# CLINICAL AND PHYSICAL ASPECTS OF OBSTETRIC VACUUM EXTRACTION

## KLINISCHE EN FYSISCHE ASPECTEN VAN OBSTETRISCHE VACUUM EXTRACTIE

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To my parents,
to Irma, Suze and Julius.

# CONTENTS

Chapter 1

# GENERAL INTRODUCTION

Until one century ago the natural wonder of spontaneous childbirth was the turning point in a woman's chances of surviving her pregnancy. When obstructed labor occurred the midwife or surgeon had nothing to offer but patience, blessing and fundal expression, and their frustation was compensated by skillful use of craniotomes in case the mother was alive. At present childbirth is still appreciated as an intriguing and fascinating event, but it is not considered anymore in the perspective of maternal life and death. This is caused to a large extent by the development of techniques to effectively assist in or bypass vaginal delivery, which became in general use in the course of the twentieth century.

After the establishment of forceps delivery and safe cesarean section, vacuum extraction has emerged as an approach to instrumental vaginal delivery. The prevalence of assisted vaginal delivery is now 7 - 16 % in developed countries[175], with considerable differences in the relative use of cesarean section, forceps delivery and vacuum extraction[15]. These differences may be due, at least in part, to the fact that the available evidence from the literature is not strong enough to establish practical guidelines that are generally accepted. Without published evidence or theory to adhere to, an audit of experience within a group of practitioners may help to assess effective obstetric care, but few of such studies have been published.

From a physical point of view childbirth is the passage of an object through a resistant medium, which can only succeed if the energy provided by myometrial contractions, pushing or pulling at the object, is sufficient to overcome friction. From a physiologic point of view the amount of energy used must be limited and distributed in a limited period of time to prevent damage to fetus and mother. The resistance of the birth canal can be bypassed by abdominal delivery. In case of vaginal childbirth the obstetrician can augment the biological expulsive forces due to myometrial contractions and pushing efforts by fundal expression and by pulling at the fetus. Fundal expression, the pushing mode to add energy to the passage process, is inefficient and not acceptable as a prolonged intervention[1]. The other solution to expedite vaginal delivery with a fetus in cephalic presentation is pulling the fetus out by means of an obstetric forceps or vacuum extractor. In modern obstetrics few studies have addressed the physical aspects of forceps and vacuum delivery and their consequences with regard to efficacy and maternal, fetal and neonatal complications. The obvious difference between an obstetric forceps, gripping under the cheeks of the fetus, and the vacuum extractor attached to the fetal scalp, was addressed in 1921 by De Lee mentioning "the protective helmet function of the obstetric forceps", but this aspect has not been elaborated since. With this gap in mind, it is surprising that the rigid and the pliable vacuum cups and their presumed differences with regard to obstetric outcome have gained so much attention in the literature.

The widespread use of vacuum extraction that rapidly followed its introduction in Europe almost five decades ago must be attributed to the qualities of the instrument and the method. However, attachment of the rigid Malmström cup to the fetal scalp has been shown to be associated with scalp injury and cosmetic damage, which has had a negative effect on the popularity of vacuum extraction, in particular in the U.S. Soft synthetic materials have been used to manufacture less traumatic, pliable cups to make vacuum extraction acceptable to a larger group of obstetricians, but as yet there is little agreement on issues concerning instrument efficacy and safety. Parameters of obstetric care, such as statistics of perinatal mortality, and of gross neonatal neurologic pathology, do not discriminate between the use of rigid and soft cup types[236]. Whether long term neurologic follow-up may be expected to detect differences in outcome of different modes of instrumental delivery is questionable, because of the variability in indications for instrumental delivery. However, further research to detect subtle neonatal effects is warranted by the huge number of newborns involved, and may require the introduction of more sophisticated parameters. One of these could be the assessment of hemorrhage in the neonatal retina, a presumed indicator of neonatal brain damage[220].

Attachment of the vacuum cup to the fetal scalp requires suction during a certain period of time to allow formation of an adequate caput succedaneum. Based on Malmström's original recommendations a suction time of 8-10 minutes with an incremental increase in negative pressure has become an accepted standard[152]. Such a period of time may be too long when faced with fetal distress, and this aspect has curtailed the use of vacuum extraction in such cases. There is a lack of data with regard to the actual time needed for formation of an adequate caput succedaneum in a rigid vacuum cup. Such data is indispensable before a reduction in vacuum suction times may be attempted under clinical conditions.

Two generations of obstetricians after the introduction of vacuum extraction, first year residents rapidly learn to apply vacuum extraction without supervision, in contrast to their slower and much more limited introduction to the complicated use of the obstetric forceps. This may be expected to lead to less experience with complicated forceps delivery, and a further shift towards vacuum extraction or anticipated easy forceps deliveries in the next generation of obstetricians[254]. Whether or not this development is to be encouraged depends on the balance of neonatal and maternal morbidity, of which no recent data are available.

On the basis of the considerations presented above, the objectives of this thesis are:

- to provide an overview of the literature concerning obstetric vacuum extraction, including a summary of its physical aspects;
- to assess the obstetric experience with the pliable vacuum cup in clinical practice in The Netherlands;
- to provide evidence to assist in making a rational choice between rigid and pliable vacuum cups, based on a randomized trial of both instruments and including assessment of neonatal retinal hemorrhage and neurologic optimality;
- to compare perinatal outcomes, including results of neurologic and ophthalmologic examination of newborns, of delivery by nonrandom use of vacuum extraction or obstetric forceps;
- to investigate the development of the artificial caput succedaneum in a rigid vacuum cup in relation to the length of time of vacuum suction.

The studies related to these objectives are described in chapters 2 to 6 of this thesis and followed by a general discussion.

Chapter 2

# VACUUM CUPS AND VACUUM EXTRACTION; A REVIEW

## 2.1. Introduction

The first application of vacuum extraction to a difficult delivery was described by Simpson 150 years ago, but it was only after the introduction of the Malmström vacuum cup in the 1950's that the method gained acceptance in obstetric practice in Europe and in some developing countries. In other parts of the world, in particular in the United States, obstetricians continued to prefer forceps for instrumental delivery, due to technical difficulties with the use of the vacuum extractor and also because of cosmetic and safety concerns with regard to the fetus. Recognition of the possible disadvantages has led to reconsideration of the mechanical forces to which the fetus may be subjected during vacuum extraction and to modifications of the design of the vacuum cup with the use of pliable materials.

The purpose of this review is to briefly consider the historical background of instrumental delivery by vacuum extraction, to assess current knowledge about its mechanics, to analyze its fetal and maternal side effects and complications, and to examine the place of vacuum extraction in obstetric practice today. Weight in kg has been chosen as the unit of force and kg/cm$^2$ as the unit of pressure instead of the SI units newton and pascal, to facilitate the text for the medical reader.

## 2.2. Obstetric vacuum cups in past and present

In 1632 Hildanus reported the use of a vacuum cup for reposition of an impression fracture of the fetal skull[47] and although James Yonge already in 1705 suggested its application to deliver the fetal head[255], the first successful use of a "suction-tractor" was not described until 1849, when James Young Simpson published his report "On a Suction-Tractor, or new mechanical power, as a substitute for the forceps in tedious labours"[216]. In the course of time Simpson turned away from his "suction-tractor"

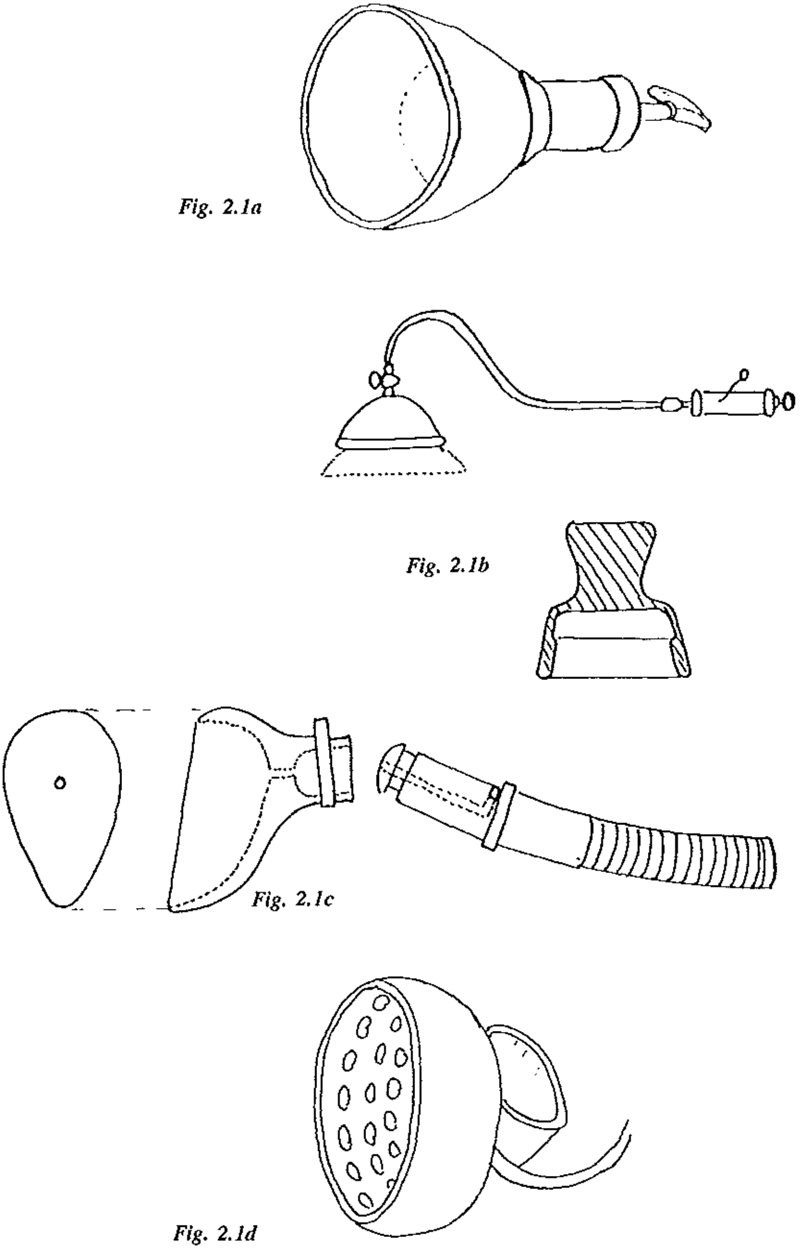



*Fig. 2.1.* *Illustrations of historical vacuum extraction instruments.*

in favor of a forceps of his own design[47,50], but many obstetricians adapted the suction concept and tried to design clinically effective suction instruments, which will be briefly described and discussed in the following paragraphs.

Table 2.1. *Summary of one century of vacuum extractor designs, 1849-1953.*

| Year | Designer | Details |
|---|---|---|
| 1849 | Simpson[47,216] | "Suction-Tractor"; several designs: a preserved example features an inner metal cup, fitting in a larger vulcanized rubber cup. The mouth of the inner cup was covered by a diaphragm of open brass wire gauze. A piece of sponge or flannel was placed inside the cup to prevent injury to the scalp. A suction cylinder on top of the dome was also the instrument's handle (Fig.2.1a). Trial reported. |
| 1875 | Stillman[99,217] | Flexible cup with pump, including a set of cervical dilators. |
| 1890 | MacCahey[99,152] | "Atmospheric tractors"; at least 14 designs of elastic material, some with no more than a handle, some completed with a suction pump connected to the cup by flexible tubing (Fig.2.1b). |
| 1912 | Kuntzsch[126] | "Vakuumhelm"; helmet-like instrument of metal with rubber interior. Pump included, first application of manometer introduced. Trial reported. |
| 1933 | Gladish[30] | "Pneumoceps"; oval-shaped cup of hardened rubber, "having a resilient mouth and a substantially egg-shaped contour". No pump (Fig.2.1c). |
| 1934 | Cornu[30] | "Forceps Pneumatique"; long, cone-shaped instrument with a pump fixed to it. |
| 1938 | Torpin[37] | "Extractor"; flexible hemispheric cup with notches on the interior surface. An eye on the dome's exterior served as attachment point for a cord, or the operator's finger. Suction tube placed excentrically. Vacuum level of 17 inches of mercury described[152](Fig.2.1d). |
| 1938 | Castallo[37] | "Extractor"; oval-shaped flexible cup with thickened edge. |
| 1941 | Price[30] | "Obstetrical instrument"; consisting of two parts: a solid concave plate with a suction nozzle and four threads to be placed on the vertex, and a rubber bonnet meant to be covering this. A spatula for intravaginal positioning of the bonnet was included in the patent. |

contd.

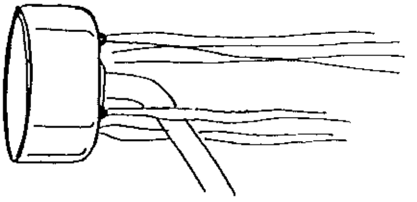


*Fig. 2.1.e*

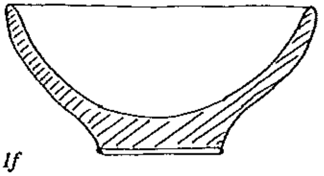


*Fig. 2.1f*

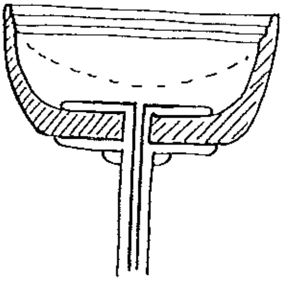


*Fig. 2.1g*

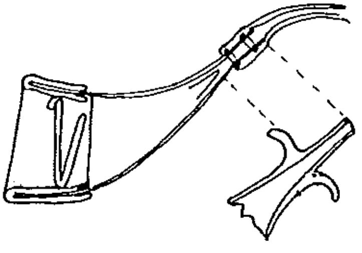


*Fig. 2.1h*

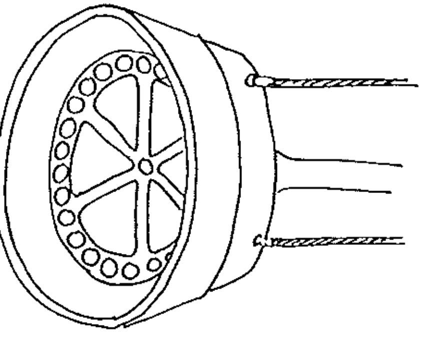


*Fig. 2.1i*

*Fig. 2.1 contd.* *Illustrations of historical vacuum extraction instruments.*

### 2.2.1. *Historical background*

Several authors have presented the history of the obstetric suction device in detail[30,47,50,99,152,226]. In order to facilitate the understanding of the modern vacuum extractors, the main features of ancient historic instruments are summarized in Table 2.1.

Table 2.1 contd. *Summary of one century of vacuum extractor designs, 1849-1953.*

| Year | Designer | Details |
|---|---|---|
| 1947 | Couzigou[58] | "Ventouse eutocique" aluminium cup of 60 mm diameter, with strings attached to the dome. Distant suction pump and bottle collecting fluids in between. Trials reported (Fig.2.1e). |
| 1948 | Cunningham[60] | "Rubber sucker cup"; flowerpot-like rubber cup with rubber tubing, mercury manometer, bottle interposed and an electric vacuum pump. One prototype described. |
| 1948 | Koller[121] | "Rubber suction cup"; bowl-shaped shallow rubber cup, with thickened bottom. No pump or tubing attached. Trial reported as an alternative to the Gauss-Willet forceps procedure at incomplete cervical dilatation, mean duration of traction over 4 hours (Fig.2.1f). |
| 1949 | Körber[30] | "Gerät zur Erfassung und Bewegung des kindlichen Körpers während der Geburt"; cup with a semi-rigid base and flexible ribbed ledge (Fig.2.1g). |
| 1951 | Gastaldo[88,150] | "Speculum tocacetabolo"; hemispheric metal cup covered with rubber. This 'speculum' was to be placed in the lower part of the birth canal, without attachment to the fetal head, and without traction. The underpressure in the vagina, between the head and the speculum was considered to help the expulsive forces. |
| 1952 | Finderle[82] | "Extractor"; a horn-shaped metal instrument with a rubber cuff around the edge. A T-bar at the end of the horn facilitates traction. A 200 cc syringe is applied to induce underpressure (Fig.2.1h). Trial reported[83], recently from China[140]. |
| 1953 | Vincent & Montague[152] | "Suction plate"; shallow design with a rigid bottom, perforated inlay, and a flexible ledge. Centrally attached tube (Fig.2.1i). |

Both pliable[99] and rigid[46] materials were used in the construction of suction cups. Following the introduction of a manometer to monitor the vacuum level[126], and protection of the system against fluids by interposing a bottle[58], the development of a vacuum extraction system for assisted delivery was essentially completed many years before the sucessful introduction of the instrument by Malmström in 1953[153]. The potential danger of sucking fetal scalp into the suction tube was recognized and measures to prevent this, such as perforated inlays[152] or pieces of cloth inside the cup[46], were part of some of these devices. However, the majority of these instruments never got past the design or patent stage.

Despite claims of success of some of the instruments, only the Finderle cup has survived beyond sporadic clinical use[140]. There are three main reasons why the other types of vacuum cups have vanished. First, these cups have a hemispherical or cone-like shape, which may not be the optimal shape to establish sufficient fixation. Second, in the few clinical trials reported, failures have frequently occurred because the suction devices were unwieldy and allowed only minimal levels of negative pressure. Third, in several instances a new vacuum cup model was introduced as a replacement of forceps[58,60,83], thus creating high expectations. In an atmosphere of scholastic scepticism this may have led to a rapid denial of the method as soon as failures occurred.

All this changed when the Swede Tage Malmström in 1953 introduced the first design of his "sugklocka"[153]. As in Stillman's[50] and Koller's work[121] this vacuum cup was meant to adhere to the fetal head at incomplete cervical dilatation in order to increase the speed of the first stage of labor[150], replacing the use of a small scalp forceps[248].

The extractor consisted of a hemispherical metal cup, with a perforated metal inner dome. A rubber cover over the exterior of the cup and extending over the edge provided a force-dispersing rubber ring of 10 mm width. This cup, "model 1953" was available with 55, 60, 70 and 80 mm opening diameters, allowing selection according to the actual cervical aperture. After gradual augmentation a negative pressure of 0.5 $kg/cm^2$ was established. Continuous traction was applied with weights totalling 2-4 kgs, during several hours if needed. A total of 30 cases were described in which the traction improved labor, although three babies were lost.

2.2.2. *The Malmström cups*

***The orginal Malmström Vacuum Extractor.*** In the same article in which Malmström described his first vacuum cup and its use in the first stage of labor, he also reported 15 successful applications during the second stage of labor instead of forceps delivery[150]. This approach was followed up, and Malmström experimented with rubber membranes in order to determine a cup shape for optimal suction and traction performance. This led to the development of the socalled "second generation" vacuum cup. Malmström showed that the vacuum was best maintained by plying the rubber membrane around the edge of the cup, which provided a high "seal pressure". These experiments resulted in an inward curve of the edge of the cup; the rim itself had a circular cross-section with a small radius (Fig.2.2.). Other experiments showed that the traction capacity of the cup, theoretically determined by the product of the area of the cup's opening and the negative pressure, was highly dependent on friction conditions. According to Malmström, the vacuum-induced caput succedaneum or "chignon"[202] behaves as "a semi-firm scalp knob", and provides grip to the cup even in the absence of vacuum, like "interlocking pieces in a jig-saw puzzle" (Fig. 2.2.)[167].

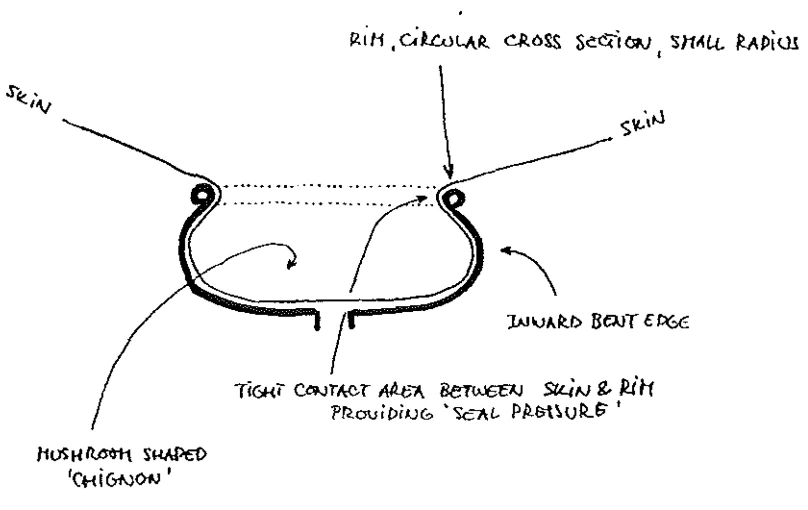
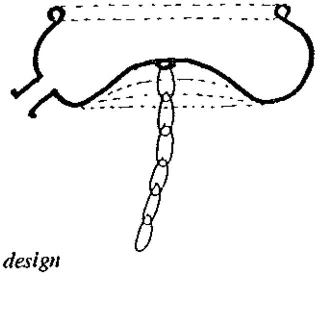



*Fig. 2.2. Alignment of the skin of the fetal scalp in a Malmström type dome.*

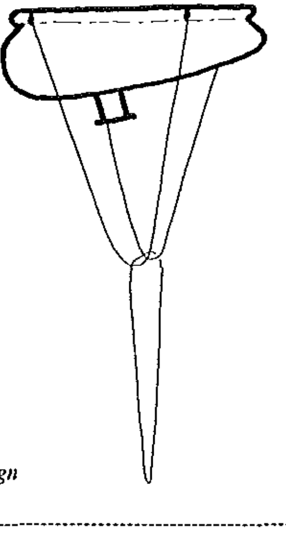
Malmström's definitive design, the Vacuum Extractor or "model 1956" or "VE"[19,217] is manufactured with opening diameters of 33, 42, 49, and 60 mm, called VE 30, VE 40, VE 50, and VE 60, respectively. It consists of a flat metal dome with a depth of 20 mm for the VE 40, 50, and 60. The recurved edge and the semicircular convex sides result in outer diameters that are about 14 mm larger than the cup opening. The suction tube is attached to a nozzle placed centrally on the dome. A perforated metal inlay in the cup prevents suction of skin into the suction tube, and is fixed to a chain that leads through the suction tube to a T-bar handle. From the handle the suction tube is connected with a manometer and a hand-held pump.

Sjöstedt[217], and Bird[21] introduced a minor modification called the "model 1967", in which the suction nozzle is shorter and placed in a slight depression of the dome, making the nozzle less pronounced and introduction of the cup into the vagina easier[217]. The "model 1967" is available with diameters of 50 and 60 mm. It features a silicon rubber disc instead of the metal inlay, and the traction handle is separate from the tube. In Europe the main cup manufacturers market the "model 1956".

***Modifications of the Malmström Vacuum Extractor.*** Trends for improvement of the Malmström cup were set by Halkin and Lövset (Fig.2.3).



*Halkin's design*



*Lövset's design*

*Fig. 2.3. Historical modifications of the Malmström cup.*

Halkin designed an indented dome with a chain attached near the plane of the cup opening and claimed that this modification improved the effectivity of oblique traction forces[92]. The suction nozzle was placed excentrically, away from the chain. Lövset designed a dome that was flattened on one side, with the aim to improve the possibility of deep sacral positioning[145]. As in Halkin's design the suction nozzle was placed eccentrically. Four wires were attached symmetrically to the cup's bulging side (Fig.2.3.) and formed loops sliding in another loop of wire. In this fashion the traction force was meant to be distributed equally over four points of attachment, also with the cup in a tilted position. These ideas to achieve effective oblique traction and to improve the possibility of excentric placement were original, but Halkin's as well as Lövset's design never became accepted in clinical practice.

In 1969 Bird presented a modification of Malmström's cup (Fig.2.4.) with a traction chain directly attached to the top of the dome. The suction tube is connected to a nozzle mounted eccentrically on the dome and no longer contains the traction chain (Fig.2.4.). In the original modification, a separate perforated neoprene inlay is used (Fig.2.5.); the interior end of the suction nozzle has a grooved metal washer to prevent the inlay from occluding the nozzle opening. As important advantages of his design Bird claims[21] the ease of deep posterior placement of the cup; its much simpler traction apparatus with variable distance between the handle and the cup; and its simple and rapid assembly. This version of the "modified cup"[22] has been named "anterior" or "occiput anterior" or OA cup (Fig.2.6.)[227]. Bird also designed a version with the suction tube placed on the bulging side of the cup, pointing sidewards, for occipito-posterior positions of the fetal head. This version is called the "posterior" or "occiput posterior" or OP cup (Fig.2.6.)[22]. A ring that locks the tube to the nozzle and a polypropylene mesh as bottom plate (Fig.2.5.) were later added to both cup designs[19].

In a more recent design, Bird uses a loop of wire as traction apparatus: two eyes are placed opposite from each other on the rim of the cup and the wire runs above the rim from eye to eye. The traction handle is hooked into the loop of wire (Fig.2.4.). Bird claimes that the traction device of this socalled "New Generation" cup enables the operator to pull obliquely without causing the cup to tilt[19]. However, when the knot in the string gets trapped in the traction handle, traction may promote tilting. This cup is also available in OA and OP versions.

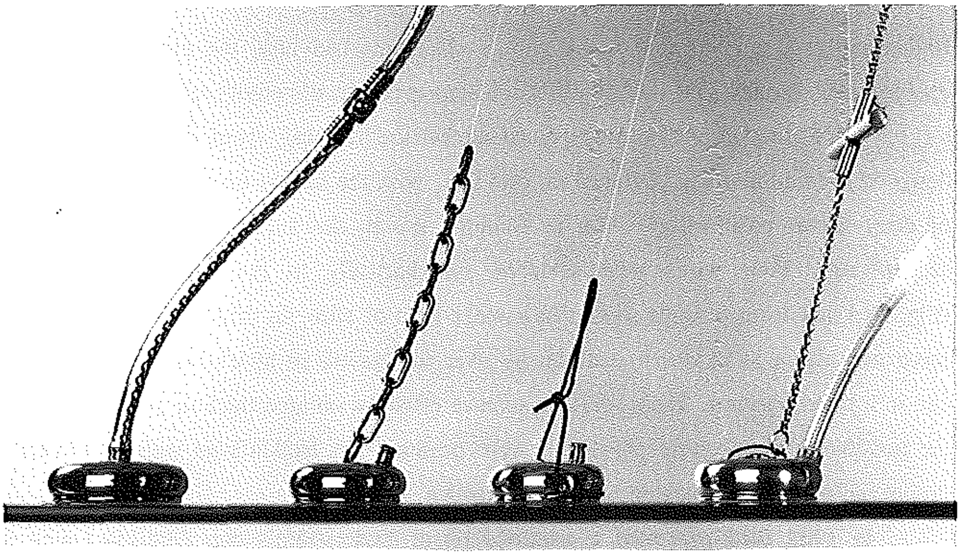


*Fig. 2.4.* *The Malmström vacuum extractor cup and its modifications. From left to right: the Malmström design; the Bird "modified" cup; the Bird "New Generation" cup; the O'Neil cup.*

*Fig 2.5.* *Several types of inlays in the metal cup. From left to right: a metal plate, connected to the traction chain, inside a 40 mm diameter Malmström cup; a polypropylene mesh inside a 50 mm metal cup; a neoprene inlay in a 60 mm cup.*

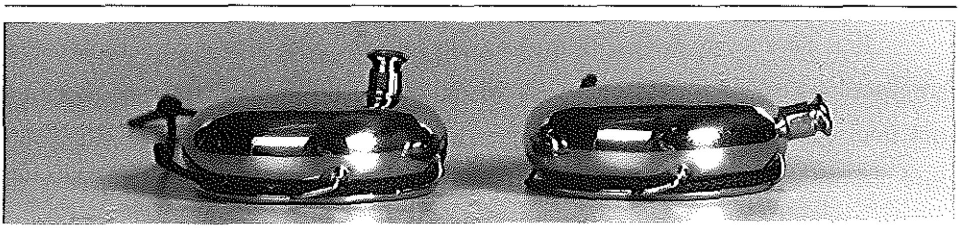


*Fig 2.6.* *The difference between OA and OP versions of the metal cups. Left: Occiput Anterior version (OA), nozzle points upwards; right: Occiput Posterior version (OP), nozzle points sidewards.*

In 1981 O'Neil, Skull and Michael presented an ingenious modification. A rotating circular plate constitutes the top surface of the dome, and a curved metal rod is mounted on the plate. The rod forms the perimeter of a circle around the center of the cup's opening, and is perpendicular to the plane of the cup's opening (Fig.2.4.). As long as traction is no more than 35° oblique, the vector of oblique traction is always through the center of the cup's opening[178]. O'Neil et al. claim that this construction will prevent the cup from lifting at one edge. The cup is in clinical use with a 55 mm opening diameter[227].

2.2.3. *The pliable cups*

Efforts have been made to produce soft, pliable vacuum cups that would be less likely than the rigid metal cups to injure the fetal scalp. A pliable cup was designed by Wood as early as 1963[252]. In a later publication he reported his experience with a disposable injection-moulded polyethylene cup that featured an outward bent, flared edge[253]. According to Wood the material allows the cup to adapt to the shape of the fetal head, which would prevent scalp damage. The cup needs no assembly prior to application[252]. As part of the Mityvac$^R$ obstetric vacuum delivery system, the cup has become known as the "Mityvac$^R$" cup (Fig.2.7.)[61,64]. Recently a similar design called the "Soft Touch" cup was marketed by Columbia Medical Inc.[234].

Another moulded plastic cup was introduced in 1973 by Paul et al.[181]. The dome is deliberately similar to that of the Malmström cup[182], and the suction tube is also the traction handle. Pliability of the base of the handle enables insertion into the vagina. The cup is currently available as the "M" style extractor cup in polyethylene (Fig.2.7.)[171]. The pliability of the cup is minimal and in its present form the cup may be considered rigid.

The name of Kobayashi is linked with a silicone vacuum cup since its introduction in 1973. The cup is also known as the "Soft Cup"[228] and, after Dow Corning patented it, as the "Silastic$^R$" obstetric vacuum cup[17,156,185,215]. The trumpet-shaped device has a 65 mm wide opening and a hemi-ellipsoïd bell. Radially arranged grooves are meant to transfer suction to the slightly thickened edge of the cup. The flexible shaft leads to a metal T bar-grip with a trumpet valve for vacuum release (Fig.2.7.).

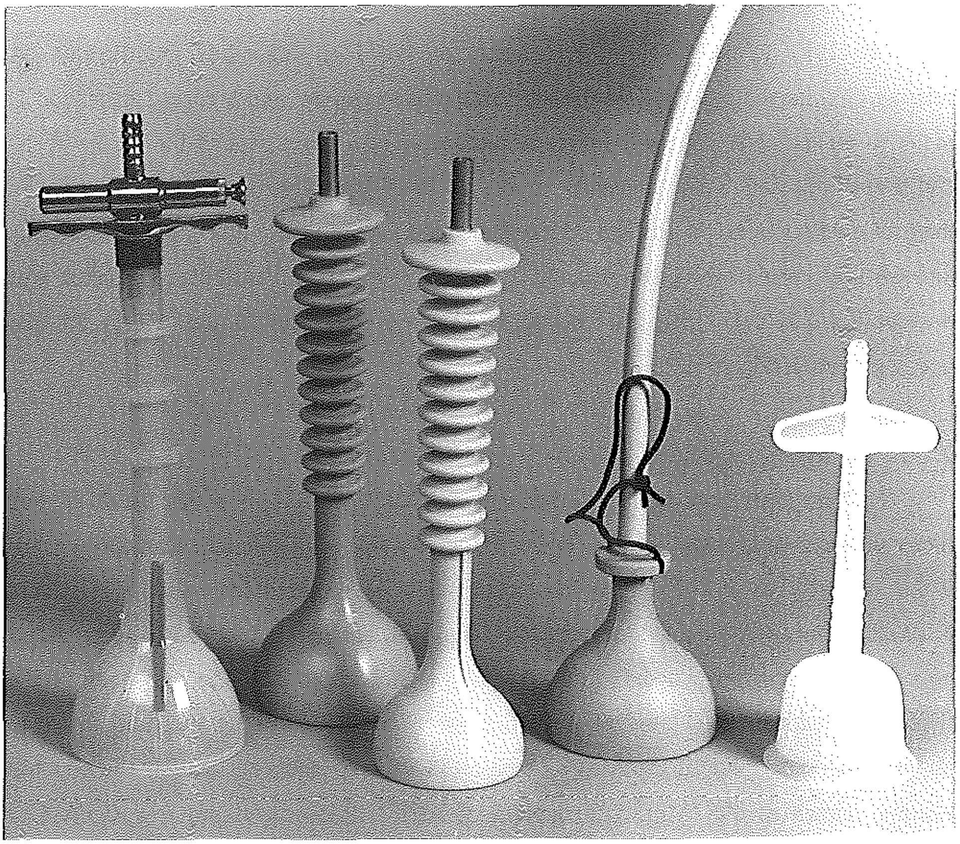


*Fig 2.7a* *The pliable cups. From left to right: the "Silastic^R" cup (65 mm diameter); the "Silc^R" cup (60 mm diameter); the "Silc^R" cup (50 mm diameter); the "Silc^R" cup with a loop of wire for traction (60 mm diameter); the "Mityvac^R" cup (55 mm diameter).*

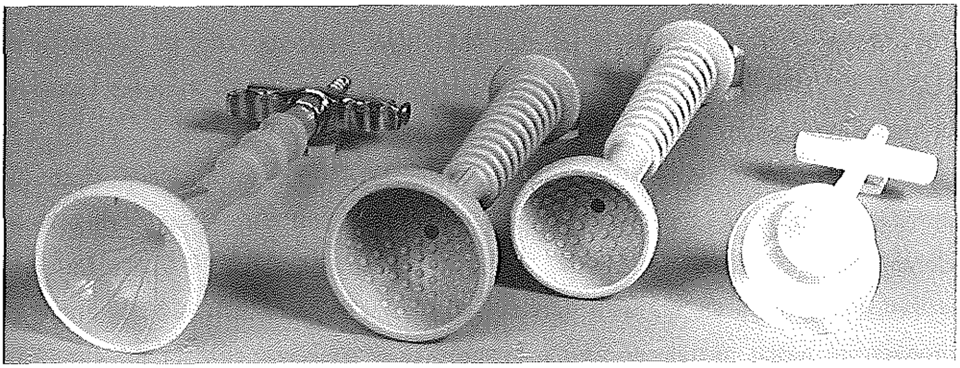


*Fig. 2.7b* *The inside of the dome of the flexible cups. From left to right: the "Silastic^R" cup; two "Silc^R" cups; the "Mityvac^R" cup.*

In comparison with the rigid Malmström cup several advantages of this cup are claimed[215]. The softmaterial is easily folded and inserted through the vaginal introitus, with minimal risk of trauma. The 65 mm diameter of the cup and the placement of the vacuum ports distribute the extraction force evenly over the entire occiput, thereby reducing the risk of cephalohematoma. The ability of the cup to distribute the force over a large area makes its use practical in cases with a large caput succedaneum. The first series of vacuum extractions performed with this cup was published in the English literature by Horwitz[109]. This author found the cup also suitable for extraction of the fetal head during cesarean section[108], a feature later published by others[185]. The Columbia Medical Inc. "Tender Touch$^R$" cup, introduced in 1989, is also made of silicone material and in shape comparable to the "Silastic$^R$" cup[234]. The opening bends a little outward, giving the cup a tulip shape. Unlike the Silastic$^R$ instrument, this cup lacks a vacuum release valve.

The hemispherical "Silc$^R$" cup, introduced in 1984 by the Menox company, is also made of a soft silicon plastic material. The initial design has a 70 mm outer and a 60 mm inner diameter[251]; a cup with a 50 mm inner diameter also exists[134]. The thickened edge of these cups bends 3 mm inwards. The inner surface is scattered with notches, to preserve some space between the cup and the scalp. The handle stem is made of the same silicon material cast around a metal suction pipe (Fig.2.7.). A recent model lacksthe handle stem: a loop of wire is connected to a ridge on top of the dome and a T shaped handle can be hooked into it (Fig.2.7.)[233]. The manufacturer states that both the fetal head and the soft cup deform, thereby ensuring optimal adhesion and a minimal risk of trauma to the fetal scalp. The negative pressure of 0.8 kg/cm$^2$ for the 50 mm cup, and 0.6 kg/cm$^2$ for the 60 mm cup may be obtained at once. In the manual it is recommended that the head should be at, or just above, the pelvic floor, and that the cup should not be used with the fetal head above the pelvic floor, or when oblique traction is necessary[134].

Elliot et al. recently introduced a disposable latex bonnet that is designed to unroll over the fetal occiput and tighten against the fetal head under stretching[70]. Stable adherence of the "obstetric bonnet" to a model of the fetal head was shown, but its clinical application has not yet been reported.

## 2.3. Mechanics of vacuum extraction

Vacuum is defined as the absence of matter. True vacuum does not exist on earth, but also the presence of air or another gas at reduced pressure is called vacuum. In vacuum extraction the term vacuum refers to the difference between the pressure under the dome and the atmospheric pressure. The pressure difference is always negative, reason to discard the minus sign. The maximum negative pressure that can be achieved equals the atmospheric pressure, which fluctuates around 760 mm Hg or 1,03 kg/cm$^2$ or 100.9 kPa at sea level.

### 2.3.1. *Attachment to the fetal scalp*

The early vacuum extractors were equipped with a hand-held pump that needed two hands to operate[152]. Subsequently, single hand and foot-operated pumps were developed[43,61,90,181]. Electric pumps are now widely used[17,113,151,176], in some cases with pedal controlled valves for use by a single operator[227,242]. Also the hospital wall vacuum system can be used[55], provided that a pressure-limiting device is included[57,100].

The negative pressure to be used in vacuum extraction systems is generally accepted to be 0.7 - 0.8 kg/cm$^2$, and a temporary increase to 0.8 - 0.9 kg/cm$^2$ is considered acceptable, independent of the type of cup[11,43,100,129,149,151,161,188,204,227,203,242]. Some authors advocate the use of less negative pressure[61,90,176] and some of more[61,95,164], in particular with the use of the Silastic$^R$ cup[95,228]. The negative pressure is usually maintained throughout the delivery, but the application of negative pressure during pulls only has been reported[61,89].

An identical mechanism is responsible for the development of the physiologic and the artificial caput succedaneum[152], also called "cup caput"[236] or "chignon"[202]. The content of the cup caput is described as sero-sanguinous[4], but reported systematic analysis of the chignon is limited to ultrasound scanning[17]. By means of insufflation of air under the scalp of a stillborn baby Malmström showed that the scalp behaves as an independent cap surrounding the cranium[152], a phenomenon also accidentally demonstrated in a live newborn[23]. The vacuum cup creates a pressure gradient across the scalp, which reacts as a membrane to the excess of pressure inside, and a spherical bulge is formed by redistribution of fluids. While developing a vacuum of 0.8 kg/cm$^2$ inside a cup in 2 minutes, intrapartum pressure measurements assessed 0.007 kg/cm$^2$ of underpressure in the chignon of dead fetuses, with a threefold increase of underpressure during more rapid augmentation of vacuum, and just before detachment of the metal cup[29]. This increase in underpressure in the chignon may demonstrate that the flow of fluid into the chignon has restrictions.

Malmström emphasized the importance of allowing sufficient time for the development of the chignon, preferably at least 10 min, without providing any evidence[152,148]. Subsequently, other authors have recommended a variety of modes to establish a slow or rapid, stepwise or continuous increase in vacuum[13,19,223,246]. The influence of artificial caput formation on traction forces has been studied in a canine model[167]. For the rigid Malmström cup a nonsignificant positive effect of chignon formation was demonstrated, but the adhesiveness of the bell-shaped pliable cups was found to be less after the development of the chignon because of reduction of the available vacuum area[167]. This finding implies that the grooves or notches in the interior of the flexible cup fail to disperse the underpressure. Muise et al. recommend to reduce chignon development in these cups by applying vacuum only during traction[167].

The single nonrandomized comparative study of slow and rapid application of suction that has been published shows similar mean tractive forces with both methods and does not indicate any adverse effects of rapid induction of vacuum using rigid cups[223]. Selection bias in this study precludes conclusions concerning the general applicability of rapid suction with a metal cup. Wider et al. assessed chignon formation in a transparent plexiglass vacuum cup. The establishment of a negative pressure of 0.7 $kg/cm^2$ in 1-2 minutes resulted in almost immediate maximum filling of the cup, regardless of the size of the preexistent caput succedaneum[246]. However, the exact shape and size of the transparent cup were not specified[246]. As the speed of chignon development may depend on cup size and/or cup shape, the rationale for rapid suction with the rigid domes remains to be established.

### 2.3.2. *Placement, traction and traction forces*

*Placement.* A vacuum cup should be placed on the fetal scalp in such a way that traction will promote flexion and synclytism, and will result in presentation of the most favorable diameters of the fetal head[22,238]. For this reason the cup should be placed in the "flexing median position" with its center over the socalled "flexion point" located on the sagittal suture, 6 cm posterior of the anterior fontanelle, or 3 cm anterior of the posterior fontanelle (Fig.2.8.)[20,236,238].

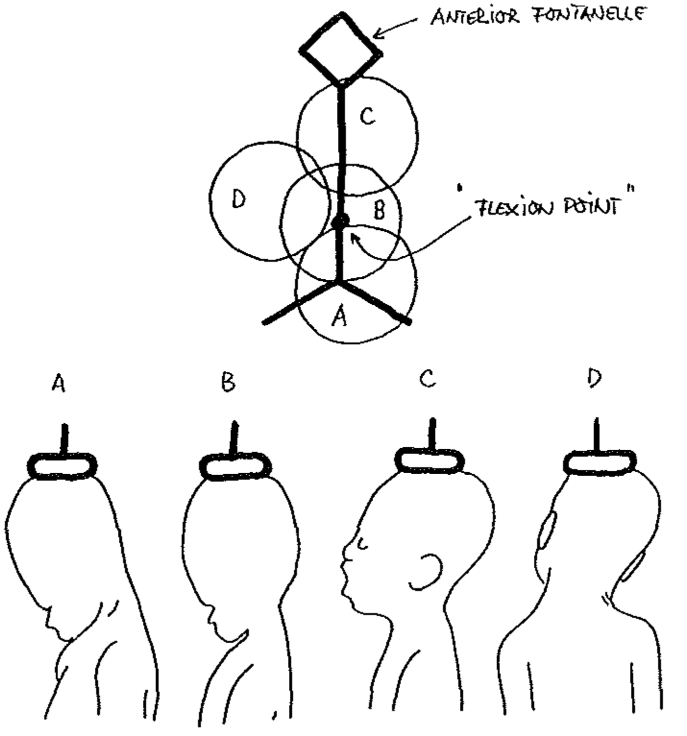



*Fig. 2.8.* *Application site of the vacuum cup and the effect on the attitude of the fetal head: A: Hyperflexing position. B: Flexing median position. C: Deflexing position. D: Paramedian position. Illustration adapted from Bird*[20].

This is of particular importance in cases of malrotation, where the rigid vacuum extractor is considered superior to forceps[41]. Rotation from occipito-lateral and occipito-posterior positions to occipito-anterior is a physiologic mechanism, caused by friction in the birth canal and facilitated by flexion[41,74,101]. This mechanism is supported by traction on a vacuum cup placed in the flexing median position (Fig.2.8.), for which purpose the Bird modification has an advantage over the original Malmström design[235]. Persistent occiput-posterior position and extraction failure occurred significantly less often with the use of Bird's modified cup compared with the Malmström cup[22,41,101,235].

Eccentric placement in cases of malrotation and subsequent fixation of a pliable cup in a flexing median position will often be hard to accomplish due to the height of the pliable cups[238].

***Straight traction force.*** The force to which a vacuum cup in frictionless and airtight contact with a flat and nondeforming surface can be subjected before it detaches equals the product of the negative pressure (dP; difference between pressure outside and inside the cup) and the surface area of the cup opening, provided that traction is straight, i.e. is exerted in the axis of the cup. This force is the theoretical maximum traction force, F theor max:

(1) F theor max = dP x area

The theoretical maximum traction forces for several diameters of circular cup openings at negative pressures of 0.8 and 1.0 $kg/cm^2$ have been calculated and are presented in Table 2.2. A systematic comparison of traction forces of some of the cups, performed on a fetal scalp model consisting of a rigidly mounted 10-cm solid sphere covered with canine skin, demonstrated that actual maximum traction forces approach the theoretical values (Table 2.2.)[64].

Several investigators have reported measurements of traction forces under clinical conditions during instrumental delivery[106,162,165,207,223,229,228]. Some relevant data are also presented in Table 2.2. Few authors specify the level of underpressure applied or distinguish between mean and maximum traction force. A comparative clinical study demonstrated a significant difference in maximum traction force between soft (mean 11.1 kg) and rigid (mean 15.8 kg) cups[106]. The central part of the soft cups, to which the traction is applied, is described as to "tent away" from the fetal skull, concentrating the traction force on a smaller area and thus resulting in a lower maximum traction force[106]. Traction forces have generally been measured by load-cells incorporated in the chain between traction handle and dome[106,162,165,167,229,223]. None of the articles mentions whether or not the operator's free hand was used to correct cup position, as is usual in obstetric practice. Because such correction introduces a force opposite to the direction of traction, the measured force will be greater than the effective force applied to the head.

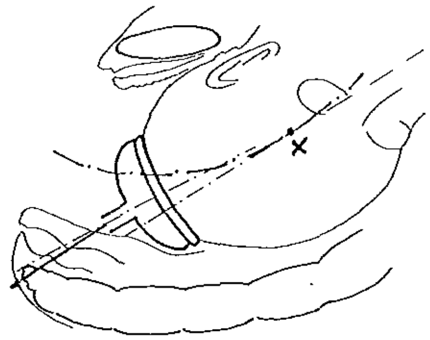



*Fig. 2.9a*

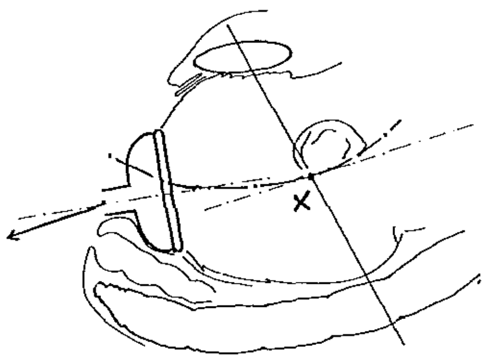



*Fig. 2.9b*

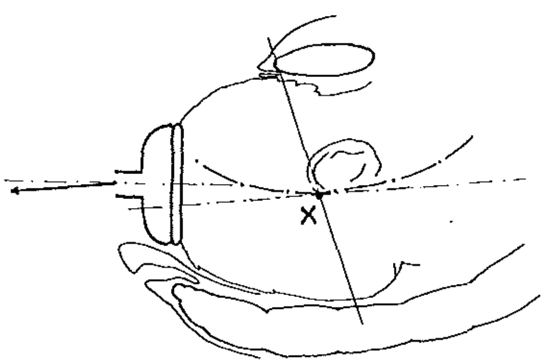



*Fig. 2.9c*

*Fig. 2.9a-c.* *The optimal direction of traction is a vector parallel to the tangent of the pelvic axis in the point X where the pelvic axis crosses the plane of the largest presenting diameters of the fetal head. Schematic drawing of three phases of a vacuum extraction.*

Table 2.2. *Theoretical traction force, traction force measured in vitro[64], and traction force measured in vivo[163,223,228], as a variable of cup diameter and two levels of underpressure. All forces in kg.*

| underpressure | 0.8 kg/cm² | | | 1.0 kg/cm² | |
|---|---|---|---|---|---|
| traction force | in theory | in vitro | in vivo | in theory | in vivo |
| cup diameter(mm): | | | | | |
| 30 | 5.7 | | | 7.1 | |
| 40 | 10.0 | 11 * | | 12.6 | |
| 50 | 15.7 | 16 * | 17 * | 19.6 | |
| 55 | 19.0 | | | 23.8 | |
| 60 | 22.6 | 22 * <br> 21 ** | | 28.3 | 35 * |
| 65 | 26.5 | 22.5*** | 17 *** | 33.2 | |

* : Malmström cups; ** : Silc cup; *** : Silastic cup.

The influence of the correcting hand can be avoided by measuring the contact pressure of the fetal scalp to an inlay in the cavity of the cup. This approach was tried out with a Malmström dome, but the unreliable estimate of the surface of scalp in contact with the inlay precluded accurate force calculations[160].

***Oblique traction force.*** Oblique traction is frequently necessary in cases of malrotation or midpelvic station, caused by the restrictions of the pelvic outlet[7,238] (Fig. 2.9a), but also unavoidable if the obstetrician complies with the advice to direct the traction force tangential to the axis of the birth canal[152] or, more precisely, to direct the force parallel to the tangent in the point where the plane of the largest diameters of the fetal head crosses the pelvic axis[238,130] (Fig.2.9a-c).

Halkin[92] and O'Neil et al.[178] performed an analysis of the vectors of axial and oblique traction and compared leverage. Essential in their model, shown in Fig. 2.10., was the assumption of a fulcrum in the rim of the cup. In an equilibrium of leverage, the maximum oblique traction force was calculated to relate to the maximum axial traction force as:

(2) $F$ axial max x $R$ = $F$ oblique max x $(R \cos \alpha + H \sin \alpha)$ , or

(3) F oblique max $=$ F axial max / ( cos $\alpha$ + H sin $\alpha$ / R ).

Equation (3) shows that the maximum oblique traction force can be increased by reducing H, which means in practice that the point of attachment of traction should be brought closer to the plane of the opening of the cup, as can be realized by means of the modifications of the original Malmström cup. The vector model shows that the relatively high Malmström and Bird "modified" cups may be expected to suffer from a considerably reduced maximum oblique traction force relative to the maximum axial force (Table 2.3.).

These results have been quite influential, and have decreased the popularity of the original Malmström cup in favor of its modifications that have subsequently been regarded as essentially different cups[237], despite the incomplete interpretation of the model. The authors can be criticized in that they do not explain that in the presence of the lever arm R, the maximum axial traction force is a priori reduced compared to the maximum theoretical traction force of equation (1), irrespective of the direction of traction and also irrespective of the design of the cup.

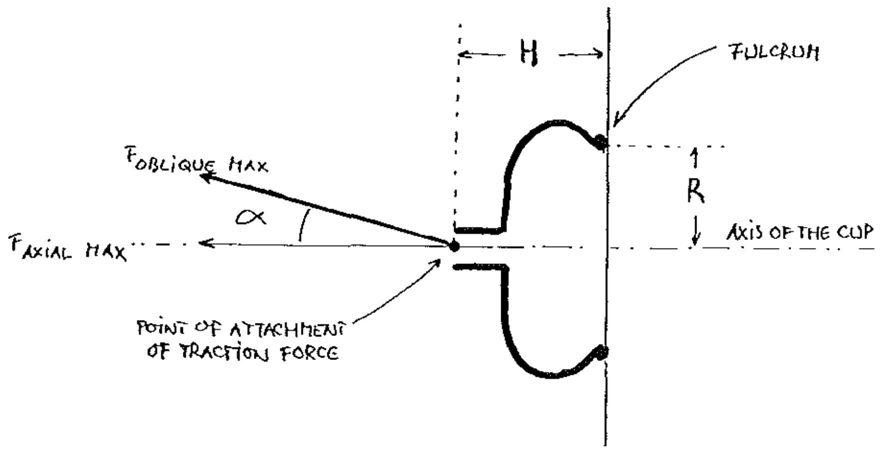



*Fig. 2.10. Symbols in O'Neil's and Halkin's calculations referring to oblique traction.*

Table 2.3. *Cup type and maximum oblique traction force as a percentage of maximum axial traction force, for several angles of oblique traction. Axial height of the attachment of the traction force (H) and radius of the cup (R) in mm.*

| Cup type | H/R | angle 0° | 10° | 20° | 30° |
|---|---|---|---|---|---|
| Malmström | 35/25 | 100 | 81 | 70 | 64 |
| | 35/30 | 100 | 84 | 75 | 69 |
| Bird "modified" | 25/25 | 100 | 86 | 78 | 73 |
| | 25/30 | 100 | 89 | 82 | 78 |
| Bird "New Generation" | 2/25 | 100 | 100 | 103 | 110 |
| | 2/30 | 100 | 100 | 104 | 111 |
| O'Neil | 0/28 | 100 | 102 | 106 | 115 |

A vacuum cup arrested by a fulcrum in its rim will overturn; one side of the cup will stay in place while the other side moves away from the fetal head. With this unequal displacement the skin will unfold from the rim of the cup opposite the fulcrum, and because of the lever the limit of leakage will be reached at a lower traction force compared to that of a cup that moves away from the fetal scalp with circular symmetry (Fig. 2.11.), as if R were indefinitely large.

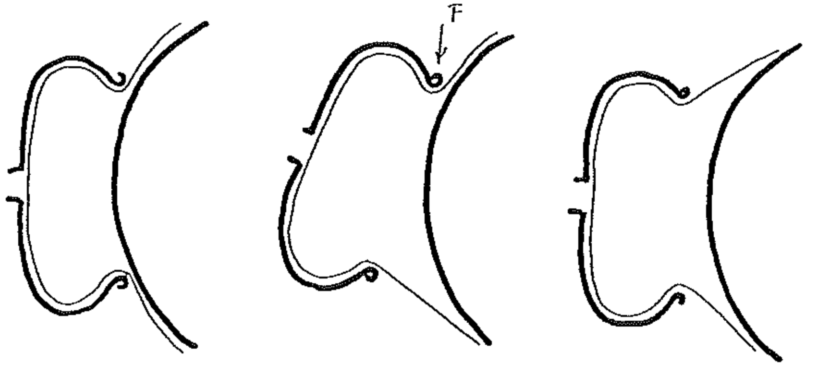



*Fig. 2.11a* *Fig. 2.11b* *Fig. 2.11c*

*Fig. 2.11a-c.* *Alignment of the fetal skin in a Malmström dome. Left: cup placed on the fetal head, no traction. Middle: traction performed as in the model of Halkin and O'Neil with reduced angle of scalp wrapped around the lower rim of the cup, and the fulcrum indicated as F. Right: Circular symmetry with regard to the cone-shaped caput succedaneum.*

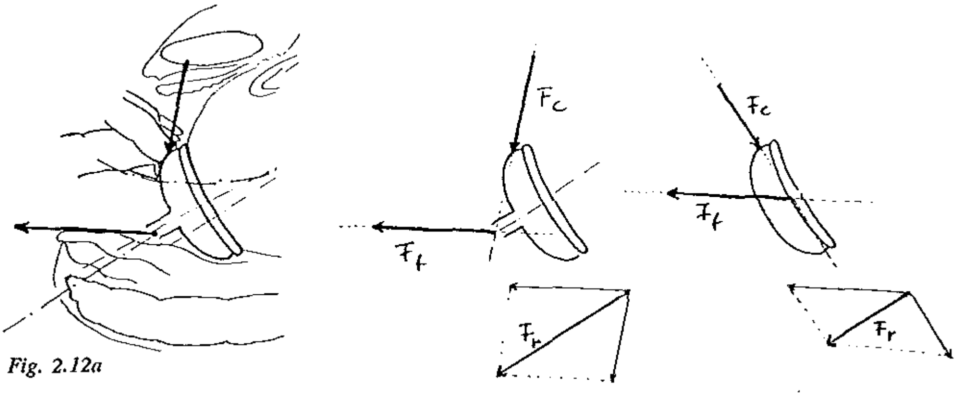



Fig. 2.12a

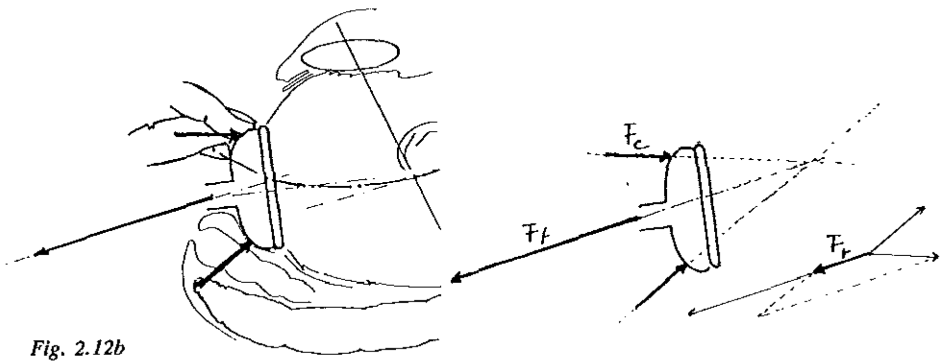



Fig. 2.12b

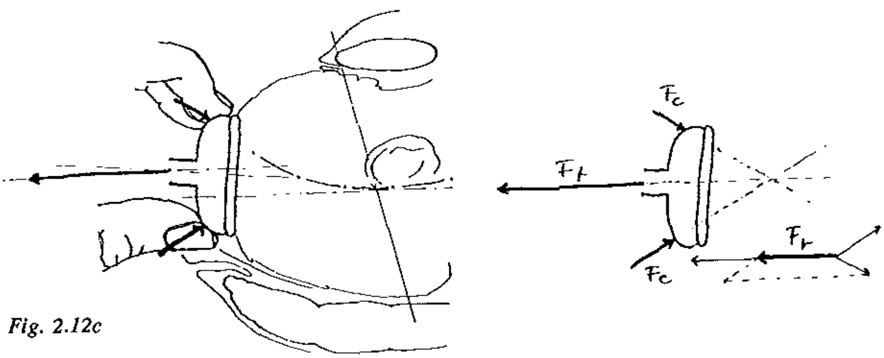



Fig. 2.12c

*Fig. 2.12a-c.* *Vector diagrams of traction (F t) and correction forces (F c). The resultant force (F r) is constructed by vectors. In Fig. 2.12a the vector diagram is drawn for a Malmström (middle) and a "New Generation" cup (right).*

The possibility to manipulate R, the distance of the fulcrum to the center of the cup, was probably overlooked by Halkin and O'Neil because it was regarded and illustrated as the radius of the cup, which is a fixed measure, and because the generally applied "finger-thumb position" of the correcting hand[151,238,20] suggests that there is indeed a fulcrum under the correcting fingers on the rim of the cup.

If R is made equal to zero, equation (3) and the influence of H are eliminated. This may unintentionally happen during an actual vacuum extraction. Paradoxically, every obstetrician experienced in vacuum extraction will recognize the usefullness of the finger-thumb position to correct the tendency of the near side of the cup to detach, especially at crowning of the fetal head. It seems logical to assume that this correction balances a lever working on the lower side of the cup, which may be caused by the resistance of the pelvic floor. The force vector diagram of this configuration (Fig. 2.12b) shows that the operator can balance the force vectors in such a way that they intersect in one point located on the line of the resultant force, which coincides with the tangent to the pelvic axis, thus achieving that the resultant force does not introduce a lever, despite oblique traction. The vector diagram that considers the outlet extraction phase is presented in Fig. 2.12c. The fingers on the upper side of the cup maintain the cup in its uncanted position relative to the chignon, but the downward force component must be compensated by the operator's thumb. Again, the arrangement can be chosen in such a way that there is no lever of the resultant force vector. The diagram becomes more difficult when the cup is placed at midpelvic station (Fig. 2.12a). In this case the pulling force can not be directed ideally, but has to be upward, above the axis of the cup. To obtain the optimal resultant force vector, the upper side of the cup must be corrected by adding a downward force component by the finger-thumb position. It is possible to construct a resultant force vector along the tangent to the pelvic axis and not to introduce a lever, as is shown for a classic Malmström cup in the middle of Fig. 2.12a, however, the required correcting force will be easier to impose with a cup with reduced H (Fig. 2.12a, right drawing).

In theory, an oblique traction force exerted on a vacuum cup that is in frictionless and airtight contact with a flat surface will center the cup in such a way that the direction of the traction force will no longer be oblique but will run in the axis of the cup. Shifting of a cup as a result of oblique traction has also been recognized in practice[166]. In the diagrams presented in Fig. 2.12. the resultant force vector is slightly oblique. While maintaining the cup in an uncanted position relative to the chignon, the chignon will shift with the cup over the fetal head. With dimensions according to Fig. 2.9. and Fig. 2.12. this shift will be small. The exact position of the cup relative to the fetal skull, and the circular symmetry of the cup on the cone shaped caput succedaneum under traction, will determine what the actual angle of the axis of the cup is relative to the tangent with the pelvic axis.

The true difficulty of pulling in the right direction is the necessity to relate the direction of traction to a point higher up in the birth canal than the place where the cup is seen or felt. The right traction force may not only result in a higher chance of a successful extraction, but also the pubic os that may act as an obstruction or a hinge around which the fetal skull can be stressed[75], is than safely bypassed.

Muise et al performed the only in vitro study of the effect of oblique traction on their scalp model[166]. The Bird "New Generation" cup withstood oblique traction as theoretically predicted, but the O'Neil cup detached with less than predicted traction force. The Malmström cup resisted higher oblique forces than predicted. The authors consider their experimental method a valid imitation of clinical conditions and note that the cups drifted at oblique forces, which "required manually steadying the cup while applying traction". It is unfortunate that the authors do not specify their corrections of cup tilt. This study also included the various types of pliable cups. The MityVac$^R$, M-type, and the Tender-Touch$^R$ cup lost little tractive force at a 30° angle, but the Silc$^R$ and the Silastic$^R$ cup suffered a considerable loss[166]. This is probably due to deformation of these cups when subjected to the lateral forces of some sort of finger-thumb position.

Cup detachment or pop-off is usually preceded by an audible hiss, but at relatively high traction forces this phase is often too short to allow correction. A modification of the metal cup that featured a double wall has been reported. Air would first leak into the space between the walls and this suction channel was connected to an alarm system, allowing the obstetrician to reduce traction force before leakage in the main vacuum channel occurred[122]. Cup detachment data from randomized trials are summarized in Table 2.4. In these series, unselected for position of the fetal head, no significant differences between the various metal cups were observed[34,227]. Flexible cups detached significantly more often than rigid cups[54,106].

Table 2.4. *Relative incidence (%) of deliveries with cup detachment in randomized comparisons of rigid and pliable cup types.*

| | Malmstr. | Modified | New Gen | O'Neil | MityVac | Silc | Silastic |
|---|---|---|---|---|---|---|---|
| Dell, 1985[61] | | | | | 35 % (n=37) | | 28 % (n=36) |
| Carmody, 1986[34] | | 6 % (n=63) | 15 % (n=60) | | | | |
| Thiery, 1987[227] | 13 % (n=210) | | | 9 % (n=200) | | | |
| Cohn, 1989[54] | | 8 %* (n=127) | | | | | 20 % * (n=131) |
| Hofmeyr, 1990[106] | | | 6 % * (n=18) | | | 38 % * (n=13) | |

*: $p < 0.05$

### 2.3.3. *Forces exerted on the fetus*

During contractions and bearing down efforts the fetal head encounters forces opposite to the direction of movement. With small pressure transducers placed between the pelvis and the fetal head average local pressure values during maternal bearing down efforts were found to be 0.17 kg/cm$^2$ [165,222], with maximum values of 0.61 kg/cm$^2$[165]. Significantly higher values were found during vacuum extraction, with average local pressures of 0.32 kg/cm$^2$ and maximum values of 0.77 kg/cm$^2$ [165,199].

Rosa assumed that the force of vacuum extraction was only transferred to the fetus by the scalp, compressing the spherical skull by forming a "sliding bag" around it[203,219]. The elastic properties of the skin would further increase this compression. Assuming a traction force of 10 kg and a radius of the fetal skull of 5 cm, traction would lead to an increase in intracranial pressure of 0.075 kg/cm$^2$ [203] (Fig 2.13). The assumptions made in such models are variable[26]. In another approach the intracranial pressure due to traction force can be calculated as:

(11) $P = F / \pi R^2$;

which with a traction force of 10 kg, and a radius of the fetal skull of 5 cm, results in an intracranial pressure rise of 0.127 kg/cm$^2$.

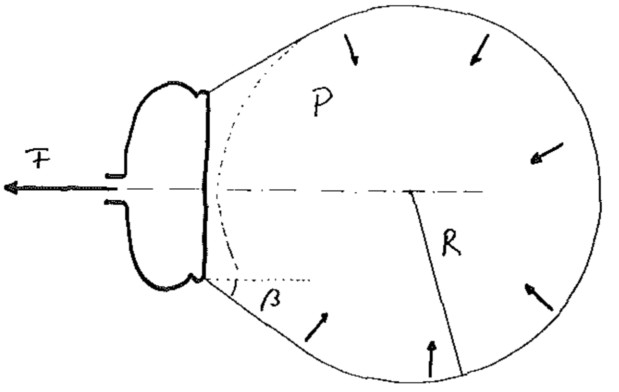



*Fig. 2.13. Symbols applied in the calculation of pressure on the fetal head caused by vacuum extraction.*

The results of these two calculations of the intracranial pressure rise due to traction differ by almost a factor two, but the predicted values are in the order of magnitude of the difference in local compressive force as assessed during spontaneous and vacuum cup assisted delivery[165,222]. The agreement between theory and practice is remarkable because the theory is based on hydrostatic principles and homogenous extracranial pressure[139,199], while in principle the contact of the movable bones of the fetal skull with the wall of the birth canal may be expected to result in variable contact pressures with a potential maximum where bony structures meet.

Compression in the birth canal leads to deformation of the fetal head[8,138], may cause a shift in cerebral mass, and may be expected to change intracranial pressure[110]. An increase in intracranial pressure proportional to extracranial compression has been postulated[222], but this is not supported by results of measurements during vacuum extraction of dead fetuses. Intracranial measurements revealed a decrease in pressure of 0.017 kg/cm$^2$ in the cerebral tissue, and of 0.020 kg/cm$^2$ in the sagittal venous sinus, when the vacuum cup was placed over the anterior fontanelle. Placement of the cup on the posterior fontanelle did not cause detectable intracranial pressure changes[29]. This is possibly due to an unaffected shape of the fetal skull with placement of of the cup over the posterior fontanelle. Because the (hemi)spherical shape combines a given surface with a maximum content, a change in the shape of the skull would lead to a decreasing content and an increased intracranial pressure, as in the case of placing the cup over the anterior fontanelle. In the absence of the possibility of in vivo intracranial measurements, only an elaborate theoretical and experimental model may help us to understand the physical intracranial effects of physiologic and instrumental parturition.

## 2.4. Fetal and neonatal effects associated with vacuum extraction

### 2.4.1. *Pain and Injury*

Placement of an obstetric vacuum cup on the calf of an adult volunteer appeared to be so painful, that the experiment was stopped before traction was begun. There is good evidence that in the human fetus pain pathways and cortical and subcortical centers necessary for pain perception are well developed, and that the neurochemical systems known to be associated with pain transmission and modulation are intact and functional late in gestation[5]. Cardiorespiratory, hormonal and metabolic changes, and behavioral changes such as simple motor responses, facial expression, and crying, are associated with noxious stimuli in the neonate[5]. In a small study, endorphin immunoreactivity in umbilical cord blood of healthy full-term newborns was found significantly higher after vacuum extraction deliveries than following vaginal births[195]. This has been interpreted as a fetal reaction to pain[5,195]. A functional limbic system and diencephalon, necessary for long term memory, are present in the newborn period[193]. The existence of memory of pain experience early in life is suggested by the persistence of behavioral changes after circumcision in non-anesthetized neonates[71]. These data indicate that attention should be paid to fetal pain during instrumental vaginal delivery.

***Scalp trauma.*** Numerous reports deal with lesions of the fetal scalp following application of the Malmström cup. The superficial scalp changes are edematous[188] or erythematous[80,191]; they may consist of bruising[113], or of disc-shaped[168,179] echymotic areas[148,156] or suction purpura[159]. Contour defects[11] such as a circular red mark[191], abrasions[148,188], blistering[168], hemorrhagic vesicles[176], tiny ulcers[148], or even ischemic necrosis[191] may accompany the discoloration along the periphery of the application site of the cup[168,176,188]. Scalp lesions are more pronounced after traction exceeding 20 minutes[168,176], after application of maximum vacuum[148,151], after difficult extraction manoeuvres[43], or after repetitive cup detachments[19]. In over 3500 deliveries with the metal vacuum extractor cup Plauché noted 12.6 % scalp abrasions or lacerations[189]. What Plauché called the "cookie-cutter" effect[189] of this cup is reported to have resulted in avulsions of large scalp flaps[3].

Pictures of circular formations of scalp crusts following vacuum extraction were published by Malmström[152,151]. In these pictures the affected scalp area had been shaved to show the lesions more clearly, but the photographs were reproduced incorrectly as illustrations of neonatal alopecia as a complication of vacuum extraction[99]. Neonatal alopecia is rarely observed following vacuum extraction[123,188,189], but reduced growth of hair in small circumscribed areas has more often been noted[13], in particular in relation to scar formation after laceration[205,43]. Other rare sequelae of vacuum extraction include subcutaneous emphysema after application of the cup next to the site of a spiral electrode[23], and fetal hemorrhage into the vacuum system after fetal blood sampling[200]; the latter complication is considered preventable[231].

The typical swelling of the chignon is described to subside within minutes to hours to dimensions indistinguishable from normal caput succedaneum[43]; atypical swelling, either persistent in time or extensive in appearance, is usually caused by hemorrhage. Tangential forces, causing displacement of scalp over the skull, are held responsible for rupture of diploic veins[78,189]. The diploic veins occupy channels between the inner and outer table of cranial bones and are connected with emissary veins that traverse the periost and loose subaponeurotic tissue, and run through the galea aponeurotica to the subcutaneous tissue. In the fetus and neonate, prior to fusion of suture lines, each diploic vein system is confined to the limits of the underlying cranial bone, without anastomoses across the sutures. Cephalohematomas are subperiostal and thus confined to the limits of the underlying skull bone. Cephalohematoma incidences are similar for rigid and pliable cup delivery in the observational and nonrandomized studies with a mean incidence of 10 % (Table 2.5.), which is higher than the 4.5 % and 6 % found in older reviews[148,189]. The risk of cephalohematoma following vacuum extraction is clearly increased in comparison with the incidence after spontaneous[50,7] or forceps delivery as demonstrated in randomized studies[61,79,239]. Obviously, tangential forces exerted on the scalp may be more pronounced during vacuum extraction than during spontaneous delivery[78]. Cephalohematomas may appear immediately or several hours after delivery. The lesion usually resolves slowly over a period of weeks and it may calcify[189]. The parietal bone is most often involved, the right parietal bone more frequently than the left one[189]. In a study of 2670 vacuum extractions with 116 cephalohematomas (incidence 4.3 %), Fahmy noted a significant increase in the occurrence of cephalohematoma when the extraction was difficult e.g. if the extractor was applied to a high head, if the cup had slipped, if the baby weighed over 3.6 kg, and if traction had been applied longer than 10 minutes[78]. Cefalohematomas should be distinguished from subcutaneous ecchymoses or extensive scalp effusion[41,54,189], which is possible by ultrasound examination[17]. Bleeding into the subaponeurotic space may lead to extensive hematoma, elevating a portion or all of the scalp[189,201]. The origin of the bleeding is usually rupture of an emissary vein beneath the galea aponeurotica[189,190]. In some cases autopsy has revealed hemorrhage caused by rupture of the sagittal venous sinus after dislocation of the interparietal synchondrosis[33,93,131].

Table 2.5. *Incidence of cephalohematoma in vacuum extractions with rigid or pliable cups.*

| rigid cups | | | pliable cups | | |
|---|---|---|---|---|---|
| Leijon, 1980[132] | 8.7 % | (2/23) | Maryniak, 1984[156] | 6.0 % | (26/431) |
| Greis, 1981[90] | 21.1 % | (19/90) | Berkus, 1985[17],86[16] | 14.7 % | (19/129) |
| Baerthlein, 1986[10] | 21.7 % | (35/161) | Meyer, 1987[161] | 14.7 % | (43/293) |
| Broekhuizen, 1987[31] | 3.9 % | (10/256) | Dell, 1985[61] | 15.1 % | (11/73) |
| Svenningsen, 1987[220] | 14.0 % | (7/50) | | | |
| Svenningsen, 1987[223] | 11.7 % | (14/120) | | | |
| Herabutya,1988[104] | 26.8 % | (38/142) | | | |
| Thiery, 1987[227] | 2.5 % | (10/400) | | | |
| Carmody, 1986[35] | 3.3 % | (4/123) | | | |
| total | 10.2 % | (139/1365) | total | 10.7 % | (99/926) |

In a review in 1980 no fewer than 123 cases of subaponeurotic hematoma were collected from the literature, of which 49 % occurred after vacuum extraction, 14 % after forceps and 28 % after spontaneous delivery[190]. The mortality of 23 % in this review stresses the importance of early recognition, the monitoring of coagulopathies, and treatment with blood transfusion[4,12,39,120,201,247]. For unknown reasons the condition has been recorded more frequently in African and West Indian newborns, and in males[190]. Besides difficult instrumental delivery and hemorrhagic disease of the newborn, also prematurity, macrosomia, extensive moulding, positional dystocia and precipitous labor predispose to subgaleal hematoma[190].

Infection of cephalohematomas[96] and scalp lesions[102] has been reported, but this complication appears to be rare[77].

The application of soft cups has been observed to reduce superficial scalp injury[52,95], but no effect has been noted on the incidence of cephalohematoma[54] in randomized comparison of rigid and pliable cups. These series are too small to detect differences in the occurrence of subaponeurotic hematomas, which have also been observed after pliable cup vacuum extraction[85,156].

***Intracranial trauma.*** Vacuum extraction is associated with increased compression of the fetal skull as compared to spontaneous delivery, (see Chapter 2.3.3), which may result in intracranial damage and hemorrhage[119].

Three mechanisms have been postulated[119]: First, when intracranial pressure exceeds intravascular pressure, arrest of the cerebral circulation will result. The ensuing anoxia may not only damage the brain cells, but also the blood vessel walls, making them sensitive to rupture. Second, the dura, falx cerebri, and tentorium cerebelli represent a framework that fixes the brain. Stretching of these structures occurs whenever the mobile and separated skull bones are distorted. The resultant pull and stretch on the tentorium and falx may cause them to tear. Bleeding into the subdural space may occur if the laceration extends into the venous sinuses[93,97]. Third, compression forces may cause fracture of skull bones[224] with laceration or direct injury to the underlying brain tissue[98,105].

Changes in fetal intracranial pressure, in particular when associated with vacuum extraction[81,97,127], are supposed to be a cause of subdural and intracerebellar hemorrhages[247]. The other types of intracranial hemorrhages - subarachnoïd, intracerebral and intraventricular bleeding - appear to be mainly due to asphyxia, prematurity, and hemostatic disorders[120,247]. Also retinal hemorrhages may be a consequence of abrupt changes in fetal intracranial pressure associated with delivery, and will be discussed in the next paragraph (Chapter 2.4.2.)

In over 14.000 vacuum extraction deliveries Plauché found an incidence of 0.35

% anatomically proven cases of intracranial bleeding[189]. It has been suggested that this figure may present an underestimate because modern imaging techniques[7,38] and cytology of cerebrospinal fluid have revealed higher incidences of intracranial hemorrhage in unselected and clinically healthy full term newborns[25,147,235]. In fatal cases of tentorial tears and hemorrhage the vacuum extractor plays a prominent part, but it may often not present the single cause[148,190].

### 2.4.2. *Neurologic complications*

In the early years of vacuum extraction research, neurologic evaluation of the newborn focussed on gross pathologic disturbances, such as convulsions and palsy, and on less specific conditions, such as photophobia and persistent high-pitched crying[148,189]. Fetal electroencephalography showed abnormalities during[218] and after vacuum extraction[9,25,68,105], but the results are subject to variable interpretations[25,189]. Plauché estimated neonatal "signs of cerebral irritation" to occur in 3.3 % of vacuum extractions, an incidence considered similar to that after forceps deliveries[189]. This incidence is supported by results of studies comparing vacuum extarction and forceps delivery published after Plauché's review. These studies are summarized in Table 2.6; the reports did not allow to differentiate between the type of forceps used

More reliable and detailed information can be gained from systematic assessment of neonatal behavior and neonatal reflexes[17,72,133,132,209,210,220], and by the study of neurologic responses to standard stimuli[28,63,192], performed in a standard environment on a standard moment in the newborn's rhythm[192]. Various prospective, although not randomized, studies showed no significant differences in neonatal neurobehavior between newborns delivered by vacuum extraction using a metal cup, and babies born by spontaneous vaginal delivery[25,192,220]. When Silastic cup deliveries were compared with spontaneous or forceps delivery or cesarean section, the results of the studies of neonatal neurologic behavior also showed no differences[17,16]. However, in one study newborns delivered by vacuum extraction from occiput posterior position, or born after attempts of vacuum extraction lasting over 15 minutes, presented significantly more abnormal neurobehavior than spontaneously delivered controls and than the remaining group of vacuum delivered infants[132].

Table 2.6. *Incidence of abnormal neurologic signs in reports of vacuum extractions with various cup types and compared with forceps deliveries.*

| reference | cup | neurologic sign | vacuum | | forceps | |
|---|---|---|---|---|---|---|
| Punnonen, 1986[194] | Malmstr | "irritation" | 2.2% | (5/223) | 2.7% | (6/223) |
| Svenningsen, 1987[223] | Modified | "irritation" | 10.0% | (12/120 | | |
| Broekhuizen, 1987[31] | Modified | convulsions | 0.4% | (1/256) | 0.7% | (2/300) |
| Maryniak, 1984[156] | Silastic | convulsions | 0.2% | (1/431) | | |
| Meyer, 1987[161] | Silastic | convulsions | 1.0% | (3/293) | 0.4% | (2/468) |
| Vacca, 1983[239] | Modified | convulsions | 0.6% | (1/152) | 0.0% | (0/152) |
| | | total | 1.6% | 23/1475 | 0.9% | 10/1143 |

Only one small randomized and prospective standardized neurologic study could be found in the literature comparing delivery by vacuum extraction and spontaneous delivery. After metal cup vacuum extraction on maternal indication assessment of neonatal behavior with the Brazelton scale[28] showed significantly lower scores for orientation items on day 1 and day 5, compared with spontaneously delivered controls[132]. Simultaneous neurologic examination according to the method of Prechtl & Beintema[192] showed a significantly lower number of optimal items in the vacuum extraction group on day 1, but not on day 5, compared to the spontaneously delivered group.

The variability in the selection of cases and the methods of neurologic assessment of the newborn, as well as the paucity of randomized prospective studies preclude reliable conclusions about the effect of vacuum extraction on the general neurologic status of the neonate.

Long term follow-up studies of small groups of spontaneously born infants and those delivered by vacuum extraction showed similar psychomotor development at one[25,257] and four years[24] of age, and similar neurologic test results and school performance at the age of 10[172]. Temperament characteristics at 6, 12, and 24 months of age showed no consistent relationship to delivery by vacuum extraction[186].

Comparison between vacuum- and forceps-delivered individuals revealed no differences in pediatric screening tests at the age of 9 months[172]. Epidemiologic studies, based on military draft board exams, revealed no physical or cognitive differences between vacuum-delivered, forceps-delivered and spontaneously delivered 17 year olds in over 50.000 Israelis[213]. A similar Norwegian study of a hundred boys at the age of 18 years showed a significantly elevated intelligence score after forceps delivery, a finding for which no explanation other than chance occurrence is available. After vacuum extraction the intelligence score was equal to that of the national average of conscripts[174].

It is clear that conclusive results from follow-up assessments will be difficult to obtain as the summation of antenatal, perinatal and environmental factors may overshadow the late effects of any obstetric instrumental intervention[24].

*The retina.* Considering the fetal and neonatal neurologic complications of vacuum extraction, the effects on the fetal retina deserve special attention. A review by Sanchez Ibanez et al. covering over 24.000 newborns gives a mean incidence of retinal hemorrhages of 22.3 % with a range of 2.6 % - 46 %[208,245]. The variation in incidence is considered to be due to variable periods of time elapsed between birth and examination[170,208]. Subsequent investigations have indeed revealed decreasing frequencies of retinal hemorrhages with increasing time intervals between birth and examination of the neonate[187,245], but no significant differences were found within the first 30 hours of life[69]. The usual explanation of the relatively high incidence of neonatal retinal hemorrhage is compression of the fetal cranium during the second stage of labor[67,170,177,135,208], and the sudden release of intracranial pressure[211]. The central retinal blood vessels are directly connected with the cerebral vascular system[187]. The observation that the central vessels rather than the capillaries are involved in the hemorrhages[187] indicates that the retina may reflect cerebral microhemorrhages[170]. Indeed, some investigators have suggested a relationship between retinal hemorrhages and minor cerebral dysfunction[59,154], but the neurologic significance of the retinal hemorrhages is still an open question[67,69,118,235,236]. Follow-up studies of newborns with retinal hemorrhages demonstrated no pathological findings in the neurologic assessment at 6 and 18 months[135] and at 4-5 years of age[124]. Data of retinal hemorrhages in relation to different modes of delivery are listed in Table 2.7. Two studies are not included in the table because the numbers of assessed newborns were not specified[124,250]. The incidences of retinal hemorrhages recorded in the various studies are disparate, but the overall incidence in the group of neonates delivered by vacuum extraction (40 %)

appears to be approximately twice that in the group of spontaneous and forceps deliveries (20 %). The incidence of retinal hemorrhages after forceps deliveries is thought to be similar to that after spontaneous deliveries because of the "helmet function" of the forceps that protects the fetal head from surplus strain[67]. The incidence in neonates born by cesarean section is only 4 %, but the numbers are small. When differentiated by type of cup, the newborns delivered by pliable cup vacuum extraction tend to show less retinal hemorrhages (under 30 %) than those delivered with a rigid cup (over 50 %)[17,52,249]. However, randomized comparisons of soft and rigid cups have not included standardized ophthalmic evaluation of the newborns and at present no reliable data are available with regard to the incidence of neonatal retinal hemorrhage after soft and rigid cup vacuum extraction.

Increased degrees of retinal hemorrhage are associated with fetal distress, umbilical artery pH below 7.20, and small-for-date newborns[250], but not with a generalized hemorrhagic tendency[187]. One report indicates that epidural analgesia may result in a significantly reduced occurrence of neonatal retinal hemorrhages in spontaneously delivered neonates[155], but such an effect was not observed in association with vacuum extractions[240].

There is some evidence that the occurrence of retinal hemorrhage is increased when the second stage of labor is less than 30 minutes[250], and with primiparity[244]. Besides vacuum extraction itself[250], increased duration of the vacuum extraction attempt[211], increased number of pulls[208], increased traction force[220] and failed vacuum extraction[16,250] were shown to be associated with an elevated incidence of retinal hemorrhages. Mechanical factors contribute to retinal lesions[187,250] but changes in compressive force may have more impact than compressive force on the fetal head per se[250]. In contrast to retinal hemorrhage. the incidence of bleeding of the conjunctival vessels of the neonate is about 2% after spontaneous[17] as well as after instrumental vaginal deliveries[11,17,31]. This finding supports the suggestion that retinal hemorrhage is a result of a rise in intradural pressure[244] with subsequent squeeze of blood into the orbita, where the intradural pressure changes are not balanced.

The prognosis of retinal hemorrhage with regard to later vision is good. Although macular lesions have been interpreted as the more serious ones[69], follow-up has given no reasons to assume an increased risk of amblyopia or squint in patients with retinal hemorrhages at birth[67,124,187].

Table 2.7. *Incidence of neonatal retinal hemorrhages by mode of delivery; age at examination 0-24 hrs, unless specified otherwise.*

| reference | mode of delivery | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | spontaneous | | vacuum | | forceps | | cesarean section | |
| Sanchez, 1963[208] | 33.6 % | 109/324 | 59.3 % | 32/54 | 30.7 % | 4/13 | 4.0 % | 1/25 |
| Schenker,1966[211] | 17.3% | 42/244 | 52% | 13/25 | 31.2% | 5/16 | 0% | 0/20 |
| Neuweiler,1967[170] | 72.4% | | 34.8% | | 3.0% | | 42.8% | |
| Weiden,1970[245] | 23.5% | 103/438 | 50.0% | 55/110 | 66.7% | 6/9 | 0% | 0/19 |
| Planten,1971[187] | 22.1% | 34/154 | 40.0% | 8/20 | 21.7% | 5/23 | 16.7% | 2/12 |
| Ehlers,1974[69] and Egge,1981[66] | 27.5% | 57/207 | 63.8% | 60/94 | 38.4% | 38/99 | | |
| Egge,1980[67]** | 41.0% | 41/100 | 49.0% | 25/51 | 16.3% | 8/49 | | |
| O'Leary,1986[177] | 10.5% | 2/19 | 31.6% | 6/19 | | | | |
| Berkus,1985[17],1986[16] | 24.4% | 20/82 | 28.6% | 22/77 | 18.8% | 15/80 | 4.8% | 2/42 |
| Fall,1986[79] | 9.1% | 1/11 | 22.2% | 4/18 | 18.8% | 3/16 | | |
| Williams,1991[249]* | | | 37.8% | 14/37 | 16.7% | 6/36 | | |
| Johanson,1989[113] | | | 6.6% | 1/15 | 6.6% | 1/15 | | |
| total | 25.6% | 409/1579 | 46.2% | 240/520 | 25.6% | 91/356 | 4.2% | 5/118 |

* : age of examination 0-48 hrs; ** : 0-72 hrs

### 2.4.3. *Fetal and neonatal morbidity and mortality*

***Jaundice***. The literature concerning vacuum extraction contains many reports of retrospective studies suggesting an association between vacuum delivery and neonatal jaundice[6,18,32,86,157,197]. Bruising[86], extravasation of blood in the chignon[31,32] or resorption from suction ecchymosis[18] are held responsible for an increased incidence of neonatal jaundice after vacuum extraction[6,161]. There is some evidence of an elevated rate of red blood cell destruction in vacuum-delivered neonates with only superficial scalp lesions and no significant bruising[32,137]. It seems likely that cephalohematomas may contribute to neonatal jaundice[157,225]. In two studies on newborns born by vacuum extraction mean bilirubin levels were indeed higher in infants with cephalohematoma than in neonates without cephalohematoma, but the difference did not reach statistical significance[10,137] and the trend was not confirmed in two other studies[31,105]. The variability of the effect of cephalohematoma on the degree of neonatal jaundice may be explained by considering it a sequester from which the hemoglobin metabolites are slowly absorbed[6]. Recent nonrandomized as well as prospective randomized studies comparing vacuum and forceps deliveries do not show significant differences between the incidence of jaundiced neonates and/or phototherapy (Table 2.8.).

Table 2.8. *Incidence of phototherapy in nonrandomized and randomized comparative studies of vacuum and forceps delivery.*

| non-randomized studies | vacuum | | forceps | |
|---|---|---|---|---|
| Meyer, 1987[161] | 15.1 % | (44/293) | 9.6 % | (45/468) |
| Carter, 1987[36] | 14.2 % | (43/302) | 11.2 % | (23/205) |
| Hastie, 1986[100] | 8.0 % | (8/100) | 4.0 % | (2/50) |
| total | 13.7 % | (95/695) | 9.7 % | (70/723) |
| **randomized studies** | **vacuum** | | **forceps** | |
| Carmody, 1986[35] | 7.2 % | (11/152) | 5.3 % | (8/152) |
| Dell, 1985[61] | 2.7 % | (2/73) | 0 % | (0/45) |
| Johanson, 1993[114] | 3.0 % | (4/132) | 3.8 % | (5/132) |
| Williams, 1991[249] | 0 % | (0/40) | 0 % | (0/40) |
| Johanson, 1993[114] | 1.0 % | (3/296) | 2.3 % | (7/311) |
| total | 2.9% | (20/693) | 2.9% | 20/680 |

Also no differences were observed in rigid cup vs rigid cup[34,227], flexible cup vs flexible cup[61] and rigid cup vs flexible cup comparisons[52,54]. In three of the randomized studies serum bilirubin values showed no significant differences[113,114,249], although only selected subgroups were assessed and the results may suffer from observer bias[113]. It may be concluded that the available studies do not indicate that uncomplicated vacuum extraction contributes significantly to the development of neonatal hyperbilirubinemia.

*Acidosis.* An increased incidence of neonatal acidosis has been demonstrated after instrumental delivery in general, but this observation may be explained by the fetal distress that formed the indication for instrumental delivery, rather than by the use of the instrument itself[89,141,173,243,256]. Indeed, no adverse effects of elective vacuum extraction were shown with regard to fetal-neonatal acid-base status in nonrandomized comparisons with spontaneous deliveries[62,117]. In most randomized studies comparing vacuum extraction and forceps deliveries cord blood collection was inconsistent or absent, except in one small study that showed significantly lower cord blood pH after vacuum extraction[79]. Significant differences in Apgar scores[61,79,113,239] or clinical asphyxia[129] were not observed.

***Mortality.*** On the basis of over 7000 cases of vacuum extraction collected from 31 reports in 1964 Malmström calculated a corrected perinatal mortality rate of 2.2 %[148]. For the period from 1964 to 1979 a corrected perinatal mortality of 1.35 % can be calculated from Plauché's review, covering over 6000 cases from 19 reports after deletion of the studies already covered by Malmström[189]. Perinatal mortality data from reports after 1979 are listed in Table 2.9. Not all authors have defined perinatal mortality. Excluding those reports, uncorrected perinatal mortality is 0.5 % in recent series of vacuum extraction deliveries. This figure is below the overall perinatal mortality rate in the western world, and may be explained by the selection criteria, e.g. live fetus at start of extraction, that had to be met before entry into the various trials. The table shows that a direct relationship of neonatal death and the use of the vacuum extractor is apparent in only a small number of cases.

Tabel 2.9. *Perinatal mortality in vacuum extraction series published after 1979.*

| reference | | | identified cause of death |
|---|---|---|---|
| Carmody, 1986[35] | 0.8% | (1/123) | antiepileptic agent in mother, cerebral bleeding in neonate |
| Thiery, 1987[227] | 0.0% | (0/410) | |
| Cohn, 1989[54] | 0.4% | (1/258) | intrapartum death |
| Dell, 1985[61] | 0.0% | (0/73) | |
| Vacca, 1983[239] | 0.6% | (1/152) | intrapartum placental abruption |
| Leijon, 1980[132] | 0.0% | (0/23) | |
| Punnonen, 1986[194] | 1.3% | (3/223) | septicemia (2); congenital cerebral atrophy |
| Hastie, 1986[100] | 2.0% | (2/100) | tentorial hemorrhages, one in a premature newborn, one at term after a vacuum-forceps-cesarean section procedure |
| Maryniak, 1984[156] | 0.0% | (0/431) | |
| Greis, 1981[90] | 0.0% | (0/90) | |
| Svenningsen, 1987[220] | 0.0% | (0/50) | |
| Meyer, 1987[161] | 0.0% | (0/293) | |
| Broekhuizen, 1987[31] | 0.4% | (1/256) | intracranial hemorrhage and asphyxia |
| Herabutya, 1988[104] | 0.0% | (0/142) | |
| Blennow, 1977[25] | 4.5% | (2/44) | subgaleal and cerebellar hemorrhage in a premature newborn; intrapartum cessation of heart tones at term |
| Berkus, 1986[16] | 1.6% | (2/129) | polycystic kidneys; multiple bleeding after severe shoulder dystocia, family history of hemophilia |
| total | 0.5% | (13/2797) | |

## 2.5. Maternal complications associated with vacuum extraction

Most authors state that the risk of injury to maternal tissues due to vacuum extraction is comparable to that associated with spontaneous vaginal delivery[27,43,158,242], and is smaller than that associated with forceps delivery[20,65,164,176,194,246]. Vaginal trauma as indicated by the number of episiotomies[13,45], perineal third or fourth degree lacerations and extensions of episiotomies[13,17,31,56,217,239], and vaginal lacerations extending into the fornices is reported significantly less often after vacuum extraction than following forceps delivery[91,113,128,161,239].

Several authors have noted excess maternal soft tissue injury after dual use of vacuum extractor and forceps[31,61,100]. Entrapment of vaginal or cervical tissue into the cup is a possible cause of laceration[116], in particular during the first stage of labor[11,20,164]. On the other hand, cervical laceration may also accompany forceps delivery, and the results of comparative studies are inconclusive as to which instrument is the safest for the cervix[44,128,129,161].

Some publications suggest that vacuum extraction compared to using forceps, may result in less estimated maternal blood loss[17,36,90,113], and in a smaller fall in hemoglobin concentration[90] but no significant differences in maternal postpartum hemoglobin concentrations could be demonstrated[113]. No differences have been noted between the use of forceps and vacuum extractor with regard to urinary infections[10,45], bladder complications[10,45], pelvic infection or febrile puerperal episodes[17,90,113].

Prophylactic administration of antibiotics in cases of instrumental vaginal delivery has not proven to be useful[111,198]. Symphysiolysis and symphysiodynia are complications too seldomly noted to allow statistical analysis. Maternal mortality primarily due to the vacuum extractor has not been reported.

Pain and anxiety experienced by the mother in association with instrumental deliveries have been the subject of a few publications. In two nonrandomized studies women allocated to vacuum extraction reported somewhat less pain than those after forceps delivery, but no statistical significance was reached[87,196]. Administration of any form of analgesia was less often considered necessary in cases of vacuum delivery than with the use of forceps[11,36,42,94,100,129,202,239].

One study showed that one sixth of patients did not understand why a particular instrument was used for assisted delivery[196]. One study showed higher numbers of mothers worrying about their babies after vacuum delivery compared to a forceps group[87], but this was not confirmed in another study[196]. Infants delivered by vacuum extraction or by cesarean section were found to start suckling later, and their mother's milk came in later than after spontaneous vaginal delivery, but this did not affect the prevalence of breast feeding after discharge[241].

## 2.6. Vacuum extraction in clinical practice

The clinical applications and indications for vacuum extraction have frequently been reviewed[20,48,51,65,73,91,94,116,158,180,206]. Between 1964 and 1993 nine randomized controlled trials were published that assessed the clinical success and failure of the vacuum extractor in comparison to forceps[61,69,79,113,114,129,143,239,249]. Although one report[143] does not allow to verify randomization, e.g. with regard to fetal distress, it was included in a recent meta-analysis of the nine trials that shows that the vacuum extractor compared to forceps is[114]:

- significantly more likely to fail at achieving a vaginal delivery;
- significantly less likely to be associated with delivery by cesarean section;
- significantly less likely to be associated with maternal regional/general analgesia;
- significantly less likely to be associated with maternal perineal and vaginal trauma;
- significantly more likely to be associated with neonatal cephalohematoma;
- significantly more likely to be associated with retinal hemorrhages;
- more likely to be associated with low 5 min Apgar scores;
- not more likely to be associated with need for phototherapy.

These results support the statement of Chalmers and Chalmers in 1989 that "The obstetric vacuum extractor is the instrument of first choice for operative vaginal delivery"[42,112].

The majority of authors indicate that the vacuum extractor or forceps should not be used in case of minimal or absent engagement of the fetal head[20,48,65,73,91,94,116,158,180,235]. Bird has recommended not to persist in a vaginal route of delivery if two strong pulls with the vacuum extractor have not brought the head down to the pelvic floor[20]. Sudden release of the extractor cup should be avoided, and if signs of vacuum leakage are felt or heard, traction force should be reduced[94]. An absolute time limit for vacuum extraction was long considered to be 30 minutes[94,148], but this has more recently been adjusted to 15 min[2,238].

Vacuum extraction may fail, even when properly indicated. Failure may be due to incorrect traction technique, suboptimal application site and faulty equipment. Instrumental deficiencies, as torn traction chains, leaking tubes and missing inlays, have been reported in 3-4 % of all vacuum extraction cases[188]. Reported overall failure rates vary from 0.7 %[148] to 80 %[91]. Vacca calculated failure rates of 4.5 % (213/4741) for rigid cups and 14 % (150/1074) for pliable cups from noncomparative and comparative series[238]. Seven randomized comparisons of the various cup types are summarized in Table 2.10.

The various metal cups perform without significant differences in failure rates[34,227]. Analysis of the four randomized comparative studies of pliable and metal cups shows that the overall failure rate of the pliable cup (16.2%) is significantly ($p < 0.02$) higher than that of the metal cup (9.2 %)[52,54,94,106](Table 2.7.). The cause of the relatively high failure rate of the pliable cup is attributed to the fact that pliable cups detach significantly more often than do rigid cups (Table 2.4.). The effect of detachment on method failure is somewhat reduced because one or two cup replacements are generally accepted and often followed by success[16,54,61]. The pliable cups, such as the Silastic[R] cup, may easily detach just before the fetal head is delivered, when a partly uncovered rim of the cup presents; the vacuum seal becomes weaker and the cup is prone to detachment[61,16]. This may explain some of Hammarström's results, in which the Silastic[R] group contained significantly more procedures initiated from the pelvic floor, demonstrating significantly more failures compared to the metal cup[94]. Performing an episiotomy prior to application of the larger flexible cups in order to make insertion easier[54] may have a negative influence on method succes for the same reason. Also entrapment of scalp electrode wire and an abundant hairy scalp impair adherence of a flexible cup[61,64]. In a cohort study of Silastic[R] cup deliveries with a failure rate of 35 %, neonatal morbidity did not differ between successful and unsuccessful pliable cup vacuum extractions, except for an increased incidence of retinal hemorrhage in the failure group[16].

Some authors consider the vacuum extractor an appropriate instrument for a trial of vaginal delivery[41,179]. The calculated risk of failure in a carefully conducted trial of instrumental delivery should be distinguished from the unexpected failures due to poor judgement[115,146] unfortunately often also described as 'trial'. Low succes rates, multiple instrumentation and seriously increased perinatal mortality and morbidity accompany such trial procedures with the metal ventouse[76,116,125,184], in particular in cases of fetal distress[125,148].

Table 2.10. *Percentages and group sizes of failed instrumental deliveries in randomized vacuum cup comparisons.*

| | Malmstr. | Modified | New Gen | O'Neil | MityVac | Silc | Silastic |
|---|---|---|---|---|---|---|---|
| Dell, 1985[61] | | | | | 11 % (n=37) | | 28 % (n=36) |
| Hammarström, 1986[95] | | 2 % * (n=50) | | | | | 18% * (n=50) |
| Carmody, 1986[35] | | 6 % (n=63) | 7 % (n=60) | | | | |
| Thiery, 1987[227] | 0.5 % (n=210) | | | 3 % (n=200) | | | |
| Cohn, 1989[54] | | 10 % (n=127) | | | | 16% (n=131) | |
| Chenoy, 1992[52] | 13 % (n=98) | | | | | 15% (n=101) | |
| Hofmeyr, 1990[106] | | | 0 % * (n=18) | | | 23 % * (n=13) | |

$* : p < 0.05$

## 2.7. Conclusions

The first vacuum cup to survive in obstetric practice was Malmström's metal cup with an inward bent rim, designed in the early 1950s. A number of modifications have been developed, but all of them feature the dome of the original Vacuum Extractor, which indicates the quality of Malmström's design. The mechanical properties of vacuum extractor cups under static conditions are well known, but cup behavior in a dynamic equilibrium under clinical conditions of vacuum extraction delivery has hardly been investigated. The maternal expulsive force, comparable to a weight of 15 kg, can easily be doubled by vacuum extraction. The specific aspect of vacuum extraction relative to forceps is that the traction force is transferred to the base of the skull; the practical problem is that the direction of traction has to be translated from the vacuum cup on top of the fetal skull to a virtual point inside the fetal head. The obstetrician should be aware of the specific configuration of force vectors, and of the possibillity of corrections with the finger-thumb position because all rigid cups can be corrected for the leverage due to oblique traction or caused by the resistance of the birth canal.

The most common neonatal complication associated with vacuum extraction consists of scalp lesions. The vast majority of scalp changes following vacuum extraction disappear within hours or days and are only of cosmetic concern. The incidence of cephalohematoma is probably increased after vacuum extraction. An association of vacuum extraction with neonatal jaundice is often suggested but has yet to be demonstrated. The subaponeurotic hematoma of the neonate is a rare complication associated with vacuum extraction that should be recognized because immediate treatment may be life-saving. Intracranial hemorrhage and tentorial tears are rare complications of vacuum extraction at term.

If gross neurologic pathology is absent, adverse short-term or long-term neurologic effects of vacuum extraction are unlikely to occur. The incidence of neonatal retinal hemorrhage after vacuum extraction is increased as compared with that after abdominal, spontaneous or forceps delivery, but the prognosis with regard to later vision appears to be good.

The growing popularity of the vacuum extraction method has induced the development of pliable cups in an attempt to reduce the risk of fetal scalp injury. No mechanical reasons are apparent to advocate the use of flexible vacuum cups; oblique traction is not well possible, the seal of the vacuum is suboptimal, and at increasing chignon formation the effective surface area decreases, which are all factors that make the pliable cups vulnerable to detachment. Vacuum extraction with a pliable cup seems to be associated with a reduced incidence of neonatal retinal hemorrhage in comparison with delivery by means of a rigid cup, but no data based on standardized ophthalmic evaluation of the newborn are currently available. At present, no neonatal endpoint substantiates a preference for a specific rigid or pliable cup.

Analysis of the available literature comparing vacuum and forceps delivery leads to the conclusion that vacuum extraction is the first choice for operative vaginal delivery if maternal trauma is to be avoided. No data is available on the preference of the women themselves for a certain instrument when they need assisted vaginal delivery.

Chapter 3

# THE PLIABLE OBSTETRIC VACUUM CUP: APPLICATION AND OPINIONS IN THE NETHERLANDS*

## 3.1. Introduction

Vacuum extraction is an accepted method of instrumental vaginal delivery. The purported risk of injury to the fetal scalp associated with the use of rigid metal vacuum cups led to the development of pliable soft suction cups[254]. Both rigid metal and pliable plastic and silicone soft cup designs for vacuum extraction are widely available. Though the relative use of forceps and vacuum extractor is well documented[144], a search of the literature revealed no data on the frequency of the use of soft cups compared to that of rigid cups.

During a number of years both rigid and pliable soft cups for mid and low pelvic vacuum extraction were used simultaneously in the delivery rooms of the "Stichting Deventer Ziekenhuizen" in Deventer, The Netherlands, but doubt about differences in neonatal complications remained. For that reason a randomized clinical trial comparing a rigid and a pliable cup was designed, which will be described in Chapter 4. Before embarking upon the trial we wished to assess the acceptance of the pliable soft cup in The Netherlands, and be informed of clinical experiences with it. For that reason a written inquiry was conducted among hospital obstetric units in The Netherlands.

## 3.2. Maternal and methods

All instrumental deliveries in the Netherlands take place in a hospital obstetric unit. In 1988 a questionnaire was sent to all 156 units in the country. The questions concerned:

* *The main substance of this chapter was published in: Kuit JA, Wallenburg HCS, Huikeshoven FJM: The pliable obstetrical vacuum cup: application and opinions in The Netherlands. Eur J Obstet Gynecol Reprod Biol 1992;44:107-110.*

- the type of obstetric unit: university hospital, university affiliated hospital with a postgraduate specialist training program, or non-university affiliated hospital;
- the number of deliveries in 1987 under supervision of an obstetrician;
- the number of instrumental vaginal deliveries in 1987 specified for forceps deliveries and vacuum extractions;
- the types of rigid and/or pliable cups used, and the numbers of vacuum extractions performed with them;
- restrictions applied to the use of the distinct cups.

The number of questions was kept small in order to obtain a maximum response. Items as failure rate or neonatal trauma were not specified. The addition of free comments was suggested.

## 3.3. Results

Replies were received from 141 obstetric units (response rate 90.4 %), in which over 89000 deliveries per year were performed under supervision of an obstetrician. The results of the inquiry are summarized in Table 3.1. Instrumental vaginal delivery was performed in 16.0 % of cases, 10.5 % by vacuum cup and 5.4 % by forceps. The relative use of vacuum extraction was lowest in the university hospitals, and highest in the hospitals without specialist training authority, in which the greater part of the deliveries under specialist supervision occurred. In two hospitals the vacuum extractor was not used at all and in three hospitals all assisted vaginal deliveries were performed by vacuum extraction.

Table 3.1. *Instrumental vaginal deliveries in three categories of hospitals in the Netherlands.*

| | university | non-university | | all |
|---|---|---|---|---|
| | | training | non-training | |
| | n=8 | n=30 | n=118 | n=156 |
| response (n) | 8 | 28 | 105 | 141 |
| deliveries in 1987 (n) | 10100 | 24650 | 54550 | 89300 |
| instrumental vaginal (%) | 12.2 | 16.0 | 16.6 | 16.0 |
| by vacuum extraction (%) | 7.2 | 10.6 | 11.1 | 10.5 |
| by forceps (%) | 5.0 | 5.4 | 5.5 | 5.4 |

The majority of the respondents (52 %) could not specify the type of metal ventouse that was applied; 44 % indicated the use of the original Malmström cup. The use of Bird and O'Neil metal cups was reported by 5 % and 4 % of the hospitals, respectively.

Experience with pliable cups was reported by 63 % of university and 41 % of non-university hospitals. The median frequency of use of a pliable cup was 30 % (range 1-100 %) of vacuum extraction deliveries. Pliable cups were used in 13 % of the total number of vacuum extraction deliveries.

Many respondents were not able to specify the type of pliable cup used. The Silastic$^R$ - or Kobayashi - soft cup was available in 13 % of all hospitals, in 22 % the Silc$^R$ cup was used.

Of the 59 obstetric units (42 %) in which pliable cups were used, 12 reported that they applied no specific restrictions: a soft cup was used in 60 % of the vacuum extraction deliveries in these hospitals. The remaining 47 units restricted their use to special conditions shown in Table 3.2. Generally the pliable cup was used only for 'lift-out' deliveries: low outlet procedures and/or situations in which only a small traction force was anticipated. In these units the pliable cup was used in 25 % of the vacuum extractions. All free comments regarding vacuum extraction with a soft cup were given by this group of respondents. The free comments are arranged according to their positive, negative or neutral character.

Table 3.2. *Restrictions and contraindications applied to the use of flexible cups in 59 units.*

| | | Number of obstetric units |
|---|---|---|
| No restrictions | | 12 |
| Use restricted to | outlet extractions | 22 |
| | small force extractions | 11 |
| | fetal distress | 4 |
| | malrotation | 2 |
| | second twin | 1 |
| | unspecified | 7 |
| Contraindications | vaginal prolaps | 1 |
| | malrotation | 2 |
| | extensive caput succedaneum | 1 |

Positive comment

- with the pliable cup maximum vacuum can be applied immediately (1x);
- the pliable cup procedures are easier to perform than those with the rigid cup, with less trauma to the neonate and perineum (1x);
- application of the pliable cup causes less discomfort to the patient compared to the metal cup (1x);
- neonates after pliable cup vacuum extraction have fewer scalp injuries and are jaundiced less often than after delivery with a metal cup (1x).

Negative comment

- the pliable cups are too big and difficult to insert (3x);
- inserting the pliable cup is uncomfortable to the women;
- the pliable cup deforms, it folds and leakage occurs (2x);
- the soft cup detaches easily (4x), in particular when strong forces are required (5x), and when the fetal scalp has much hair or is covered with much vernix (1x);
- the soft cup deforms during sterilization (1x).

Neutral comment

- the soft cup competes with forceps (2x).

## 3.4. Discussion

In the year on which the inquiry is based, 1987, vacuum extraction appeared to be the method of first choice for instrumental vaginal delivery in the Netherlands: the ratio of vacuum extraction to forceps delivery was 2:1. Because this ratio also applied to obstetric units involved in specialist training, there is no reason to presume that the relative use of forceps has increased in recent years. Indeed, in 1994 instrumental delivery was performed in 16.4 % of cases; 12.1 % by vacuum cup and 4.3 % by forceps[214] which is a ratio of 2.8:1 The figure of 16.0 % instrumentally assisted vaginal deliveries needs clarification. This number refers to deliveries under supervision of an obstetrician in the responding hospitals. By extrapolation it is likely that 7500 deliveries under specialist supervision occur yearly in the hospitals that failed to respond, and that also 16 % of these were instrumental vaginal deliveries. Since general practitioners and midwives are responsible for about 90.000 spontaneous vaginal deliveries per year[40], the incidence of instrumental vaginal delivery in the Netherlands in 1987 could be estimated at about 8%; this incidence is estimated to be 6 % in 1994[214].

The results of our inquiry indicate that vacuum extraction with the pliable obstetric vacuum cup is an accepted procedure in the Netherlands: over 40 % of the hospital obstetric units had experience with the pliable cup, and in 1987 about 13 % of all vacuum extraction deliveries in the country were performed with such a device. No preference for any of the available soft cups was indicated; in fact, the majority of respondents were unable to specify the exact type of cup used.

In a large number of hospitals the obstetricians appear to apply certain restrictions to the use of a pliable cup. We could not determine if these restrictions were based on personal experience, published evidence, or prejudice. Many respondents considered the pliable cup only useful for anticipated easy low outlet extractions as an alternative to forceps, a quality not recognized in randomized trials (see Chapter 2.6.). Some respondents indicated that the pliable cup may deform under traction, and that loss of suction easily occurs on a hairy fetal head, phenomena also reported in the literature (see Chapter 2.3.). The size of some of the soft cups sometimes appeared to cause problems; one investigator mentioned that this was overcome by performing an episiotomy before inserting the cup[54], a procedure that has been shown to favor detachment (see Chapter 2.6.).

Some comments concerned maternal or fetal trauma, a subject that on purpose was not included in the questions. The reference to the smaller number of jaundiced neonates after soft cup procedures is intriguing; this issue has not systematically been investigated in the available randomized trials (see Chapter 2.4.).

On the basis of the results of this inquiry a randomized comparison between the efficacy and complications of a pliable cup and a classic rigid cup was considered justified.

Chapter 4

# A RANDOMIZED COMPARISON OF VACUUM EXTRACTION DELIVERY WITH A RIGID AND A PLIABLE CUP*

## 4.1. Introduction

Malmström's Vacuum Extractor or "ventouse" has almost replaced forceps as an instrument for operative vaginal delivery in most European countries[206], including The Netherlands (see Chapter 3). Cosmetic concerns related to the artificial caput succedaneum - the chignon - and in particular reports of lacerations and hematomas of the fetal scalp[189] have limited the use of vacuum extraction in the United States[116]. In an attempt to reduce scalp injury, the use of soft, pliable suction cups has been advocated since 1969[253]. These cups shape to the fetal head and have no rigid edges[156]. Randomized studies of soft cup and rigid cup vacuum extraction have indeed demonstrated a tendency for the soft cup to cause less neonatal scalp trauma[52,54,95].

A lower incidence of neonatal retinal hemorrhage has been observed after pliable cup vacuum deliveries compared to newborns delivered by means of a rigid cup[17,67]. The randomized comparisons of soft and rigid cups have not included ophthalmologic evaluation of the newborns and at present no reliable data are available concerning the relative frequencies of neonatal retinal hemorrhage after soft and rigid cup vacuum extraction.

The present randomized controlled trial was designed to compare the efficacy and complications of vacuum extraction with a rigid cup with those of a pliable cup, in patients who met predetermined criteria for operative vaginal delivery, focusing on a standardized neonatal screening program including assessment of retinal hemorrhages.

* *The main substance of this chapter was published in: Kuit JA, Eppinga HG, Wallenburg HCS, Huikeshoven FJM: A randomized comparison of vacuum extraction delivery with a rigid and a pliable cup. Obstet Gynecol 1993;82:280-4.*

## 4.2. Material and methods

Eligible for the trial were women admitted to the labor ward with a duration of pregnancy of 37 completed weeks or more and a single live fetus who required instrumental delivery and met all of the following criteria: ruptured membranes and fully dilated cervix; vertex presentation; low or mid station of descent. The decision to perform an instrumental delivery and the choice of vacuum extraction or forceps was made by the attending obstetrician. The research protocol applied to all instrumental vaginal deliveries, to the vacuum extractions as well as to the forceps deliveries. When it was decided to perform vacuum extraction, the study design was explained to the patient and informed consent was obtained prior to delivery. When the decision was made to use the obstetric forceps, informed consent to use perinatal data for analysis was obtained after delivery. The study was performed in the Stichting Deventer Ziekenhuizen, at Deventer, The Netherlands, after approval of the study protocol by the Hospital Ethics Committee.

The deliveries were performed by six obstetricians at the consultant level or by three junior residents under their supervision. The presentation, position and degree of descent of the fetal head were carefully determined. When the lowermost portion of the fetal skull was at the level of the ischial spines or less than 2 cm below, it was designated mid-station; when it was lower it was recorded as low station. The bladder was emptied and all patients received left lateral perineal infiltration with 20 ml of 1 % lidocaine, prior to the application of an instrument as preparation for episiotomy.

Vacuum extraction by means of the rigid or the soft cup was randomly allocated by opening the next of a series of sealed and consecutively numbered envelopes. Randomization was performed by means of a table of random numbers and balanced in groups of six. The suction cup was then applied to the vertex and interposition of maternal tissue between cup and scalp was excluded by digital examination. For the rigid cup we used the original 50 mm metal Malmström mushroom-shaped design, with the suction tubing attached to the center of the dome and the traction chain passing through the tubing (Fig.2.4.). For the soft cup we chose the Silastic silicone plastic cup after Kobayashi (Fig.2.7.), with a diameter of 65 mm (Dow Corning Corporation, Midland, Michigan, U.S.A.)[156].

Vacuum was induced by means of an electric suction pump. When the

Malmström cup was applied, vacuum was created gradually by increasing the vacuum by 0.2 $kg/cm^2$ every 2 minutes until a negative pressure of 0.8 $kg/cm^2$ was reached. With the soft cup negative pressure was increased to 0.8 $kg/cm^2$ in 1 minute. Traction was applied in conjunction with uterine contractions. Left-lateral episiotomy was performed in all cases shortly before delivery of the fetal head.

The period of time between reaching the decision to perform instrumental delivery and the start of traction was recorded. If a cup slipped off it was replaced once; if a second detachment was not followed by immediate spontaneous delivery, vacuum extraction was considered to have failed and the baby was delivered by forceps or cesarean section. The same was done if delivery was not accomplished within 30 minutes after beginning of traction attempts. According to the protocol only the suction cup to which the patient had been allocated was to be used. Every instrumental method other than vacuum extraction to deliver the patient was recorded as a failure. Comparison of the results is based on intention to deliver by rigid or pliable cup.

The umbilical cord was clamped immediately after birth and umbilical arterial blood was sampled for acid-base analysis. The course of the third stage, maternal blood loss, vaginal trauma, Apgar scores and the results of examination of the neonate were recorded by the attending obstetrician. Particular attention was given to the fetal scalp: the presence of instrumentation marks, bruising, lacerations or hematoma was described. Inspection of the fetal scalp was repeated by the investigators between 48 and 72 hours after birth.

Indirect ophthalmoscopy was performed in every neonate within 30 hours after birth, after instillation of one drop of tropicamide 0.5 % in both eyes. The ophthalmologist who performed the examinations was unaware of the cup used for delivery. Retinal hemorrhage was classified into three grades[67,69]: grade I was characterized by small and relatively few hemorrhages; grade II included 1-2 large bleedings, or many small lesions; hemorrhages involving the central macula or many large hemorrhages were classified as grade III. Both eyes were examined and the highest grade of retinal hemorrhage was recorded.

In all neonates serum bilirubin levels were measured by spectrophotometry between 48 and 72 hours after birth, and repeated if higher than 205 micromol/L. All neonates underwent a neurologic examination according to the method described by

Prechtl[192], between 48 and 72 hours after birth. By means of this standardized method of examination 60 neonatal neurologic features are evaluated, and optimal responses of the newborn are credited with one point: a maximum of 60 points represents a neurologically optimal infant[232]. A newborn was considered neurologically suspect or neurologically abnormal on the basis of scores and combinations of suboptimal or lacking responses[232]. The neurologic examinations were carried out by two trained investigators.

The vacuum extraction group size was predetermined in order to have sufficient statistical power to detect a difference in the occurrence of retinal hemorrhage, which we considered the most important neonatal variable. With about 50 women in each group we would be able to demonstrate statistical significance with an alpha of 0.05 (two sided) and 85% power, assuming the occurrence of retinal hemorrhages in 30 % of the newborns after pliable cup procedures[17] and in 60 % of the babies after use of the rigid cup[67,69]. The study was terminated when 100 patients were randomized, 50 to the rigid and 50 to the pliable cup. The chi-square test (with Yates correction where applicable) was used to compare relative frequencies, and differences between continuous variables were analyzed using Wilcoxon's rank sum test. A p-value of less than 0.05 was taken to indicate significance.

## 4.3. Results

During the study period 148 instrumentally assisted vaginal deliveries were performed, which represent 16 % of the total of 925 births under specialist supervision during the study period. Of these 108 (12 %) were vacuum extractions, 40 (4.3 %) were forceps deliveries. Ten instrumental deliveries were not eligible for the study protocol due to prematurity (n=3), multiple pregnancy (n=5) and failure to randomize between rigid and pliable vacuum cup (n=2). The results refer to 100 randomized vacuum extraction deliveries and 38 forceps deliveries. The results of the forceps deliveries are presented in Chapter 5, this section deals with the results of the randomized vacuum extractions.

Maternal and obstetric characteristics of the two groups are shown in Table 4.1. In The Netherlands it is common to accept a second stage of one hour of frequent pushing efforts before deciding that there is delay of second stage: most vacuum extraction procedures occurred just after this time limit.

Table 4.1. *Maternal and obstetric characteristics. Values are median (range) or numbers, as appropriate.*

| | rigid cup n=50 | pliable cup n=50 |
|---|---|---|
| Maternal age (yrs) | 29 (18-37) | 27.5 (21-38) |
| Gestational age at delivery (wks) | 40 (37-43) | 40 (37-43) |
| Nulliparous | 38 | 40 |
| Multiparous | 12 | 10 |
| with previous instrumental delivery or cesarean section | 8 | 7 |
| Oxytocin in 2nd stage | 18 | 12 |
| Duration of second stage at decision to intervene (min) | 75 (15-140) | 66 (10-144) |
| Indication for intervention | | |
| delay of second stage | 48 | 45 |
| fetal distress | 2 | 5 |
| Station of fetal head | | |
| mid station, $< +2$ cm | 38 | 38 |
| low station, $\geq +2$ cm | 12 | 12 |
| Presentation of fetal head | | |
| occiput anterior | 44 | 43 |
| occiput posterior or transverse | 6 | 7 |

The outcome of vacuum extraction is summarized in Table 4.2. The average time between the decision to perform vacuum extraction and the first pull was 5 minutes less with the pliable than with the rigid cup. This significant difference is reflected in the number of patients delivered within 10 minutes: 13 in the soft cup group and one in the rigid cup group ($P < 0.001$). Loss of suction occurred significantly more often with the use of the pliable cup (34%; 95% CI) than with the rigid cup (6%; 95% CI). The majority of detachments with the pliable cup occurred at the crowning of the fetal head and were followed by spontaneous progress and delivery. Also the number of vacuum extraction failures was higher with the pliable cup (10%; 95% CI 3.3-22%) than with the metal cup (4%; 95% CI 05-14%), but the difference was not significant.

Table 4.2. *Outcome of vacuum extractions. Values are median (range) or numbers, as appropriate.*

| | rigid cup n=50 | pliable cup n=50 |
|---|---|---|
| Time between decision to intervene and start of traction (min) | 12(5-25) | 5(1-15)* |
| Number of tractions | 4(1-11) | 4(1-12) |
| Time from start of traction to birth (min) | 7(1-25) | 7(2-25) |
| Delivered with allocated cup | 48 | 45 |
| one detachment | 3 | 12** |
| two detachments | 0 | 5 |
| Failed procedures | 2 | 5 |
| two detachments: | | |
| forceps | 1 | - |
| cesarean section | 1 | - |
| other cup | - | 1 |
| no progress: | | |
| forceps | - | 2 |
| cesarean section | - | 2 |
| Blood transfusion required | 3 | 6 |
| Traumatic extension of episiotomy | 7 | 7 |
| anal sphincter injury | 0 | 1 |
| Other vaginal laceration | 8 | 5 |

* : $p < 0.01$ vs rigid cup
** : $p < 0.05$

Maternal morbidity was negligible in both groups except for one case of partial sphincter rupture as an extention of episiomoty in the soft cup group; there was no significant difference in estimated blood loss or trauma to the birth canal between both groups.

Neonatal outcome is summarized in Table 4.3. There were no significant differences between groups with regard to Apgar score or umbilical artery pH. The median birthweight was 200 g higher in the group delivered with the rigid cup than that in the soft cup group ($P < 0.05$). The highest serum bilirubin concentration in the rigid cup group was similar to that in neonates delivered with the pliable cup.

| Table 4.3. | *Neonatal outcome. Values are median (range) or numbers, as appropriate.* | |
|---|---|---|
| | rigid cup n=50 | pliable cup n=50 |
| Birthweight (g) | 3680 (2840-4830) | 3483 * (2840-5405) |
| Infants above 4000 g | 14 | 7 |
| Apgar score at 1 min < 7 | 6 | 6 |
| Apgar score at 5 min < 7 | 2 | 2 |
| Umbilical artery pH < 7.20 | 20 | 16 |
| < 7.10 | 6 | 4 |
| < 7.00 | - | 2 |
| Retinal hemorrhage | | |
| none | 21 | 25 |
| grade I | 13 | 10 |
| grade II | 10 | 9 |
| grade III | 6 | 6 |
| Neurologic examination | | |
| suspect | 9 | 8 |
| abnormal | - | 1 |
| Optimality score | 57 (49-60) | 57.5 (40-60) |
| Highest bilirubin value (μmol/l) | 135(20-285) | 130(20-235) |
| Bilirubin levels exceeding | | |
| 170-205 mmol/L between 24-48 hrs | - | 4 |
| 206-220 mmol/L between 49-72 hrs | 3 | 4 |
| Scalp trauma after 49-72 hrs | | |
| no visible injury | 5 | 14* |
| swelling/petechiae/ecchymoses | 27 | 19 |
| cup marks | 26 | 12* |
| lacerations/blisters | 15 | 7 |
| cephalohematomas | 12 | 4* |

* : $p < 0.05$ vs rigid cup

All infants with a serum bilirubin concentration exceeding 170-205 micromol/L (9.95-12.0 mg/dL) within 24-48 hrs, and 206-220 micromol/L (12.0-12.9 mg/dL) within 49-72 hours of life were examined by a neonatologist. Six babies from the pliable cup group required phototherapy compared with one delivered by the rigid cup, but the difference was not statistically significant. Ophthalmic examination showed a similar incidence of retinal hemorrhage of all grades of severity in both groups. Also the number of neurologically suspect infants was similar in both groups. The single neurologically abnormal newborn was delivered by pliable cup extraction 25 hours after spontaneous rupture of the membranes, and was found to have Salmonella septicemia at the time of examination. Examination after recovery showed normal neurologic responses. Totals of optimality scores were distributed evenly, and median values were similar in both groups.

Neonatal scalp trauma assessed immediately after delivery by the nine operators was too variable with regard to terminology and interpretation to allow further evaluation. Inspection of the fetal scalp on the third day of life showed more superficial skin lesions associated with the rigid than with the flexible cup. The typical ring originating from the sharp edge of the metal cup was found significantly more often than the star-type print of the radially arranged grooves in the soft cup. The occurrence of such minor scalp effects as swelling, edema, bruising and discoloration was not different between the two groups on the third day of life. Significantly more cephalohematomas were observed in the rigid cup group, but subaponeurotic hematomas were not observed in any of the newborns. Comparison between babies with and without cephalohematoma showed no differences with regard to the number of tractions, the station and the presentation of the fetal head.

## 4.4. Discussion

We wished to perform the vacuum extraction trial in general obstetric practice and tried to prevent a shift between the numbers of vacuum extraction and forceps delivery by applying the same research protocol to both methods. This resulted in 12 % vacuum extractions and 4.3 % forceps deliveries in the trial period, which is comparable to the respective percentages of 9.2 % and 5.6 % in the year preceding the trial.

The results of our study show failure rates for the rigid and the pliable cup, with one reapplication allowed, that are in agreement with the other randomized comparisons (see Chapter 2.6.). Inclusion of the present study in the meta-analysis of cup failure does not affect the conclusion that in general the soft cup fails significantly more often than the rigid cup (typical Odds 2.36, 95 % confidence interval 1.39-4.01).

In our study the pliable cup detached significantly more often, which is a consistent finding in randomized studies (Table 2.4.). The observation that the pliable cup detaches easier is at variance with experimental studies; under laboratory conditions the 65 mm soft cup used in our study allowed a higher traction force than the 50 mm metal cup at the same vacuum[64]. In clinical practice the soft cup relies on a large surface area rather than on the development of a chignon to allow sufficient traction. The relatively frequent loss of vacuum with the soft cup may be attributed to less effective sealing of its soft rim which lacks the inward bend originally designed to obtain maximal "seal pressure"[150]. Also, a flexible cup may assume an oval shape under traction resulting in a curved plane of the cup opening, or show "rolling of the rim"[228], which are both factors that may cause leakage. The tissues of the birth canal may be important to support the seal of vacuum, as indicated by our observation that the majority of the detachments of the soft cup occurred at crowning of the fetal head, when the cup lost its cover of vaginal or vulvar tissue. For this reason the pliable cup may not be the best choice for low station deliveries.

We encountered none of the serious neonatal complications, such as skin ablations or alopecia, that have been reported to occur with the metal but not with the pliable cup[17,16,52,54,61,156,228]; also no subaponeurotic hematomas were diagnosed. The plying of the skin to align to the cup's interior, and subsequent dermal compression due to suction may cause (epi)dermal ischemia and injury. If so, it may be argued that the longer the period of suction lasts, the more skin injury may occur. However, such an effect was not observed in a study of slow and rapid application of suction with a rigid cup[223]. We therefore accepted the difference in speed of induction of vacuum as a confounding variable, with the purpose to compare the cups including the augmentation of vacuum as usually applied in general obstetric practice. The soft cup's large surface area and soft edge may be held responsible for the significantly lower incidence of neonatal scalp injury and cephalohematoma as compared with the rigid cup. There is no explanation for the incidences of cephalohematoma in both groups being above the average incidence published in the literature, other than that, in the absence of ultrasound assessments, the clinical diagnosis of cephalohematoma has been made liberally: also if the neurologic investigator and the pediatrician did not agree on the presence of a cephalohematoma, it was scored a cephalohematoma.

We observed retinal hemorrhage in about half the number of neonates in both groups, which is in agreement with studies of rigid cup vacuum extraction[67,69]. Assuming that neonatal retinal hemorrhage reflects the exposure to (sudden) changes of intracranial pressure[244], our finding indicates that such changes are inherent in the method of vacuum extraction, independent of the type of cup used. The low incidence of retinal hemorrhage after successful pliable cup vacuum extraction (28 %) as observed by Berkus et al.[17] may be explained by the smaller proportion of midpelvic extractions (39 %) in that series compared to our group (76 % midpelvic deliveries).

In conclusion, the pliable silicon cup causes fewer neonatal scalp injuries than the rigid metal cup. This may well be the only advantage of the soft cup as the incidence of neonatal retinal hemorrhage is not reduced.

Chapter 5

# A PROSPECTIVE COMPARISON OF VACUUM AND FORCEPS DELIVERY

## 5.1. Introduction

In the Netherlands the vacuum extractor cup is used twice as often as forceps for instrumental vaginal delivery (see Chapter 3). This may be due to the fact that the application of the vacuum extractor cup is generally considered to be easier than that of the obstetric forceps, and that the risk of serious fetal and maternal trauma is considered to be lower with the use of the vacuum extractor, in particular when used for midpelvic delivery[73]. Meta-analysis of the randomized studies comparing vacuum extraction and forceps delivery[114], described in Chapter 2.6., demonstrates that forceps and vacuum extractor are not equivalent instruments, and in general provides arguments favoring the use of the vacuum extractor[42]. The analysis does not allow to detect factors that may contribute to the relative differences associated with the use of both instruments, because stratification of the results, e.g. towards operator experience, presentation of the fetal head, fetal condition, or station of descent, is not possible.

The station of descent of the fetal head prior to assisted vaginal delivery is a possible factor of influence on the choice of an instrument and on maternal and neonatal outcome. Among the nine randomized studies that are included in the previously mentioned meta-analysis, the numbers of midpelvic deliveries with forceps or vacuum cup are specified in only four[61,114,129,249]. These four studies comprise 40 % midpelvic forceps deliveries and 37 % midpelvic vacuum extractions in 1076 assisted vaginal deliveries. The nonrandomized studies of vacuum and forceps usually fail to indicate the station of descent of the fetal head.

The present prospective, nonrandomized, study was designed to compare perinatal outcomes and results of neurologic and ophthalmologic examination of newborns delivered by vacuum extraction with those delivered by obstetric forceps at low and midstation. An aspect of vacuum and forceps deliveries that is mentioned in the literature in few investigations is the experience of the women themselves[87,196]. For that reason the maternal assessment was completed by means of a questionnaire of the women's opinion on the instrumental delivery.

## 5.2. Material and methods

The study protocol followed was identical to that outlined in detail in Chapter 4. The decision to perform an instrumental delivery and the choice of vacuum extraction or forceps was made by the attending obstetrician. The patients who gave their consent to the study on vacuum extraction were randomized with regard to the use of the rigid or soft vacuum cup as described in Chapter 4. The obstetricians who chose to use forceps had sufficient experience with the method. The presentation, position and degree of descent of the fetal head were carefully determined. When the lowermost portion of the fetal skull was at the level of the ischial spines or less than 2 cm below, it was designated mid-station; when it was lower it was recorded as low station. The procedure was explained to the patient and informed consent to use perinatal data for analysis was obtained in all cases after delivery. The bladder was emptied before application of the instrument, and all patients received left lateral perineal infiltration with 20 ml of 1 % lidocaine prior to the application of the forceps as preparation for episiotomy. Traction was applied in conjunction with uterine contractions. Left-lateral episiotomy was performed in all cases before delivery of the fetal head.

In addition to the research protocol described in Chapter 4 all mothers were given a questionnaire with questions pertaining to:

- understanding why a specific instrument, vacuum extractor or forceps, was used;
- awareness of the delivery and the instrumental assistance provided;
- experience of pain during application of the instrument;
- the amount of time that the instrumental procedure took;
- experience of active participation after instrumental assistance had begun;
- awareness of potential injury to the newborn by the instrument, in particular of artificial caput or forceps marks;
- reflections on the visible injury of the newborn.

Since forceps delivery was not part of the randomized trial between rigid and soft cup vacuum extraction reported in Chapter 4, no separate power analysis to estimate the required group size of the forceps group was performed. The chi-square test (with Yates correction where applicable) was used to compare relative frequencies, and differences between continuous variables were analyzed using Wilcoxon's rank sum test. P less than 0.05 was taken to indicate significance.

## 5.3. Results

One patient in the forceps group failed to answer the questionnaire. All mother-infant pairs remained in the hospital for at least 72 hours after instrumental delivery.

Maternal and obstetric characteristics of the vacuum extraction and forceps delivery groups are presented in Table 5.1. In the forceps group the fetal head was at low station in 71 % of cases, significantly more often than the 24 % in the women delivered by vacuum extraction. None of the forceps procedures failed compared with 7% of the vacuum extractions, but the difference is not statistically significant.

The outcome of the instrumental deliveries is summarized in Table 5.2. The times between the decision to terminate the second stage and the start of traction, and between the start of traction and actual delivery were significantly shorter in the forceps compared with the vacuum group. These significant differences are reflected in the number of patients delivered within 10 minutes: 84 % in the forceps group, and 14 % in the vacuum group ($p < 0.001$). Also in cases with midpelvic station the time between the decision to intervene and actual delivery was significantly shorter in the forceps group (median 7 min vs. 18 min; $p < 0.001$). Despite episiotomy partial or complete sphincter involvement in a traumatic extension of the episiotomy occurred in five nulliparae after forceps delivery and in one nullipara after a soft cup vacuum extraction that failed ($p < 0.01$); the latter patient was delivered by metal cup vacuum extraction, the single deviation from the protocol. The subgroups of instrumental deliveries on the indication of fetal distress contained no sphincter ruptures; these were spread evenly over the midpelvic (1/11) and the low forceps (4/27) applications.

Neonatal morbidity is summarized in Table 5.3. There were no significant differences between groups with regard to Apgar score, umbilical artery pH or birthweight. The highest neonatal serum bilirubin concentration in the vacuum cup group was similar to that in the forceps group.

| Table 5.1. | *Maternal and obstetric characteristics. Values are median (range) or numbers, as appropriate.* | |
|---|---|---|
| | vacuum group<br>n=100 | forceps group<br>n=38 |
| Maternal age (yrs) | 28(18-38) | 30(18-38) |
| Gestational age at delivery (wks) | 40(37-43) | 40(37-43) |
| Nulliparous | 78 | 36* |
| Multiparous | 22 | 2 |
| with previous instrumental delivery or cesarean section | 15 | 1 |
| Oxytocin in 2nd stage | 30 | 7 |
| Duration of second stage at decision to intervene (min) | 71(10-144) | 84(0-190) |
| Indication for intervention | | |
| delay of second stage | 93 | 31 |
| fetal distress | 7 | 7 |
| Station of fetal head | | |
| mid station $< +2$ cm | 76 | 11** |
| low station $\geq +2$ cm | 24 | 27 |
| Presentation of fetal head | | |
| occiput anterior | 87 | 36 |
| occiput posterior or transverse | 13 | 2 |

* : $p < 0.05$ vs vacuum group
** : $p < 0.001$

All infants with a serum bilirubin concentration exceeding 170-205 micromol/L within 24-48 hrs, and 206-220 micromol/L within 49-72 hours of life were examined by a pediatrician. Seven babies required phototherapy in the vacuum cup group compared with one infant delivered by forceps, a nonsignificant difference. Ophthalmologic examination showed a significantly higher incidence of retinal hemorrhage in the vacuum than in the forceps group (54 % vs. 26 %, $p < 0.02$), the hemorrhages were spread evenly over the midpelvic and the low applications in both groups (38/76 vs 16/24 in the vacuum group; 2/10 vs 8/28 in the forceps group). Neurologic optimality scores were distributed evenly, and median values were similar in both groups. The single neurologically abnormal newborn in the vacuum group - suffering from

Salmonella septicemia - is described in Chapter 4. Two neurologically abnormal infants were encountered in the forceps group. One infant had facial paresis, after delivery in occiput posterior position, which recovered spontaneously in six weeks. Another infant, the one with the lowest optimality score of 44 in the forceps group, showed asymmetrical reflexes after birth, but normal responses were found on day six.

Table 5.2. *Outcome of instrumentally assisted deliveries. Values are median (range) or numbers, as appropriate.*

| | vacuum group n=100 | forceps group n=38 |
|---|---|---|
| Time between decision to intervene and start of traction (min) | 10(1-25) | 3.5(0-15)* |
| Number of tractions | 4(1-12) | 1(1-4) |
| Time from start of traction to birth (min) | 7(1-25) | 1(1-15)* |
| Delivery with allocated instrument | 93 | 38 |
| one detachment | 15 | - |
| two detachments | 5 | - |
| Failed procedures | 7 | 0 |
| two detachments: | | |
| forceps | 1 | |
| cesarean section | 1 | |
| other cup | 1 | |
| no progress | | |
| forceps | 2 | |
| cesarean section | 2 | |
| Blood transfusion required | 9 | 5 |
| Traumatic extension of episiotomy | 14 | 9 |
| Anal sphincter injury | 1 | 5** |
| Other vaginal laceration | 13 | 1 |

* : $p < 0.001$ vs vacuum group
**: $p < 0.01$ vs vacuum group

Neonatal scalp trauma assessed immediately after delivery by the nine operators was variable with regard to clarity of description and interpretation. The number of explicit and detailed assessments was significantly higher in the vacuum group (75 %) than in forceps deliveries (34 %, $p < 0.001$). Inspection of the fetal head on the third day of life revealed skin lesions significantly more often in babies delivered by the vacuum extractor than in the forceps group; in the forceps group the lesions consisted predominantly of reddish marks on the cheeks. Cephalohematomas were not observed in the forceps group but occurred in 16 % of the babies delivered by vacuum extraction.

Table 5.3. *Neonatal outcome. Values are median (range) or numbers, as appropriate.*

| | vacuum group n=100 | forceps group n=38 |
|---|---|---|
| Birthweight (g) | 3550 (2840-5405) | 3490 (2670-4400) |
| Infants above 4000 g | 21 | 7 |
| Apgar score at 1 min < 7 | 12 | 3 |
| Apgar score at 5 min < 7 | 4 | - |
| Umbilical artery pH < 7.20 | 36 | 11 |
| < 7.10 | 10 | 1 |
| < 7.00 | 2 | - |
| Retinal hemorrhage | | |
| none | 46 | 28* |
| grade I | 23 | 5 |
| grade II | 19 | 4 |
| grade III | 12 | 1 |
| Neurologic examination | | |
| suspect | 17 | 4 |
| abnormal | 1 | 2 |
| Optimality score | 57(40-60) | 57(44-60) |
| Highest bilirubin value (µmol/l) | 135(20-285) | 145(20-145) |
| Bilirubin levels exceeding | | |
| 170-205 mmol/l between 24-48 hrs | 4 | - |
| 206-220 mmol/l between 49-72 hrs | 7 | 1 |
| Scalp trauma after 49-72 hrs | | |
| no visible injury | 19 | 31** |
| swelling/petechiae/ecchymoses | 46 | 1 |
| cup marks/forceps marks | 38 | 5 |
| lacerations/blisters | 22 | 4 |
| cephalohematomas | 16 | - |

*: $p < 0.02$ vs vacuum group **: $p < 0.001$

The results of the questionnaire are summarized in Table 5.4. Significantly fewer patients experienced the duration of the intervention as long; with forceps delivery than with vacuum extraction significantly more patients denied active participation in forceps than in vacuum delivery, and fewer patients knew about potential skin lesions of their newborn.

Table 5.4. *Outcome of the questionnaire. Answers are presented in numbers.*

| Answers to the questions | vacuum group n=100 | forceps group n=37 |
|---|---|---|
| Yes, aware of what happened | 76 | 28 |
| Yes, understood what happened | 94 | 35 |
| Insertion of the instrument | | |
| not noticed | 23 | 10 |
| discomfort | 41 | 16 |
| painful | 36 | 11 |
| Impression of duration of instrumental intervention | | |
| unknown | 30 | 7 |
| short | 59 | 29 |
| long | 11 | 1* |
| Active participation | | |
| unknown | 20 | 9 |
| yes | 78 | 28 |
| no | 2 | 5** |
| Knowledge of potential neonatal skin damage | | |
| yes | 95 | 25 |
| no | 5 | 12*** |
| Free comments | | |
| none | 62 | 28 |
| negative | 7 | 4 |
| indifferent | 7 | 3 |
| positive | 25 | 7 |
| Subject commented | | |
| pain | 5 | 2 |
| explanation given | 22 | 10 |
| miscellaneous | 11 | 2 |

* : $p < 0.05$ vs vacuum group
** : $p < 0.02$
*** : $p < 0.001$

## 5.4. Discussion

Naegele's forceps was chosen to perform forceps delivery, although this type of forceps may not be ideal for the indications of fetal distress and failure of progress for which the instrument was used in this study[73]. The data on the station of descent in Table 5.1 show that the obstetric forceps was mainly applied in cases of low station or outlet delivery, and that the vacuum extractor was mainly used for midpelvic deliveries. Comparison with the randomized trials of vacuum extraction and forceps delivery (see Introduction) shows that the present study contains both a significantly higher proportion of midpelvic vacuum extractions and a significantly higher proportion of low forceps applications ($p < 0.05$). The results of the inquiry among the obstetric units (Chapter 3) suggest that this is common practice in the Netherlands.

The results of this study are in support of the conclusions of the meta-analysis of random use of forceps and vacuum extractor (Chapter 2.6.); also after differentiating application of the instruments with regard to the station of descent, the vacuum extractor compared to forceps is:

- more likely to fail, although the difference was not statistically significant;
- significantly less likely to be associated with maternal anal sphincter rupture;
- more likely to be associated with neonatal cephalohematoma, although not statistically significant;
- significantly more likely to be associated with neonatal retinal hemorrhage.

Among the published nonrandomized comparisons of vacuum extraction and forceps delivery, four studies indicate the station of descent and include a significantly higher number of deliveries from station +2 or lower in the forceps group than in the vacuum extraction group[31,90,176,212]. These studies are in support of the conclusions regarding the significant differences in instrument failure[176,212], in maternal anal sphincter injury[31], in neonatal cephalohematoma[176], and also regarding the nonsignificant difference in low 5 min Apgar scores[90,176]. No data were specified for need of phototherapy, nor for retinal hemorrhages or neurologic trauma, other than in the present study. The selection of forceps to lower station has not decreased the incidence of neonatal retinal hemorrhage, which was 27 % in our forceps group (95 % CI: 14-44 %), similar to the incidence after spontaneous delivery or forceps delivery in general (see Chapter 2.4.). One case of facial nerve paresis was encountered after a low outlet forceps delivery, which was the most serious neonatal neurologic complication encountered in the study. This does not suggest that selection of forceps to low station prevents serious neonatal trauma.

The difference in numbers of midpelvic applications between vacuum cup and forceps may explain the higher number of cases of vaginal lacerations in the vacuum extraction group, but the selection of forceps to use at lower station has not changed the significant difference in occurrence of the more serious anal sphincter injuries. There are two reasons why forceps may be associated with an elevated incidence of maternal perineal injury. First, forceps delivery can be accomplished rapidly, more rapidly than vacuum extraction even with immediate maximum vacuum[176], and the muscle and connective tissues of the pelvic floor may not be allowed the time needed to stretch. Second, the operating hands and the forceps itself may compromise a clear view of the perineum, and the operator may not notice when to slow down the extraction[103].

The parturients experience the forceps procedure as short, and compared to the women delivered by vacuum extraction a significantly lower number of mothers experience active participation in their forceps delivery. The late effects of such a deprived life event are unknown.

In conclusion, the comparison of available data from the literature and from the present study fail to indicate merits of restricted use of forceps to low station or outlet delivery in comparison to random use of forceps and vacuum extractor.

Chapter 6

# SPEED OF DEVELOPMENT OF THE CHIGNON IN THE MALMSTRÖM TYPE VACUUM EXTRACTOR CUP.

## 6.1. Introduction

In Malmströms research the experiments designed to investigate the seal of the vacuum determined the typical shape of the metal cup. Optimal seal necessitates a large and tight contact surface of skin and metal at the cup's opening, which can be realized by plying the scalp around an inward bent rim[152]. This condition is only present if the metal cup is completely filled by caput succedaneum, which then becomes the typical mushroom shaped chignon. Malmström emphasized to allow 8 to 10 min for a gradual build-up of 0.7 or 0.8 kg/cm$^2$ of negative pressure to allow the cup to fill completely with caput succedaneum[167], but he failed to report evidence in support of his advice[152].

Gradual augmentation of the vacuum, with steps of 0.2 kg/cm$^2$ every 2 minutes until 0.8 kg/cm$^2$ is reached, has become accepted practice in many centers[235], and some of the electric pumps have been adapted to this four step build-up of negative pressure[238]. Already in the early days of the ventouse some authors reported the installment of maximum negative pressure within one minute, with the purpose to avoid waiting time[176,246]. Further evidence that the chignon may develop rapidly with immediate maximum negative pressure may be derived from two studies. Wider et al. reported the use of a transparant cup and observed that the artificial caput succedaneum completely filled the cup within 1 to 2 minutes. However, essential information such as the shape of the cup and the number of experiments was not documented[246]. A nonrandomized study comparing slow and rapid development of vacuum in a metal cup showed that maximum traction forces were similar in both groups. Due to selection bias, inherent to the study design and demonstrated by the significantly higher number of low outlet deliveries in the rapid suction group, also this study provides no conclusive evidence that rapid suction is compatible with optimal adherence of the metal cup[220].

In order to assess the attachment of the metal cup to the fetal head, we studied the development of the artificial caput succedaneum by applying a transparent vacuum cup with shape and dimensions identical to a 50 mm Malmström cup, and determined the time needed for complete formation of the artificial caput succedaneum.

## 6.2. Material and methods

A transparent cup was constructed of Macrolon, a synthetic polycarbonate, and polished to obtain maximum transparency (Fig.6.1.). With inner diameters identical to those of the 50 mm Malmström dome, the outer diameters had to be slightly larger to obtain sufficient wall thickness. The traction chain and suction nozzle were placed centrally. A neoprene mesh was used as a pressure dispersing inlay.

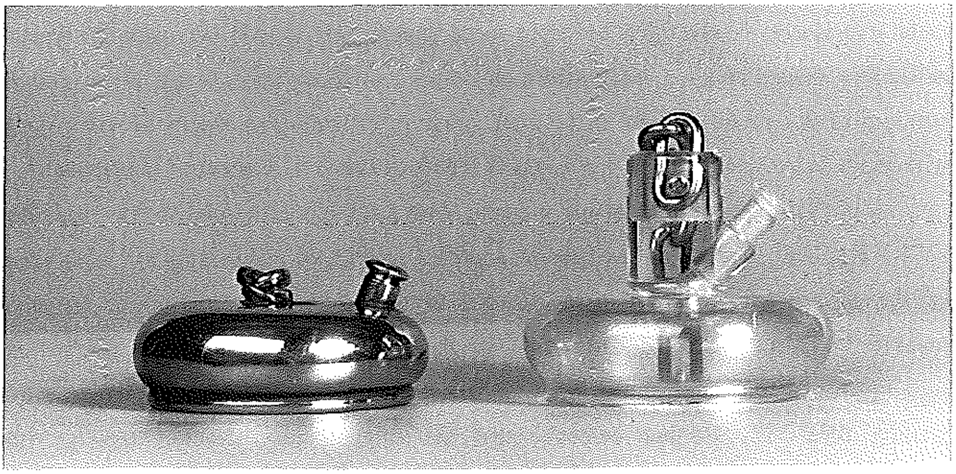


*Fig. 6.1. Profile of the polycarbonate replica of the 50 mm Malmström metal dome.*

The study was conducted in the Zuiderziekenhuis in Rotterdam, The Netherlands. Patients eligible for application of the transparent cup were those with a prolonged second stage of labor, occiput anterior position and station at or below +2. The study protocol was explained to the patients and informed consent was obtained. If the clinical circumstances allowed, the procedure was recorded on videotape after obtaining separate informed consent. The caput succedaneum was classified prior to application of the cup as absent, intermediate or marked.

Vacuum was established with a Gyn Med type 2 electrical suction pump, and one of two modes of increment was chosen.

Mode A: An incremental increase in vacuum of 0.2 kg/cm$^2$ every 2 minutes until 0.8 kg/cm$^2$ was obtained.

Mode B: Establishment of a vacuum of 0.8 kg/cm$^2$ in a single step.

Formation of the chignon was examined through the transparent dome by the operator and by an independent observer. When the observer and the operator agreed on the moment of completed filling of the cup, the time since the start of suction was noted and was rounded off to the next ten seconds. The available video recordings were examined by a third observer. Complete filling was defined when fetal hair and skin were compressed against the bulging sides of the cup and against the neoprene mesh, as indicated by the disappearance of condensate against the interior surface of the cup, by kinking of hair, by flattening of fluid films, and by dispersion of vernix (Fig.6.2.).

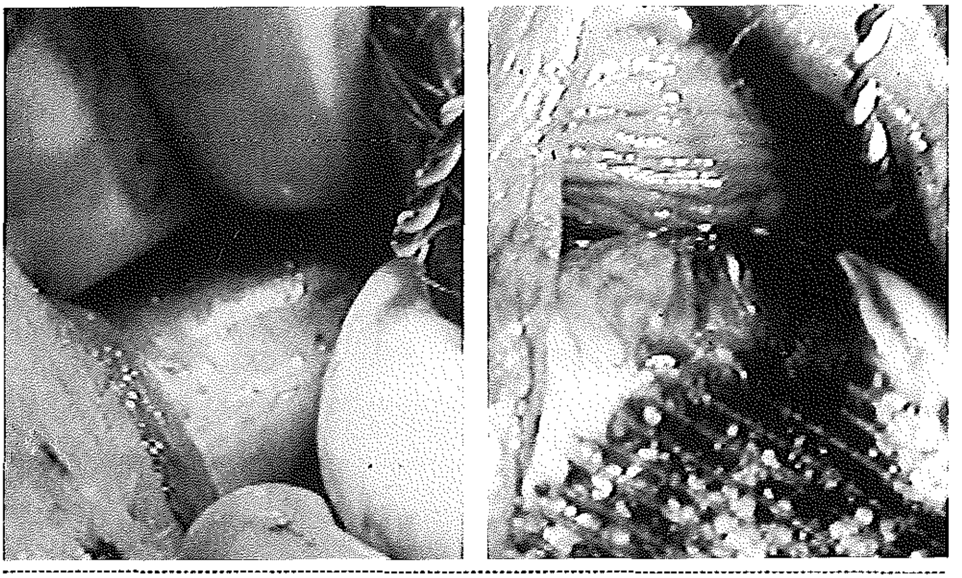


*Fig. 6.2.* *Difference between an empty and a filled transparent cup: the interior wall of the transparent cup is covered with condensate (left); the condensate has disappeared and skin, hair and vernix are compressed against the side of the cup (right).*

Traction was not begun until 0.8 kg/cm$^2$ of vacuum was established and complete filling of the cup was observed.

## 6.3. Results

Twenty-one patients were recruited for the study, and there were no experiment failures. Eight patients underwent slow suction, thirteen rapid suction. All babies were born in good condition, with Apgar scores at 1 and 5 min of 8 or above. An overview of the results is given in Fig. 6.3. Incremental increase of vacuum with steps of 0.2 kg/cm$^2$ every 2 minutes resulted in complete chignon formation at 0.4 kg/cm$^2$ after about 3 min in 6 of 8 cases, and always before the maximum underpressure of 0.8 kg/cm$^2$ was installed. When a negative pressure of 0.8 kg/cm$^2$ was applied at once, complete filling of the cup invariably occurred within 60 seconds (mean 42, sd 13 seconds). Revision of the available video tapes by a third observer revealed no differences in the times needed for complete filling of the cup. In seventeen cases the fetus was delivered with the transparent cup; in four patients detachment occurred after handling difficulty due to the height of the cup, in which cases a Bird "modified" cup was succesfully applied with rapid suction. No differences were apparent between fetal scalps with absent, intermediate, or marked caput succedaneum.

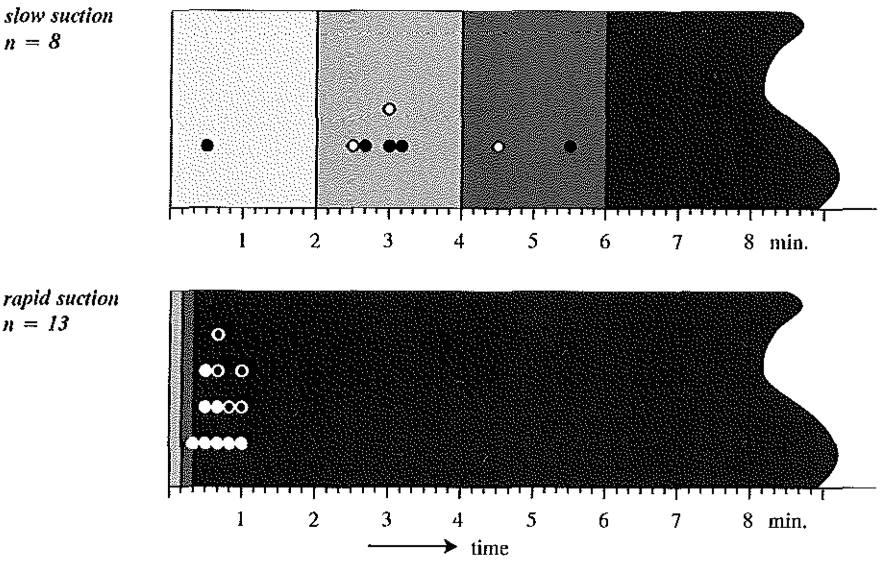



*Fig. 6.3. The time needed to obtain complete filling of the vacuum cup after slow (upper graph) and rapid suction (lower graph). The time scale (horizontal axis) is divided in 10 sec increments. The measurements with absent caput succedaneum are indicated by open dots, the measurements with intermediate or marked caput succedaneum are solid dots.*

## 6.4. Discussion

The time needed for the chignon to develop in a 50 mm Malmström cup appears to be markedly shorter than the 8-10 min suggested by Malmström, even if there is no caput succedaneum at the beginning of a procedure. It appears rational to start traction after complete filling of the cup, because at that moment no further improvement of the seal of the vacuum can be expected. Taking a confidence interval of two times the standard deviation, the 50 mm Malmström cup was completely filled within 68 seconds after immediate establishment of the maximum negative pressure of 0.8 $kg/cm^2$. Keeping in mind that the measurements were rounded off, and that during the first 10 to 20 seconds after the beginning of suction the underpressure had not yet reached 0.8 $kg/cm^2$, it seems advisable to wait for 1 minute at 0.8 $kg/cm^2$ of vacuum for the chignon to develop, also in cases without preexistent caput succedaneum, before starting traction.

During construction of the 50 mm diameter Macrolon cup it became apparent that a 60 mm diameter Macrolon cup would no longer combine sufficient rigidity and practical feasibility due to large external dimensions; for that reason a transparent 60 mm cup could not be made. Because the 60 mm cup is frequently used in obstetric practice, the question arises if the results obtained with a 50 mm cup can be extrapolated to a 60 mm Malmström cup. The 60 mm Malmström cup has an inner surface area of 100.1 cm2, 5/4 the inner surface of the 50 mm cup, and a content of 90.4 $cm^3$, 4/3 the interior volume of the 50 mm cup. Under the assumption of a constant influx of fluid into the chignon and a mean filling time of 56 seconds, and taking the preceding suction time at lower degrees of underpressure into account, a waiting time of 1 minute at 0.8 $kg/cm^2$ may also be expected to be sufficient when using a 60 mm cup, In case of absent caput succedaneum the low number of such cases encountered in the study does not justify to accept a 1 minute waiting time, and a 2 minute waiting time at 0.8 $kg/cm^2$ is advised with the 60 mm cup.

The assumption that a completely developed artificial caput succedaneum warrants the reliable attachment of a Malmström vacuum dome, regardless of the time that the artificial caput exists, has found support in a recent publication of a randomized clinical comparison of rapid and stepwise suction[136]. No difference in the occurrence of cup detachments was found, but the group sizes were too small to exclude such a difference. The fundamental approach in the present study of the developing artificial caput may do away with the necessity of a much larger comparative clinical investigation.

The question as to whether rapid suction could be associated with an increased risk of fetal-neonatal complications cannot be answered with confidence. However, no differences in skin necrosis, scalp lacerations, cephalohematomas, Apgar scores, cerebral irritation, Sarnat neurological scores and neonatal jaundice between rapid and slow suction were observed in the two available comparative studies[221,136].

Chapter 7

# GENERAL DISCUSSION AND CONCLUSIONS.

The method and design of vacuum extraction introduced into obstetric practice more than four decades ago by Malmström still dominate the field. Fine-tuning of the Malmström vacuum extractor has been realized by various modifications of the connection of the traction chain to the metal dome. Oblique traction has become easier to perform with these modifications, of which the Bird "modified" OA and OP cups, with their metal chain connected to the top of the dome, are considered superior with regard to clinical reliability, solidity, handling, and cleaning.

The metal vacuum cups currently in use rely on the original design of the dome by Malmström, who thoroughly investigated the seal of the vacuum. He postulated that an inward curved edge and a relatively thin rim of the cup would combine the right skin area and contact pressure for an optimal seal. However, the skin becomes stretched when plied, in particular while applying traction, which may result in scalp lesions. The influence of images of infants with scalp avulsions, in fact a rare complication and often due to inappropriately prolonged vacuum extraction, has been devastating to the popularity of the metal cup in some parts of the world, in particular in the U.S.

The introduction of soft and pliable cups in the early 1970s has contributed to an increase in the acceptance of the vacuum extraction method. The pliable cups have wide openings, thick rims, and the ability to shape to the fetal head. The quality of the seal of the vacuum and the grip on the fetal scalp is less than that of the metal cup. For that reason pliable cups are less likely to produce cosmetic damage to the baby, but their effectiviness in achieving delivery is reduced. The likelihood of successful vacuum extraction with a pliable cup can be improved by limiting its use to nonrotational delivery and by allowing as little time as possible for development of the chignon. In this regard the Silastic$^{R}$ cup, with its large opening diameter and a valve to release the vacuum if no force is applied, may be considered the best choice for pliable cup vacuum extraction. The temptation to use the pliable cup predominantly for low outlet delivery, as noted in the inquiry among Dutch obstetricians (Chapter 3), may increase the number of failed procedures, because of the absence of extra seal of vacuum provided by the vaginal wall.

During vacuum extraction the direction of traction should be tangential to the axis of the birth canal at the point where it crosses the plane with the largest presenting diameters and the highest resistance, which will be in or very near the base of the fetal skull. Placement of a vacuum cup on top of the skull means that both amount and direction of traction force has to be transferred to the base of the skull by the mouldable skull itself, which implies the possibillity of affecting the shape and possibly the anatomy of the fetal head. Tangential direction of traction is likely to result in maximum progress and minimal change in shape of the fetal head. Hypothetically, traction perpendicular to the axis of the birth canal will result in no progress of descent, and maximum distortion of the shape of the skull, with maximum risk of affecting the intracranial anatomy. Non-tangential traction may induce more than minimal changes in the shape of the fetal skull and in the majority of rigid vacuum cup deliveries the direction of traction may indeed be non-tangential. This may not be noticed by the operator, because the Malmström dome does not slide easily and is also prevented from moving by the finger-thumb position of the correcting hand. If a pliable cup is used, pulling in the correct axis is imposed by the lower detachment forces associated with this type of cup. It is helpful that the pliable cup slides more easily over the fetal scalp, thus adapting its position to the direction of traction.

In theory, two safety features appear to be associated with the pliable cup in comparison with the rigid cup: lower maximal traction force and lower risk of non-tangential traction, both resulting in less risk of affecting the shape and anatomy of the fetal head. However, the potential beneficial effects of these safety mechanisms are not supported by the results of clinical studies: there is no reported evidence that neonatal morbidity with pliable cups is lower than that associated with the use of rigid cups, except for the occurrence of scalp lesions. The data provided in this thesis (Chapter 4) demonstrate that the increased rate of neonatal retinal hemorrhage typical for rigid cup vacuum extraction also applies to the pliable cup. Accepting the concept that neonatal retinal hemorrhage may serve as a sign of intradural pressure disturbances caused by changes in the shape of the fetal skull implies that vacuum extraction with the pliable cup affects the shape of the fetal skull to an extent comparable to that with the use of the rigid cup. Because of the absence of the mechanism of "squeeze" within the skull

(Chapter 2.4), neonatal retinal hemorrhage and cerebral tissue trauma may not be confounding factors. The similarity in the neonatal neurologic optimality score after rigid and pliable cup vacuum extraction (Chapter 4) therefore adds to the conclusion that the supposed safety features of the soft cup may have no clinical relevance.

There is place for the use of pliable cups in the instruction of vacuum extraction to beginning obstetricians. The pliable cups provide better sight on and insight into the process of progress of the fetal head during traction than the rigid cups. The skills needed to deliver a baby with a pliable cup may induce more gentleness in handling the more powerful metal cup and forceps, and the experience of having no possibility to correct the behavior of the pliable cup with the second hand may improve an awareness of how and why the second hand should be used during extractions with a rigid cup.

The use of the rigid cup offers a higher probability of a successful assisted delivery than the pliable cup, without evidence of long term neonatal sequelae. Because of its effective adherence to the fetal scalp, use of the rigid cup offers the practical advantage that pop-off implies the end of a trial of vaginal delivery. The cascade of repetitive cup replacements, secundary forceps application and eventual abdominal delivery is to be avoided because of the significant neonatal morbidity and mortality associated with these cases. The modest cosmetic side-effects of the soft cup in comparison with the rigid cup may lead to more liberal use of vacuum extraction in general. Such a trend should be discouraged because, even in the absence of detectable long-term consequences, the incidence of retinal hemorrhages may indicate that mechanical stress due to vacuum extraction is more pronounced than that in any other mode of delivery. Vacuum extraction is not a replacement for patience, oxytocin or episiotomy. In addition, the effects of (repetitive) cup detachments are unknown.

Choosing between a pliable cup and a rigid cup for vacuum extraction means choosing between the possibility of cosmetic injury or that of cup detachment. This dilemma is also reported in the response to the inquiry among the obstetric units in the Netherlands, in which the rigid and the pliable cups were found to be used in a ratio of 7:1 (Chapter 3). Na data are available on the use of rigid and pliable cups in other countries, so it remains unclear how much international agreement exists on the conclusion of this thesis that at present the rigid cup should be the first choice for vacuum extraction.

The obstetric forceps is often regarded as the most elegant instrument for assisted vaginal delivery, at least by obstetricians. It offers the operator the possibility to show obstetric skills, to deliver the infant quickly and to spend as little time as possible in the labor ward. The patients replying to the questionnaire reported in Chapter 5 did not notice any of these qualities of the forceps, they experienced an extraction instead of a delivery. The mothers did not appear to weigh the known effects of forceps and vacuum extractor with regard to well-being of their babies.

In general, forceps delivery appears to be more harmful to the parturient than vacuum extraction, in random use as well as after selection of forceps for low outlet deliveries (Chapter 5). Fetal distress constitutes the strongest indication for forceps delivery if vaginal delivery can be achieved, because of the possibility of quick and decisive action. But the quick formation of the artificial caput succedaneum in the Malmström dome after rapid suction (Chapter 6), and the established reduction of time that a vacuum extraction procedure takes after rapid suction (Chapter 4) make delivery by vacuum extraction competitive to that by forceps in case of fetal distress. Because of the demonstrated higher evidence of maternal trauma associated with the use of forceps, a randomized trial of forceps and vacuum extraction in cases of fetal distress seems needed and ethically justifiable.

On the basis of the evidence presented in Chapter 5, it is concluded that vacuum extraction should be the first choice for instrumental vaginal delivery, but there are cases in which there is no other way out other than skillful application of forceps. For that reason specialist training in the use of forceps remains necessary. Future research should be directed towards the elaboration of a theory of fetal cranial stress, and the development of a physical model of the fetal head to assess the effects of spontaneous, vacuum, and forceps delivery on e.g. circulatory changes, cerebrospinal fluid displacement, and bruising of the fetal brain, as a prerequisite in the search for new parameters of neonatal well-being.

# SUMMARY

**CHAPTER ONE** presents a brief description of the development of assisted vaginal delivery, in particular with regard to vacuum extraction. Questions are formulated that lead to the objectives of this thesis:

- to present a review and analysis of the scientific literature with regard to vacuum extraction, including its physical aspects;
- to assess the clinical experience with the pliable vacuum cup among Dutch obstetricians;
- to obtain by means of a randomized comparative trial data that could contribute to making a rational choice between the use of the rigid and pliable vacuum cup;
- to obtain by means of a nonrandomized comparative trial data on the consequences for mother and infant of an assisted vaginal delivery by vacuum and forceps extraction;
- to assess the development of caput succedaneum in a rigid cup with various speeds of increment of vacuum.

**CHAPTER TWO** presents a review of the literature on obstetric vacuum extraction. Malmström's metal cup marks the final introduction of obstetric vacuum extraction. The expulsive force of a woman in labor can easily be doubled by means of vacuum extraction, but it appears difficult for the obstetrician to maintain an optimal direction of traction because the point of attachment of the cup cannot be used as a point of reference. Various modifications of the Malmström cup have been developed to allow oblique traction. The vector model that would demonstrate the superiority of these modifications appears to be incomplete; correction of the position of the vacuum cup with the nonpulling hand appears to be more important than the choice of the model of the cup.

In comparison to the obstetric forceps vacuum extraction has the advantage of an absent risk of injury to the fetal facial nerve and a smaller risk of trauma of the birth canal and the anal sphincter, but the bruising of the skin of the fetal head that occurs in all cases may be regarded as a disadvantage. With vacuum extraction the fetal head is pulled out, whereas it is being pushed out when an obstetric forceps is used. The consequences for

the neonate of this fundamental difference between vacuum extraction and forceps delivery have hardly been investigated. The clinical relevance of the increased risk of neonatal retinal hemorrhage associated with vacuum extraction (50 %) compared with that of forceps delivery (25 %) is not clear. The trauma of the skin of the fetal head associated with the use of the metal vacuum cup has led to the application of soft material to construct pliable vacuum cups. Cosmetic lesions of the fetal scalp are less frequent with the use of a pliable cup than when a rigid cup is applied, which may be associated with the lesser seal of the vacuum provided by the flexible cup. Apart from the suggestion in the literature that neonatal retinal hemorrhage occurs less often with the pliable than with the rigid cup, there is no evidence of other differences between the neonatal complications of rigid and pliable vacuum cups that could determine a clinical preference.

**CHAPTER THREE** deals with the results of an inquiry into the experience with the use of pliable vacuum cups by Dutch obstetricians. The response of 90% allows to conclude that in The Netherlands at the time of the inquiry:

- the pliable cup was used in one out of eight vacuum extractions;
- the pliable cup was considered the replacement of obstetric forceps;
- the pliable cup was mainly used with the fetal head at low station;
- the pliable cup was regarded as safer for the fetus than the metal Malmström cup, but this assumption appeared not to be based on objective arguments.

Based on the results of this inquiry a randomized trial to compare the efficacy and complications of the pliable and the rigid vacuum cup was considered acceptable and desirable.

**CHAPTER FOUR** describes a randomized clinical trial to compare the clinical results and complications of vacuum extraction with a rigid Malmström cup (n=50) and a pliable Silastic cup (n=50). Failure was defined as unsuccessful delivery after two cup detachments or 30 minutes after the start of traction. The necessary group size was estimated in advance on the basis of published rates of neonatal retinal hemorrhage using pliable or rigid vacuum cups. The neonate was examined for scalp lesions, retinal hemorrhage and neurologic optimality. Cup detachments occurred more often with the pliable than with the rigid cup, but the failure rate was not significantly different. Scalp lesions occurred significantly less frequently with the pliable than with the rigid cup. The occurrence of retinal hemorrhages was equal in both groups (50-58 %) and also the results of determination of umbilical arterial pH, Apgar scores, bilirubin concentration and neurologic optimality were similar, as was the occurrence of maternal complications. We conclude that the advantage of the pliable vacuum cup is limited to a smaller risk of neonatal scalp lesions, at the expense of more frequent cup detachments.

**CHAPTER FIVE** describes a nonrandomized prospective trial to assess the clinical results and complications of vacuum extraction with a pliable or rigid cup (n=100) compared with those of forceps extraction (n=38). The station of descent of the fetal head at the time of application of the instrument was low in 24 % of cases of vacuum extraction and 71 % of forceps deliveries. Vacuum extraction failed in 7 % of cases, all forceps extractions were successful. Lesions of the anal sphincter were less frequent in association with vacuum extraction (1 %) than after forceps delivery (13 %). Retinal hemorrhage was observed in 54 % of neonates delivered with vacuum extraction and in 26 % of infants after forceps delivery ($p < 0.02$). Other variables of neonatal condition were not different between groups.

An inquiry among the mothers showed less awareness of their delivery following forceps than after vacuum extraction. The investigation confirms differences between vacuum and forceps delivery, and shows that selection of forceps for application at low station of the fetal head does not present any advantage.

**CHAPTER SIX** reports experiments to determine the time needed to completely fill a Malmström cup with caput succedaneum during slow and fast increment of vacuum. A transparant macrolon Malmström type vacuum cup with a diameter of 50 mm was used for the experiments. The classic increase in vacuum with 0.2 $kg/cm^2$ in two minute steps resulted in all cases in complete filling of the cup with caput succedaneum before an underpressure of 0.8 $kg/cm^2$ was reached; following immediate establishment of 0.8 $kg/cm^2$ complete filling of the cup was observed within one minute, also when no caput succedaneum was present before application of the instrument. The experiments showed that a waiting time of one minute at 0.8 $kg/cm^2$ vacuum was sufficient for the development of a complete caput succedaneum and for reliable attachment of a

Malmström type cup to the fetal scalp. When a 60 mm cup is used and no caput succedaneum is present before application, a waiting time of two minutes at 0.8 $kg/cm^2$ seems advisable.

**CHAPTER SEVEN** combines the conclusions reached in the previous chapters. Vacuum extraction is associated with a lower risk of maternal injury than forceps delivery, whereas there are no relevant differences between both instruments with regard to efficacy and fetal-neonatal risk. This makes the vacuum extractor the instrument of choice for instrumental vaginal delivery. Neonatal retinal hemorrhage may be a sign of the effect that vacuum extraction has on the molding of the fetal skull during delivery; these hemorrhages occur more frequently in association with vacuum extraction than after spontaneous or forceps delivery, or cesarean section. The presumed greater safety of the pliable compared with the rigid vacuum cup is not evident from a reduced risk of neonatal retinal hemorrhage. Because neonatal retinal hemorrhages have no apparent late effects, their occurrence should not influence obstetric management. On the other hand, the relatively high incidence of occurrence of such hemorrhages underlines the importance of maintaining strict indications for vacuum extraction. These considerations as well as the high success rate support the application of the metal cup with Malmström's dome as the first choice in vacuum extraction. The possibilities of manipulation of the rigid cup to obtain an optimal direction of traction should be used to guide the fetal head through the birth canal as atraumatically as possible. Rapid establishment of vacuum in a rigid cup results in reliable attachment of the cup to the fetal scalp and allows fast delivery in case of fetal distress. The use of obstetric forceps remains indispensable in a limited number of obstetric situations, and for that reason training in the use of forceps should be continued.

# SAMENVATTING

**HOOFDSTUK EEN** beschrijft in het kort de ontwikkeling van de vaginale kunstverlossing, in het bijzonder de vacuum extractie. Vragen worden geformuleerd, die leiden tot de doelstellingen van dit proefschrift:

- een overzicht en analyse bieden van de wetenschappelijke literatuur betreffende vacuum extractie met inbegrip van de fysische aspecten;
- de klinische ervaring met de flexibele vacuum cup onder de nederlandse obstetrici bepalen en analyseren;
- door middel van een gerandomiseerd vergelijkend onderzoek gegevens verkrijgen die een bijdrage kunnen leveren aan het maken van een rationele keuze tussen het gebruik van de starre en de flexibele cup;
- door middel van een niet-gerandomiseerd onderzoek gegevens verkrijgen over de gevolgen voor moeder en kind van de vaginale kunstverlossing met vacuum extractie en forceps;
- de ontwikkeling onderzoeken van het caput succedaneum in een starre cup bij verschillende snelheden van opbouw van het vacuum.

**HOOFDSTUK TWEE** geeft een overzicht van de literatuur over obstetrische vacuum extractie. De metalen cup van Malmström markeert de definitieve introductie van de verloskundige vacuum extractie. De uitdrijvende kracht van een barende kan met vacuum extractie gemakkelijk worden verdubbeld. Het is daarbij moeilijk om een optimale trekrichting aan te houden, omdat het aanhechtingspunt van de cup niet kan worden gebruikt als referentiepunt. Ten behoeve van scheve tractie zijn een aantal modificaties van de Malmström cup ontwikkeld. Het vector model dat de superioriteit van deze modificaties zou aantonen blijkt echter onvolledig te zijn; de correcties van de positie van de vacuumcup met de niet-trekkende hand blijken van groter belang te zijn dan de keuze van het model cup.

Ten opzichte van de obstetrische forceps heeft de vacuum extractor het voordeel van het ontbreken van risico op, onder andere, letsel van de N.facialis van het kind en een kleinere kans op trauma van het baringskanaal en van de M. sphincter ani van de barende, maar een nadeel is de altijd optredende kneuzing van de neonatale hoofdhuid.

Ondanks een fundamenteel verschil in benadering van het kinderlijke hoofd - bij vacuum extractie wordt de schedel naar buiten getrokken en bij een tangverlossing naar buiten geduwd - is er weinig samenhangend onderzoek verricht naar gevolgen van dit verschil voor het kind. De klinische betekenis van de verhoogde kans op neonatale netvliesbloedingen na vacuum extractie (50 %) ten opzichte van de tangverlossing (25 %) is onduidelijk.

Letsel van de hoofdhuid van de foetus bij toepassing van metalen cups leidde tot toepassing van zacht materiaal voor flexibele cups. Cosmetisch letsel van de hoofdhuid komt bij gebruik van een flexibele cup minder vaak voor dan bij een starre cup, wat lijkt samen te hangen met de minder goede afdichting van het vacuum. Behalve dat in de literatuur ook wordt gesuggereerd dat neonatale netvliesbloedingen minder vaak zouden voorkomen bij gebruik van een flexibele cup, zijn er geen verschillen tussen de neonatale complicaties met de starre en de flexibele vacuum cup die zouden kunnen leiden tot een klinische voorkeur.

**HOOFDSTUK DRIE** beschrijft de resultaten van een enquête naar de ervaring met het gebruik van de flexibele cup door gynaecologen in Nederland. De grote respons (90 %) staat toe te concluderen dat ten tijde van de enquête in Nederland:

- de flexibele cup werd gebruikt bij een van de acht vacuum extracties;
- de flexibele cup werd gezien als een vervanging van de obstetrische forceps;
- de flexibele cup voornamelijk werd toegepast bij indaling tot in de bekkenuitgang;
- de flexible cup werd beschouwd als veiliger voor het kind dan de metalen Malmström cup, zonder dat daarvoor objectieve argumenten werden aangevoerd.

Op grond van de resultaten van de enquête werd een gerandomiseerd vergelijkend onderzoek naar de doeltreffendheid en de complicaties van de flexibele en de starre cup wenselijk en toelaatbaar geacht.

**HOOFDSTUK VIER** geeft het verslag van een gerandomiseerd vergelijkend onderzoek naar de klinische resultaten en complicaties van vacuum extractie met een starre Malmström cup (n=50) en een flexibele Silastic cup (n=50). Uitblijven van geboorte na tweemaal loslaten van de cup of 30 min na het begin van de tractie werd als falen aangemerkt. De noodzakelijke groepsgrootte werd tevoren geschat op grond van het verschil in gepubliceerde percentages van neonatale netvliesbloedingen met de starre en de flexibele cup. De pasgeborene werd onderzocht op beschadiging van de hoofdhuid, op netvliesbloedingen en op neurologische optimaliteit. De flexibele cup schoot vaker af, maar de extractie faalde niet significant vaker. Letsel van de hoofdhuid van het kind kwam significant minder vaak voor na gebruik van de flexibele cup. Het voorkomen van neonatale netvliesbloedingen bleek gelijk te zijn in beide groepen (50-58 %), evenals de uitkomst van de arteriële navelstreng pH, Apgar scores, serum bilirubine en neurologische optimaliteit, en van moederlijke complicaties. De conclusie is dat het voordeel van de flexibele cup zich beperkt tot een lagere graad van cosmetisch letsel van de kinderlijke hoofdhuid, ten koste van vaker loslaten van de cup.

**HOOFDSTUK VIJF** behandelt een niet-gerandomiseerd prospectief onderzoek naar de klinische resultaten en complicaties van vacuum extractie met een flexibele of starre cup (n=100 %) en forcipale extractie (n=38 %). De indaling van het foetale hoofd bij het aanleggen van een instrument was significant verschillend, met indaling tot in de bekkenuitgang bij 24 % van de vacuum extracties en bij 71 % van de tangverlossingen. Vacuum extractie mislukte in 7 % van de gevallen, alle forcipale extracties slaagden. Laesies van de M. sphincter ani traden significant minder vaak op bij vrouwen bevallen via vacuumextractie (1 %) dan na forcipale extractie (13 %). Netvliesbloedingen werden waargenomen bij 54 % van de pasgeborenen na vacuum extractie en bij 26 % van de door middel van forcipale extractie geboren kinderen ($p < 0,02$). Andere variabelen van de neonatale toestand waren niet verschillend tussen de groepen.

Een enquête onder de moeders liet zien dat zij na een tangverlossing minder besef hadden van hun bevalling dan na een vacuum extractie. Het onderzoek bevestigt de verschillen tussen vacuum en forcipale extractie en toont aan, dat het selecteren van de forceps voor toepassing bij indaling van het foetale hoofd tot in de bekkenuitgang geen voordelen biedt.

**HOOFDSTUK ZES** beschrijft een experimenteel onderzoek naar de tijd die nodig is om een Malmström type cup geheel te vullen met caput succedaneum tijdens langzame en snelle opbouw van het vacuum. Voor het onderzoek werd een doorzichtige macrolon vacuum cup gebruikt van het type Malmström met een diameter van 50 mm. Het klassieke verhogen van de onderdruk met 0,2 kg/cm$^2$ in stappen van 2 minuten leidde steeds tot complete vulling van de cup voordat 0,8 kg/cm$^2$ onderdruk werd bereikt; na onmiddellijk aanzuigen tot 0,8 kg/cm$^2$ was de cup in alle gevallen binnen 1 minuut geheel gevuld, ook indien vooraf geen caput succedaneum bestond. Eén minuut wachten bij een onderdruk van 0,8 kg/cm$^2$ is voldoende voor de ontwikkeling van een compleet caput succedaneum en voor betrouwbare hechting van een Malmström type cup. Bij de combinatie van een 60 mm cup en afwezig caput succedaneum lijkt een wachttijd van twee minuten bij 0,8 kg/cm$^2$ wenselijk.

**HOOFDSTUK ZEVEN** verbindt de conclusies van de voorgaande hoofdstukken. Vacuum extractie heeft een lager risico op moederlijk letsel dan de tangverlossing en is, door het ontbreken van relevante verschillen tussen beide instrumenten voor wat betreft doeltreffendheid en risico voor de foetus-neonatus, de methode van eerste keus voor een vaginale kunstverlossing. Vacuum extractie heeft invloed op de vervorming van de foetale schedel tijdens de geboorte, waarvan netvliesbloedingen van de pasgeborene een symptoom kunnen zijn; de kans op het voorkomen van deze bloedingen is na vacuum extractie groter dan na spontane geboorte, na tangverlossing en na keizersnede. De veronderstelde veiligheid van de flexibele ten opzichte van de starre cup uit zich niet in een verlaagd risico op neonatale netvliesbloedingen. Door het ontbreken van late gevolgen van neonatale netvliesbloedingen dienen zij geen invloed te hebben op het verloskundige beleid. Wel zal de relatief hoge incidentie van deze bloedingen reden moeten zijn om stricte indicaties voor vacuum extractie aan te houden. Deze overwegingen en de hogere kans op succes maken gebruik van een metalen cup met een koepel volgens Malmström tot eerste keus bij vacuum extractie. De mogelijkheden van manipulatie van de metalen cup ten aanzien van optimalisering van de trekrichting dienen te worden benut om het kinderlijke hoofd zo atraumatisch mogelijk door het geboortekanaal te begeleiden. Snel aanzuigen van de metalen cup leidt tot betrouwbare hechting en maakt snelle geboorte mogelijk in geval van foetale nood. Vanwege de noodzaak tot gebruik van de obstetrische forceps in een aantal situaties blijft oefening in het gebruik van de forceps nodig.

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