

Management of Premature Cervical Shortening

HOW TO PREVENT PREGNANCY LOSS FROM A SHORT CERVIX

February 2011 Edition

Cervical insufficiency or incompetence is a condition where the uterine cervix (the opening of the womb) is weak and unable to keep the fetus inside the uterus until the end of the pregnancy (37-40 weeks). This weakness may be functional in nature or structural (either traumatic or congenital). Functional weakness is often times the result of excessive production of inflammatory cytokines, which are produced by damaged placental tissue and occasionally by intrauterine or cervical infection. Inflammatory cytokines cause degradation (break down) of the cervical collagen tissue; cervical collagen is the primary structural component of the cervix. The etiology of cervical weakness is frequently the result of a combination of structural and functional weakness. In a normal pregnancy, the cervix remains intact and as known in obstetrical lingo, it remains long and closed. This allows the fetus to stay in utero for the duration of a normal pregnancy that lasts at least 37 weeks.

Approximately 12.4% of pregnancies end in preterm delivery in New York State as of the year 2006. This number represents a very poor performance on our part as obstetricians. Preterm birth was happening to only 8% of the patients just 30 years ago. Despite all efforts and the advanced knowledge we have obtained since then, premature births are happening now to 50% more patients than in 1980. In 2005, we spent \$26 billion for prematurity related complications and in trying to prevent prematurity. Since 1996, when March of Dimes has started recording birth statistics, prematurity has increased in every year except one (<http://tinyurl.com/yk2lyxq>). A delivery is defined as premature when it occurs before 37 completed weeks of pregnancy (the average pregnancy lasts 37-40 weeks). Premature birth is a major cause of serious health problems in neonates (newborn babies), including respiratory distress, difficulty regulating body temperature, and infection. More than 85% of long-term disabilities in otherwise healthy babies and 75% of deaths among newborns occur as a result of preterm birth. A woman with an incompetent cervix is 3.3 times more likely to deliver prematurely. The exact number of patients who deliver prematurely is difficult to calculate because cervical weakness is in many occasions associated with preterm labor also. However, according to the most conservative estimates, at least one third of preterm births is due to cervical problems of some sort. The cervix is the neck-shaped opening at the lower part of the uterus and is normally closed tight during pregnancy until the baby is ready to be delivered, at which point it expands (dilates) to roughly

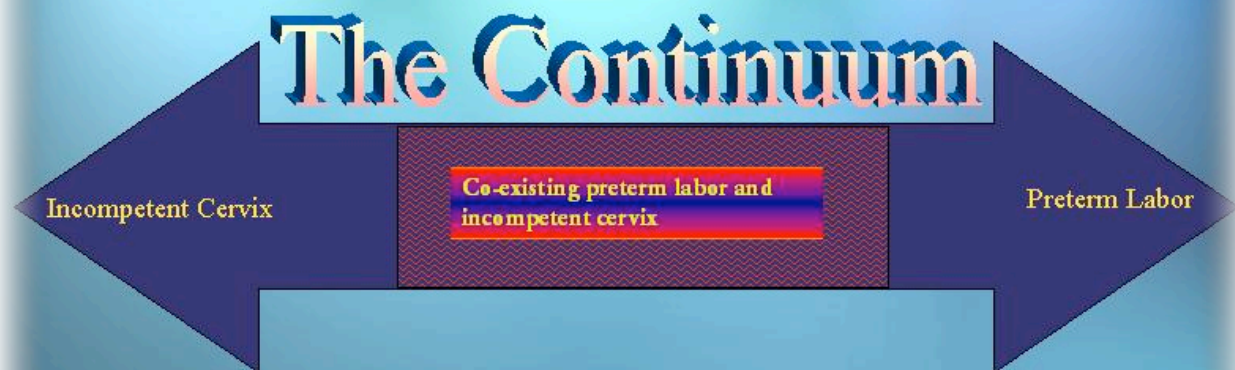
10 cm (4 in) in diameter. An incompetent cervix is prone to effacing (shortening) and/or dilating prematurely during the second trimester. The growing fetus subsequently places too great a strain on the cervix, leading to miscarriage (loss before week 20 of pregnancy) or premature delivery (birth before 37 completed weeks of gestation). Approximately 1% of women will be diagnosed with an incompetent cervix (one in a hundred). It is the cause of 25% of losses during the second trimester. The problem here is that a lot of women lose their babies but because these losses happen away from the physician's office or the hospital, the diagnosis of the condition does not reflect the real incidence. The treatment for incompetent cervix is cervical cerclage; a purse-string like suturing of the cervix done either vaginally or abdominally as we will discuss later on.

The use of cervical cerclage has been controversial for many decades. Despite the controversy however, it still remains the treatment of choice for most patients who present with recurrent pregnancy loss and mid-second trimester loss of unknown etiology. The reasons for the controversy are simple and the result of the common propensity of researchers who always assume that solutions to problems must be complicated. One of the biggest offenders that has delayed the recognition that most of the losses are not the result of incompetent cervix but a combination of incompetent cervix and preterm labor is the misconception that infection is the most common reason for preterm labor. Incompetence and preterm labor coexist in almost 95% of the patients according to our research at Kofinas Perinatal. In fact, we failed to identify but a small number of patients with infection. Infection is usually a secondary event or a misdiagnosed situation. When the cervix thins completely and quietly (without symptoms), it loses its protective effect on the amniotic membranes. As a result of this loss, bacteria enter the amniotic cavity and may cause a secondary infection, which of course, expedites the process of labor. Many researchers detected a high frequency of inflammatory changes in placentas of premature babies and they made the wrongful assumption that these inflammatory changes were the result of some kind of infection. What makes things worse is that any placenta that passes through the vagina after the delivery of the baby, is very likely (almost 100% likely) to pick up some germs and give us the wrong impression that infection is the problem. The fact however is that the placental inflammatory changes preceded any cervical changes and any signs of clinical or subclinical infection. These inflammatory changes are the result of placental tissue necrosis from disturbed maternal and fetal placental blood flow. Such flow problems cause necrosis of placental tissue. Our immune system then comes to the rescue and cleans such dead tissues. The problem is that this process of cleaning causes the production of significant amounts of inflammatory cytokines. Inflammatory cytokines are chemicals that cause breakdown of collagen tissue and cervical weakness. In addition, cytokines cause uterine muscle stimulation and increased uterine contractility. So, we now have abnormal contractions that are mild enough to not be detected and strong enough to dilate a weak cervix. The cervix has become weak because of the breakdown of its collagen fibers that keep it strong. To put this in perspective, when the cervix is not soft enough at term and we want to deliver a patient we use pharmacological inflammatory cytokines (prostaglandins) to breakdown the cervix and then induce labor. Such prostaglandins are also used to induce abortions in the second trimester prior to viability.

Dr. Iams, a well-respected researcher has studied premature cervical changes extensively in the 1990s. His well-designed studies have proven beyond a doubt that preterm labor and incompetent cervix are part and

parcel of the same continuum. They coexist in most of the patients. Most obstetricians and perinatologists, to our patients' detriment, have not yet accepted this simple and beautiful concept. It is too simple for them to accept. Instead, they are in a never-ending quest for the discovery of some peculiar molecule or gene or whatever else, which is solely responsible for premature labor and / or incompetent cervix. This continued ignorance/neglect of Dr. Iams' concept prevents proper management of patients who present with short

Preterm Labor Versus Incompetent Cervix



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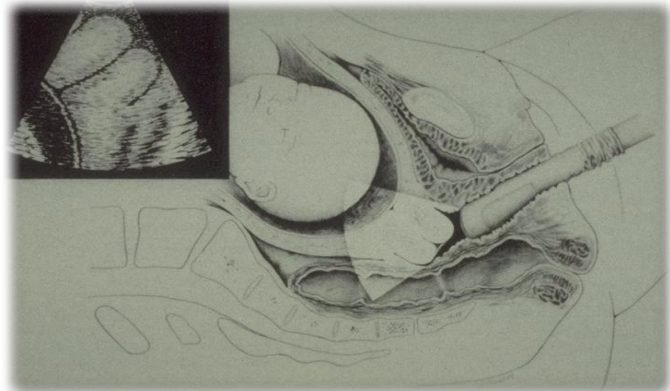
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cervix. Obstetricians and perinatologists (the vast majority of them) see incompetent cervix and preterm labor as two distinct entities that are mutually exclusive. This is a fatal mistake and a relic of the past. By maintaining this wrongful perception, when they suspect that a patient suffers from incompetent cervix, they only do a cervical cerclage and do not even think about the coexisting preterm labor. Likewise, when they treat a patient for premature labor, cerclage is a contraindication and never used. No wonder then that all clinical studies that have been published so far on the usefulness of cervical cerclage have failed to find any benefit. None of the patients was treated adequately since they only received a cerclage but their preterm labor was left alone. In such a case, the contractions continue to weaken the cervix along with the inflammatory cytokines. The result is a failed cerclage with a new loss and sometimes, severe damage to the cervix when the suture cuts through the cervix. This is a loud and profound failure of the caring doctor and not a failure of the cerclage procedure.

A prominent researcher on premature labor in a recent editorial article in the American Journal of Obstetrics and Gynecology, came close to realizing that cerclage may not be the issue. Instead, he added, it seems that we place cerclages on the wrong patients. He went on to say, that we must find a way to identify the

patients who have inflammatory changes and preterm labor and treat them accordingly. Cerclage in patients with preterm labor is inappropriate and can cause more complications. Unfortunately, he proposed the development of a cervical test that will evaluate for the presence of inflammatory cytokines and preterm labor. This is the wrong approach. It is the usual medical approach where one looks for a silver bullet for a problem that is complex in nature but its result is simple. The mechanism of cervical shortening is the result of complex –almost chaotic- interactions of tens or even hundreds of signaling molecules. Trying to identify the one important molecule that we can measure in cervical mucous is an exercise in futility. We will end up spending hundreds of millions of dollars for something that is not necessary in today’s medical settings. All obstetricians have an ultrasound machine in their office and should be able to identify cervical shortening with a simple transvaginal ultrasound.

If the cervix is short, then a very simple and inexpensive test, which can be performed at home, can distinguish between incompetence and preterm labor. Here comes the usefulness of Indomethacin. Indomethacin is an old non-steroidal anti-inflammatory drug. In fact, it is the first of such drugs other than aspirin. It is similar to Motrin[®], Advil[®], Vioxx[®] and all the latest anti-inflammatory drugs used for pain and chronic inflammatory conditions like arthritis. Indomethacin is less potent than the rest of them and causes fewer complications. In addition, Indomethacin has been around for many years and we are very familiar with its risks and benefits as well as its effects on the fetus. The fetal effects are very well known and can be monitored with ultrasound and fetal cardiac Doppler. Fetal complications include, oligohydramnios and constriction of the ductus arteriosus. Both of these side effects are reversible when the treatment is stopped. However, what is important is the fact that if Indomethacin is not used after 32 weeks gestation, the risk for such side effects is almost zero. In fact, if Indomethacin is used according to the [Kofinas Perinatal protocol](#), there will be no complications that could materially affect the baby. Even if one is to experience some of these complications, one should contrast the impact of such reversible complications with the severe impact and life-long implications of prematurity.

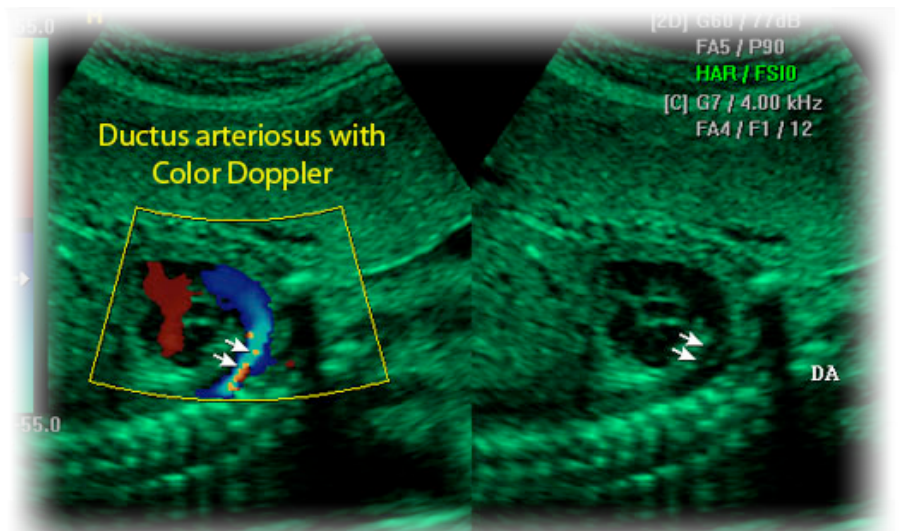


Transvaginal ultrasound for the evaluation of the cervix

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The technology is here and most if not all perinatologists should be capable of monitoring such treatment. Unfortunately, “should be capable” is not the case and in reality, most perinatologists lack the skills to monitor such a treatment. The lack of skills along with the lack of familiarity with the concept of the cervical continuum prevents the majority of perinatologist from applying such a simple concept and treatment. At Kofinas Perinatal, we have applied this concept for the last 20 years with remarkable results. [Kofinas Perinatal reduces prematurity by 90%](#). Indomethacin makes a cervix regain its length if preterm labor is the problem but fails to do so if incompetence is at play. Overall, our study has proved that on average, treatment with Indomethacin improves cervical length by 50%. In fact, in patients who suffer primarily from

preterm labor, the cervix returns to normal. It is the patients that suffer from incompetence that do not respond at all. Seventy percent of patients respond to Indomethacin and they reach full-term and only 30% require a cerclage to do so. This management is responsible for a 90% reduction in prematurity in patients with short cervix. This is in contrast to a study published by a researcher at Cornell Medical College recently. In their high risk unit, neither cerclage nor Indomethacin are part of the treatment for cervical shortening; they believe that there is nothing one can do about a short cervix and therefore they do nothing. In their study of patients with short cervix, by doing nothing, they recorded a 60% prematurity. This is dreadful! In exactly similar patients, our protocol helped us reduce prematurity by almost 90% by accepting Dr. Iams' concept of the cervical continuum and doing something about it. Very simple!



Color Doppler and real time ultrasound in the evaluation of constriction of the ductus arteriosus

How have we achieved such a fit? In addition to the medical concepts discussed above, we provide our patients with a lot of education, both, in writing and in person. We constantly educate our patients about the signs and symptoms of preterm labor and premature cervical shortening. Usually, due to the insidious nature of the underlying pathology, the symptoms and signs patients experience are frequently perceived as normal. In the rare occasions that patients call their obstetrician to report such symptoms, their complaints are dismissed as normal pregnancy symptoms or are attributed to non-obstetrical reasons such as round ligament pain or gastrointestinal pain. This simple confusion is responsible for many fetal losses. As a specialist, I have met too many patients who lost their babies because their obstetricians dismissed their symptoms as other than preterm labor. We encourage our patients to call us with all symptoms and signs they might experience. The list below is representative. We encourage our patients to call their obstetrician or us whenever they experience any of these symptoms 24 hours a day and to demand to be seen.

The following symptoms have been described by patients who either lost their pregnancies in the early second trimester (between 13 and 24 weeks gestation) or delivered prematurely (between 24 weeks and 37 weeks gestation):

- Pelvic pressure
- A feeling of stretching and pulling in the pelvis
- Low back pain (in the region of the tail-bone).

- Pressure in the vagina
- Excessive discharge (feeling wet in the vagina)
- Having pelvic discomfort that they cannot define clearly
- A feeling of menstrual cramping
- Intermittent deep pelvic discomfort
- Gas pains
- Rectal pressure and constipation

It is this level of intense scrutiny and availability to our patients along with our treatment protocol that makes it possible to achieve the superior outcomes we have achieved in such patients.

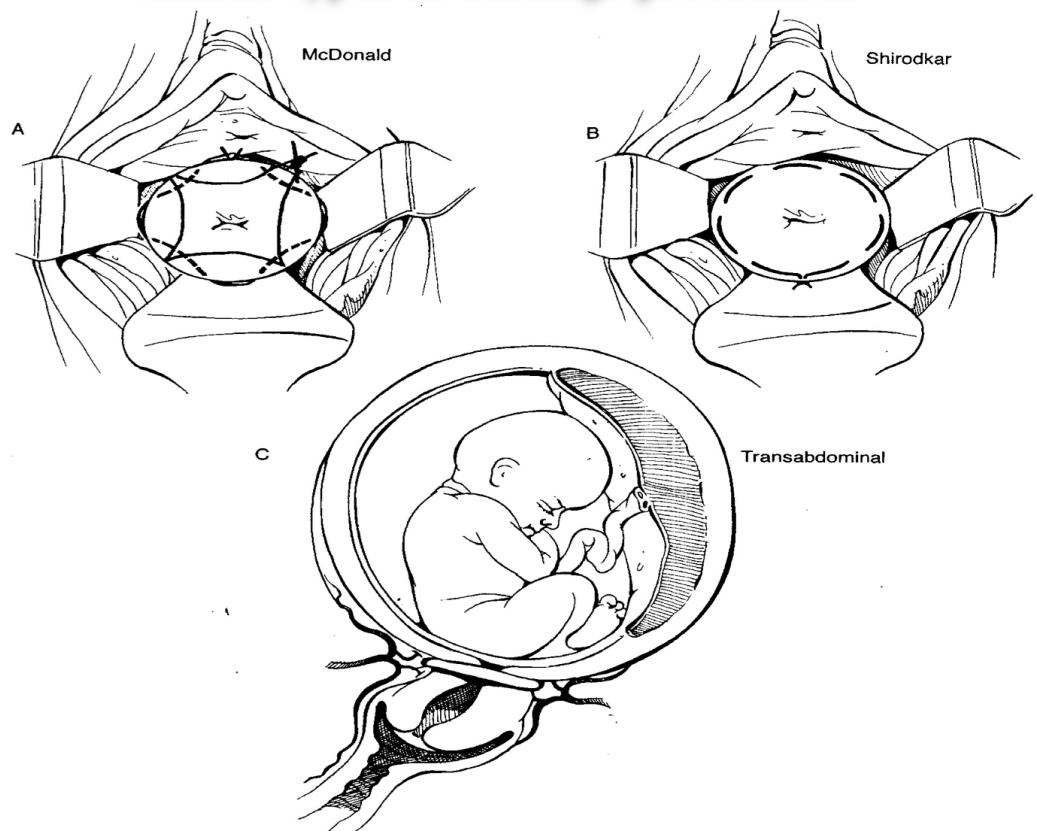
Finally, I would like to touch upon the technical issues of the cerclage procedure. There are in general 3 types of cerclage that have been described with some minor differences here and there.

- McDonand cerclage; this cerclage is removed at term and vaginal delivery is allowed.
- Shirodkar cerclage; if successful, it is left in place and the patient delivers by c-section.
- Abdominal cerclage; if successful, it is left in place and the patient delivers by c-section.

Regardless of the procedure one choses, as any surgical procedure, success depends on the surgeon's competence. Unfortunately, not all surgeons are the same. In fact, in my experience, most obstetricians are not trained properly on cerclage placement and more or less they perform few such procedures during their professional life. This does not allow them to become proficient and successful. This lack of skill has been a significant factor in the failure of most randomized clinical trials to prove any benefit from cerclage. We use the McDonald type of cerclage because it is less traumatic, easy to remove and allows the patient to have a spontaneous vaginal delivery. Shirodkar cerclage is not performed anymore in the manner it was designed to be performed because it requires the excision of a strip of fascia (the fibrous tissue that covers the muscles) from the thigh. This strip of fascia is then stitched in the cervix in a circular manner (like a purse string) and left in place indefinitely. Nowadays, the surgeons that perform the so-called "Modified Shirodkar cerclage" use a 5 mm band (interwoven synthetic material) suture. This can be quite destructive if the patient goes into labor. Not only she loses her baby, but also her cervix. I have seen too many patients whose cervix was severed by 75% and could not be repaired. Such patients can never have a successful pregnancy again. Abdominal cerclage is placed after 12 weeks gestation by means of laparotomy or laparoscopy. This type of cerclage could only be successful in a patient with true cervical incompetence and no labor at all. If the patient goes into labor with the cerclage she will have to have a cesarean section or else the uterus and the cervix could be damaged severely. If she aborts in the second trimester, the patient ends up with a procedure known as hysterotomy. This is a classical cesarean section in an early pregnancy. The morbidity of such a procedure is significant. In my judgment, abdominal cerclage should be relegated to the history

books. With a simple technique one can place a suture at the same high cervical position via the vagina. Such is the procedure we perform at Kofinas Perinatal and we never needed to perform an abdominal cerclage with the exception of one patient with cervical malignancy.

Below are representative schematics of the various types of cerclage procedures



Some practical advice for patients who think that they might have premature cervical shortening

1. Make sure your obstetrician is competent in the evaluation of the cervix by ultrasound. If not, he should refer you to a specialist who knows better.
2. Do not accept cerclage treatment as the first response to a short cervix. Ask your doctor to rule out premature labor before the placement of cerclage regardless of gestational age. Many specialists tend to dismiss pregnancies prior to 24 weeks as abortions and if labor is the problem, they label such pregnancies “inevitable abortions” and do nothing to stop them. It is a self fulfilling prophesy.
3. In the presence of cerclage with signs of premature labor, stopping the contractions with tocolytic treatment is important. Indomethacin is the best choice and the only one that has proved to be successful in stopping preterm birth. Avoid by all means the use of magnesium sulfate and/or Terbutaline. They are **ineffective and dangerous** to you and your unborn [Kofinas Perinatal protocol](#).
4. If the cervix is dilated and completely thinned out, ask your doctor to refer you to an expert who can restore the amniotic membranes back into the uterine cavity and then place the cerclage.
5. If you are told that you have an inevitable abortion do not accept it. Ask to be seen by an expert with a lot of experience in such cases. The only reason I would call a pregnancy inevitable abortion is when the maternal health is at risk and prevents us from performing any procedure to save the baby.

6. If you have any of the symptoms that we have listed above, demand to be seen and have the cervix measured by transvaginal ultrasound.
7. If you have a cerclage for any reason, demand that the cervical length is measured every two weeks or sooner if you have any of the above symptoms. If the cerclage is failing, an experienced specialist should revise it higher.
8. If your obstetrician refuses to acknowledge any of the above recommendations and he dismisses your concerns, you are in the wrong place and you should look for a better physician to take care of you and your baby. There is too much at stake and you should never be intimidated for any reason. Protect your life and your baby.

If a patient has a history of loss or known cervical problems it should be a no brainer that she should be treated carefully in order to avoid the complications and adverse outcomes that are common in such conditions. It is a dictum that patients with preexisting high-risk conditions receive more attention by their health care providers. It is a truism also that at least half of the patients who lose a baby due to cervical abnormalities or experience preterm birth do so in the absence of any prior history. It is these patients also that we need to protect not only the ones with prior history. Unfortunately, the system is geared only one way. One must lose 2-3 babies before one “qualifies” for proper monitoring and testing. This is the standard of care today and it is appalling. We object to such mentality and we provide the same degree of surveillance to all of our patients. To us, every pregnancy is a high-risk pregnancy until proven otherwise. This is the only reason that our outcomes are far superior to the outcomes delivered by the “standard of care” crowd. Thousands of babies are lost every year and a lot more are born prematurely. These premature babies are not the babies God meant them to be. This is a preventable human calamity and it is upon you to protect your health and your unborn. Expand your knowledge on the subject and help yourself as well as your friends from becoming the victims of ignorance.



One loss is one too many!!

To your health!

Alexander Kofinas, M.D.