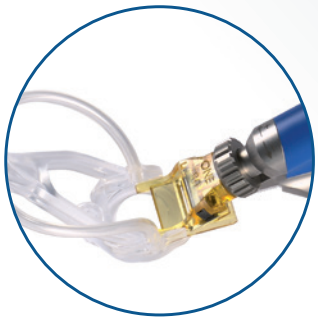
Moria

SBK without compromise
Clinical Data Sheet



One Use-*Plus* SBK

Made in France

Predictible thin sub-Bowman flaps

#	Author	Year	Nb of eyes	Clinical topic	Clinical proof
2	Chen et al.	2010	82		*"The central flap thickness was dramatically thinner in the OUP SBK group"*: • intended: 110 µm (Speed 1) • accuracy: OD: 114.7 µm / OS: 109.4 µm • predictability: OD: ± 10.1 µm / OS: ± 11.0 µm • reproducibility: 5.3-µm difference between OD and OS
3	Lian et al.	2010	20		*"The least variation in flap thickness is SBK"*: • intended: 100 µm (Speed 2) • accuracy: OD: 97.50 µm / OS: 96.73 µm • predictability: OD: ± 11.39 µm / OS: ± 10.45 µm • reproducibility: <1.0-µm difference between OD and OS
4	Du et al.	2011	60		*" The SBK head demonstrated the most accurate flap thickness"*: • intended: 100 µm (Speed 2) • accuracy: OD: 97.50 µm / OS: 96.73 µm • predictability: OD: ± 11.39 µm / OS: ± 10.45 µm • reproducibility: <1.0-µm difference between OD and OS
5	Sun et al.	2012	57		*"SBK is better than LASIK in creating much uniform corneal flap"*: • ±2 mm from apex: 91.09 ± 7.85 µm • ±3 mm from apex: 89.58 ± 7.88 µm • temporal: 89.30 ± 7.64 µm • nasal: 89.20 ± 7.96 µm • superior: 89.91 ± 8.38 µm • inferior: 90.44 ± 7.69 µm
6	Zhang et al.	2012	32		Mean central flap thickness at Speed 1: • intended: 110 µm • obtained: 108.15 µm ➜accuracy: <2.0 µm from intended
7	Zhai et al.	2013	44		Mean central flap thickness at Speed 1: • intended: 110 µm • obtained: 113.85 ± 8.07 [97.50-130.00] µm ➜accuracy: <2. µm from intended
8	Zhang et al.	2014	60		*"The flaps in the […] SBK group were more regular, showing an almost planar configuration"*. Mean central flap thickness at Speed 1: • intended: 110 µm • accuracy: OD: 110.6 µm / OS: 108.2 µm • predictability: OD: ± 7.4 µm / OS: ± 6.1 µm • reproducibility: 2.4-µm difference between OD and OS
9	Al-Thomali et al.	2014	70		*"The One Use-Plus SBK is a reliable microkeratome with reasonable predictability for the creation of SBK flaps"*: ➜mean central flap thickness: 88.74 µm
10	Mimouni et al.	2015	2560		*"The eyes in [SBK] group had statistically significantly thinner flaps"* in this large-scale study: • intended: 110 µm (Speed 1) • accuracy: OD: 110.1 µm / OS: 107.6 µm ➜ 108.9 µm • predictability: OD: ± 15.2 µm / OS: ± 15.4 µm ➜ ± 15.3 µm • reproducibility: 2.5-µm difference between OD and OS
11	Xu et al.	2015	40		*"At each time period after SBK, flap thickness in the Moria group was significantly thinner*: • at 1 day post-op: 95.8 ± 7.6 µm • at 1 week post-op: 95.5 ± 7.8 µm • at 2 weeks post-op: 96.5 ± 7.9 µm • at 1 month post-op: 98.2 ± 8.2 µm
12	Katz et al.	2015	344		Mean central flap thickness at Speed 2: • intended: 100 µm • accuracy: 96 µm In a subgroup of 132 eyes of 66 patients: • accuracy: OD: 97.29 µm / OS: 93.77 µm • reproducibility: <4.0-µm difference between OD and OS
TOTAL			**3369**		

CLINICAL DATA SHEET

Flap creation in less than 4 seconds

#	Author	Year	Nb of eyes	Clinical topic	Clinical proof
1	Xu et al.	2014	82		*"The application of the microkeratome suction ring has been shown in other studies to induce changes in the perilimbic conjunctiva, especially on goblet cell density, which contributes to the pathology of dry eye. In Femto-LASIK and SMILE procedures, the control suction is longer and lighter. The effect on goblet cells needs to be investigated in future studies.*
TOTAL			**82**		

Very fast visual recovery

#	Author	Year	Nb of eyes	Clinical topic	Clinical proof
1	Xu et al.	2014	82		*"No significant difference was found between groups [SBK vs SMILE vs LASIK with either a femtosecond laser or mechanical microkeratome]"*
11	Xu et al.	2015	40		*"At 1 month postop, all the eyes had UCVA of 20/20 or better [SBK vs Femto-LASIK]."*
TOTAL			**122**		

Excellent safety profile

#	Author	Year	Nb of eyes	Clinical topic	Clinical proof
14	Falcon et al.	2016	2883		*"The Moria One Use-Plus SBK microkeratome is an excellent device that allows the easy creation of thin corneal flaps and regular and smooth corneal beds, safely and predictably even in extremely flat corneas without complications."* *"There were no intraoperative nor immediate postoperative complications: - intraoperatively: free cap 0%; incomplete flap 0%; button hole 0%; epithelial erosion 0%; bleeding 0%; irregular stromal bed 0% - postoperatively: flap displacement 0%; punctate keratitis: 8%; LASIK retreatments: 12%; safety: 100% (no loss of lines of visual acuity)."*
15	Gauthier et al.	2019	146		*"The cornea was exposed and a flap was cut at 100 µm with a Moria microkeratome, selecting the suction ring and the settings to achieve maximum flap diameters (> 9.5 mm)."* *"High hyperopia can be treated with LASIK, if wide OZ, TZ, and TAZ are used, and the flap is large enough to perform this extreme peripheral photoablation."*
16	Kasetsuwan et al.	2016	157		*"In the femtosecond laser group, 2.0% of eyes had early postoperative diffuse lamellar keratitis (DLK) compared with 0% in the [Moria SBK] microkeratome group."*
17	Friehmann et al.	2018	30574*		*"In this [large-scale retrospective cohort] study, the incidence rate (0.49%) of epithelial ingrowth was somewhat lower than previously reported studies."*
18	Pokroy et al.	2016	9177		*"Retreatment rates decrease as surgeon's experience is gained and technology improved. The myopic LASIK retreatment rate in recent years improved to below 0.5%."*
19	Mimouni et al.	2018	1104		*"In this study, the use of a Moria M2-90 microkeratome (as opposed to Moria SBK-90) was associated with a higher retreatment rate."*
TOTAL			**> 13467**		

* 30574 eyes of 15287 patients treated with two different automated microkeratomes (M2SU 90 then One Use-Plus SBK by Moria) between January 2006 and December 2014; split not provided by the authors

CLINICAL DATA SHEET

Excellent stromal surface smoothness

#	Author	Year	Nb of eyes	Clinical topic	Clinical proof
6	Zhang et al	2012	32		*"The flap margin after the […] OUP SBK technique[s] appeared microscopically as a clear-cut edge."*
13	Duffey et al.	2008	-		Laboratory study with human corneas not suitable for transplantation.
TOTAL			**32**		

Supported by in-vivo confocal microscopy

#	Author	Year	Nb of eyes	Clinical topic	Clinical proof
6	Zhang et al.	2012	32		*"[…] in the OUP SBK group, it [the density of stromal keratocytes] was higher than that of the FS-LASIK […] at 3 months postsurgery (P<0.05)."* *"The repairing velocity of subbasal nerve fibers in the OUP SBK group was a little faster than that of the FS and conventional LASIK groups."*
TOTAL			**32**		

Excellent quality of vision

#	Author	Year	Nb of eyes	Clinical topic	Clinical proof
9	Al-Thomali et al.	2014	70		*"[…] the absence of correlation of flap thickness with postoperative CDVA and induced HOAs [Higher Order Aberrations] indicates that flap thickness does not influence visual outcomes.*
20	Hassanin et al.	2013	114		*To evaluate changes in corneal HOAs (spherical, coma, trefoil, aberration coefficients, total aberration coefficient) as well as corneal asphericity (Q-value) following optimized LASIK ablation for moderate to highly myopic eyes.*
21	McAlinden et al.	2010	65		*To compare the change in HOAs after LASIK and LASEK and to determine which method of flap creation induced a greater increase in HOAs.*
22	McAlinden et al.	2011	100		To investigate the internal HOAs following LASIK.
23	Malhotra et al.	2015	50		*"Flaps created using the Moria Evo 3 One Use-Plus SBK mechanical microkeratome were associated with significantly lower induction of total HOAs and spherical aberrations as compared with 150 KHz iFS flaps at the end of 3 months follow-up."*
24	Wang et al.	2013	67		*"When comparing straylight values in the femtosecond laser group with those in the [OUP SBK] mechanical microkeratome group, differences were not statistically significant at any follow-up time point."*
TOTAL			**466**		

REFERENCES

Refer to brochure #66065 available on Moria website:
https://www.moria-surgical.com/resources-center

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