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## Safety, effectiveness, and cost-effectiveness of immediate versus delayed sequential bilateral cataract surgery in the Netherlands (BICAT-NL study): a multicentre, non-inferiority, randomised controlled trial

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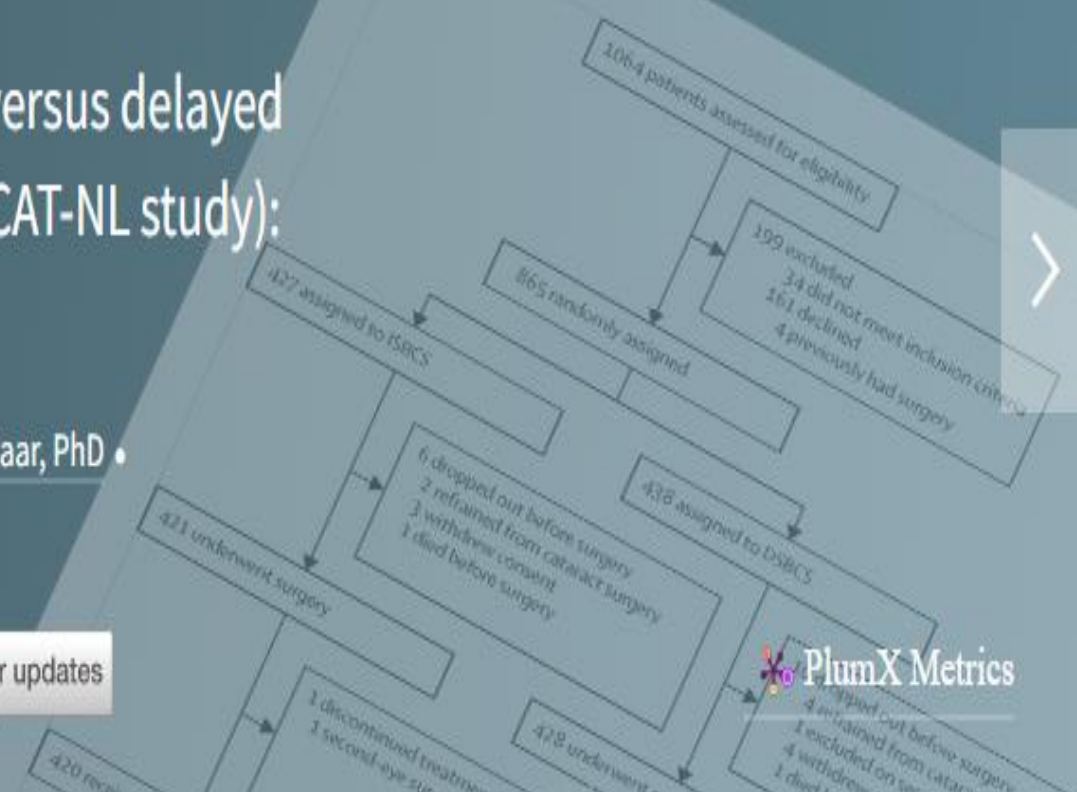
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# Introduction



In the Netherlands, approximately 224 800 new individuals were diagnosed with cataract in 2021. Age related cataract can be treated by surgical removal of the cloudy lens and replacement with an artificial intraocular lens, and is fully reimbursed by Dutch health insurance. Routine practice consists of surgery in both eyes on separate days, known as delayed sequential bilateral cataract surgery (DSBCS). One way to improve efficiency is to perform same-day surgery on both eyes, called immediately sequential bilateral cataract surgery (ISBCS)



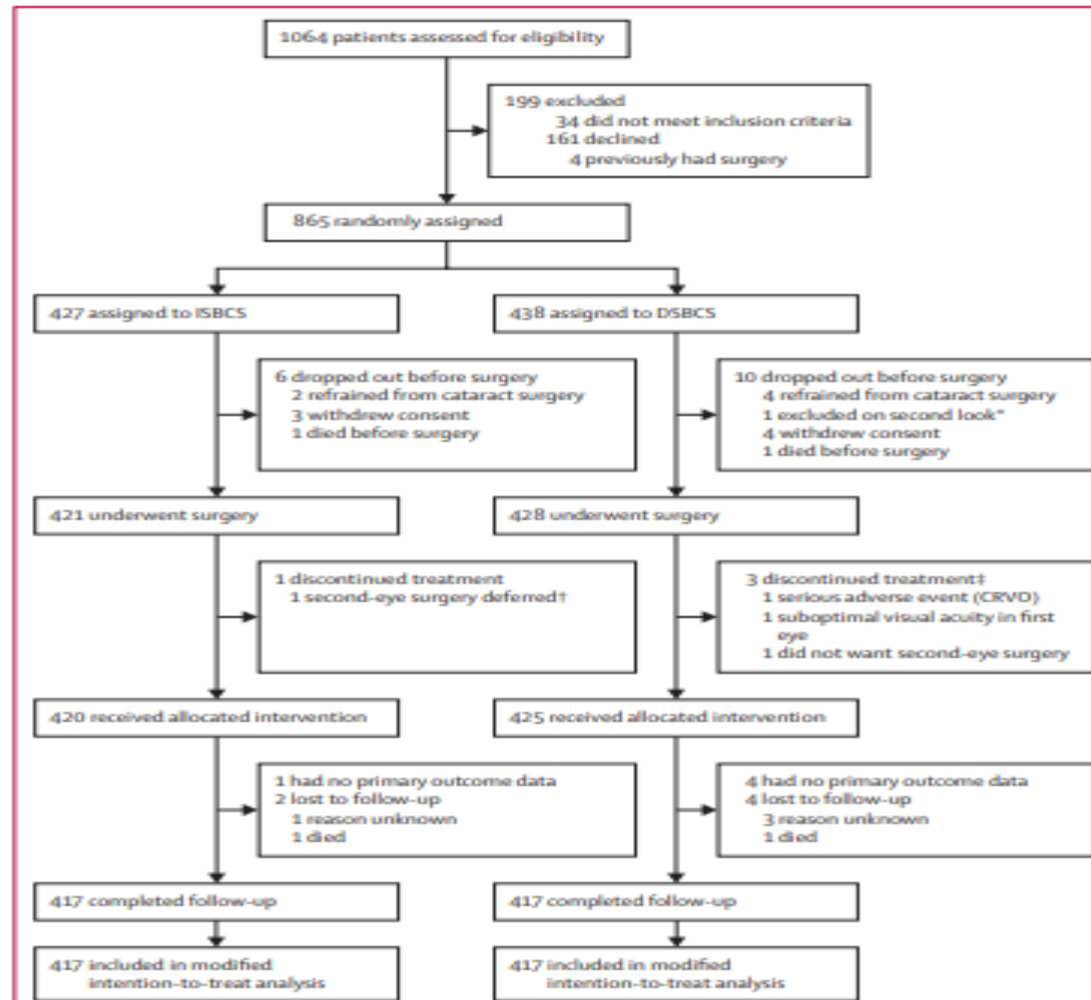
## Aim of the study

The BICAT-NL, bilateral cataract surgery in the Netherlands, study was designed to address the knowledge gaps on refractive outcomes (as a safety and effectiveness measure) and cost-effectiveness of ISBCS compared with DSBCS.

We hypothesised that ISBCS is non-inferior to DSBCS, regarding safety and effectiveness, and being superior in cost-effectiveness.

# Methods

Patients who were 18 years or older requiring expected uncomplicated bilateral phacoemulsification cataract surgery were included. Patients unable to follow study procedures, or with increased risk of endophthalmitis or refractive surprise were excluded



EXCLUDED

DROPPED OUT

DISCONTINUED



# Outcomes

The primary outcome of this non-inferiority trial was the proportion of second eyes with a target refractive outcome of 1.0 dioptre (D) or less 4 weeks postoperatively for ISBCS versus DSBCS.

Secondary outcomes were the proportion of second eyes with a target refractive outcome of 0.5 D or less 4 weeks postoperatively and UCDVA and BCDVA in second eyes 4 weeks after second-eye surgery

	ISBCS	DSBCS	Percentage difference (90% CI)	p value*	Adjusted OR (95% CI)	p value†
<b>Primary outcome</b>						
Postoperative refraction $\leq 1.0$ D	404/417 (97%)	407/417 (98%)	-1% (-3 to 1)	0.526	0.763 (0.330-1.762)	0.526
<b>Secondary outcomes</b>						
Postoperative refraction $\leq 0.5$ D	331/417 (79%)	322/417 (77%)	2% (-2 to 7)	0.450	1.130 (0.811-1.575)	0.470
Postoperative UCDVA $\leq 0.1$ logMAR	208/412 (50%)	197/407 (48%)	2% (-4 to 8)	0.551	1.134 (0.856-1.500)	0.381
Postoperative BCDVA $\leq 0.1$ logMAR	369/411 (90%)	362/404 (90%)	0 (-3 to 4)	0.934	1.095 (0.687-1.745)	0.702

## Results

\*Baseline characteristics are summarized in table below.

Intraocular pressure, visual acuity, biometry, and cataract details are presented for second eyes, since these were included in the analysis. Baseline characteristics of first eyes were similar to second eyes

The incidence of different types of complications did not differ significantly between groups, except for disturbing anisometropia

\*Total societal cost savings from implementation of ISBCS would amount to €27.4 million annually., so cost savings for ISBCS would be €298 less.



	ISBCS (n=421)	DSBCS (n=428)
Age (years)	73 (6.9)	73 (7.2)
Sex		
Male	201 (48%)	186 (43%)
Female	220 (52%)	242 (57%)
Ethnicity		
African	0	1 (<1%)
Asian	5 (1%)	9 (2%)
White	416 (99%)	418 (98%)
Intraocular pressure (second eyes in mm Hg)	15.63 (3.29)	15.83 (3.31)
Uncorrected-distance visual acuity (second eyes in logMAR)	0.61 (0.31)	0.58 (0.32)
Best-corrected-distance visual acuity (second eyes in logMAR)	0.25 (0.19)	0.21 (0.18)
Medical history		
Any ophthalmic condition other than exclusion criteria	105 (25%)	99 (23%)
Diabetes (systemic)	54 (13%)	57 (13%)
Previous use of an $\alpha$ 1-adrenoceptor antagonist	17 (4%)	15 (4%)
Biometry (second eyes)		
Axial length	23.61 (1.08)	23.61 (1.11)
Short (<22.5 mm)	61 (14%)	61 (14%)
Medium (22.5–25.5 mm)	333 (79%)	332 (78%)
Long (>25.5 mm)	27 (6%)	35 (8%)
K1	43.30 (1.45)	43.40 (1.45)
K2	44.12 (1.49)	44.17 (1.53)
Anterior chamber depth	3.11 (0.38)	3.12 (0.36)
Lens thickness	4.74 (0.38)	4.73 (0.38)
White-to-white distance	12.01 (0.46)	12.03 (0.44)
Cataract type (second eyes)		
Nuclear	162 (38%)	162 (38%)
Cortical	7 (2%)	6 (1%)

White-to-white distance	12.01 (0.46)	12.03 (0.44)
Cataract type (second eyes)		
Nuclear	162 (38%)	162 (38%)
Cortical	7 (2%)	6 (1%)
Corticonuclear	250 (59%)	256 (60%)
Posterior capsular	98 (23%)	93 (22%)
Cataract intensity (Lens Opacification Classification System III)		
Nuclear opalescence	2.85 (1.01)	2.74 (0.89)
Nuclear colour	2.88 (1.02)	2.80 (0.93)
Cortical	2.46 (0.98)	2.66 (1.00)
Posterior	2.23 (1.21)	1.94 (1.00)
Measures of effectiveness (mean [SE])		
HUI3 Health-related utility	0.658 (0.012)	0.649 (0.012)
EQ-5D-5L Health-related utility	0.851 (0.007)	0.841 (0.008)
VFQ-25 composite score	75.8 (0.7)	77.9 (0.7)
Catquest-9SF Rasch score	-1.53 (0.09)	-1.66 (0.09)

Data are mean (SD) or n (%), unless otherwise specified. Baseline costs for ISBCS and DSBCS groups are presented in the appendix (p 9). DSBCS=delayed sequential bilateral cataract surgery. ISBCS=immediate sequential bilateral cataract surgery. logMAR=logarithm of the minimum angle of resolution. HUI3=Health Utilities Index Mark 3. VFQ-25=Visual Functioning Questionnaire-25.

**Table 1: Baseline characteristics**

## discussion

We believe the BICAT-NL study provides high-quality evidence on non-inferiority of ISBCS compared with DSBCS regarding safety and effectiveness. Due to the multicentre study design, the results are generalisable to current cataract surgery practice in the Netherlands. Although the cost-effectiveness analysis was based on Dutch cost-prices, the results can be translated to other countries



In conclusion, the BICAT-NL study showed non inferiority of ISBCS compared with DSBCS regarding safety and effectiveness, while being superior in terms of cost-effectiveness.