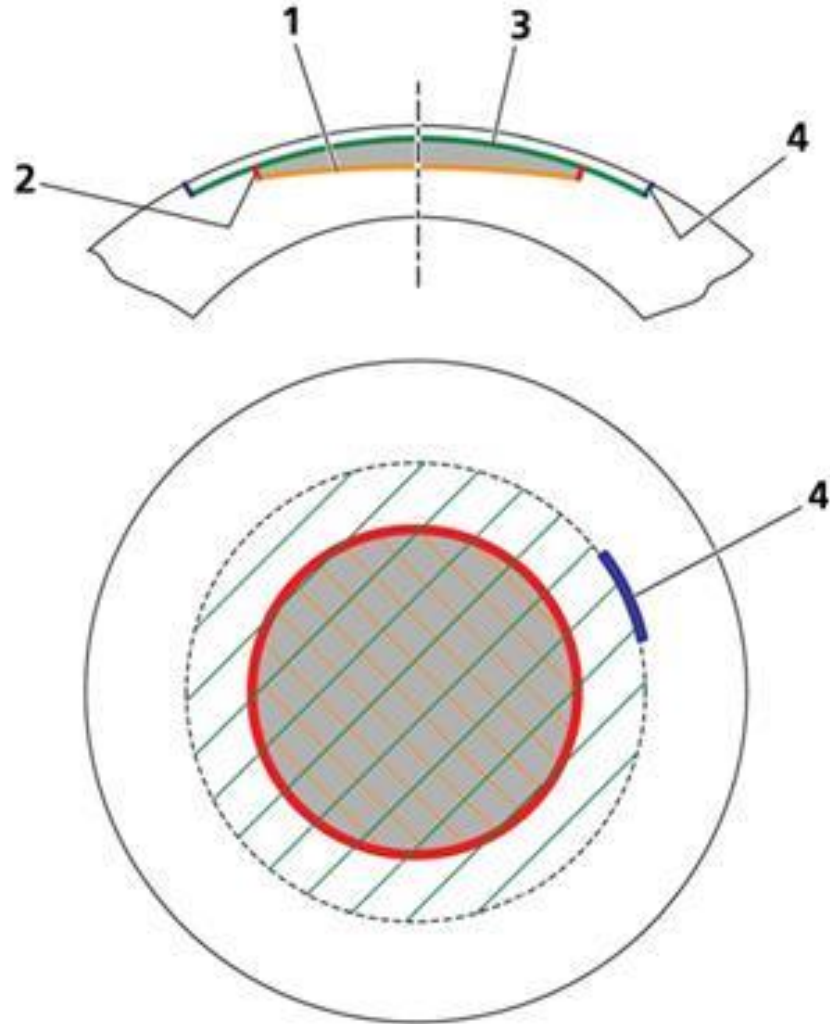




# Retrospective Review of Small Incision Lenticule Extraction (SMILE) at the Joint Warfighter Refractive Surgery Center (JWRSC)

- No financial disclosures
- The view(s) expressed herein are those of the author(s) and do not reflect the official policy or position of Brooke Army Medical Center, U.S. Army Institute of Surgical Research, the U.S. Army Medical Department, the U.S. Army Office of the Surgeon General, the department of the Army, the Department of the Air Force, or the Department of Defense or the U.S. Government



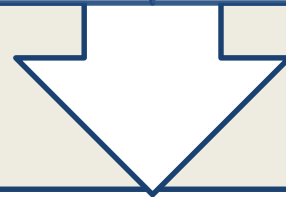
- 1 Lenticule cut (underside of lenticule)
- 2 Lenticule side cut
- 3 Cap cut (concurrently upper side of lenticule)
- 4 Cap opening incision

**Fig. 1 Incision geometry of the SMILE Procedure**

# JWRS Database Search

**Inclusion criteria** active-duty personnel, underwent SMILE from 2018-2020

**Exclusion criteria:** retreatments; age < 18 yo or > 65 yo; lack of POM6 or 12 follow-up

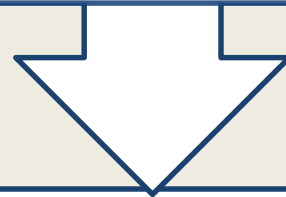


N=107 POM12

Mean age:  $29.6 \pm 6.8$  years

Mean Pre-operative MRSE:  $-4.5 \pm 1.8$  diopters

Sex: 67.3% male, 32.7% female



## Primary Outcome Measures

UCDVA

Post-operative MRSE

High myopic outcomes

Demographic Characteristic	Frequency	Percentage
<b>Age (Years)</b>		
18-24.9	33	30.8
25-34.9	49	45.8
35-44.9	21	19.6
45-54.9	4	3.7
Mean: 29.6 ± 6.8	107	
<b>Sex</b>		
Male	72	68.3
Female	35	32.7
<b>Pre-MRSE (D)</b>		
0.00--1.99	2	1.9
-2.00--3.99	40	37.4
-4.00- -5.99	46	43.0
-6.00- -7.99	12	11.2
-8.00- -9.99	7	6.5
Mean: -4.5 ± 1.8 D		

- 107 eyes
- Range MRSE: 0 to -9.63 D
- Majority -2.0 to -5.99 D

Cylinder Treated (D)	Frequency	Percentage
0	40	37.4
+0.75	24	22.4
+0.75-1.99	29	27.1
+2.00-2.99	9	8.4
+3.00	3	2.8

- 67/107 (62.6%) eyes had cylinder treated
- Range cylinder treated: 0 or 0.75 to 3.25D
- Majority +0.75 to +2.00 D (average 1.27 D)

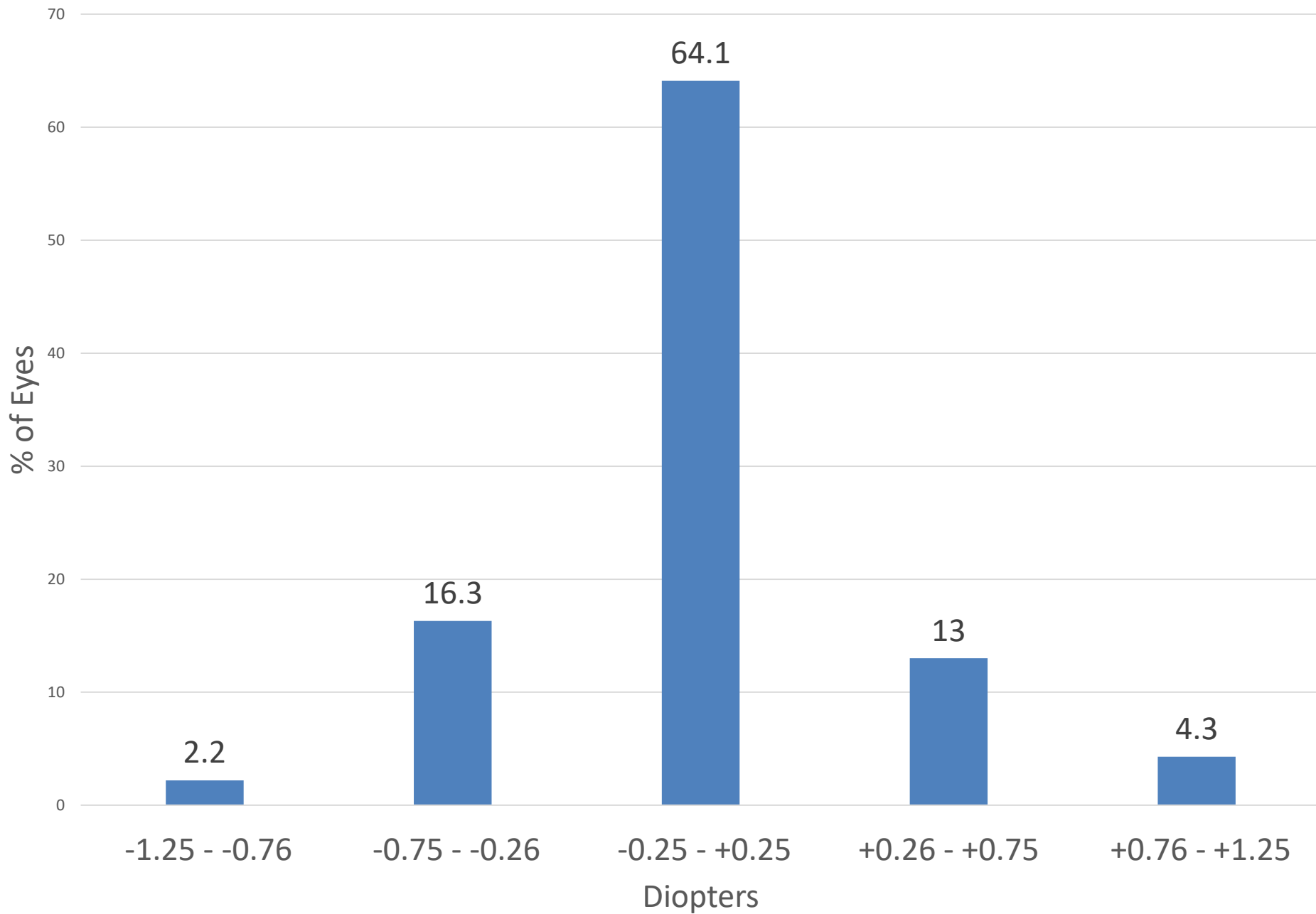
# Refractive Outcome at POM12

Accuracy of Achieved MRSE (D)	Frequency	Percentage
-1.25- -0.76	2	2.2
-0.75--0.26	15	16.3
-0.25--+0.25	59	64.1
+0.26---+0.75	12	13.0
+0.76- --+1.25	4	4.3

- N=92 with MRx at POM12
- 12 eyes didn't have MRx at POM12 (All were 20/20 UDVA)
- Majority eyes within +/- 0.25 D target

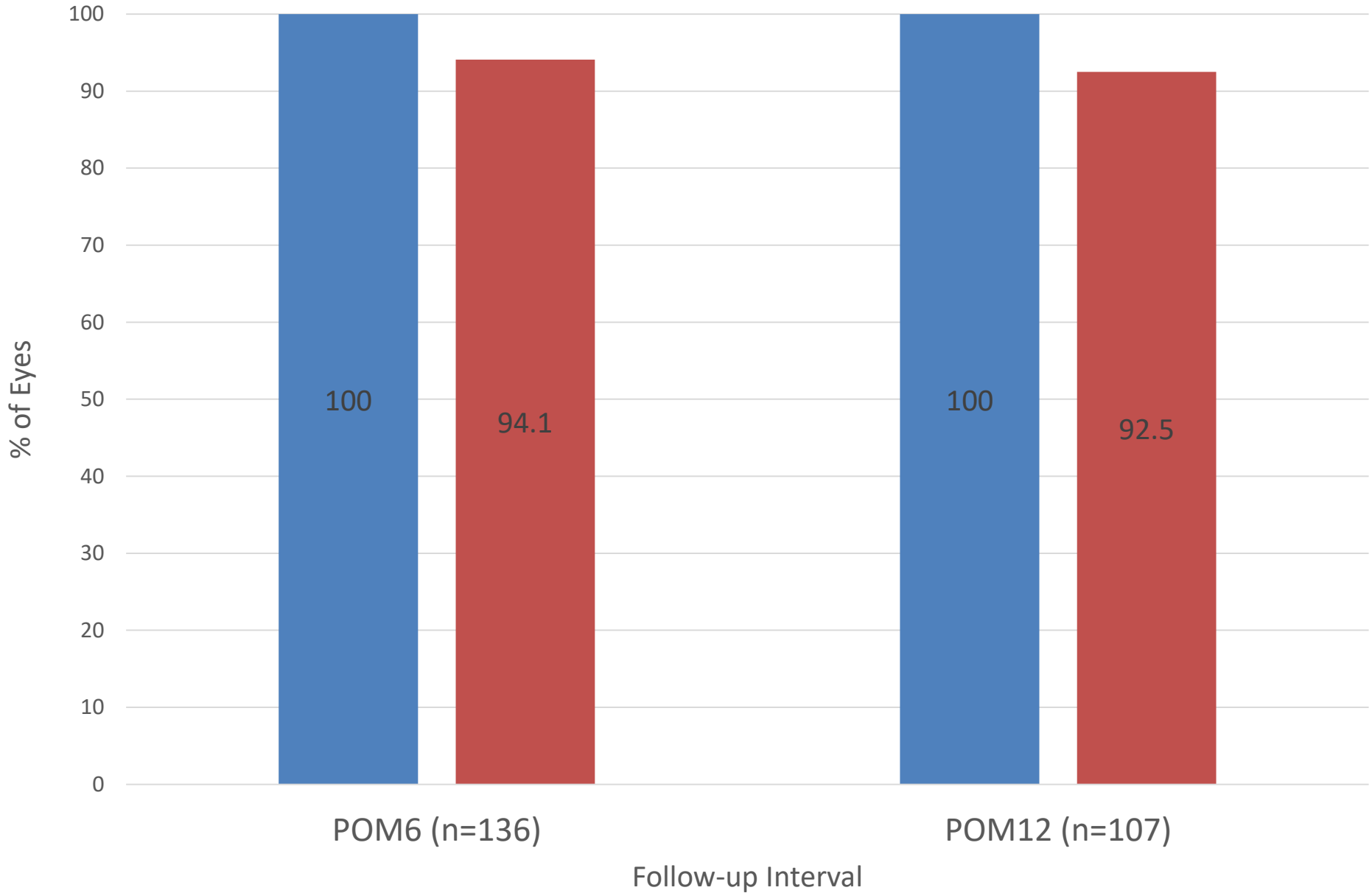
- 97.8% of eyes were within  $\pm 1.00$  D of target MRSE
- 87.0% were within  $\pm 0.5$  D
- All 15 eyes without MRx at POM12 were 20/20 UDVA

# Accuracy of Achieved MRSE at POM12



# UDVA following SMILE

■ 20/40 or better ■ 20/20 or better



# Vision at POM12

- 8/107 eyes did not achieve UDVA 20/20
- All 8 eyes  $\leq -4.75$  D myopia MRSE
- Average preoperative MRSE  $-7.1 \pm 1.5$  D
  
- 99/107 eyes achieved UDVA 20/20
- Average preoperative MRSE  $-4.2 \pm 1.7$  D
- POM12 CDVA all 20/20 except for 1 eye (was 20/20 CDVA at POM1)
- All eyes  $< -4.75$  D MRSE had UDVA  $\geq 20/20$

# Vision at POM12 continued

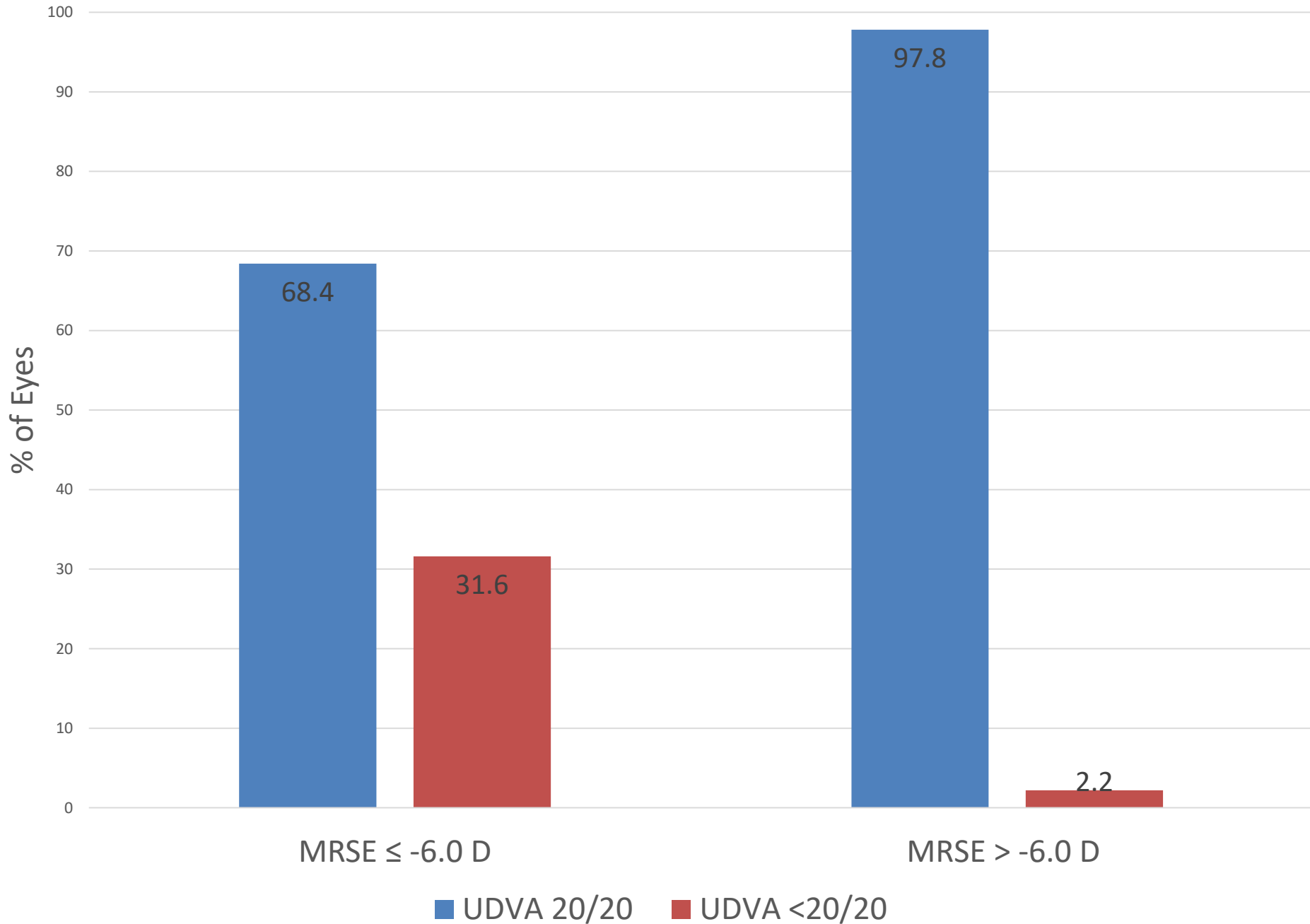
- 5/8 eyes with UDVA < 20/20 had cylinder treated
- Average cylinder treated in those eyes = 2.2 D (versus 1.1 D overall)

# High Myopes vs Not High Myopes

POM12	Frequency (# of Eyes)	Percentage
High Myope ( $\leq -6.0$ D MRSE)	19	100
UCVA $\geq 20/20$	13	68.4
UCVA $< 20/20$	6	<b>31.6</b>
Not High Myope ( $> -6.0$ D MRSE)	89	100
UCVA $\geq 20/20$	87	97.8
UCVA $< 20/20$	2	<b>2.2</b>

- Relative Risk of developing UDVA  $< 20/20$  at POM12 in high myopes versus not high myopes:
- **RR= 14.1, P = 0.0007**

# % of Eyes Achieving UDVA 20/20 in High Myopes vs Not High Myopes

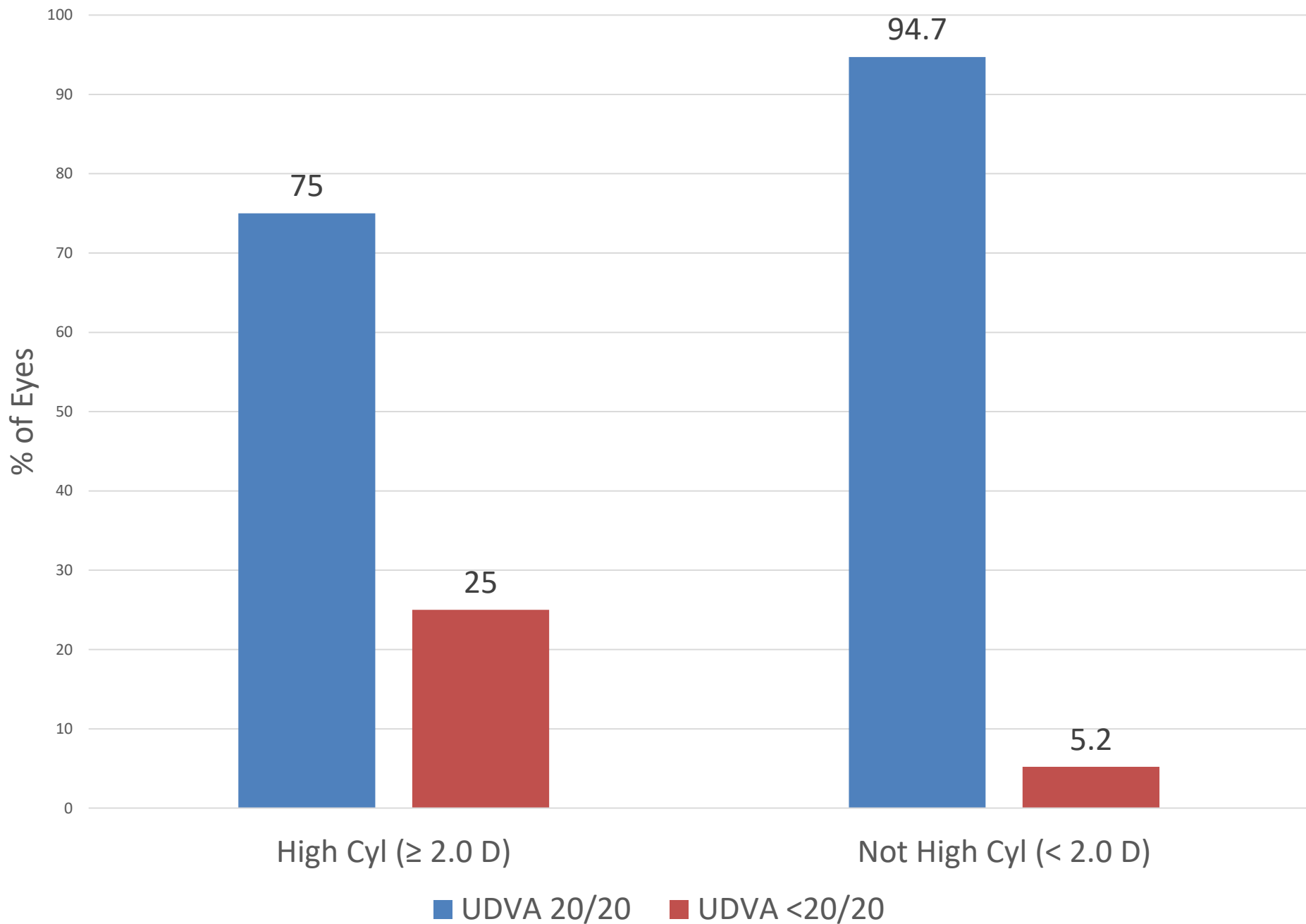


# High Cylinder vs Low or No Cylinder Treated

POM12	Frequency (# of Eyes)	Percentage
High Cyl ( $\geq 2.0$ D)	12	100
UCVA $\geq 20/20$	9	75
UCVA $< 20/20$	3	<b>25</b>
Not High Cyl ( $< 2.0$ D)	95	100
UCVA $\geq 20/20$	90	94.7
UCVA $< 20/20$	5	<b>5.2</b>

- Relative Risk of developing UDVA  $< 20/20$  at POM12 in high cyl tx vs low or no cyl tx:
- **RR= 4.75, P = 0.0188**

# % of Eyes Achieving UDVA 20/20 in High Cyl Tx vs Not High Cyl Tx



# Postoperative Complications

Complication		
	POM6	POM12
<b>Corneal Haze</b>	N=9	N=4
% of Eyes	6.6	3.7
% UDVA 20/20	88.9	75*
<b>Punctate Epithelial Erosions</b>	N=4	N=0
% of Eyes	2.9	0
<b>Scattered Anterior Chamber Cell</b>	N=1	N=0
	0.07	

- 3/9 of Eyes with Corneal Haze at POM6 had POM12 appointments. All had UDVA 20/20
- \*One eye with haze at POM12 had UDVA 20/25, corrected to 20/20

# Review of Literature

- Sia et al., JCRS, 2020:

POM1: 87.9% UDVA 20/20

POM3: 95.1% UDVA 20/20 (N= 131)

**POM6:** 96.3% achieved MRSE within  $\pm 0.5$  D;  
94.9% achieved UDVA 20/20 (N=78)

# Review of Literature, continued

- Ang et al., Ophthalmology, 2020:  
**POM12: 85% UDVA 20/20** (N=70 patients, with equal MRSE between eyes)  
99% within  $\pm 1.0$  D achieved MRSE

# Review of Literature, continued, POM12

- Seukundo et al, 2014: 54 eyes: **88%** UDVA 20/20 or better
- Agca et al, 2014: 40 eyes: **65%** UDVA 20/20 or better
- Ang et al, 2014: 17 eyes: **77%** UDVA 20/20 or better
- Ang et al, 2020 (SMILE vs LASIK): 70 eyes: **85%** UDVA 20/20 or better vs 83% for LASIK
- Chansue et al, 2015: 98 eyes: 90% UDVA 20/20 or better

# Review of Literature, High Myopes

- Burazovitch et al, J French Ophth, 2017: 140 eyes, no UDVA reported in abstract
- 87% eyes within 0.5 D of target

Study	Eyes	Follow-Up	Preoperative Spherical Equivalent, D	Postoperative Spherical Equivalent	SpEq within $\pm 0.5$ D, %	PreOP CDVA 20/20 or Better, %	PostOp UDVA 20/20 or Better, %	Loss of CDVA >2 Lines, %
Sekundo et al <sup>22</sup> (2014)	54	1 y	-4.68 $\pm$ -1.29		92	98	88	0
Shah and Shah <sup>20</sup> (2011)	51	6 mo	-4.87 $\pm$ -2.16	+0.03 $\pm$ 0.30	91	67	62	0
Hjortdal et al <sup>23</sup> (2012)	670	3 mo	-7.19 $\pm$ 1.30	-0.25 $\pm$ 0.44	80	88	61	2.4
Kamiya et al <sup>24</sup> (2014)	26	6 mo	-4.21 $\pm$ 1.63	0.01	100	100	96	0
Agca et al <sup>25</sup> (2014)	40	1 y	-4.03 $\pm$ 1.61	-0.33 $\pm$ 0.25	95	NA	65	0
Ganesh and Gupta <sup>26</sup> (2014)	50	3 mo	-4.95 $\pm$ 2.09	-0.14 $\pm$ 0.28	96	96	96	0
Kim et al <sup>27</sup> (2015)	125	1 y	-7.67 $\pm$ -1.01	-0.24 $\pm$ - 0.35	88	NA	80	0.3
Chansue et al <sup>28</sup> (2015)	318	1 y	-4.96 $\pm$ -1.88	+0.09 $\pm$ -0.31	93	98	90	0
Zhang et al <sup>29</sup> (2015)	98	1 y	-5.55 $\pm$ -1.39	NA	NA	96	80	0
Hansen et al <sup>30</sup> (2016)	722	3 mo	-6.43 $\pm$ -1.59	-0.06 $\pm$ -0.01	88	88	58	1.6
Messerschmidt-Roth et al <sup>31</sup> (2017)	50	3 y	-6.18 $\pm$ -1.91	-0.18 $\pm$ -0.39	78	86	47	0
Agca et al <sup>32</sup> (2019)	54	5 y	-4.11 $\pm$ -0.98	-0.13 $\pm$ -0.29D	93	93	80	0

CDVA indicates corrected distance visual acuity; UDVA, uncorrected distance visual acuity.

# Xu et al, 2014

- Increased Schirmer secretion for SMILE vs LASIK at POM6
- SMILE had longer tear breakup time than LASIK at POM1

## Review of Literature, continued

- Liu et al, Taiwan J Ophthalmol, 2017: PRK -8 to -13D and cyl up to -4D
- POM12: 94% eyes UDVA **20/25** or better
- Tananuvat et al, Dovepress, 2021: PRK in high myopia, n=26 eyes
- POM12: 89.7% UDVA 20/20
- Fu et al, PLoS one, 2021. SMILE vs LASIK for high myopia: 1400 eyes: no difference in UDVA
- Yang et al, Ophthalmic Res, 2020: Smile vs LASIK in high myopia -8.0 to -10.0 D: POM6: 96.6% vs 91.3% UDVA 20/20

# Limitations

- Retrospective design
- Limited treatment for low cyl
- Lack of 100% follow up across all time periods
- Differing clinicians during preop, intraop, and postop (possible inconsistency in treatment plan, surgical technique, and postoperative assessment)
- Lack of control (in future plan to compare to LASIK and PRK for high myopes)

# Conclusions

- Largest study of POM6 and POM12 SMILE outcomes at Military Facility
- High Myopic Treatments ( $MRSE \leq -6.0$  D) and High Cylinder Treatments ( $\geq 2.0$  D) lead to higher risk of not achieving UDVA 20/20 at POM12
- Future studies are needed to compare SMILE versus LASIK or PRK for High Myopic and High Cylinder Eyes to determine best treatment
- Minimal postoperative complications at POM12

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