

The Moria Option for SBK

One Use-Plus **SBK**



**One Use-Plus SBK**  
**versus**  
**competitors**

# ONE Use-*Plus* SBK

## Sub Bowman's Keratomileusis

1. The rationale of SBK
2. Product description
3. Product performances
4. Comparison with other microkeratomes
5. References and contact of investigators

# ONE Use-*Plus* SBK

## Sub Bowman's Keratomileusis

### 4. Comparison with other microkeratomes

1. Comparison with other Femtosecond lasers
  - IntraLase (AMO)
  - Femto LDV Da Vinci (Ziemer)
  - VisuMax (Zeiss)
2. Comparison with conventional microkeratomes

# Comparison with IntraLase-SBK

Femto Laser	Surgeon	Nb of eyes	Intended flap thickness	Flap thickness	Complications
IntraLase 30kHz	A. Wolfgang, MD <sup>(28)</sup> (2008)	287	100	100.4 ± 13.6 (57-138)	Measured with online OCP
IntraLase 60kHz	Guy Kezirian, MD <sup>(2)</sup> (2006)	N/A	100	109 ± 10 (N/A-131)	N/A
	S.A. Updegraff, MD <sup>(29)</sup> (2007)	164	100	112.9 ± 17.1 (72 – 165)	N/A
One Use-Plus SBK	Richard J. Duffey, MD <sup>(1)</sup> (2008)	50	100	102.64 ± 9.6 (83-123)	None

See more results in chapter § 3 - Product performances (slides 26 to 49) in terms of visual outcomes, HOA and corneal hysteresis

# One Use-*Plus* SBK vs IntraLase

## Logistically:

1. Lower costs -- Financially
2. No maintenance costs
3. No space consuming (IntraLase non compatible with excimer laser platform)
4. Less servicing
5. Faster turnaround

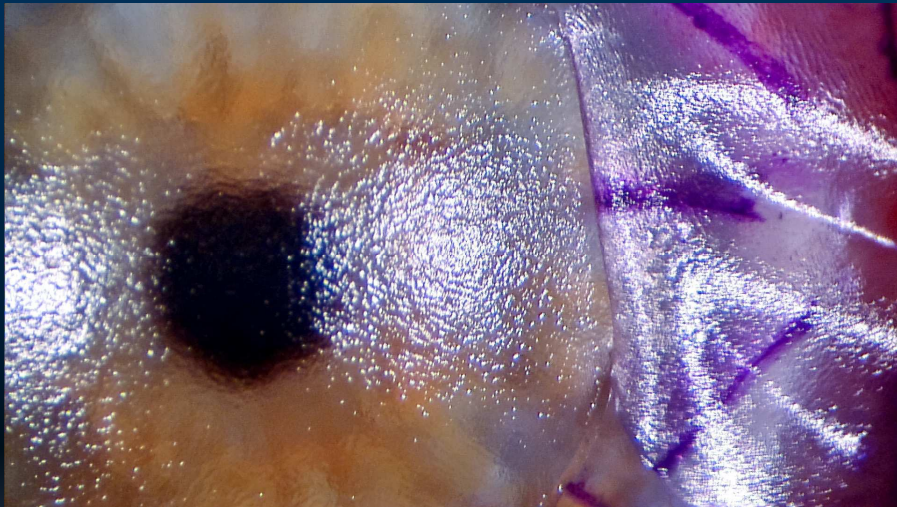
## Clinically:

1. No TLS, DLK, OBL, vertical gas breakthrough complications
2. No bubbles at the interface: no waiting time to start excimer laser procedure
3. Less time consuming
4. No problem of intraoperative visibility
5. Less learning curve
6. Longer time for IOP elevation with IntraLase

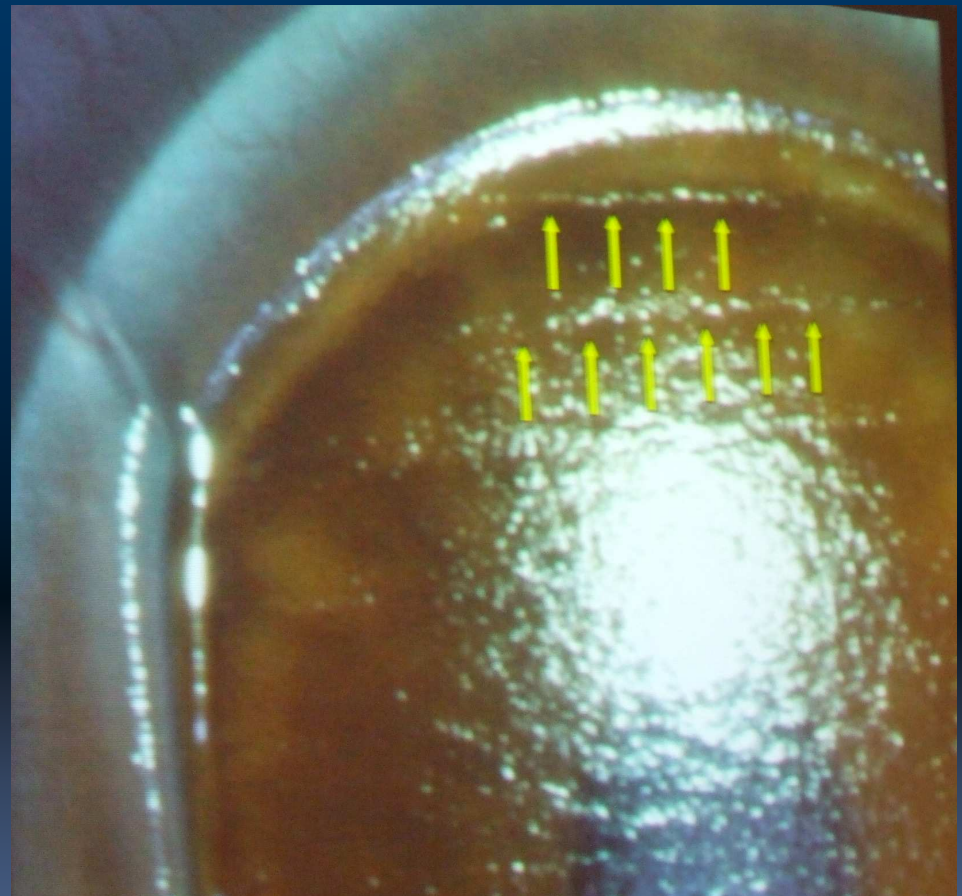
# Comparison with Ziemer LDV

Femto Laser	Surgeon	Nb of eyes	Intended flap thickness	Flap thickness	Complications
LDV Da Vinci	Theo Seiler, MD <sup>(30)</sup> (2008)	200	N/A	114 ± 13 (91-135)	<ul style="list-style-type: none"> <li>▪ Strong adhesions (1%)</li> <li>▪ Failure of treatment (1%)</li> </ul>
	Jérôme Vryghem, MD <sup>(31)</sup> (2008)	70	90	89.29 ± 11.71 (70-125)	<ul style="list-style-type: none"> <li>▪ Mini flaps, requiring manual cuts</li> <li>▪ Strong flap adhesions</li> <li>▪ 3 microstriaes</li> <li>▪ 1 epithelial ingrowth</li> </ul>
		436	110	110.08 ± 9.13 (69-135)	
	P. Stodulka, MD <sup>(19)</sup> (2008)	200	100	102 ± 9	<ul style="list-style-type: none"> <li>▪ Limbal bleeding (13.5%)</li> <li>▪ Stronger adhesion (1.5%)</li> <li>▪ Microstriae (0.5%)</li> </ul>
One Use-Plus SBK	Richard J. Duffey, MD <sup>(1)</sup> (2008)	50	100	102.64 ± 9.6 (83-123)	None

# Smoother stromal bed than Ziemer LDV



One Use-*Plus* SBK  
James S. Lewis, MD<sup>(8)</sup>



Femto LDV Da Vinci  
P. Stodulka, MD<sup>(19)</sup>

# One Use-*Plus* SBK vs Ziemer LDV

## Logistically:

1. Lower initial investment cost
2. No maintenance costs
3. Less treatment time per eye (7.5 minutes per eye with LDV femtosecond laser, 6 min with Moria by the same surgeon)<sup>(20)</sup>

## Clinically:

1. No strong adhesions requiring manual cuts or recuts
2. No mini flap, needing recuts
3. No microstriae on the residual stromal bed
4. No problem of intraoperative visibility
5. No learning curve for centering (slipped flaps with LDV)
6. Deep set eyes more difficult with Femto LDV
7. Limited depth of flap thickness and angle side cut with Femto LDV
8. No uneven beds: stromal bed always smooth with One Use-*Plus* SBK

# Comparison with Zeiss VisuMax

Femto Laser	Surgeon	Nb of eyes	Intended flap thickness	Flap thickness	Flap measurement
VisuMax	Dan Z. Reinstein, MD <sup>(32)</sup> (2008)	24	110	112.31 ± 7.89 (102.6–132.9)	Artemis very high frequency ultrasound
One Use-Plus SBK	Richard J. Duffey, MD <sup>(1)</sup> (2008)	50	100	102.64 ± 9.6 (83 -123)	US pachymetry

Not so many published clinical results with VisuMax used as a flap maker.

# One Use-Plus SBK vs Zeiss VisuMax

## Logistically:

1. Lower investment costs
2. No maintenance costs
3. No space consuming (VisuMax is a bulky system, incompatible with excimer laser platform)

## Clinically:

1. Very few datas about VisuMax and its amount of clinical experience
2. No TLS, DLK, OBL, gas breakthrough complications
3. No bubbles at the interface: no waiting time to start excimer laser procedure
4. Less flap making time: less time consuming
5. No problem of intraoperative visibility
6. Less learning curve
7. Longer time for IOP elevation with VisuMax

# ONE Use-*Plus* SBK

## Sub Bowman's Keratomileusis

### 4. Comparison with other microkeratomes

1. Comparison with Femtosecond lasers
2. Comparison with conventional microkeratomes
  - Zyoptix XP (Bausch&Lomb)
  - Carriazo-Pendular (Schwind)
  - Amadeus II (Ziemer)
  - Rondo (Alcon, WaveLight)

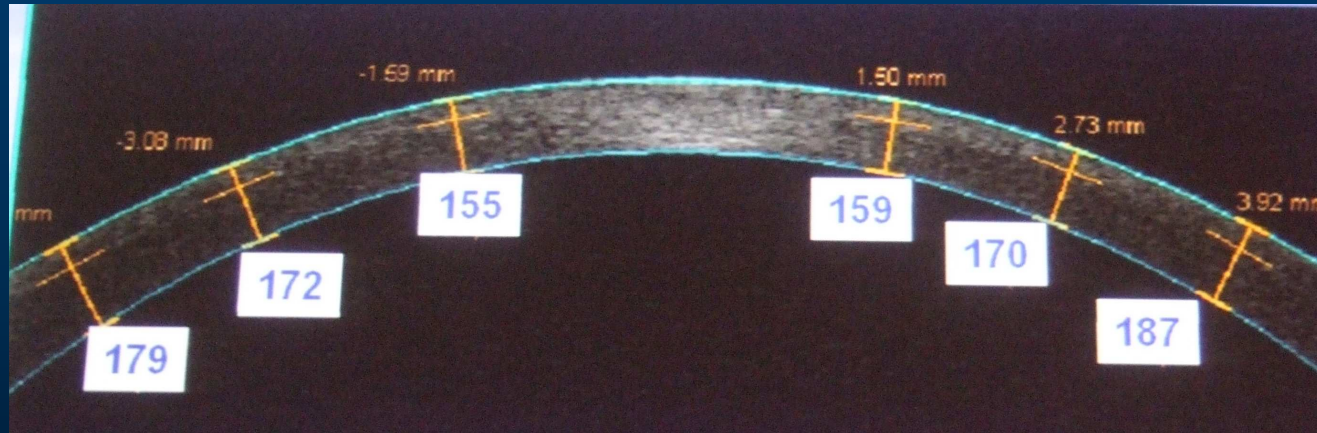
# Zyoptix XP unable to achieve SBK

Keratome	Surgeon	Intended flap thickness	Nb of eyes	Flap thickness Mean $\pm$ SD	Range
Zyoptix XP	S. Stottmeister, MD <sup>(33)</sup> (2008)	120	231	110 $\pm$ 22	70 - 167
	Barbara A.M. Lege, MD <sup>(34)</sup> (2007)	120	136	126,5 $\pm$ 15.5	N/A
	A. Rosa, MD <sup>(35)</sup> (2007)	120	20	124,7 $\pm$ 23.8	67.5 - 160.5
	Jay S. Pepose, MD <sup>(36)</sup> (2007)	120	41	126.5 $\pm$ 14.6	103 - 169
		140	34	143,74 $\pm$ 15.0	110 - 172
	Arthur CK Cheng, MD <sup>(37)</sup> (2008)	120	39	112,79 $\pm$ 19,71	N/A
Thomas Ho, MD <sup>(38)</sup> (2007)	120	1st eye: 64	115.34 $\pm$ 16.34	70 - 145	
		2 <sup>nd</sup> eye: 64	104.55 $\pm$ 14.34	71 - 130	

# Only 1 surgeon reported SBK datas with Zyoptix XP<sup>(39)</sup>

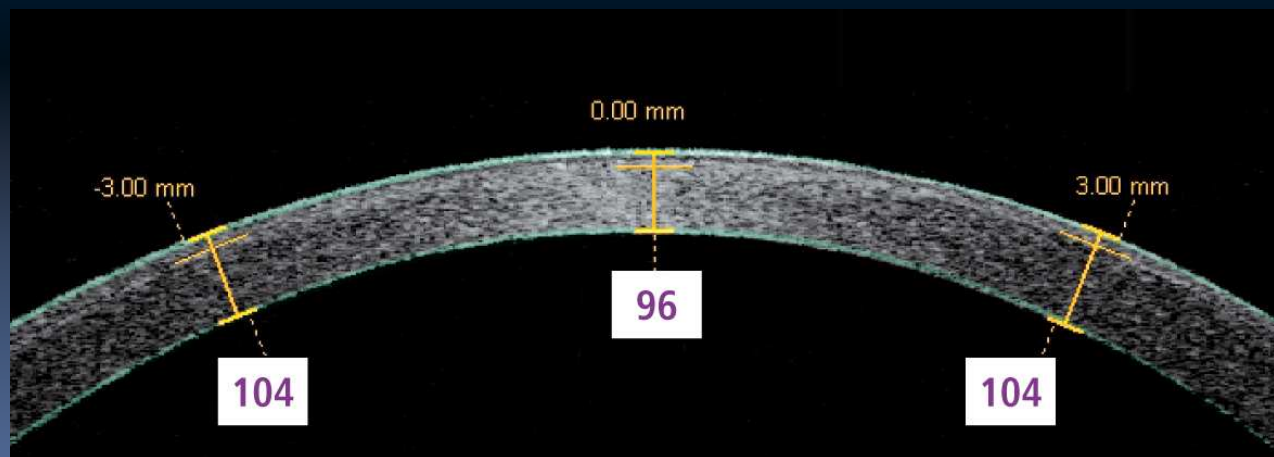
- First eye:
  - 9.5 mm diameter
  - 19 mm suction ring
  - 120- $\mu$ m microkeratome head
- Second eye:
  - 9.5 mm diameter
  - 20 mm suction ring
  - 120- $\mu$ m microkeratome head
- Surgical technique in all eyes:
  - Neutral to the z-axis
  - Results in suction inherent to that from the machine
- See datas slide #22

# One Use-Plus SBK vs Zyoptix XP



**Zyoptix XP**  
**Meniscus flap :**  
**20 microns between**  
**center and periphery**

Flap thickness profile with Zyoptix XP<sup>(40)</sup>



**One Use-Plus SBK**  
**Planar flap**

Flap thickness profile with One Use-Plus SBK<sup>(11)</sup>

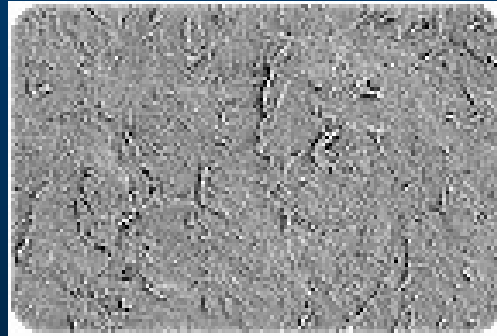
# One Use-Plus SBK vs Zyoptix XP

Keratome	Surgeon	Nb of eyes	Intended flap thickness	1 <sup>st</sup> eye	2 <sup>nd</sup> eye	Diff
Zyoptix XP	Hung Ming Lee, MD <sup>(41)</sup> (2007)	100	120	123 ± 14,8	112 ± 18,0	11
	Thomas Ho, MRCOphth <sup>(38)</sup> (2007)	62	120	115,3 ± 16,3	104,5 ± 14,3	10.8
	David R. Shapiro, MD <sup>(39)</sup> (2008)	1 <sup>st</sup> eye: 20 2 <sup>nd</sup> eye: 12	100	105.4 ± 9.8 (93 – 134)	94.5 ± 7.0 (84 – 107)	10.9
One Use-Plus SBK	Richard J. Duffey, MD <sup>(1)</sup> (2008)	1 <sup>st</sup> eye: 50 2 <sup>nd</sup> eye: 50	100	101.4 ± 12.5 (80 – 128)	98.1 ± 11.5 (79 – 115)	3.3
	James S. Lewis, MD <sup>(8)</sup> (2008)	158	100	99.22 ± 8.87	97.15 ± 10.39	2,1

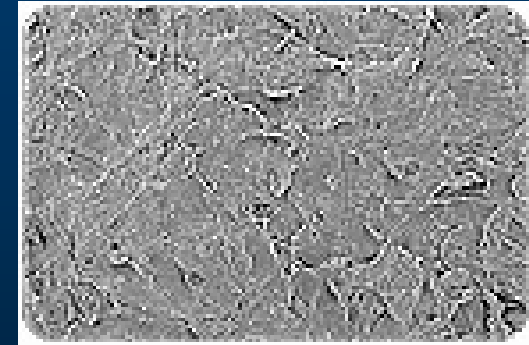
# One Use-Plus SBK vs Zyoptix XP



x 9



x 135



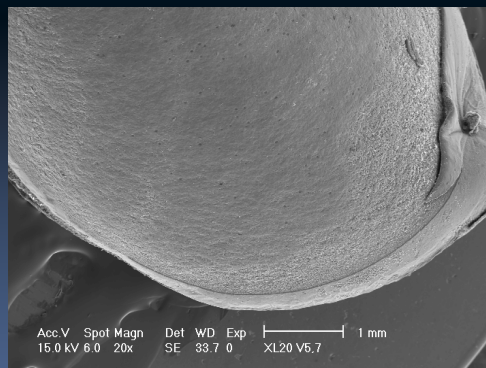
x 300

## Scanning Electron Microscopy

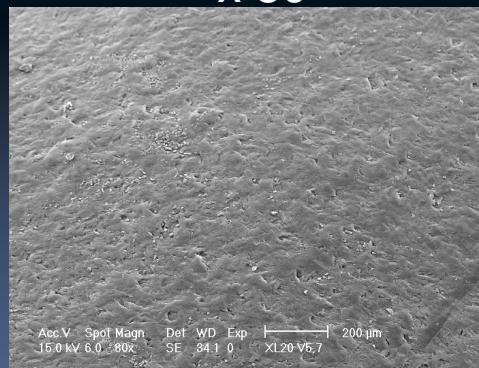
**Up:** after cutting a flap with Zyoptix XP with an intended flap thickness of 120 microns <sup>(40)</sup>

**Down:** after cutting a flap with **One Use-Plus SBK** with an intended flap thickness of 100 microns <sup>(1)</sup>

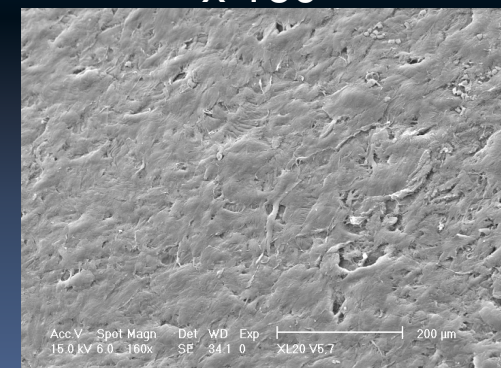
x 20



x 80



x 160



↪ Smoother stromal beds than XP

# One Use-Plus SBK vs Zyoptix XP

Surgeon	Nb of eyes	Suction time Mean – SD (sec)	Range of suction time (sec)
Colin S.H. Tan, MD <sup>(42)</sup> (2007)	41	43.2 ± 11.6	24-93

MORIA One Use-Plus SBK suction time: 10 sec

↳ 4 times less suction time with One Use-Plus SBK

↳ No risks of excessive transient loss of light perception after the suction

# One Use-Plus SBK vs Zyoptix XP

Keratome	Surgeon	Nb of eyes	Intended flap thickness (µm)	Intraoperative complications	Postoperative complications
Zyoptix XP	A. Rosa, MD (35) (2007)	20	120	10% DLK 1 and DLK 2	N/A
	YK Han, MD (43) (2007)	230	120	0.4%	2.7% wrinkling

MORIA One Use-Plus SBK complication rates:

Single Use plastic ring: 0.24%

Reusable metal ring: 0.31%

↳ Less complications with One Use-Plus SBK

# One Use-Plus SBK vs. Carriazo-Pendular

Keratome	Surgeon	Head size (µm)	Nb of eyes	Flap thickness (µm)	Range	Complications
Carriazo-Pendular (Schwind)	Ioannis G. Pallikaris, MD <sup>(44)</sup> (2007)	90	47	80 ± 6.9	70-93	<ul style="list-style-type: none"> <li>▪ interface particles: 8.5%</li> <li>▪ microstriae: 4.3%</li> <li>▪ DLK: 2.1%</li> </ul>
	Stephen E. Pascucci, MD <sup>(45)</sup> (2007)	110	>200	111.3 ± 11.8	N/A	N/A
	Maria Clara Arbelaez, MD <sup>(46)</sup> (2007)	110	406	107 ± 12.4	71-155	1 354 eyes: 1.03% microstriae: 0.7%, flap dislocation: 0.2%, epithelial defect: 0.2% free cap: 0.1%
	A. Charonis, MD <sup>(47)</sup> (2007)	130	154	110.2 ± 13.92	72-144	<ul style="list-style-type: none"> <li>▪ Flap slippages: 1.3%</li> <li>▪ Incomplete flap: 0.6%</li> </ul>

MORIA: SBK performed with less complication rates

# One Use-Plus SBK vs. Amadeus II

Keratome	Surgeon	Head size ( $\mu\text{m}$ )	Nb of eyes	Flap thickness ( $\mu\text{m}$ )	Range	Complications
Amadeus II (Ziemer)	Bojan Pajic, MD <sup>(48)</sup> (2008)	140	92	$144 \pm 16.9$	93 - 178	N/A

Amadeus II can not achieve SBK

# One Use-Plus SBK vs. Rondo

Keratome	Surgeon	Head size (μm)	Nb of eyes	1 <sup>st</sup> eye	2 <sup>nd</sup> eye	Difference (microns)
Rondo	Arthur Cummings, MD <sup>(49)</sup> (2008)	100	11	104 ± 17 (73 – 119)	85 ± 10 (72 – 100)	19
One Use-Plus SBK	Richard J. Duffey, MD <sup>(1)</sup> (2008)	100	1 <sup>st</sup> eye: 50 2 <sup>nd</sup> eye: 50	101.4 ± 12.5 (80 – 128)	98.1 ± 11.5 (79 – 115)	3.3
	James S. Lewis, MD <sup>(8)</sup> (2008)	100	158	99.22 ± 8.87	97.15 ± 10.39	2,1

# One Use-Plus SBK vs. Nidek

Keratome	Surgeon	Head size (μm)	Nb of eyes	1 <sup>st</sup> eye	2 <sup>nd</sup> eye	Difference (microns)
Nidek MK2000	Luiz Izquierdo, MD <sup>(50)</sup> (2008)	130	26	103.46 ± 19.81 (89 - 140)	96.62 ± 15.59 (85 - 133)	6.84
		160	23	112.86 ± 16.48 (104 - 154)	106.14 ± 22.4 (103 - 147)	6.72
One Use-Plus SBK	Richard J. Duffey, MD <sup>(1)</sup> (2008)	100	1 <sup>st</sup> eye: 50 2 <sup>nd</sup> eye: 50	101.4 ± 12.5 (80 - 128)	98.1 ± 11.5 (79 - 115)	3.3
	James S. Lewis, MD <sup>(8)</sup> (2008)	100	158	99.22 ± 8.87	97.15 ± 10.39	2.1

# One Use-*Plus* SBK vs. others microkeratomers

1. Zyoptix XP (Bausch&Lomb): SBK impossible
2. Amadeus II (Ziemer): SBK impossible
3. Carriazo-Pendular (Schwind): worse accuracy and predictability
4. Rondo (Alcon, WaveLight): 100 $\mu$ m head, but poor clinical report with SBK
5. Nidek: no results in the literature with SBK intended flap thickness



**MORIA with the One Use-*Plus* SBK: the only mechanical microkeratome that can compete with femtosecond lasers**

# One Use-*Plus* SBK: the choice to do

## ... TECHNICALLY SPEAKING:

Automated linear microkeratome

Single-Use solution

Flap customization thanks to a full range of suction rings with multiple stop positions

Simple assembly

## ... CLINICALLY SPEAKING:

Accuracy and predictability equivalent to Femto-SBK

Smoother stromal bed surface with One Use-*Plus* SBK

Faster visual recovery than with Femto-SBK at Day 1 postoperative

Equivalent visual outcomes at Month 1 postoperative

Equivalent quality of vision

Better biomechanical stability

Greater patient comfort

# One Use-*Plus* SBK

## Economical advantages

For your customers:

- Single Use heads and rings for reduced maintenance costs
- Quicker surgical turnover
- Very attractive price

For you:

- Less service and maintenance required
- A whole offer with LASIK and Epi-LASIK systems
- A very good margin guaranteed

# One Use-*Plus* SBK

SBK is a new tendency in refractive surgery, with a few devices

**BUT**

- an automated linear microkeratome with single use heads and rings is a unique product on the market
- with equivalent or better results compared to other microkeratomes (femtosecond lasers and mechanical microkeratomes)
- and at a fraction of the cost.

**Moria One Use-*Plus* SBK is the ideal solution**

The new One Use-*Plus* SBK creates thin, planar, predictable flaps and stromal beds of unrivaled smoothness...

- Thin flaps
- Planar architecture
- Beveled edges
- Customized diameters
- Unrivaled bed smoothness
- Accuracy and predictability equivalent to Femto-SBK

... At a fraction of the cost.

# ONE Use-*Plus* SBK

## Sub Bowman's Keratomileusis

1. The rationale of SBK
2. Product description
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4. Comparison with other microkeratomes
5. References and contact of investigators

# References

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# Contact of investigators

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