Force and pressure measurement during vacuum extractions in obstetrics

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In vacuum extractions in obstetrics a tractive force is applied to the cranium of the baby using a suction device known as a suction cup. The maximum tractive force that can be applied is determined by the adhesive force due to the vacuum in the cup and by the matching fit between the instrument and the head deformation cause by the vacuum. Since breakaway of the cup from the scalp can lead to injury to the baby, the criteria for premature breakaway have been investigated. Two measuring disks fitted with strain-gage diaphragm rosettes were mounted in a suction cup for measuring the subpressure and the tractive force applied to the baby's head. The article describes the design and calibration of the measurement device and gives examples of measurement results found on a phantom and during actual delivery.

Introduction

In obstetrics a differentiation is made between normal and operative deliveries. Since Malmström developed the present shape of the suction cup as an obstetric instrument in 1954 [1,2], vacuum extraction has been used as an operative method of concluding the delivery.

With a vacuum extraction the suction cup, as shown in **Fig. 1** with its accessories, is used for transferring tensile forces to the infantile cranium. After fitting the cup to the baby's scalp a partial vacuum is produced in the cavity in the cone of the instrument with a vacuum pump. This leads to the formation of a deformation or swelling on the head. The size of the swelling corresponds to the internal volume of the suction cup cone. The force transfer due to the vacuum and the fit between the cephal haematome, i.e. head swelling, and the instrument determine the maximum possible tensile force on the infantile cranium.

Due to the tight fit this is significantly above the value given by the diameter and internal pressure of the instrument. The transferable force is substantially reduced for deviations from the axial pulling direction. Tensile forces up to 300 N (67.5 lbf) are stated in the literature [3] for instruments with a suction opening of 50 mm (2 in) and a vacuum of 200 hPa (2.9 lbf/in^2). With this order of forces the question arises of the risks to mother and child.

Whereas this can be neglected for the mother, damage to the baby may occur, such as hemorrhaging of the retina and brain or cranial fractures [4].

It is thought that the sudden breakaway of the suction cup when the maximum possible tractive force is exceeded markedly increases the risk of injury to the child due to the abrupt change in pressure in the infantile cranium. To prevent this risk no attempts have been spared [5, 6] to find a criterion indicating to the obstetrician the onset of breakaway of the suction cup, thereby giving him the option of reducing the tractive force or changing the pulling direction to prevent breakaway.

Problem definition

Within the scope of a diploma project in the Department of Precision Mechanics at the Technische Fachschule Berlin an investigation was undertaken to find out which force or which pressure reliably indicated the onset of breakaway of the suction cup during a vacuum extraction. The following mechanical quantities were measured to obtain an answer to this question:

- Totalforce: Measurement of the total tractive force independent of the angle.
- Axial force: Tractive force in the axial direction of the suction cup
- Diaphragm pressure: Pressure of the head swelling on a diaphragm attached to the suction cup.
- Partial vacuum: Measurement of the subpressure produced in the suction cup by the vacuum pump.

Whereas existing industrially manufactured transducers could be used for the measurement of the total force and the partial vacuum, the measurement of the diaphragm pressure and the subpressure in the suction cup demanded laboratory-made transducer ar-

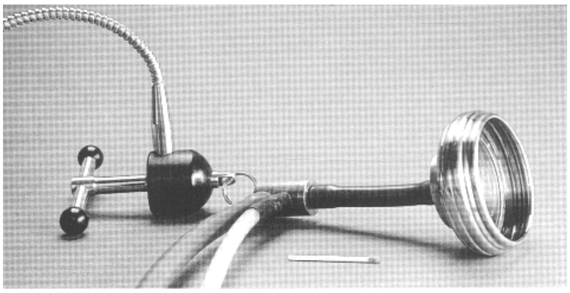

Fig. 1: Overall view of the instrument, the suction cup, which was fitted with strain gages.

rangements on which the following requirements were placed:

- Capability of being sterilized in autoclaves (26 minutes at 2.2 bar (32 lbf/in^Z) and a temperature of 134°C (273°F).
- No changes or only slight changes to existing Malmström suction cups with 60 mm (2.36 in) cone diameter.
- The axial transducer should be as insensitive as possible to transverse forces.
- The transducers must be insensitive to humidity.
- The measurement uncertainty must be lower than ± 2% of the actual value.

Construction and calibration

Figure 2 shows a section through a Malmström suction cup. A circular shaped metal plate used as the diaphragm prevents the cephal haematome penetrating the lower tube connection and blocking the vacuum. The chain passing down the vacuum tube joins the handle with the diaphragm and transfers the tractive force.

The suction cup, modified with the installation of the axial force transducer and the diaphragm for the measurement of the diaphragm pressure, is shown in the cross-section in **Fig. 3**. The deformation element for measuring the axial force was designed as shown in **Fig. 4** as a diaphragm in the shape of a pan [7]. The axial force to be measured is transferred to the diaphragm by a pin guided in a bush. The bush for radial guidance is integrated as shown in **Fig. 3** in the top of the cup. This prevents undesired transverse forces reaching the diaphragm. The connecting lead for the strain gages and the vacuum tube are passed, as can be seen also in **Fig. 5**, through the holes in the mounting area of the diaphragm pan in the interior of the suction cup. **Figure 5** is a photograph illustrating the partly disassembled suction cup, showing the transducer arrangement with the two diaphragm rosettes for the pressure and force transducers. The calculation of the diaphragm thickness for a specified maximum load was carried out according to the formula for the bending of flat plates [8]. For strength reasons, tempering steel 50CrV4 (DIN 17200) was selected as the material for the pan. Since it was not possible for design reasons to limit the deflection of the diaphragm by a mechanical stop, a maximum load of 500 N (112 lbf) (safety factor 2) was used for the calculation. This value would with certainty not be exceeded. The resulting reduced transducer sensitivity due to this overdimensioning had to be taken into consideration. A strain-gage rosette of the type HBM MK12M 15/350 mounted on the diaphragm was used for measuring the force. The use of this diaphragm rosette had benefits compared to bonding four separate strain gages, since with the rosette the four measuring grids are fixed in position and orientation to one another in a full bridge circuit. The

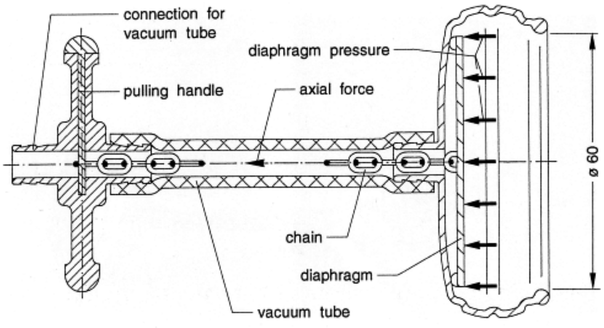

Fig. 2: Cross-section of Malmström's suction cup.

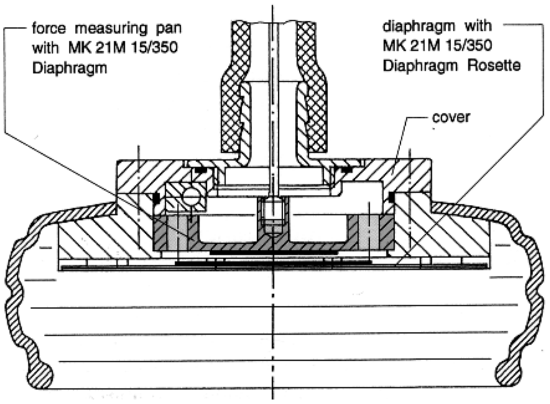

Fig. 3: Cross-section of the transducer parts fitted to the suction cup for measurement of axial force and diaphragm pressure.

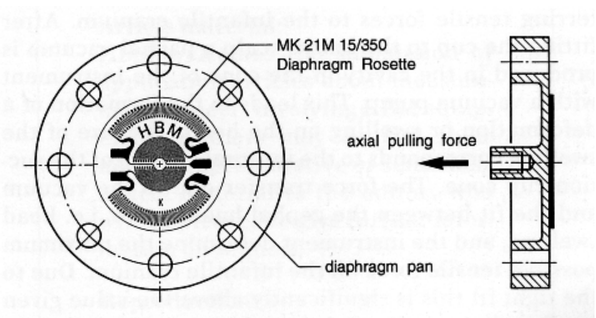

Fig. 4: Diaphragm pan with strain-gage rosette for measuring the axial force.

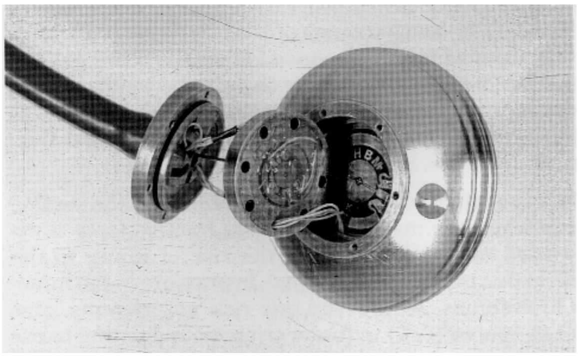

Fig. 5: View of the diaphragm rosettes of the two transducers mounted in the suction cup for measuring diaphragm pressure and axial force.

mounting of the strain-gage rosette on the diaphragm was carried out using the EP250 Hot-Curing Cement. The SG250 Transparent Silicone Rubber was applied as protection against moisture. The materials ensure that sterilization of the transducer is maintained in the autoclave.

Ort account of the restricted space available, it was also not possible to fit a diaphragm pan for measuring the diaphragm pressure. A simple diaphragm in X12-CrNi199 with a thiclcness of 0.6 mm (0.024 in) acted as a bending element. During the dimensioning a safety factor of two was also applied here for the reasons already mentioned above. The HBM type MK21K 25/350 was chosen as the strain-gage rosette. The bonding and covering of this diaphragm rosette was made with the same materials as with the axial force transducer. The clamping of the diaphragm was provided by a clamping ring and 10 screws (M 1.4 x 4) arranged at equal distances around the circumference. The hysteresis occurring due to the mechanical clamping could be neglected during the measurements.

To calibrate the diaphragm pressure transducer, the clamped diaphragm was loaded with a pressure of 0 to 0.07 MPa (10.2 lbf/in^2). The relationship between the pressure and the output signal from the strain-gage bridge circuit is mainly linear and it remains within the limit specified for the measurement uncertainty. The calibration of the axial force transducer was carried out using weights up to a maximum force of 250 N (56 lbf). With this transducer a significantly improved linearity compared to the diaphragm pressure transducer was found due to the pan shape of the bending element.

In order to ensure the safety of the patient the two transducers were connected to electrically isolated signal processing modules. The direct voltage for exciting the strain-gage bridge circuits was 10 V For the first time in the Perinatal Medical Unit a computer controlled measurement acquisition system was used for evaluating the measurement signals. The multi-channel strip recorder, which with other measurement projects always led to acceptance problems in the delivery room due to its size, was no longer needed. The program package DIA/DAGO-PC from GfS, Aachen was employed as the software.

Measurement results

Measurements on the phantom

In order not to put the unborn child at risk, the breakaway of the suction cup during vacuum extraction was to be prevented. Since this breakaway is a relatively seldom occurrence in practice, the low case-figures do not enable any conclusions about possible warning criteria to be formed. To be able to carry out objective breakaway tests, measurements on a phantom were carried out. Fatty pig's belly with dimensions (150 mm x 250 mm x 35 mm [6 x 9.8 x 1.4 in]) was fastened to a board with screws and used for tests as it has properties similar to the infantile scalp.

During the breakaway tests on the pig's belly the procedure adopted was the same as with normal vacuum extractions. After the suction cup had been placed on the pig's belly the vacuum pump was started and the vacuum increased slowly so that the "head swelling" could form. After a short dwell period at 450 hPa (6.5 lbf/in^2), the pressure was reduced to the minimum possible value. **Figure 6** shows this trace of pressure against time.

In synchronism with the reduction of the internal pressure, the pressure of the "head swelling" on the diaphragm increases and this is represented in **Fig. 6** with the Curve c. After 60 s it reaches the value of 300 hPa (4.3 lbf/in^2).

As Curve b in **Fig. 6** shows, after about 60 s the suction cup was pulled in the axial direction six times, one after the other. The tractive force was increased alter each two pulls. All the pulls resulted in a temporary reduction of the diaphragm pressure, as Curve c indicates. It can be seen that each application of the tractive force leads to a reduction in the diaphragm pressure and therefore to a reduction in the adhesion of the suction cup. Between the first four pulls the diaphragm pressure increases slightly up to its maximum value. A further increase in the axial tractive force (C) leads to the diaphragm pressure passing through zero. After relief of the pressure it increases again to its maximum value. A further increase in the axial tractive force (D) up to the breakaway of the suction cup at a tractive force of 162 N (36.5lbf) again shows the diaphragm pressure passing through zero. This is characteristic of all the breakaway tests on the pig's belly. The tractive force which leads to the breakaway of the suction cup is significantly lower on the pig's belly than

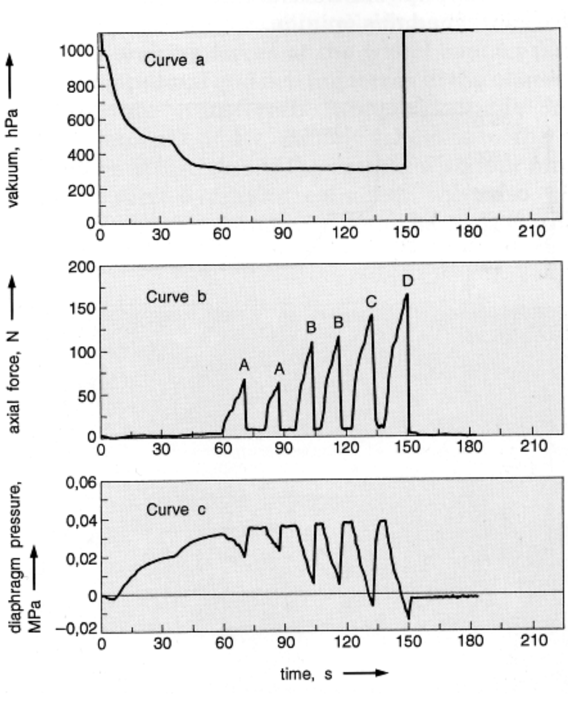

Fig. 6: Results of measurements on the phantom:
a) trace of the subpressure in the suction cup
b) axial tractive force transferred to the suction cup
c) trace of the pressure loading on the diaphragm

for vacuum extractions with babies. If the "head swelling" on the pig's belly is viewed after the brealcaway of the suction cup, then the reduced force can be explained. It is caused by the behavior of the tissue through which blood no longer flows. The "head swelling" rises in a cylinder shape to the diaphragm and molding to the beaded edge of the suction cup does not take place. This expiains the reduced adhesive force of the suction cup.

Whereas no conclusions about the onset of suction cup breakaway can be formed from the Curves a and b in Fig. 6, the diaphragm pressure in Curve c indicates the onset of release of the suction cup by passing through zero. This zero crossing occurred with all the pulling tests on pig's belly when the tractive force was about 80% of the force at breakaway; it would appear therefore to be suitable as a criterion for the onset of the suction cup breakaway. Of course, there is the question of an explanation for this zero crossover. Tests in which film was inserted between the pig's belly and the diaphragm showed that the adhesion forces are not the cause of this effect. It could be that during the release of the "head swelling" from the diaphragm the forces no longer hold over an area, but just at a ring or point shape at the edges. Tests showed that the clamped diaphragm with point-shaped loading at two diametrically opposed points in the vicinity of the edge produced similar behavior.

Malmström [1, 2] suggested that during the introduction of vacuum extraction the subpressure in the suction cup should only be increased in steps so that the "head swelling" can form slowly and the suction cup holding force is at a maximum. Svenningsen [3] found no measurable relationship between the holding force of the suction cup and the speed with which the vacuum built up. The measurements on the pig's belly have confirmed this opinion.

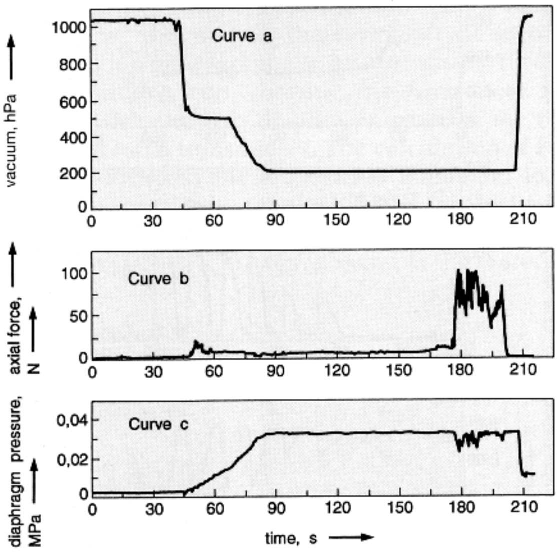

Fig. 7: Results of measurements on the infantile cranium during delivery:
a) trace of the subpressure in the suction cup
b} axial tractive force transferred to the suction cup
c) trace of the pressure loading on the diaphragm

Measurement during delivery

The forces and pressures occurring during a light vacuum extraction from the center of the pelvic cavity are shown in **Fig. 7**; similar curve traces are produced as those obtained with the measurements on the phantom shown in **Fig. 6**.

Since it is thought that not only the magnitude of the applied tractive force, but also its duration could be significant with regard to damage to the baby, the overall tractive force-time integral was computed as a further quantity and displayed on the monitor.

With the measurements in the delivery room no breakaway of the suction cup has occurred to date. Confirmation of whether a zero crossing of the diaphragm pressure also occurs *in vivo* before breakaway is still awaited.

The measurements on the phantom and *in vivo* show that strain-gage techniques can be successfully applied even by beginners to this field, as were the authors at the beginning of the project.

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