

TUMMY SHIELD

by Greg Durocher CEO of Safe Ride 4 Kids

Objective

First, to bring awareness to an existing risk that should concern every pregnant woman and her family
“Automobile crashes are the largest single cause of death for pregnant females (Attico et al., 1986) and the leading cause of traumatic **fetal injury mortality** in the United States (Weiss, 2002). **Each year, 160 pregnant women are killed in motor-vehicle crashes and an additional 800 to 3200 fetuses are killed when the mother survives (Klinich et al., 1999b) in the U.S.**” (Duma et al, 2004)

Second, to offer a solution that can save lives of potentially hundreds of fetuses every year.

Introduction

As a firefighter of 18 years and paramedic of more than 12 years, I have an intimate understanding of the massive amounts of energy that need to be managed in a car crash and how the human body is affected by the forces involved. As a Safe Kids Certified Child Passenger Safety Technician Instructor of almost 15 years, I have a deep appreciation for the role that prevention, in the form of appropriate use of child restraints, plays in increasing the safety and survivability of motor vehicle crashes for our children.

Most people do not realize the Federal Motor Vehicle Safety Standards, regulating the design and effectiveness of current seat belt systems in cars, do not address the pregnant occupant in any way. We all believe that every aspect of our vehicle is maximized for our safety but the sad truth is that not all variables are addressed. Some times it is up to us to protect ourselves.

Another commonly unknown fact is that there are not any Federal Safety Standards to test the effectiveness or safety of other “seat belt positioning” products for pregnant women found on the market today. Products like the Tummy Shield are by definition “unregulated products” because of the absence of a safety standard to test them to. This leaves manufacturers to perform and document their own due diligence testing in an effort to demonstrate the effectiveness and safety of their “unregulated” products.

As a consumer or as an educator, it is important to realize that “unregulated” does not necessarily equal “unsafe”.

Some Perspective

Before we go into the statistics of the frequency of injury or fatality to moms and babies (fetuses) from car crashes, lets look at some other relevant statistics.

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- **Hot Car Deaths:** Average 38 per year and a total of over 600 since 1990. (<http://www.KidsandCars.org>)
- **Car crash:** For children ages 1-4 in 2012, there were 405 fatalities. This averages to about 100 children per year in each age of the 4 year age span covered (<http://www-nrd.nhtsa.dot.gov/Pubs/812032.pdf>)
- **Fire:** For children ages 0-4 in 2007 there were 275 fatalities. This averages to about 55 children per year in each age of the 5 year age span covered. (<https://www.usfa.fema.gov/downloads/pdf/statistics/v11i9.pdf>)
- **Drowning:** For children 1-4 in 2011 there were 401 fatalities. This averages to about 100 children per year in each age of the 4 year age span covered. (http://www.cdc.gov/injury/wisqars/pdf/leading_causes_of_death_by_age_group_2011-a.pdf and <http://www.cdc.gov/homeandrecreationalafety/water-safety/waterinjuries-factsheet.html>)
- **New Testing Requirements:** Did you know that the USA FMVSS 213 Crash testing requirements have never included a side-impact testing requirement? This year, 2014, that could change, impacting all car seat manufacturers who make car seats for children up to 40 pounds. How many lives does NHTSA expect to be saved by this sweeping legislation? 5 deaths and 65 severe injuries per year may be prevented.

As a society we rightly put vast amounts of attention, energy, money and focus on preventing these common causes of injury and fatality to our children. Coming from a career in fire and emergency response services, I am a firm believer that we MUST focus on prevention to have the most meaningful impact on these statistics.

Even more importantly, we have to remember these are not just numbers. They represent real families, real children going through real suffering.

By the time someone calls 911, the emergency has already occurred. As 911 responders we are simply there to stop the damage from getting worse and do whatever we can to create the most positive outcome possible from that point forward. In the case of a fatality there is simply nothing we can do for the victim. I believe “active prevention is almost always the most effective method of avoiding injury, illness and death in our child population.”

The Problem at Hand

Remember, pregnancy spans only a 9 month time period.

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The real number and extent of fetal fatalities will likely never be known for several reasons:

- Lost pregnancies before 20 weeks gestation are exempt from reporting requirements.
- There is a general lack of standard, consistent or uniform reporting and coding mechanisms for documenting fetal outcome post traumatic injury of the mother.
- There also is the reality that a miscarried pregnancy may never be associated to injuries sustained during a motor vehicle incident that occurred days, weeks or months prior.

Once I was introduced to the Tummy Shield, I started to look even more deeply into this huge problem and the injury mechanisms that occur in a crash or even a sudden breaking scenario. What I discovered is:

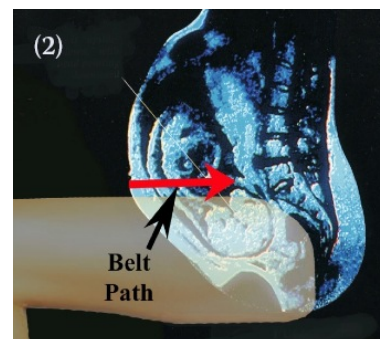
1. There is a lot of room for improvement in the education of pregnant women on the importance of wearing their seat belts — even as uncomfortable as it may become. It would be optimal for this education to happen as part of their routine prenatal care.

“These risk curves indicate that an 84% reduction in risk of adverse fetal outcome is obtained by properly wearing a seatbelt.” (Klinich et al, 2008)

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- When the seat belt is worn, it must be positioned properly to have the best outcome.

These images show the NHTSA recommended placement of the seatbelt on the pregnant woman (1) and (2) a diagram of where the belt would lay in relation to the growing baby. (Hofferbrth, 2013)



- Even when these two steps are taken, there is still a large number of injuries and lost pregnancies to be addressed.

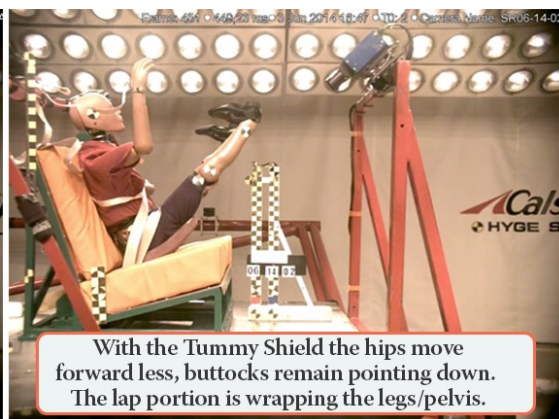
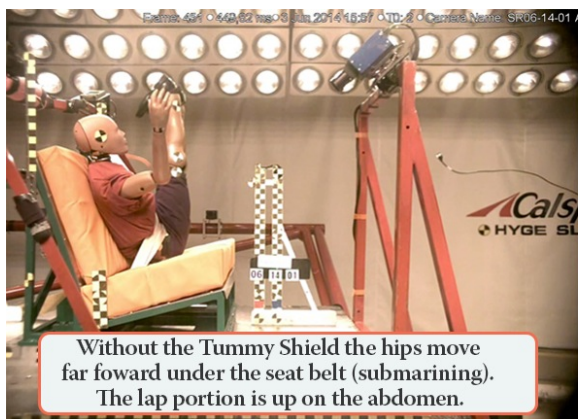
"Of 41 properly restrained pregnant occupants, 12 (29%) experienced adverse fetal outcomes." (Klinich et al, 2008)

What this means is, even though proper restraint use significantly improves the odds of a positive outcome, there is still an almost 30% opportunity for improvement. That is one place where we believe the Tummy Shield can have a significant impact.

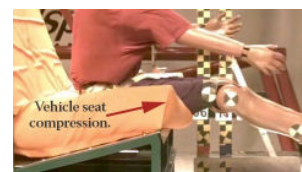
To understand better the how, let's talk about what happens in a crash. Even in a "non-crash" sudden change of speed or direction event, the lap portion of the seatbelt can intrude into the pregnant abdomen causing injury—potentially fatal injury— to mom, baby or both.

Why does this happen? There seem to be a couple likely scenarios:

- Seat belts that are not properly positioned pre-crash will be more likely to cause injury
- In a forward crash, which is by far the most common type of crash, a process called "submarining" occurs. This is where the lower extremities of the body (ie. legs) pull on the pelvis as their momentum continues in a forward motion. At the same time the upper body is being prevented from moving forward by the vehicle's seat belt system. This pulling action on the pelvis causes it to rotate down and under the lap portion of the seat belt which then slides up off the iliac crest (hip bones) and intrudes into the abdomen. All of this happens in about 1/10th of a second.



While doing crash testing using an instrumented crash test dummy (Hybrid III 5% female), we compared the dynamics of using only a seat belt with a seat belt and the Tummy Shield. I was surprised to see how deeply the seat cushion was compressed by the test dummy in both scenarios. The video footage shows a noticeable difference in the extent of submarining when using only the



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seat belt versus the virtual elimination of submarining when using the seat belt and the Tummy Shield. It makes intuitive sense that this compression, while it is beneficially absorbing energy, would proportionally increase the extent and incidence of submarining as the severity of the crash increases. The seat belt, even though it may have been properly positioned pre-crash is not designed to dynamically adjust to the path of the pelvis as it sinks into the seat cushion. This may explain why it was uncovered that:

“Crash severity is the factor most strongly associated with fetal outcome in this study.” (Klinich et al, 2008)

I now have deeper appreciation why, as a paramedic, we always did our very best to persuade pregnant moms to go to the ER for evaluation after a crash, no matter how minor it appeared to be based on damage to the vehicles.

Tummy Shield: The Solution

Not wearing a seat belt, as many mothers are tempted to do —and some admittedly do— because of the discomfort from the seat belt, puts them and their child at several times more risk of fatal injury than wearing a seat belt. A pediatrician in Australia says, “I’m a pediatrician and I’m fully aware of the danger of driving while pregnant, I refused to wear a seat belt during my first pregnancy, since I bought your Tummy Shield I have been using it constantly. I find it simple to use and very comfortable.”

“This study shows that proper use of a belt restraint by the pregnant occupant has a significant, positive effect on fetal outcome. Seventy-nine percent of the pregnant women who were **properly** wearing a 3-point belt, with or without airbag deployment, had acceptable fetal and maternal outcomes in lower severity crashes.” (Klinich et al, 2008)

We believe using the Tummy Shield will help increase seat belt use by making it comfortable to do so.

What about when a crash or other sudden change in velocity occurs? The design of the Tummy Shield virtually eliminates the possibility of “submarining” by creating an anchor point for the vehicle’s seat belt between the mother’s legs and transferring the restraining action of the lap portion of the seat belt from the top of the pelvis (iliac crest) to the legs and lower front aspect of the pelvis. The seat belt is essentially anchored to the legs and lower pelvis and tracks with them as the crash unfolds, regardless of crash severity. In more severe crashes it is possible that injury will occur along the belt path but the concern of the lap portion protruding into the abdomen and directly causing injury to the fetus, pregnancy organs or mom’s abdomen is mitigated.

Common Questions

How can I trust that the Tummy Shield can withstand the crash energy, does not introduce slack into the seat belt system, and keeps both mom and baby safe?

The Tummy Shield, though elegant and soft looking, is a deceptively strong and highly engineered piece of equipment. At the center of the technology is over 8 pounds of patented, high tensile strength, single piece construction, stainless steel plate and hook assembly which is designed and tested to stand up to the several thousands of pounds of restraining force necessary to keep the seat belt in place under even the most extreme situations.

- The hook and plate assembly of the Tummy Shield is static load tested to the same amount of force required in FMVSS standards for the bolts that anchor the seat belt to the vehicle.
- The Tummy shield has been crash tested in both Australia and the USA using standard Crash Testing protocols with the 5th percentile female instrumented ATD.
- In Australia it was also integrity tested with the 100kg (225 lbs)



male test dummy and was tested at speeds higher than the 30mph standard test required for seat belt testing.

- In all tests it performed as designed with zero indications of fatigue or failure.
- All resulting instrumented measurements were within the standards for seat belt performance.

Because the Tummy Shield anchors the seat belt in front of the pelvis, doesn't that allow the occupant to move dangerously toward the steering wheel in a frontal crash?

During the testing of the Tummy Shield in the USA at Calspan, measurements were taken from the fixed camera video that demonstrate that there was a small net movement forward of about 1/2" using a target on the knee as the indicator. We believe that this small movement forward is far outweighed by the benefits offered by the Tummy Shield. Also, the Tummy Shield's entire assembly is anchored to the vehicle seat via a 1" wide, seat belt strength, webbing strap that wraps the vehicle seat.

Does using the Tummy Shield compromise the webbing of the seat belt?

The biggest concern is that somehow the Tummy Shield could compromise the integrity of the seat belt webbing itself by having sharp edges or creating excessive friction during a crash. To mitigate the possibility of either of these problems the manufacturing specifications require that all surfaces of the "hook" be machined to a smooth curve and polished to a near mirror finish. This ensures minimal friction and abrasion to the webbing itself.

In Conclusion

The Tummy Shield, which we like to consider Baby's First Car Seat™, is a safe, viable choice to increase maternal seat belt comfort and, thereby, the likelihood of seat belt use. An added benefit is an increased ability of mom-to-be to focus on driving versus constantly adjusting her seat belt. By completely redirecting the crash forces to the legs and lower pelvis, the concern of seat belt intrusion into the pregnant abdomen is eliminated. This will likely have a significant increase in positive outcomes from motor vehicle crashes for both mom and baby. To date with more than 14,000 Tummy Shields in use globally since their release in 2008, while there have been several reports to the manufacturer of crashes, there have been zero reports of adverse outcomes for mom or baby. In fact, there are testimonials where EMS responders and ER physicians told the mother that there would likely have been a disastrous outcome had they **not** been using the Tummy Shield. We believe the Tummy Shield technology should and will become a standard recommendation for all pregnant women.