

# Consequences of mechanical pupil dilation, a study based on the Swedish national cataract register

Ruben Kreku and Anders Behndig 

Department of Clinical Sciences/Ophthalmology, Umeå University, Umeå, Sweden

## ABSTRACT.

**Purpose:** To describe the outcomes and demographics of patients undergoing mechanical pupil dilation (MPD) during cataract surgery.

**Setting:** All cataract procedures performed in Umeå University Hospital and Sunderbyn, Gällivare and Piteå hospitals reported to the Swedish National Cataract Register (NCR) during 2013–2019.

**Design:** Retrospective cohort study based on the Swedish NCR and electronic patient records.

**Methods:** The number of control visits, pre- and postoperative visual acuities, surgical complications/intraoperative difficulties, ocular comorbidities and postoperative treatment regimens were retrieved for all cataract procedures with MPD. For each procedure, the consecutive procedure in the NCR from the same clinic without MPD was chosen to form a control group. A multinomial regression analysis with MPD as the dependent variable was performed to identify factors and outcomes independently associated with MPD.

**Results:** A total of 25 349 patients aged 18–97 years underwent cataract surgery in these hospitals during the study period. Of these, 653 (2.6%) had MPD. Factors such as pseudoexfoliations and capsule staining were over-represented among MPD eyes. As a group, eyes with MPD had more postoperative visits and more postoperative anti-inflammatory drops, and more frequently needed augmentation of the anti-inflammatory treatment at the first postoperative visit.

**Conclusions:** MPD is independently associated with a more complicated intra- and postoperative course with more follow-up visits and requires more anti-inflammatory treatment postoperatively. This information could be added to the postoperative counselling, and more postoperative anti-inflammatory treatment could be considered in cases with MPD.

**Key words:** capsular hook – capsular tension ring – cataract – mechanical pupil dilation – phacoemulsification – posterior capsular tear – visual acuity

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## Introduction

Cataract is the most common reversible cause of visual impairment worldwide (Flaxman et al. 2017), and cataract extraction is the most frequently performed surgical procedure in the western world (Spalton & Koch 2000). In Sweden, approximately 130 000 procedures are being performed yearly, of which >94% are registered in the Swedish National Cataract Register (NCR; Behndig et al. 2019).

Cataract surgery is generally safe and improves the patients' visual function and quality of life, but rare complications do occur. One of the prerequisites for successful surgery is sufficient pupil dilation. A small pupil restricts the surgical field, and almost doubles the risk of sight-threatening complications, such as posterior capsular rupture (PCR) and/or vitreous loss (VL; Narendran, Jaycock et al. 2009). Inadequate pupil dilation can be associated with pseudoexfoliation syndrome (PEX), intraoperative floppy iris syndrome (IFIS), trauma and miotics for glaucoma treatment or previous surgery (Greenberg, Tseng et al. 2011).

When pharmacological dilation of the pupil is insufficient, multiple efficient techniques for mechanical pupil dilation (MPD) are available, including iris retractors, iris hooks, Malyugin rings, among other devices. Each of these techniques might, in itself, add to the surgical trauma (Taipale, Holmstrom et al. 2019). Risk factors and visual outcomes after mechanical pupillary dilation have previously only been described in small cohorts, likely due to the rarity of the intervention. At present in Sweden, the yearly

incidence of MPD is 2.9% (Behndig et al. 2019).

In this cohort study of cases with MPD matched with a control group, we aimed to investigate, for cases with MPD as a group, (a) the number of postoperative control visits, (b) pre- and postoperative visual acuities, (c) ocular comorbidities, (d) surgical complications and intraoperative difficulties and (e) postoperative anti-inflammatory therapy and other postoperative care.

## Materials and Methods

Data were extracted from the Swedish NCR, between 2013 and 2019 for all patients who underwent cataract surgery at Umeå University Hospital and Sunderby, Gällvare and Piteå hospitals. The control group was formed by selecting the consecutively registered procedure *without* MPD after each procedure *with* MPD from the NCR. Patients were identified by the Swedish personal ID number in the NCR, and complimentary data were collected from electronic patient records. The study was approved by the Swedish Ethical Review Authority and adhered to the Declaration of Helsinki.

Only phacoemulsification cataract procedures were included in the analyses. Various combined procedures or procedures with incomplete data were not included (Figure 1).

The register-derived variables included in the analyses were preoperative best-corrected visual acuity (BCVA), age, gender, presence of pseudoexfoliations (PEX), use of capsule staining, use of a capsular tension ring (CTR), ocular comorbidities – age-related macular degeneration (AMD), diabetic retinopathy, glaucoma, cornea guttata and ‘other’ ocular comorbidity, and occurrence of a PCR during surgery. The ocular comorbidities included all subgroups and grades of the diseases, as the diagnoses were collected from the NCR, where they are registered in yes/no form. The complimentary postoperative data retrieved from the electronic patient records included postoperative BCVA, number of postoperative visits, occurrence of corneal oedema, iris atrophy, cystoid macular oedema (Irvine–Gass syndrome) and postoperative anti-inflammatory treatment. Postoperative

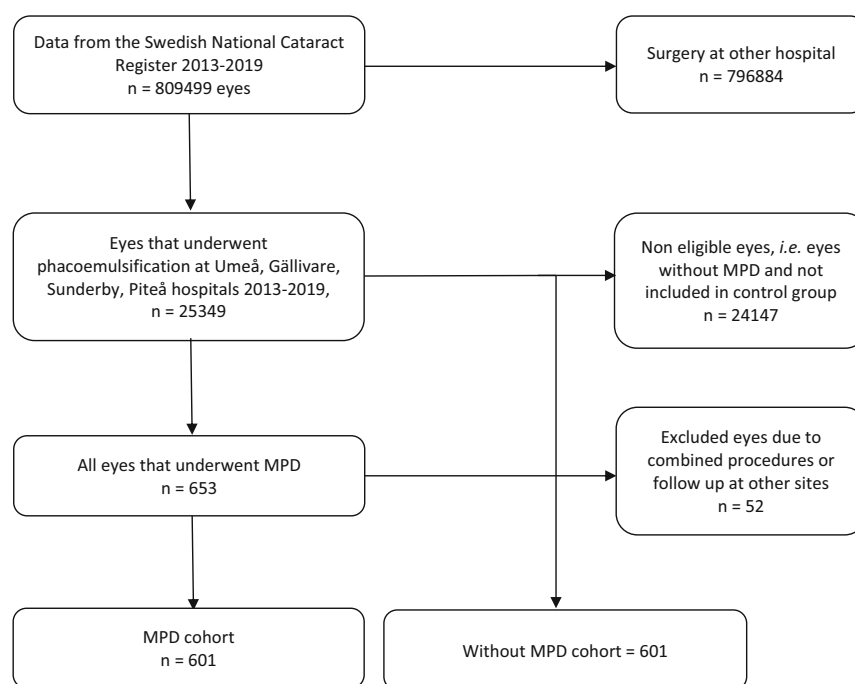


Figure 1. Selection of study sample.

BCVA was defined as the best achieved spectacle-corrected visual acuity within 6 months after surgery. For analysis of the postoperative anti-inflammatory treatment, the following categories were formed: Ordinary therapy – topical corticosteroids or NSAID: three times daily; increased therapy in direct association with surgery; augmented therapy at the first postoperative visit. For postoperative complications such as retinal detachment, a cut-off was set to 6 months. Visual acuities registered as Snellen values in the NCR were converted to Logarithm of the Minimum Angle of Resolution (LogMAR) prior to analysis using the formula  $\text{LogMAR} = -\log_{10}(\text{Snellen})$  (Holladay 1997).

Apart from the register-based variables, other possible underlying reasons for employing MPD, such as IFIS or the use of systemic medications associated with inferior pupil dilatation, were not recorded.

### Statistical analyses

Data are given as mean  $\pm$  standard deviation (SD), unless stated otherwise. Descriptive analysis of data is used to calculate means and medians for continuous variables, and frequencies for categorical variables. Linear regression was used to determine the change over

time. The unpaired *t*-test, Mann–Whitney *U*, Fischer’s exact two-sided and Chi-squared tests were used to compare an individual’s pre- and postoperative values and to compare cases to controls. Single and multiple regression analyses were performed with MPD as the dependent factor. Parameters showing significant correlations in the first step were included in a multinomial regression analysis with MPD as the dependent variable. Since augmentation of anti-inflammatory therapy was prescribed at postoperative visits, the variables augmentation and number of postoperative visits were considered interactive. Therefore, two multinomial regression analyses were made with MPD as the dependent factor, one with augmentation of anti-inflammatory therapy and one with the number of postoperative visits. Odds ratios (ORs) for single-factor analysis and adjusted odds ratios (aOR) for multiple regression analyses are shown with confidence intervals of 95% (Cis). A two-step univariate analysis of variance was used to determine whether MPD alone was related to the number of follow-up visits and postoperative visual acuity. IBM SPSS Statistics 26.0 (IBM, Armonk, NY, USA) was used for statistical analyses. For all tests, the level of significance was set to  $p < 0.05$ .

## Results

Between the years 2013 and 2019, 809 499 cataract procedures were registered in the NCR. Of these, a total of 25 349 eyes underwent cataract surgery at Umeå University Hospital and Sunderby, Gällivare, Piteå hospitals, 653 of which had MPD during surgery. 52 cases were unavailable for follow-up or had incomplete registrations, yielding 601 eyes from 541 patients that had an MPD during cataract surgery. Each case was matched with the consecutive procedure in the NCR where MPD was not performed (601 eyes from 584 patients). Pre- and intraoperative risk factors were compared between the groups (Tables 1 and 2), as were the postoperative outcomes and postoperative anti-inflammatory therapies (Tables 3 and 4).

Worth noticing is the preoperative age difference between the cohorts, 77.7 years in the MPD cohort compared with 74.0 years ( $p < 0.001$ ). Also, there were significantly more PEX ( $p < 0.001$ ) and glaucoma ( $p < 0.001$ ) in the MPD cohort. However, the groups did not differ regarding gender ( $p = 0.094$ ) or history of uveitis ( $p = 0.081$ ). Intraoperative complicating factors such as PCR/vitreous loss (PCR/VL; 27 versus 2) and the use of a CTR (91 versus 7), capsule staining (117 versus 22, or iris hooks in the capsulorhexis (135 versus 13) were all significantly over-represented in the MPD group ( $p < 0.001$ ).

All variables that differed significantly between the cohorts at the single-factor analysis (Table 5) were included in a multinomial regression model. This was done twice; once including the number of postoperative visits and excluding augmentation of postoperative anti-inflammatory therapy (Table 6), and once including augmentation of postoperative anti-inflammatory therapy, excluding the number of postoperative visits (Table 7).

The following factors were independently associated with MPD in both these multinomial regression analyses: age, PEX, capsule staining, iris hooks in capsulorhexis and iris atrophy. Augmented anti-inflammatory therapy at later postoperative visits was independently associated with MPD in the first multinomial regression analysis (Table 6). Likewise, the number of postoperative visits was independently related to MPD in the second analysis (Tables 7 and 8).

**Table 1.** Baseline characteristics.

Variable	With MPD (N = 601)	Without MPD (N = 601)	p-value*
BCVA (LogMAR)			
Mean (SD)	0.65 (0.41)	0.52 (0.36)	<0.001 <sup>†</sup>
Median (range)	0.52 (0–2.0)	0.40 (0–2)	<0.001 <sup>††</sup>
Age			
Mean (SD)	77.73 (9.71)	74 (8.91)	<0.001 <sup>†</sup>
Median (range)	79 (18–97)	75 (41–98)	<0.001 <sup>††</sup>
Male sex, n (%)	296 (49)	267 (44)	0.094 <sup>†</sup>
PEX NSCR n (%)	271 (45)	97 (16)	<0.001 $\chi^2$
PEX records n (%)	229 (38)	67 (11)	<0.001 $\chi^2$
Glaucoma, n (%)	114 (19)	53 (9)	<0.001 $\chi^2$
Diabetes, n (%)	16 (3)	24 (4)	0.198 $\chi^2$
Previous surgery, n (%)	409 (68)	361 (60)	0.004 $\chi^2$
AMD, n (%)	101 (17)	94 (16)	0.584 $\chi^2$
Cornea guttata, n (%)	13 (2)	19 (3)	0.282 $\chi^2$
Uveitis, n (%)	0 (0)	3 (<1)	0.247f
Other ocular disease, n (%)	199 (33)	326 (54)	<0.01 <sup>†</sup>
Previous vitrectomy, n (%)	0 (0)	2 (<1)	0.155f

MPD = Mechanical pupil dilation, BCVA = Best-corrected visual acuity, PEX = Pseudoexfoliation syndrome, AMD = Age-related macular degeneration, NSCR = National Swedish cataract register, f = Fisher's exact test,  $\chi^2$  = chi-square test.

<sup>†</sup> Independent samples *t*-test.

<sup>††</sup> Mann–Whitney *U*-test.

**Table 2.** Intraoperative complication.

Variable	With MPD (N = 601)	Without MPD (N = 601)	p-value
PCR/VL n (%)	27 (4.5)	2 (<1)	<0.001 $\chi^2$ & f
CTR n (%)	91 (15)	7 (1)	<0.001 $\chi^2$
Capsule staining n (%)	117 (19)	22 (3.6)	<0.001 $\chi^2$
Iris hooks in capsulorhexis n (%)	135 (22)	13 (2)	<0.001 $\chi^2$
Converted to ICCE/ECCE n (%)	5 (<1)	2 (<1)	0.452 f

MPD = Mechanical pupil dilation, PCR/VL = Posterior capsular rupture/Vitreous loss, CTR = Capsular tension ring ICCE/ECCE = Intracapsular cataract extraction/Extracapsular cataract extraction,  $\chi^2$  = Chi-squared test, f = Fishers exact test.

**Table 3.** Postoperative outcomes.

Variable	With MPD (N = 601)	Without MPD (N = 601)	Sign
Postoperative visits			
Mean (SD)	1.68 (3.66)	0.78 (2.29)	<0.001 <sup>†</sup>
Median (range)	1 (0–53)	1.0 (0–52)	<0.001 <sup>††</sup>
BCVA (LogMAR)			
Mean (SD)	0.18 (0.24)	0.12 (0.19)	<0.001 <sup>†</sup>
Median (range)	0.1 (–0.18 to 1.70)	0.05 (–0.18 to 1.0)	<0.001 <sup>††</sup>
Corneal oedema n (%)	75 (13)	31 (5)	<0.001 $\chi^2$
Iris atrophy n (%)	19 (3.2)	2 (<1)	<0.001 $\chi^2$ & f

f = Fischer's exact test,  $\chi^2$  = Chi-squared test.

<sup>†</sup> Student's *t*-test unpaired.

<sup>††</sup> Mann–Whitney *U*.

## Discussion

MPD is generally considered to be safe and convenient in small pupil cataract surgery. The postoperative consequences

of employing MPD have, however, not been thoroughly investigated.

We here show that cases with MPD entail an almost twofold increase in the number of postoperative visits and

**Table 4.** Postoperative anti-inflammatory treatment.

Prescription of anti-inflammatory therapy	With MPD (N = 601)	Without MPD (N = 601)	Sign
Initial eye drops			
Standard n (%)	495 (82)	547 (91)	<0.001 $\chi^2$
Augmented n (%)	106 (18)	54 (9)	<0.001 $\chi^2$
Eye drops at later visits			
Standard n (%)	507 (84)	583 (97)	<0.001 $\chi^2$
Augmented n (%)	94 (15)	18 (3)	<0.001 $\chi^2$

$\chi^2$  = Chi-squared test.

**Table 5.** Single-factor regression analysis. MPD as dependent factor.

Variable	B	SE	OR(95%CI)	Sign
Pre-operative				
Male gender	0.194	0.116	1.214 (0.968–1.523)	0.094
Age (years)	0.044	0.07	1.045 (1.031–1.059)	<0.001
BCVA (logMAR)	0.916	0.159	2.500 (1.832–3.411)	<0.001
Other ocular disease	0.873	0.119	2.395 (1.896–3.025)	<0.001
Glaucoma	0.884	0.178	2.420 (1.709–3.429)	<0.001
PEX	1.451	0.138	4.267 (3.256–5.591)	<0.001
AMD	0.086	0.157	1.090 (0.802–1.481)	0.584
Diabetes	–0.419	0.328	0.658 (0.346–1.251)	0.201
Other ocular disease	0.218	0.183	1.243 (0.868–1.781)	0.236
Cornea guttata	–0.390	0.365	0.677 (0.331–1.384)	0.285
Previous ocular surgery	0.348	0.121	1.417 (1.118–1.794)	0.04
Peri-operative				
PCR/PVL	2.645	0.735	14.088 (3.3335–59.513)	<0.001
CTR	2.717	0.397	15.141 (6.956–32–958)	<0.001
Capsule staining	1.850	0.240	6.362 (3.972–10.191)	<0.001
Iris hooks in capsulorhexis	2.573	0.297	13.103 (7.322–23.450)	<0.001
Postoperative				
Postoperative visits	0.304	0.53	1.355 (1.222–1.503)	<0.001
BCVA (logMAR)	1.193	0.394	3.297 (1.663–6.537)	0.001
Macular oedema	0.698	0.709	2.010 (0.500–8.075)	0.325
Iris atrophy	2.975	1.025	19.588 (2.614–146.791)	0.04
Corneal oedema	0.964	0.222	2.622 (1.697–4.50)	<0.001
Augm. eyedrops at later visits	1.793	0.264	6.005 (3.577–10.082)	<0.001

BCVA = Best-corrected visual acuity, PEX = Pseudoexfoliation syndrome, SE = Standard error, B = Slope coefficient, PCR/VL = Posterior capsular rupture/Vitreous loss, CTR = Capsular tension ring, AMD = Age-related macular degeneration, Augm = Augmented.

**Table 7.** Multinomial regression, step forward, including augmented postoperative anti-inflammatory therapy.

Variable	B	SE	p-value	OR (95% CI)
Age	0.03	0.009	0.001	1.031 (1.012–1.050)
PEX	0.844	0.192	<0.001	2.326 (1.595–3.392)
PCR/VL	2.152	1.087	0.048	8.600 (1.021–72.418)
Capsule staining	1.230	0.336	<0.001	3.420 (1.770–6.605)
Iris hooks in rhexis	1.701	0.363	<0.001	5.481 (2.692–11.157)
Iris atrophy	2.169	1.071	0.043	8.754 (1.073–71.432)
Augmented drops at first visit	0.536	0.238	0.025	1.709 (1.071–2.727)
Augmented drops at later visits	1.691	0.342	<0.001	5.423 (2.774–10.604)

MPD = Mechanical pupil dilation, SE = Standard error, PEX = Pseudoexfoliation syndrome, PCR/VL = Posterior capsular rupture/Vitreous loss, OR = Odds ratio, CI = Confidence interval.

require more postoperative anti-inflammatory treatment. These findings are consistent with those of Papaconstantinou et al, as well as Taipale et al.,

who suggested that the increased intra-operative trauma of MPD is associated with increased postoperative inflammation. (Papaconstantinou, Kalantzis

et al. 2016; Taipale, Holmstrom et al. 2019). Our data indicate that the number of postoperative controls declined by 0.166 per year, similar to unpublished results from UK showed declining rates of posterior cystic macular oedema from 4% to 2% between 2008 and 2017. In postoperative inflammation prophylaxis, it is important to ‘stay ahead of the game’ and avoid unplanned return visits and treatment augmentations due to unexpected inflammatory breakthroughs. From our findings, it would seem that a standard postoperative treatment regimen may be insufficient in many MPD eyes and that additional anti-inflammatory treatment directly after surgery might be considered in this group of patients. To further explore, this, however, would require a randomized control trial to assess the optimal anti-inflammatory therapy in patients undergoing cataract surgery with MPD.

MPD was used in 2.6% of cases in the northern region, which is lower than the 7.0–7.9% previously reported (Bucci, Michalek et al. 2017; Taipale, Holmstrom et al. 2019) but within the 2.4–3.6% reported in Sweden as a whole during the period of 2013–2019 (Behndig et al. 2019), even though the incidence of PEX and the average age at surgery are higher in the northern part of Sweden. The prevalence of PEX increases with age, and in the northern part of Sweden as much as 61% of 87-year-old individuals have PEX (Astrom, Stenlund et al. 2007). PEX itself is associated with small pupils, atrophy of the iris and weak zonulae, all factors that can complicate both the surgical procedure and the postoperative course. In the electronic records, the prevalence of PEX was lower in both groups, compared with the NCR data. There are several possible explanations for this; data are usually entered into the NCR immediately after surgery, and during surgery, PEX may be more easily identified after maximal pupil dilation – including mechanical dilation – than in an ordinary outpatient visit, in particular in cases with a poor pharmacological dilatation. Whether retrieved from patient records or from the NCR data, however, PEX was independently over-represented in cases with MPD.

Postoperative corneal oedema occurred significantly more frequently



**Table 8.** Year-by-year analysis, linear regression.

Variable	<i>b1</i>	<i>F</i>	<i>df1,2</i>	<i>Sign</i>
Postoperative visits				
MPD	−0.166	4.166	1599	0.042
Without MPD	−0.078	2.338	1599	0.127
Initial eye drops				
MPD	0.048	33.462	1599	<0.001
Without MPD	0.039	40.822	1599	<0.001
Augm. eye drops at later visits				
MPD	−0.019	5.784	1599	0.016
Without MPD	−0.007	3.620	1599	0.058

Augm = Augmented, MPD = Mechanical pupil dilation.

**Table 6.** Multinomial regression, step forward, including the number of postoperative visits.

Variable	<i>B</i>	SE	Sign	OR (95% CI)
Age	0.023	0.009	0.008	1.024 (1.006–1.041)
PEX	0.851	0.190	<0.001	2.342 (1.615–3.397)
PCR/VL	1.923	1.087	0.77	6.842 (0.812–57.623)
Capsule staining	1.297	0.33	<0.001	3.657 (1.914–6.989)
Iris hooks in capsulorhexis	1.596	0.365	<0.001	4.800 (2.349–9.806)
Iris atrophy	2.461	1.049	0.19	11.720 (1.500–91.598)
Number of postoperative visits	0.172	0.070	0.031	1.188 (1.036–1.361)

MPD = Mechanical pupil dilation, SE = Standard error, PEX = Pseudoexfoliation syndrome, PCR/VL = Posterior capsular rupture/Vitreous loss, OR = Odds ratio, CI = Confidence interval.

in the single-factor analysis after MPD, but did not remain significant in the multinomial analysis. In the present material, the postoperative corneal oedema was transient in all cases, and no case with persistent oedema relating to the cataract surgery was seen. Not surprisingly, glaucoma and PEX were significantly over-represented in the MPD group, both of which have been related to increased preoperative intraocular pressure and postoperative pressure spikes (Levkovitch-Verbin, Habot-Wilner et al. 2008). Increased pressure has been associated with a higher corneal endothelial cell loss, which in turn are associated with early postoperative corneal oedema (Gagnon, Boisjoly et al. 1997; Lundberg, Jonsson et al. 2005; Zimmermann, Wunscher et al. 2014; Aoki, Kitazawa et al. 2020). Notably, however, cornea guttata was not over-represented in cases with MPD.

Both groups showed a good visual acuity outcome after surgery (Table 3). The postoperative visual outcome in the MPD group was inferior after a single-factor regression analysis but did not remain significant in the multinomial regression model analysis, indicating that other factors than the MPD determine the visual outcome.

Intraoperative use of capsule staining, iris hooks at the capsulorhexis margin and CTR can be seen as indicators of dense cataract and phacodonesis. Our study found a strong link between these variables and MPD, which suggests that MPD is often a part of a generally more complicated surgical procedure. The findings of the present study, however, indicate that the association between MPD and more postoperative visits/more postoperative inflammation is independent of these variables, indicating that MPD in itself is responsible for a more complicated healing phase after cataract surgery.

Previous studies have associated alpha-1 antagonists – almost exclusively used by males – with IFIS, which has been highlighted as a major cause for needing MPD (Tzamalīs, Matsou et al. 2019; Christou, Tsinopoulos et al. 2020). Remarkably, there was no difference in gender between the MPD patients and the controls, which indirectly indicates that other factors than alpha-1 antagonists (*c.f.* high age, PEX) are quantitatively more important determinators of the need for MPD in cataract surgery, at least in our population.

A strength of the Swedish NCR is the high coverage rate, more than 94%

between 2013 and 2019. The data of the NCR register are also regularly validated, and in the present study also validated against and complemented with data from electronic patient records. This way, some of the inherent bias commonly associated with register studies was eliminated in the present study.

### Limitations of the study

In the present study, the selection of parameters was largely limited to those registered in the NCR, and the postoperative data retrieved from electronic records naturally depend on the quality of the documented clinical information.

The type of MPD used in the individual case (iris retractors, iris hooks, Malyugin rings, *et cetera*) is not registered in the NCR, and thus this study does not differentiate between these methods, but rather looks at MPD cases as a group. For the same reason, the presence of IFIS or systemic medications associated with inferior pupil dilatation was not included in our analyses. Although the use of MPD generally is noted in the electronic patient records, the reasons for employing MPD, the exact method used and possible underlying causes are only inconsistently detailed, and the data were not deemed sufficiently reliable for statistical analyses.

Increased knowledge of predicting factors for complicated cataract surgery can help optimizing preoperative counselling and decision-making. Based on the present findings, a small pupil that might require MPD should be regarded as such a factor, which confirms a clinical impression shared by many cataract surgeons. The two-fold increase in postoperative visits and the substantial increase in unplanned additional anti-inflammatory therapy postoperatively show the importance of taking small pupils into account in preoperative counselling and planning of both the surgical procedure and the postoperative anti-inflammatory treatment.

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*Correspondence:*  
Anders Behndig, MD, PhD  
Department of Clinical Sciences/  
Ophthalmology  
Umeå University  
SE-901 85 Umeå  
Sweden  
Tel: +46 (70) 782 75 36  
Fax: +46 (90) 13 34 99  
Email: anders.behndig@umu.se