneal thinning and melt, and dense RPM. In all such cases, a clinical judgment was made by the treating physician that repeat Kpro implantation would offer the highest likelihood of visual rehabilitation over alternatives such as tectonic keratoplasty or vitrectomy.

In the initial Kpro group, none of the patients lost 20/200 after achieving it. Two patients in the repeat Kpro group lost 20/200 vision after achieving it. In one patient, loss of 20/200 vision was due to RPM and significant macular edema that was treated with YAG membranectomy and intracameral corticosteroid, respectively. The vision at final follow-up improved to 20/60. The other patient developed an extensive retinal detachment that was considered to be inoperable. The final vision in that eye was light perception.

One eye in each group failed Kpro implantation. In the repeat Kpro group, the failure was due to fungal keratitis (*Candida albicans*) at 1 year, and in the control group, the failure was related to extrusion of the Kpro at 2 years.

Discussion

This large, multicenter study highlights the clinical outcomes of repeat Kpro implantation after initial Kpro failure. As previously reported, the rate of Kpro failure in this dataset is low, and autoimmune disease such as SJS and OCP was an independent risk factor in the failure of initial Kpro⁷, which has also been observed in other studies^{3,9,10,14}. This is supported by this sub-study, in which the only repeat Kpro failure was in a patient with an original diagnosis of SJS.

Overall, we did not find evidence that patients who undergo repeat Kpro implantation are at significantly higher risk for failure when compared to patients receiving their first Kpro. This finding is consistent with the only other study we are aware of that also focuses on the clinical outcomes of repeat Kpro implantation – of 36 cases, there were 7 failures⁹. These authors reported a retention rate of 80% after an average follow-up period of 22.7 months. 75% of initial Kpro failures and 5 out of 7 repeat Kpro failures were attributed to sterile keratolysis. In our previous study on Kpro retention, sterile keratolysis was responsible for 43% of initial Kpro failures⁷, which is similar to findings of other studies^{4,17}. To better understand ways of preventing or minimizing this complication, future studies may investigate the effects of more frequent follow up and interventions such as tarsorrhaphy. There is also currently an ongoing multi-center study examining the effect of using collagen-crosslinking to prevent sterile keratolysis in high risk patients. ([NCT02863809](#))

Importantly, fungal infection was also a significant cause of Kpro failure in our study on Kpro retention, comprising 38% of failures⁷. Furthermore, the single failure in the repeat Kpro group was due to candida keratitis. In the aforementioned multicenter study of repeat Kpro's⁹, however, there was no mention of fungal infection as a cause for Kpro failure. While they did report that 25% of their Kpro failures were due to corneal infiltrates, they did not specify whether these infiltrates were thought to be bacterial or fungal. The postoperative antimicrobial therapy regimens used in this study varied but often included vancomycin, a fourth generation fluoroquinolone, and polymyxin B/trimethoprim. Antifungals are not routinely used, but patients are closely observed and additional antifungal therapy may be considered if a corneal infiltrate does not respond to antibiotics, particularly if the infiltrate has a feathery border that is characteristic of fungal keratitis¹⁸.

Consistent with the other study⁹ that recently reported repeat Kpro outcomes, we noted favorable visual acuity outcomes in repeat Kpro eyes with 75% of patients achieving a best-recorded visual acuity of 20/200 or better. There was also no statistically significant difference between final visual acuities in the initial Kpro group compared to the repeat Kpro group. The authors of the aforementioned study noted a statistically significant correlation between favorable preoperative visual acuity and final visual acuity, and we found a similar trend. However, despite generally favorable outcomes, vision can be lost due to progression of glaucoma and posterior segment pathologies, including retinal detachment, vitreous hemorrhage, and suprachoroidal hemorrhages.

The management of failed keratoprosthesis is challenging and depends on the cause for keratoprosthesis failure. Several newer management techniques have been reported for sterile corneal stromal melt such as crescentic amniotic membrane grafting and buccal mucosal membrane allograft but limited data exists on the long term viability of these newer techniques^{19–22}. In addition, if an infectious etiology is suspected, it is generally advisable to proceed with either repeat Kpro implantation or tectonic keratoplasty. Despite possible disadvantages of Kpro reimplantation such as time to obtain new Kpro, higher intraoperative open sky time when compared to tectonic keratoplasty and increased cost, a recent systematic review and meta-analysis comparing repeat Kpro implantation and tectonic keratoplasty in Kpro failures found favorable long term visual outcomes in patients undergoing repeat Kpro implantation²³.

The strengths of our study include its multicenter nature, completeness of follow-up data, and diagnosis-matched comparative analysis of initial Kpro versus repeat Kpro outcomes. However, because of our high Kpro retention rate, there are relatively few patients who underwent repeat Kpro implantation, limiting the sample size. Even though controls were selected randomly, the small number of cases resulted in asymmetric, albeit not statistically significantly different baseline demographics (ie. preoperative logMAR acuity). Although one eye in the repeat Kpro group may overlap with the Ahmad study⁹, the case control design facilitates comparisons that allow us to draw more meaningful conclusions from this data.

Conclusions

In conclusion, our study reaffirms the observation that patients with autoimmune disease such as SJS and OCP are at higher risk for Kpro failure, but outcomes of repeat Kpro implantation are similar to those of initial Kpro implantation. Thus, repeat Kpro implantation should be considered as a viable therapeutic option for patients with failed initial Kpro, especially if preoperative visual acuity is favorable.

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APPENDIX

A complete list of the members of the Boston Type 1 Keratoprosthesis Study Group is available as an Appendix.

APPENDIX 1: BOSTON TYPE 1 KERATOPROSTHESIS STUDY GROUP

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Figure 1.

Box plots of best-recorded visual acuities of patients preoperatively and postoperatively. LogMAR = logarithm of the minimum angle of resolution; Kpro = Keratoprosthesis; Preop = Preoperative; POM = Postoperative month

Figure 2. Kaplan-Meier survival curves with 95% Hall-Wellner bands of the time to achieve 20/200 visual acuity after initial and repeat implantation of Boston type 1 keratoprosthesis.

Figure 3. Kaplan-Meier survival curves with 95% Hall-Wellner bands of the time to lose 20/200 visual acuity in the subgroup of eyes that achieved 20/200 visual acuity postoperatively after initial and repeat implantation of Boston type 1 keratoprosthesis.

Table 1.

Baseline characteristics of patients receiving Boston type 1 keratoprosthesis

	Controls (n=13)	repeat Kpro (n=13)	p
Age (years)	67.8 ± 15.4	61.1 ± 13.9	0.282
Female sex	61.5%	50.0%	0.562
Operative Side (OD)	69.2%	53.9%	0.420
Preoperative logMAR VA	2.02 ± 0.46	1.23 ± 0.61	0.127
Diagnosis			
Autoimmune (SJS or OCP)	5	5	1.000
Chemical injury	1	1	
HSV	1	1	
Keratoconus	1	1	
Infectious keratitis	1	1	
Bullous keratopathy	2	2	0.723
Trauma	1	1	
Miscellaneous	1	1	
Follow-up Time (months), range	15.4 ± 15.8, (2–50)	18.7 ± 19.3, (2–56)	0.723
Failure	7.7% (n=1)	7.7% (n=1)	1.000

Kpro = Boston keratoprosthesis type 1; logMAR = logarithm of the minimal angle resolution; VA = visual acuity; SJS = Stevens Johnson Syndrome; OCP = ocular cicatricial pemphigoid; HSV = Herpes simplex virus

Table 2.

Detailed clinical outcomes of control patients receiving Boston type 1 keratoprosthesis

Patient	Reason for 1 st PKP	Reason for 1 st Kpro	Ocular comorbidities	Preoperative and concurrent procedures	Preop VA	Best Postop VA	Final VA	Complications	Additional procedures
1	SJS	Failed graft	Glaucoma	Cataract extraction, iridectomy, synechiaelysis	HM	20/30	20/30	None	None
2	OCP	Failed graft	None	Cataract extraction	LP	20/400	CF 1'	None	None
3	Bullous keratopathy	Failed graft	Glaucoma	Vitrectomy, cataract extraction, tube shunt	HM 4'	20/200	20/200	RPM	YAG membranotomy
4	Corneal scar	Perforated corneal ulcer	Retinal detachment	Retinal detachment repair	LP	HM	LP	Kpro fell posteriorly during initial surgery but retrieved	None
5	HSV keratitis, Fuchs' dystrophy	Failed graft	None	None	20/300	20/40	20/70	None	None
6	Chemical injury	Failed graft	Glaucoma	Vitrectomy, tarsorrhaphy	HM	20/80	20/80	None	None
7	Ruptured microbial keratitis	Failed graft	None	None	HM	CF 3'	CF 3'	None	None
8	Keratoconus	Failed graft	None	None	20/400	20/25	20/50	None	None
9	Ocular trauma	Failed graft	Glaucoma, exotropia	Cataract extraction, vitrectomy, revision of Molteno valve	HM	20/50	20/100	Endophthalmitis from exposed Molteno valve	Intravitreal antibiotics, pars plana vitrectomy, Molteno valve explantation, strabismus surgery
10	Bullous keratopathy	Failed graft	None	Cataract extraction	CF 3'	20/80	20/150	RPM	YAG membranotomy
11	Not applicable	OCP	Dry eye syndrome	Tarsorrhaphy, iridectomy, cataract extraction	HM	20/40	20/40	RPM	None
12	Not applicable	OCP	Dry eye syndrome	Vitrectomy, tarsorrhaphy	LP	CF 4'	LP	High IOP, Extrusion of Kpro	Kpro replacement
13	OCP	Failed graft	Glaucoma	IOL removal, Ahmed valve	LP	NLP	NLP	None	None

PKP = penetrating keratoplasty; Kpro = Boston keratoprosthesis type 1; SJS = Stevens Johnson Syndrome; OCP = ocular cicatricial pemphigoid; HSV = Herpes simplex virus; RPM = retroprosthetic membrane; VA = visual acuity; NLP = no light perception; LP = light perception; HM = hand motions; CF = count fingers; YAG = yttrium-aluminum garnet; IOP = intraocular pressure

Table 3.

Detailed clinical outcomes of patients receiving repeat Boston type 1 keratoprosthesis

Patient	Reason for 1 st PKP	Reason for 1 st Kpro	Reason for initial Kpro failure	Ocular comorbidities	Preoperative and concurrent procedures	Preopve	Best Postop VA	Final VA	Complications	Additional procedures
1	SJS	Failed graft	Buccal mucosal graft necrosis and thinning of donor cornea	Interstitial keratitis, angle closure glaucoma	Central tarsorrhaphy, tube shunt	LP	20/125	20/125	Necrosis of donor cornea, candidal keratitis	Replacement of Kpro with PKP
2	SJS	Failed graft	Fungal keratitis	Glaucoma	Vitrectomy, tarsorrhaphy	HM	CF 2'	LP	RPM, hypotony, retinal detachment	YAG, removal of tube shunt
3	Bullous keratopathy	Failed graft	Wound leak	Glaucoma	Removal of ACIOL	CF 1'	HM	HM	Suprachoroidal hemorrhage	None
4	Not applicable	Ocular surface tumor, exposure keratopathy due to CN VII palsy	Fungal endophthalmitis	Glaucoma	Vitrectomy	HM	20/25	20/50	Atypical mycobacterial endophthalmitis	Tap and inject
5	HSV keratitis	Failed graft	Fungal keratitis	Glaucoma, age-related macular degeneration	None	20/200	20/40	20/60	RPM, macular edema	YAG, intracameral steroid
6	Chemical injury	Failed graft	Extrusion of front part of Kpro	Glaucoma	None	HM	HM	NLP	RPM, elevated IOP, progress loss of vision due to glaucoma	YAG, vitrectomy, glaucoma tube
7	Not applicable	Fungal keratitis	Fungal keratitis	Glaucoma	Anterior vitrectomy	20/200	20/60	20/150	Macular edema	Intracameral steroid
8	Keratoconus	Failed graft	Dense RPM	HSV	None	20/200	20/30	20/30	None	None
9	Not applicable	Ocular trauma, corneal scar	Corneal melt	Glaucoma	Vitrectomy	CF 1'	20/60	LP	Retinal detachment, vitreous hemorrhage, suprachoroidal hemorrhage	None
10	Bullous keratopathy	Failed graft	Corneal melt	Glaucoma	None	CF 4'	20/60	20/70	None	None
11	OCP	Failed graft	Fungal keratitis	Glaucoma, exposure keratopathy	None	20/70	20/25	20/25	RPM, suprachoroidal hemorrhage	YAG, tarsorrhaphy
12	OCP	Failed graft	Endophthalmitis	Glaucoma	Anterior vitrectomy, iridectomy, ahmed valve, cataract extraction	LP	20/70	20/150	None	None
13	SJS	Failed graft	Corneal melt	Severe dry eye	None	*	*	*	None	None

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* information not available