



# PERFORMANCE OF BASIQ-4® SURGICAL KNIFE IN 40 MEDIOLATERAL EPISIOTOMIES AT 60 DEGREES

BasiQ-4® surgical knife summary report, August 2019.

## BACKGROUND

Episiotomies used to be a routine part of childbirth however today it is only recommended in specific cases. Also, in the Netherlands episiotomies are performed on a less regular basis. The majority of episiotomies take place in general hospitals, as well as in first line midwifery. With a declining number of births, the average episiotomy rate remains stable at 30.3%<sup>1</sup>. Episiotomies are performed mediolaterally at angle of 60 degrees to avoid ruptures and injuries in the sphincter area. These complications, due to high tension on perineal tissue, however still occur. The more severe anal sphincter damage, also called OASIs, occur at a rate of 2.5%<sup>1</sup>. With 169,000 births in 2017 in the Netherlands this results in a total 4225 OASIs<sup>1</sup>. Sometimes OASI are not recognized. Average cost of repair for an OASI is €1600<sup>2</sup>. Episiotomies are performed by using episiotomy-scissors. Users often complain about the lack of a scissors' sharpness, experience difficulty in choosing the correct angle and dislike the wound edges as created by scissors. The cosmetic result after suturing is found suboptimal, patients complain about pain, scar tissue and pelvic floor dysfunction. Users involved demand alternatives offering sustainable sharpness, a better performance bringing benefits such as sharp wound edges, which are easier to suture. Alternatives preferably, should not increase cost of current episiotomy-scissors.

## 40 CASES WITH BASIQ-4®

BasiQ-4® was used in 40 cases of episiotomy at the obstetrics department of the Elkerliek hospital in the Netherlands, over a period of 6 months. A professional midwife trained staff on safe usage of the BasiQ-4® in advance of human use, using a dedicated phantom. 29 episiotomies using the BasiQ-4® were performed by gynaecologists, 11 by midwives. The design of the BasiQ-4® allows the user to perform a reverse mediolateral episiotomy. The incision is made at the point of least tension, with a 4cm cut being made at an angle of 60 degrees towards the vaginal fourchette (point of maximum tissue tension). This innovative method potentially reduces the chance of rupture and / or OASIs.

## RESULTS

Users were asked to submit their findings after completing the episiotomy on an evaluation form, marking their experiences and describing the use of BasiQ-4® in particular. The results turned out to be very positive with an average score of 8.5 out of 10. Sharpness of the surgical knife, the speed of the episiotomy, together with the ease of use were named more than once. As all users were trained in advance, none of them reported the existence of a learning curve. Positioning and use at an angle of 60 degrees was found easy to perform and repeat. In one case a scissor was used to lengthen the episiotomy. A special note was shared regarding the tension on the perineal tissue. Mentioned by several gynaecologists, during episiotomy with the BasiQ-4®, the highest tension is no longer directed towards anal sphincter but diverted in opposite direction towards the commissura posterior. Users shared that they have more control over the episiotomy and believe this direction preserves the sphincter complex. No serious adverse events have been reported<sup>3</sup>.

## VACUUM EXTRACTOR

In 6 cases the BasiQ-4® was used together with a device for vacuum extraction (VE), these cases were limited to gynaecologists. As both devices were used at the same time, comments show the existence of a learning curve. After 2-3 combined cases the gynaecologists were able to perform the episiotomy with the same ease of use as without the combined use of a VE. User feedback was limited to the remark of using the dominant hand for BasiQ-4® allowing the non-dominant hand to handle the foetus/VE.

## CONCLUSION

Users evaluated the BasIQ-4® as a valuable alternative to episiotomy scissors, offering a sharp, safe and simple mediolateral episiotomy. None of the users felt or described the need to return to episiotomy-scissors. The trial period was positively concluded, after which the department proposed its staff to include the BasIQ-4® device into their standard of care.



BasIQ-4® is a product of IQ Medical ventures bv.

This case study has been compiled by Eric Reep of IQ Medical Ventures from evaluation feedback provided by the department of gynaecology at the Elkerliek hospital, the Netherlands, lead clinician Anne Coolen.

### Source

<sup>1</sup>The effectiveness of mediolateral episiotomy in preventing OASI during operative vaginal deliveries 10-year analysis national registry IUJ 2018 29:407-413.

<sup>2</sup>NZI 2018

<sup>3</sup>Evaluation reports BasIQ-4®