



EDITORIAL

BY ROBERT L. BARBIERE, MD

■ Editor-in-Chief



It's time to target a new cesarean delivery rate

For many decades, we sought to minimize the number of cesarean deliveries, attempting to deliver vaginally as many patients as possible. In medical staff rooms and labor and delivery suites around the country, obstetricians boasted to colleagues that the cesarean rate in their practice was 10%. This approach was founded on the idea that cesarean delivery was more dangerous than vaginal birth for both mother and newborn, and its benefits relatively limited.

A total cesarean section delivery rate in the range of 30% is appropriate and clinically justified, cumulative experience now suggests.

In 1990, the US Public Health Service proposed that a total cesarean delivery rate of 15% could be achieved within 10 years.¹ Since then, however, numerous advances in the clinical science of obstetrics have expanded the indications for cesarean section. Our current cesarean rate is 26.1%.²

New findings support higher rate

Cumulative clinical experience now suggests that a total cesarean section rate in the range of 30% is appropriate and clinically justified.

- Recent advances demonstrate that cesarean is superior to vaginal delivery for most women with a breech-presenting fetus.

- For most women with arrest of labor in the second stage or a prolonged second stage, substantial observational evidence indicates that cesarean is more often preferable to midforceps delivery.
- Additional findings suggest that for many women, repeat cesarean may be preferable to the risks of planned vaginal birth.

Research is underway that may add further indications. For example, a clinical trial is assessing the benefits of planned cesarean versus vaginal delivery for twin gestation.

A most interesting clinical trial would be one that examines the relative benefits and risks of planned vaginal delivery versus cesarean delivery for women with a low-risk, vertex, singleton gestation at term.

Changing views for a changing population

Shifts in patient characteristics and in patient and physician preferences have also pushed the cesarean rate higher:

- The proportion of births among nulliparous women and older patients is higher than ever; both groups have a higher cesarean rate.
- Patient-choice elective cesarean delivery is increasingly recognized as ethical and reasonable for women who fully understand the benefits and risks.

Finally, liability risks associated with abnormal labor, such as the setting of a nonreassuring fetal heart rate tracing, contribute to a re-evaluation of the target rate.

CONTINUED

Given today's understanding of obstetrical science and patient and physician preferences, the historical goal of 15% appears inappropriate. A rate in the range of 30% is more likely to balance the relative benefits and risks to mother and fetus.

If a credentialed clinician and an informed patient both believe a cesarean section is best, then it is clearly indicated.



obg@dowdenhealth.com

REFERENCES

1. US Dept of Health and Human Services, Public Health Services. *Healthy People 2000. National health promotions and disease prevention objectives*. Washington, DC: US Dept of Health and Human Services; 1990. PHS Publication Number 91-50212.
2. National Center for Health Statistics. *Births—Method of delivery*. Available at: <http://www.cdc.gov/nchs/fastats/delivery.htm>. Accessed July 29, 2004.

Watch for UPDATE ON PELVIC FLOOR SURGERY

By Neeraj Kohli, MD, MBA
 Director, Division of Urogynecology
 Brigham and Women's Hospital
 Assistant Professor
 Harvard Medical School

Coming in October

Watch for future UPDATES

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|----------|----------------------|
| November | Osteoporosis |
| December | Urinary incontinence |
| January | Prenatal counseling |
| February | Fertility |

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 rack/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 syrup-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 stilette 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 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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