A Softer Touch

Local attorney invents device to cut injuries during birth process

By ELLYN TONEY
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During the 16 years Gary Alexander practiced law in Baton Rouge, he devoted much of his expertise to working for parents of infants injured during birth. "I've seen a lot of force injuries," says Alexander.

Alexander's Sofceps is a medical device that may change the way assisted births are performed. The device's registered trade name is Sofceps. There haven't been a new delivery device in decades, says Dr. Kenneth J. Moise, director of fetal-neonatal medicine at the Baylor College of Medicine in Houston. Moise is directing clinical tests of the device Alexander has invented.

Sofceps is created because, Alexander says, he was "angry with forceps."

Alexander had learned a lot about obstetrics medicine through his work as a plaintiff's attorney. He saw the rare but terrible cases in which an infant was "totally neurologically compromised" by the use of forceps. "They can't roll over; they can't feed themselves. Many times they're blind. They may have been perfectly healthy in the womb," he said.

The doctor is devastated. The parents are devastated. The child doesn't have a life—it needs around-the-clock care," says Alexander. "There's an emotional cost involved for everyone."

Invariably, you have litigation," he says. The doctor suffers professional annihilation. Nobody comes out a winner. It's pretty personal when you handle these cases.

The inspiration for Sofceps occurred one night in 1990 when Alexander was at home, reviewing a case involving the use of forceps during delivery. At about 2 a.m., Alexander took a break from...
Sofcops works along the same principal as the toy known as Chinese handcuffs or Chinese finger locks, shown above, by spreading pressure evenly throughout the device.

Advocate staff photo by Michael Hults

Sofcops position themselves to raise more capital in the future. Medisys went public through a share exchange with a business public company based in Utah.

Medisys stock is now traded over the counter under the letters SCFC (for Sofcops).

The company has more than 200 shareholders in 28 states and two foreign countries, says Sutherland.

Since Medisys went public, the company has raised about $12 million, Sutherland says.

Much of that has been spent on designing Sofcops.

The device is hand-fabricated in a laboratory in Clearwater, Fla., by a medical engineer and a lab technician who work for Medisys. Sofcops has been through 100 modifications.

The first one looks very different from this," says Alexander, handling the present Sofcops, which looks like a stocking cap made of specialized braided fabrics.

Sofcops is made to be fitted over the infant's head, by the use of special bands, while the baby is in the birth canal. It's designed to apply uniform circumferential pressure on the infant's skull as the doctor helps deliver the baby by gently pulling on the handle at the end of the Sofcops.

"I think the device has very positive advantages, and I'm pretty excited about working on it," says Moise, with the Baylor College of Medicine.

For the 25 percent of births that require assistance, physicians can now turn to only two devices.

They are forces, which were first invented in the 1800s and haven't been significantly altered in the last 100 years, and the vacuum extractor, which was introduced in the 1950s.

The vacuum extractor exerts force on the head of the infant through a suction cup and resembles a small plumber's helper.

Both devices have disadvantages.

The forces, says Moise, "require some significant expertise," since the obstetrician must know exactly how the baby's head is oriented in the birth canal before applying the forces.

Injuries from forces can include skull fractures, lacerations to the eyes, and neurological damage. It can even lead to lower IQs in children, depending on how the forces were applied, according to a report cited by Williams Obstetrics, the "bible" of obstetrics, as Alexander calls it.

"Obviously, not having steel around a baby's head," is one advantage that Sofcops has over forces, says Moise.

The other alternative available to obstetricians, the vacuum extractor, fits only on the top of the infant's head and pulls on the scalp. It's been associated with bleeding under the scalp, says Moise.

Again, according to Williams Obstetrics, "in spite of early enthusiasm, the instrument in the United States, the vacuum extractor is not used extensively now, partly because of reports of fetal damage... and death of infants."

The advantages of the Sofcops, then, says Moise, are that it's soft and it applies even pressure over a larger surface than the other alternatives.

Also, the physician doesn't have to know the orientation of the baby's head in the birth canal, before the device is applied.

That last advantage has gained key significance in light of the health care plan proposed by President Clinton, says Moise.

The plan calls for more deliveries to be made by family practitioners and nurse midwives.

These practitioners are likely to be "less trained in the use of forces," says Moise, "than obstetricians, Moise says.

As far as cost, Sofcops will be more expensive than either the forces or the vacuum extractor. The Sofcops device is used only once, at one birth, and then is thrown away.

Steel forceps can be sterilized and used repeatedly. While the suction cup part of the vacuum extractor is disposable, part of the device can be reused.

"The pricing (of Sofcops) is going to be something to be determined," says Sutherland.

He estimates that initially a Sofcops device could cost $300 to $400, although it could "be much lower than that.

"You can't just say 'Oh, the forces are disposable and cost X amount, and this is disposable and costs X amount, and then the effect goes far beyond that. It's not a simple comparison," Sutherland says.

Baylor is directing human clinical testing of Sofcops during delivery at two Houston hospitals, Ben Taub Hospital and St. Luke's Episcopal Hospital.

There is an element of tragedy in this early testing. The Sofcops device is being tested first in the delivery of a child that is known to have died "in utero" and will stillborn.

The women in these cases have agreed to be involved in the Sofcops clinical testing.

"Since the device has never been placed on a live baby, it would only be ethical to study this on a fetal demise," says Moise.

"We are very sympathetic to the fact that they've lost a baby," says Moise.

After sufficient testing during this phase, Sofcops will be used to assist live births. These infants will be "very carefully followed" for 18 months for any signs of impairment.