

# **Safety Clamp and Cutter (SCC 23)**

**Report on the clinical testing of a Safety Clamp and Cutter**

**Project SCC 23**

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## Summary

### Objective:

The objective of this investigation was to evaluate the ease of use and safety of the obstetric Safety Clamp and Cutter (SCC 23).

### Design:

The absolutely decisive safety parameter for such clamps is whether or not they can be placed safely and precisely on the child and then remain in position. However, given that the part of the Safety Clamp and Cutter (SCC 23) attached to the child is identical to the clamps that are already used and approved, this safety parameter was not considered in this investigation. The parameters investigated were blood splashing, ease of application and disposal after use.

### Location:

Obstetrics Clinic, University Hospital, Copenhagen in spring 1997.

### Resources:

Pregnant women admitted to the Obstetrics Clinic, University Hospital, Copenhagen, who were expected to give birth to normal, healthy full-term children. The trial covered a period of 15 weeks, during which there were 364 births.

The women were allocated randomly between the clinic's normal procedure for cutting the umbilical cord and use of the Safety Clamp and Cutter (SCC 23). This randomisation took place after the patient had agreed to participate in the project. The Safety Clamp and Cutter (SCC 23) could be used even when physical measurement of the umbilical cord was required.

### Result:

Table 1 shows the results of the five questions, divided between the two groups of women giving birth. There was no mention of blood splashing, re-application of the clamp or the need to use an alternative method. With the traditional method, in 25% of cases there was blood splashing, in 5% re-application of the clamp and in 10% a need to use an alternative method.

Table 2 shows the results of replies given on the visual scale, expressed as median and width of variation. As can be seen from the scale's structure, a high percentage state that the traditional method is more difficult. Use of the Safety Clamp and Cutter (SCC 23) method was, in statistical terms, significantly easier than the traditional method ( $p > 0.05$ ).

### Conclusion:

The Safety Clamp and Cutter (SCC 23) is a tool that has been developed to facilitate the cutting of the umbilical cord and to protect staff who undertake this procedure. The danger associated with the cutting of the umbilical cord is the risk of infection by diseases carried in the blood such as hepatitis B, C and E, and not least the HIV virus. The frequently pronounced over-pressure in the umbilical cord means that splashing of infected blood can easily occur, with the attendant risk that staff are infected. As a consequence, the staff on many obstetrics wards are encouraged to wear protective glasses. However, many regard this as an uncomfortable precaution; it is therefore unpopular and the recommendation is not observed. The tests of the Safety Clamp and Cutter (SCC 23) show that the risk of blood splashing is significantly reduced, if not eliminated. In addition, the procedure is faster and does not require the use of scissors and forceps which have to be washed, packed, sterilised and transported from the obstetrics ward to the sterilisation department and back. Even though the Safety Clamp and Cutter (SCC 23) is expected to cost around DKK 80.00, cost-benefit analysis suggests that a saving of DKK 105.00 can be achieved for each procedure. The conclusion is that the Safety Clamp and Cutter (SCC 23) must be considered a safe and practical alternative to the traditional method of cutting the umbilical cord.

## **Project participants**

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Pernille Langhoff-Roos, Midwife, Obstetrics Clinic, University Hospital, Copenhagen

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Knud Lykke Jensen, Managing Director, Price Invena ApS.

## **Concept**

It is necessary at every birth to cut the umbilical cord and place clamps or elastic bands on the separated ends of the cord. This procedure usually involves the midwife's clamping the umbilical cord at two places and then cutting between the clamps. A plastic clamp or elastic band is applied on the child's side to prevent subsequent bleeding. The placenta end is closed with forceps, which are removed after the placenta has been examined.

Blood splashing often occurs when the midwife cuts the cord. The scissors used to cut the cord can also be a potential risk for the midwife.

To simplify the cord-cutting procedure, Price Invena has developed a Safety Clamp and Cutter (SCC 23) with two clamps and a protected knife. The umbilical cord can be cut and two clamps applied in a single action. The clamp attached to the child is of the type already used.

In addition, there is no danger attached to the subsequent disposal of the knife, as it is automatically sheathed in the SCC 23.

The objective of the investigation was to evaluate whether use of the Safety Clamp and Cutter (SCC 23) developed by Price Invena to cut the umbilical cord could be undertaken in a manner that is safer and just as easy as the conventional procedure.

## **Background**

Against a background of the necessarily more stringent requirements for the protection and safety of health-care personnel during the treatment of patients, Price Invena has developed and patented a Safety Clamp and Cutter (SCC 23) for the cutting of the umbilical cord after childbirth.

There are three distinct steps in the procedure for cutting the umbilical cord after childbirth:

- 1) evacuation of blood from a section of the umbilical cord between two clamps/pairs of forceps,
- 2) cutting the umbilical cord,
- 3) securing haemostasis with the use of string, clamps, elastic bands etc.

Cutting of the umbilical cord is typically achieved by the midwife's applying two pairs of forceps and cutting between them. This procedure often results in the surrounding area being splashed with blood. The maternal part of the umbilical cord is not touched until the placenta is released. Haemostasis is achieved with a clamp or elastic band.

This method of cutting the cord involves several complicated steps and potential risks, e.g.:

- two pairs of forceps must be used
- there is the possibility of blood splashing when the cut is made

- after the cut, the section of the umbilical cord attached to the child is inspected and a permanent haemostasis established
- the sharp instruments used must be removed and perhaps cleaned.

It is therefore appropriate to be able to cut the umbilical cord, achieve haemostasis at both ends of the cord and avoid the possibility of blood splashing in a single action. It is also an advantage to be able to secure the subsequent disposal of the cutting elements in an acceptably safe way.

## **Objective**

The objective in this investigation was to evaluate the usefulness and safety of the Safety Clamp and Cutter (SCC 23) in childbirth.

In particular, we wished to assess:

- ease of use,
- if the procedure could be undertaken as a single action
- if blood splashing was minimised,
- if the positioning of the clamp on the child was satisfactory
- if disposal of the clamps and cutter was safe.

## **Size of population**

Prerequisites.

The absolutely decisive safety parameter for such clamps is whether or not they can be placed safely and precisely on the child and then remain in position. However, given that the part of the Safety Clamp and Cutter (SCC 23) attached to the child is identical to the clamps that are already used and approved, this safety parameter was not considered in this investigation.

The parameters investigated were:

- blood splashing
- ease of application
- disposal after use

It was accepted as a fact that blood splashing occurs when the conventional method is used to cut the umbilical cord.

It was stated that problems virtually never occur in connection with the application of the conventional clamps or elastic bands. Problems were not expected with the application of clamps in this investigation.

With these prerequisites, the population size was as follows:

It was decided that there should be a case-control study of 364, i.e. 182 births in which the Safety Clamp and Cutter (SCC 23) was used and 182 with the conventional procedure.

The women were randomly assigned between the traditional procedure and use of the Safety Clamp and Cutter (SCC 23) in accordance with Good Clinical Practice.

## **Material**

### **Testing:**

Pregnant women admitted to the University Hospital, Copenhagen, who were expected to give birth to normal, healthy children at full term.

The period chosen for the trial was equivalent to 364 births and lasted 15 weeks.

The women were allocated randomly either to the clinic's usual procedure for cutting the umbilical cord or to use of the Safety Clamp and Cutter (SCC 23). This randomisation was undertaken after the patient had agreed to participate in the project.

The Safety Clamp and Cutter (SCC 23) could be used even when physical measurement of the umbilical cord was necessary.

## **Method**

The Safety Clamp and Cutter (SCC 23) supplied by Price Invena ApS is shown in photograph 1. It consists of two clamps separated by a knife.

The white clamp must always be closest to the child (Figure 1).

The umbilical cord is placed as far into the Safety Clamp and Cutter (SCC 23) as possible and the fingers are positioned as shown in Figure 2. It is important to use the thumb and index finger to keep the umbilical cord in position, so that it does not slip backwards towards the lock on the clamp.

The Safety Clamp and Cutter (SCC 23) is moved approx. 1 cm away from the child's stomach and the piston is pushed in as far as it will go. The three-finger grip is used to clamp and cut simultaneously, as shown in Figure 3. The Safety Clamp and Cutter (SCC 23) then separates into two parts, with the white clamp remaining on the child and the green component, including the knife and piston, clamped onto the section of the umbilical cord attached to the placenta.

The part of the Safety Clamp and Cutter (SCC 23) attached to the placenta is designed so that it can be opened easily to enable a blood sample to be taken, the cut to be examined and, if required, the placenta to be milked.

## **Midwives and supervisor**

The clinic appointed a supervisor and a project manager.

The supervisor was a doctor employed in the clinic.  
The project manager was a midwife.

The midwives were both provided with written information and provide with oral briefing on the SCC 23 project. They were also given training in the use of the Safety Clamp and Cutter (SCC 23).

The staff who participated in the project were asked to answer the following five questions:

1. Blood splashing (yes/no)
2. Repositioning (yes/no)
3. Alternative method (yes/no)
4. Vaginal birth (yes/no)
5. Caesarean section (yes/no)

The staff were also asked to use a visual scale from 1 to 47, in which 1 was “easy” and 47 was “difficult”, to evaluate how easy/difficult they found it to use the Safety Clamp and Cutter (SCC 23) compared with the traditional method for cutting the umbilical cord.

## **Ethics**

The investigation did not expose the children or the mothers to risk.

The investigation was approved by the local ethical committee.

The protocol and practice for this investigation were in conformity with the Helsinki Declarations.

## **Statistical analysis**

The differences in the answers to the five questions and on the visual scale were analysed with the help of non-parametric statistics (Chi-square test). The results given on the visual scale were analysed by multiplying each value by the number of staff members giving that particular value. Thereafter the average value was calculated for each of the groups and then divided by the number of tests in each group.

## **Results**

Table 1 shows the results for the five questions, divided between the two groups of mothers giving birth. There were no reports of blood splashing, repositioning of the clamp or the use of an alternative method for the Safety Clamp and Cutter (SCC 23). For births in which the traditional method was used, there was blood splashing in 25% of cases, repositioning of the clamp in 5% of cases and a need to use an alternative method in 10% of cases.

Table 2 shows the results for the visual scale response, given as median and range. It can be seen from the scale that a high percentage report that the traditional method is more difficult. Statistically speaking, use of the Safety Clamp and Cutter (SCC 23) was significantly easier than the traditional method (  $p > 0.05$  ).

## **Conclusion**

The Safety Clamp and Cutter (SCC 23) is a tool that has been developed to simplify the procedure for cutting the umbilical cord and to protect staff undertaking this procedure. The danger associated with the procedure is the risk of infection with, for example, hepatitis B, C, E and not least with the HIV virus. The frequently pronounced over-pressure in the umbilical cord makes it easy for infected blood to be dispersed, with the risk that staff become infected. Staff in many obstetric wards are therefore encouraged to wear protective glasses. However, many people regard this precaution as uncomfortable; it is thus unpopular and disregarded.

The tests of the Safety Clamp and Cutter (SCC 23) that were undertaken show that this tool significantly reduces - if not prevents - the risk of blood splashing. The method is also faster and eliminates the use of scissors and forceps that have to be cleaned, packed, sterilised and transported from the obstetrics clinic to the sterilisation department and back again.

Even though the Safety Clamp and Cutter (SCC 23) is expected to cost around 2,00 US \$ it has been calculated in a cost-benefit analysis that a saving of 25,45 US \$ can be made per umbilical procedure.

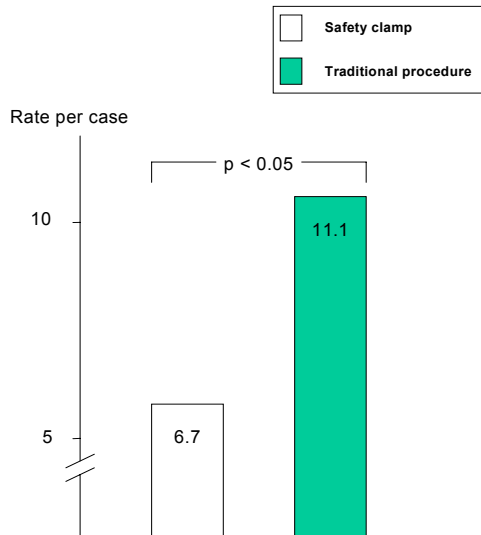
The conclusion is that the Safety Clamp and Cutter (SCC 23) is a safe and convenient alternative method for the cutting of the umbilical cord.

**Table 1**

	Safety Clamp and Cutter (SCC 23)	Traditional procedure	P
Blood splashing	0%	25.3%	p<0.001
Repositioning	0%	5.5%	p<0.01
Alt. method	0%	11%	p<0.001
Vaginal birth	83.4%	85.2%	Not applic.
Caesarean section	16.2%	14.8%	Not applic.

**Table 2**

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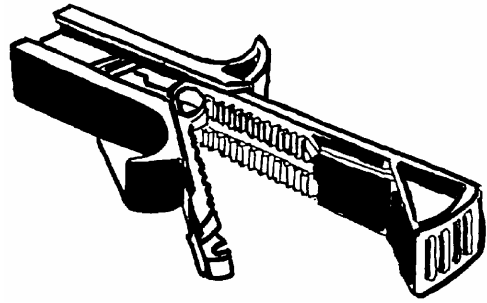


Figure 1.

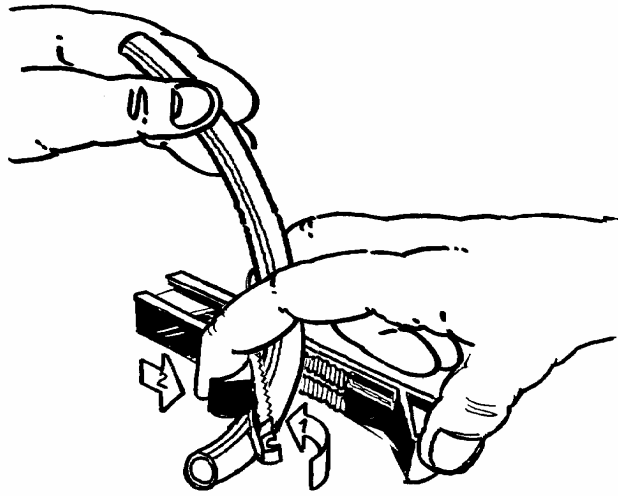


Figure 2.

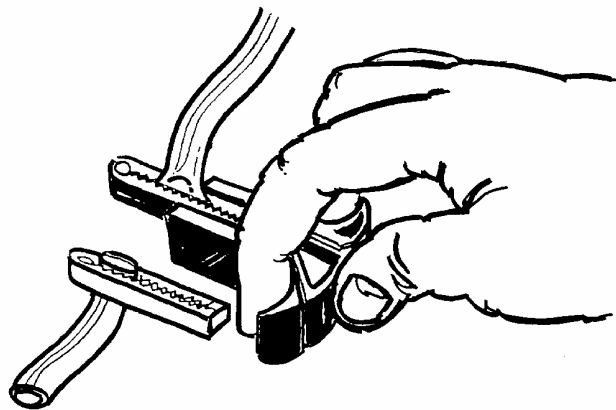


Figure 3.