



EDITORIAL

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Editor-in-Chief

How John Edwards changed case law and multiplied liability

Rapidly increasing practice costs plus stagnant or decreasing revenues continue to plague Ob/Gyns. Professional liability insurance is the fastest-growing of these costs—thanks largely to the trend toward multimillion dollar payments in personal injury cases.

John Edwards, the Democratic Vice-Presidential candidate, is one of the most successful personal injury attorneys in North Carolina history. In his recent book *Four Trials*, Edwards recounts his success in cases where the plaintiffs suffered greatly.

What he fails to recognize, however, are the major negative effects large jury awards may have on medical care. With this unbalanced view of how runaway juries impact the medical profession, Edwards fails in his duty as a potential Vice President to be a moderate voice on complex social issues.

Case snapshot. Following is a description of *Jennifer Campbell v Pitt County Memorial Hospital*, from Edwards' book:

In 1979, an Ob/Gyn performed an elective vaginal delivery of a footling breech fetus following a 7-hour labor. The child had Apgar scores of 1 at 5 minutes and 2 at 10 minutes, developed seizures in the neonatal nursery, and suffers cerebral palsy.

At trial in 1985, the plaintiff's experts stated that in 1979 elective vaginal delivery of a footling breech was not the standard of care. Further, they maintained fetal heart rate tracings clearly indicated the fetus was suffering low oxygenation.

The defendant physician settled prior to trial for \$1.5 million. Trial proceeded with the hospital as the sole defendant.

A new direction for personal injury suits. In 1985 it was not customary for plaintiff attorneys to aggressively pursue the hospital, nurses, or anesthesiologists for medical decisions made by attending physicians. Edwards' approach represented a novel change in litigation practices.

The hospital was charged on 3 counts:

- **Employing nurses that acted negligently.** Edwards claimed *the labor nurses had a professional duty to challenge the physician's plan* to pursue elective vaginal delivery, and to challenge the doctor's conservative response to nonreassuring fetal heart rate tracings with their nursing supervisor.
- **Failing to ensure the informed consent for a vaginal breech delivery.** Edwards argued *the hospital should have ensured the parents understood the benefits and risks of the procedure.* Here, the consent form for vaginal delivery was signed about 80 minutes after delivery.
- **Committing corporate negligence that directly related to the plaintiff's injury.** Edwards' claimed *the hospital had the obligation to closely oversee the attending physician's medical decisions.*

The verdict. The jury returned a "not guilty" decision for the first charge, but awarded plaintiffs \$6.5 million (later reduced to \$4.3 million) for the remaining two.

Long-term consequences. During his career, authorities estimate Edwards won over 30 medical liability judgments of \$1 million or greater.¹ Edwards claims he's proud of his success, and notes that his lawsuits fueled improvements in hospital procedures. For instance, his victories in North Carolina

Edwards' tactic of suing the hospital for a doctor's decisions was a novel change.

caused hospital boards to ratify polices giving nurses, physicians, and other clinicians a clear chain of command to report disagreements regarding patient care.

The trial noted previously, meanwhile, evolved case law on informed consent by indicating a hospital can share responsibility for ensuring patients understand a procedure's benefits and risks. This responsibility had long resided with attending physicians.

A major deficiency of Edwards' book is that he does not discuss:

- the adverse impact large jury awards may have on the cost of medical care,
- the consequences of introducing costly defensive medical practices, or
- the chilling effect potential liability may have on the stability of obstetrics, neurosurgery, and orthopedics as professions.

Of great concern is the response to this book by some senior Senators—who will be key voters in determining if professional liability reform ever passes the Senate.

Massachusetts Senator Edward M.

Kennedy, for example, stated, that those who read *Four Trials* will “instantly understand why lawyers are so indispensable to the ‘little guy’ and so hated by those in corporate America who are held accountable.”

I disagree with Senator Kennedy. After reading *Four Trials*, I was impressed by the growing negative impact personal injury lawsuits have on our entire economic system, and the vast liability that exists with all services and products offered to Americans. Medical liability suits increase medical costs and do little to improve care.

If every adverse event in American life is cause for litigation, we risk a meltdown of our entire medical and economic system.



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REFERENCE

1. Edwards' malpractice suits leave bitter taste. *Washington Times*. August 16, 2004; Article ID 200408161259500020.

DERMABOND*

Topical Skin Adhesive
(2-Octyl Cyanoacrylate)

INDICATIONS

DERMABOND and high viscosity DERMABOND Topical Skin Adhesive are intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. DERMABOND and high viscosity DERMABOND adhesive may be used in conjunction with, but not in place of, deep dermal sutures.

CONTRAINDICATIONS

- Do not use on any wound with evidence of active infection, gangrene, or wounds of decubitus etiology.
- Do not use on mucosal surfaces or across mucocutaneous junctions (e.g., oral cavity, lips), or on skin which may be regularly exposed to body fluids or with dense natural hair (e.g., scalp).
- Do not use on patients with a known hypersensitivity to cyanoacrylate or formaldehyde.

WARNINGS

- DERMABOND and high viscosity DERMABOND adhesive is a fast setting adhesive capable of adhering to most body tissue and many other materials, such as latex gloves and stainless steel. Inadvertent contact with any body tissue, and any surfaces or equipment that are not disposable or that cannot be readily cleaned with a solvent such as acetone should be avoided.
- Polymerization of DERMABOND and high viscosity DERMABOND adhesive may be accelerated by water or fluids containing alcohol. DERMABOND and high viscosity DERMABOND adhesive should not be applied to wet wounds.
- DERMABOND and high viscosity DERMABOND adhesive should not be applied to the eye. If contact with the eye occurs, flush the eye copiously with saline or water. If residual adhesive remains, apply topical ophthalmic ointment to help loosen the bond and contact an ophthalmologist.
- When closing facial wounds near the eye with DERMABOND and high viscosity DERMABOND adhesive, position the patient so that any run-off of adhesive is away from the eye. The eye should be closed and protected with gauze. Prophylactic placement of petroleum jelly around the eye, to act as a mechanical barrier or dam, can be effective in preventing inadvertent flow of adhesive into the eye. DERMABOND and high viscosity DERMABOND adhesive will not adhere to skin pre-coated with petroleum jelly. Therefore, avoid using petroleum jelly on any skin area where DERMABOND and high viscosity DERMABOND adhesive is intended to adhere. Use of DERMABOND adhesive near the eye has inadvertently caused some patient's eyelids to be sealed shut. In some of these cases, general anesthesia and surgical removal has been required to open the eyelid.
- DERMABOND and high viscosity DERMABOND adhesive should not be used below the skin because the polymerized material is not absorbed by tissue and can elicit a foreign body reaction.
- DERMABOND and high viscosity DERMABOND adhesive should not be used in high skin tension areas or across areas of increased skin tension, such as knuckles, elbows, or knees, unless the joint will be immobilized during the skin healing period.
- DERMABOND and high viscosity DERMABOND adhesive treated wounds should be monitored for signs of infection. Wounds with signs of infection, such as erythema, edema, warmth, pain and pus, should be evaluated and treated according to standard practice for infection.
- DERMABOND and high viscosity DERMABOND adhesive should not be used on wound sites that will be subjected to repeated or prolonged moisture or friction.
- DERMABOND and high viscosity DERMABOND adhesive should only be used after wounds have been cleaned, debrided and are otherwise closed in accordance with standard surgical practice. Local anesthetic should be used when necessary to assure adequate cleansing and debridement.
- Excessive pressure of the applicator tip against wound edges or surrounding skin can force the wound edges apart and allow adhesive into the wound. Adhesive within the wound could delay wound healing and/or result in adverse cosmetic outcome. Therefore, DERMABOND and high viscosity DERMABOND adhesive should be applied with a very light brushing motion of the applicator tip over easily approximated wound edges.
- DERMABOND and high viscosity DERMABOND adhesive polymerizes through an exothermic reaction in which a small amount of heat is released. With the proper technique of applying DERMABOND and high viscosity DERMABOND adhesive in multiple thin layers (at least three) onto a dry wound and allowing time for polymerization between applications, heat is released slowly and the sensation of heat or pain experienced by the patient is minimized. However, if DERMABOND and high viscosity DERMABOND adhesive is applied so that large droplets of liquid are allowed to remain unspread, the patient may experience a sensation of heat or discomfort.
- DERMABOND and high viscosity DERMABOND adhesive is packaged for single patient use. Discard remaining opened material after each wound closure procedure.
- Do not resterilize DERMABOND and high viscosity DERMABOND adhesive.
- Do not place DERMABOND and high viscosity DERMABOND adhesive in a procedure pack/tray that is to be sterilized prior to use. Exposure of DERMABOND and high viscosity DERMABOND adhesive, after its final manufacture, to excessive heat (as in autoclaves or ethylene oxide sterilization) or radiation (such as gamma or electron beam), is known to increase its viscosity and may render the product unusable.

PRECAUTIONS

- High viscosity DERMABOND adhesive has not been evaluated for use on wounds such as surgical incisions, punctures from minimally invasive surgery.
- Do not apply liquid or ointment medications or other substances to the wound after closure with DERMABOND or high viscosity DERMABOND adhesive, as these substances can weaken the polymerized film and allow for wound dehiscence. DERMABOND and high viscosity DERMABOND adhesive permeability by topical medications has not been studied.
- DERMABOND and high viscosity DERMABOND adhesive permeability by fluids is not known and has not been studied.
- DERMABOND adhesive is a free flowing liquid slightly more viscous than water. High viscosity DERMABOND adhesive, as a liquid, is syringe-like in viscosity. To prevent inadvertent flow of liquid DERMABOND and high viscosity DERMABOND adhesive to unintended areas: (1) the wound should be held in a horizontal position, with DERMABOND or high viscosity DERMABOND adhesive applied from above, and (2) DERMABOND or high viscosity DERMABOND adhesive should be applied in multiple (at least 3), thin layers rather than in a few large droplets.
- Hold applicator away from yourself and the patient and break ampule close to its center one time only. Do not crush the contents of the applicator tube repeatedly as further manipulation of the applicator may cause glass shard penetration of the outer tube.

High Viscosity

DERMABOND*

Topical Skin Adhesive
(2-Octyl Cyanoacrylate)

- DERMABOND or high viscosity DERMABOND adhesive should be used immediately after crushing the glass ampule as the liquid adhesive will not flow freely from the applicator tip after a few minutes.
- If unintended bonding of intact skin occurs, peel, but do not pull the skin apart. Petroleum jelly or acetone may help loosen the bond. Other agents such as water, saline, Betadine® Antibiotics, HIBICLENS® (chlorhexidine gluconate), or soap, are not expected to immediately loosen the bond.
- Safety and effectiveness of DERMABOND and high viscosity DERMABOND adhesive on wounds of patients with peripheral vascular disease, insulin dependent diabetes mellitus, blood clotting disorders, personal or family history of keloid formation or hypertrophy, or burst stellate lacerations, have not been studied.
- Safety and effectiveness of DERMABOND and high viscosity DERMABOND adhesive on the following wounds have not been studied: animal or human bites, puncture or stab wounds.
- Safety and effectiveness on wounds that have been treated with DERMABOND and high viscosity DERMABOND adhesive and then exposed for prolonged periods to direct sunlight or tanning lamps have not been studied.
- Safety and effectiveness of DERMABOND and high viscosity DERMABOND adhesive on wounds in vermilion surfaces has not been studied.

ADVERSE REACTIONS

Adverse reactions encountered during the clinical study for closure of trauma-induced lacerations using high viscosity DERMABOND adhesive and the clinical study comparing low viscosity DERMABOND adhesive to sutures, staples, and adhesive strips are listed below:

The safety of both high viscosity DERMABOND adhesive and the low viscosity DERMABOND adhesive control was measured in a randomized clinical study of 84 patients. 42 patients receiving high viscosity product and 42 receiving low viscosity product, by 1) the presence or the extent of an inflammatory reaction, 2) the presence of signs of clinical infection, 3) cosmetic outcome at Day 30, 4) assessment of thermal discomfort, and 5) the reported adverse events associated with use of the device. No significant differences between the two treatment groups were observed for any of these safety outcome measures, although 17 patients (44%) randomized to the high viscosity DERMABOND adhesive treatment group experienced a sensation of heat during application of the skin adhesive compared to 10 patients (26%) randomized to the low viscosity DERMABOND adhesive treatment group. Of those 17 patients in the high viscosity group, 5 of the patients noted that sensation of heat was uncomfortable. None of the patients in the low viscosity group observed objectionable sensation of heat.

As indicated under WARNINGS, high viscosity DERMABOND adhesive polymerizes through an exothermic reaction in which heat is released. It is important to use the proper technique of applying high viscosity DERMABOND adhesive in thin layers to minimize the risk that the patient may experience a sensation of heat or discomfort. This is especially important in the application of high viscosity DERMABOND adhesive, because the increased viscosity of the product relative to low viscosity DERMABOND adhesive can create a thicker applied layer resulting in a higher potential for heat to be generated. High viscosity DERMABOND adhesive should always be applied in thin layers so that large amounts of liquid are not allowed to collect, resulting in thermal discomfort for the patient.

Adverse reactions encountered during clinical study comparing low viscosity DERMABOND adhesive to sutures, staples, and adhesive strips are listed in the table below.

Clinical Study Outcomes	No Subcuticular Sutures		With Subcuticular Sutures	
	DERMABOND N (%)	Control N (%)	DERMABOND N (%)	Control N (%)
Adverse Reactions				
Suspected Infection*	8 (3.6%)	2 (0.9%)	6 (3.6%)	2 (1.2%)
Wound type				
# Lacerations	8	2	1	0
# Incisions	0	0	5	2
Dehiscence with Need for Retreatment	6 (2.5%)	5 (2.1%)	3 (1.8%)	0
Erythema	26 (11.5%)	74 (33.0%)	52 (31.3%)	75 (45.1%)
Edema	22 (9.7%)	28 (12.5%)	62 (37.3%)	71 (42.8%)
Pain	14 (6.1%)	13 (5.8%)	56 (33.7%)	57 (34.3%)
Warmth	3 (1.3%)	6 (2.6%)	3 (1.8%)	4 (2.4%)

*In the clinical study, presence of infection was to be identified by observation of redness more than 3-5 mm from the repaired wound, swelling, purulent discharge, pain, increased skin temperature, fever, or other systemic signs of infection. (See clinical study.) Confirmatory culture was not routinely obtained. Among cases of suspected infection for low viscosity DERMABOND adhesive, 7/14 (50%) were in patients less than 12 years old with traumatic lacerations; overall, 8 of the 14 (approximately 60%) low viscosity DERMABOND adhesive wounds with suspected infections were associated with sub-optimal cosmetic outcome.

- Reactions may occur in patients who are hypersensitive to cyanoacrylate or formaldehyde. See CONTRAINDICATIONS.
- The polymerization of DERMABOND adhesive on the skin releases small amounts of heat which may cause a sensation of heat or discomfort in some patients.
- Adverse reactions may be experienced following DERMABOND and high viscosity DERMABOND adhesive contact with the eye.

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