

Clinical Guidelines

## Cervical preparation for second-trimester surgical abortion prior to 20 weeks of gestation

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### Abstract

Roughly 11% of induced abortions in the United States are performed after 14 weeks of gestation, most commonly by dilation and evacuation (D&E). For a D&E procedure, the cervix must be dilated sufficiently to allow passage of operative instruments and products of conception without injuring the uterus or cervical canal. Preoperative preparation of the cervix reduces the risk of cervical laceration and uterine perforation. The cervix may be prepared with osmotic dilators, prostaglandin analogues, or both. Osmotic dilators currently available in the United States include Dilapan-S<sup>TM</sup>, Lamichel<sup>®</sup>, and laminaria. Laminaria tents are made from dehydrated seaweed and require 12–24 h to achieve greatest dilation. The synthetic products, Dilapan-S<sup>TM</sup> and Lamichel<sup>®</sup>, achieve maximum effect within 6 h. Dilapan-S<sup>TM</sup> achieves greater dilation than the others and, thus, requires fewer dilators to be placed but may be more difficult to remove. For same day procedures, Dilapan-S<sup>TM</sup> and Lamichel<sup>®</sup> are preferable to laminaria. A single set of one to several dilators is usually adequate for D&E before 20 weeks of gestation. Additional sets over 1–2 days may be needed in challenging cases. Misoprostol, a prostaglandin analogue, is sometimes used instead of osmotic dilators; however, the data to support such use are limited. Misoprostol is inferior to overnight dilation with laminaria for cervical priming prior to D&E. Misoprostol use as an adjunct to overnight osmotic dilation is only marginally beneficial for priming beyond 16 weeks and does not truly demonstrate any benefit before 19 weeks of gestation. Limited data demonstrate the safety of misoprostol prior to D&E in patients with a uterine scar. The Society of Family Planning recommends preoperative cervical preparation to decrease the risk of complications when performing a D&E prior to 20 weeks of gestation. The three currently available osmotic dilators (laminaria, Lamichel<sup>®</sup>, and Dilapan-S<sup>TM</sup>) are safe and effective for this use. Since no single protocol has been found to be superior, clinical judgment is warranted when selecting a method of preoperative cervical preparation.

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*Keywords:* Dilation and Evacuation; Cervical dilation; Dilator; Laminaria; Dilapan; Lamichel; Misoprostol

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### Background

Approximately 1.29 million legal abortions are performed in the United States each year, most of which occur early in the first trimester [1]. Roughly 11% of pregnancies terminated in the United States end in the second trimester, with only 1.4% at 21 weeks and beyond [2]. Pregnancies may be terminated in the second trimester by labor induction, dilation and evacuation (D&E), hysterotomy, and hysterectomy. Because D&E is safe, cost-effective and efficient, it is the most common means of second trimester elective abortion. In 2003, more than 98% of all second-trimester abortions in the United States were performed by D&E [2].

During D&E, the cervix must be dilated sufficiently to allow passage of operative instruments and fetal parts without injuring the cervical canal. The minimum dilation required to pass most forceps used for D&E ranges from 14

to 19 mm, though wider dilation is often required to remove products of conception at advanced gestations [3]. The cervical dilation needed for D&E increases with gestation. Both the minimal and the ideal degree of dilation required for D&E at each gestation age has not been determined.

Though the cervix may be manually dilated at the time of D&E, the degree of dilation needed for later procedures may require additional force, increasing risk of cervical trauma and other complications. Reported complications of D&E include cervical laceration, uterine perforation, retained products of conception, infection and hemorrhage. During midtrimester D&E, perforation of the uterus occurs in 0.2–0.3% and cervical laceration occurs in 0–1% [4–7]. The risk of uterine and cervical trauma can be minimized with preoperative preparation of the cervix to achieve baseline dilation and softening [7–9]. The cervix may be prepared with osmotic or hygroscopic cervical dilators (e.g., laminaria tents), and/or prostaglandin analogues (e.g., misoprostol).

Osmotic dilators are tents placed into the cervical canal that slowly expand to dilate and soften the cervix. Three types of osmotic dilators are currently available in the United States: laminaria, Lamichel<sup>®</sup>, and Dilapan-S<sup>™</sup>. Additionally, prostaglandin analogues, most commonly misoprostol, may be used as cervical priming agents prior to induced abortion.

*Osmotic dilators: laminaria, Lamichel<sup>®</sup>, Dilapan<sup>™</sup>, and Dilapan-S<sup>™</sup>*

#### *Laminaria*

The stems of the seaweed *Laminaria japonica* and *L. digitata* may be dehydrated and made into cervical tents. Currently available laminaria tents are manufactured by several suppliers. Tent size ranges from 2 to 10 mm in diameter and 60–85 mm in length (MedGyn: Lombard, IL, USA, and Norscan: Westlake Village, CA, USA). When placed, they absorb fluid within the cervix and slowly swell 3–4 times their dehydrated diameter. For example, a 3-mm laminaria tent achieves approximately 1 cm dilation in situ overnight [10,11]. Most of this dilation occurs in the first 6 h, though the maximum effect is not achieved for 12–24 h [12–14]. This slow dilation exerts radial pressure on the cervical canal, which, in addition to physical dilation, may induce prostaglandin synthesis and cervical ripening, thus making subsequent manual dilation easier [13,15–18].

Since laminaria tents are made from natural resources, drawbacks include lack of uniformity in the product and theoretical risk of infection. The dilation achieved by a specific size tent is unpredictable. Historically, there were concerns that laminaria tents may harbor infectious organisms, and the package labeling cautions that residual bacterial spores could persist even after sterilization [19]. There are no modern reports of single-use laminaria tents transmitting infection, and numerous studies demonstrate that infectious morbidity is not increased by their use [13,20–23]. No studies have been performed that address whether antibiotic administration at the time of laminaria insertion is beneficial. The greatest limitation of laminaria use for cervical preparation is the time it takes to achieve dilation. Overnight placement is often needed, resulting in a 2-day abortion procedure. **Faster-acting synthetic dilators, including Lamichel<sup>®</sup> and Dilapan<sup>™</sup>, were developed to address these concerns.**

#### *Lamichel<sup>®</sup>*

The use of Lamichel<sup>®</sup>, a synthetic osmotic dilator, was first reported in 1982 [24,25]. Lamichel<sup>®</sup> is a dehydrated polyvinyl alcohol sponge embedded with 450 mg of magnesium sulfate. Lamichel<sup>®</sup> works faster than laminaria with cervical ripening effects occurring within 2 h and maximizing at 6 h [26]. Lamichel<sup>®</sup> tents are 67 mm long and 3 or 5 mm in diameter [25]. Lamichel<sup>®</sup> swells 3–4 times its dehydrated diameter. Even when maximally dilated, however, the sponge is compressible and does not exert radial force within the cervix [16]. Lamichel<sup>®</sup> may work by inciting prostaglandin synthesis [27] or by stimulating collagenolytic activity within

the cervical stroma [28], but the exact mechanism of action is unclear. Serum magnesium levels are not increased with Lamichel<sup>®</sup> in place [29]. The necessity of magnesium within the sponge is questioned by one study that showed that identical tents of polyvinyl alcohol without added magnesium produced a similar degree of cervical priming [30].

**Because Lamichel<sup>®</sup> does not exert radial force, it may not achieve as much dilation as other cervical tents.** One 5 mm Lamichel<sup>®</sup> placed 6 h prior to midtrimester abortion only dilates the cervix approximately 8 mm [31]; however, the ripening effect makes subsequent dilation easier to achieve [26,32–34]. Lamichel<sup>®</sup> is effective as a cervical preparation agent when placed a few hours prior to surgical evacuation of gestations up to 16 weeks [32,33]. When used overnight, Lamichel<sup>®</sup> is effective up to 17 weeks of gestation [24]. Lamichel<sup>®</sup> is not commonly used as the sole means of cervical preparation in the late second trimester due to concerns that the compressible sponges will result in inadequate dilation [3].

#### *Dilapan<sup>™</sup> and Dilapan-S<sup>™</sup>*

Dilapan<sup>™</sup> is a synthetic osmotic dilator made of a polyacrylate-based proprietary hydrogel (Aquacryl) [35]. Dilapan<sup>™</sup> use for abortion was first reported in 1982 [36]. It was removed from the United States market from 1995 to 2002 and reintroduced after reformulation as Dilapan-S<sup>™</sup>. Dehydrated Dilapan-S<sup>™</sup> is available in diameters of 3 and 4 mm and lengths of 55 and 65 mm. It rapidly swells 3–4 times in diameter in situ. A significant effect is noted within 2 h with one 4-mm dilator producing 7.8–10 mm of cervical dilation. Most dilation is achieved within 4–6 h; however, the device continues to expand up to 24 h in situ. One 4-mm Dilapan-S<sup>™</sup> expands to 12.7–14.6 mm when left in place for 24 h [35]. Of all the available cervical osmotic dilators, Dilapan-S<sup>™</sup> achieves the greatest cervical dilation in the shortest timeframe. Unlike the other available dilators, it shortens by 18% as it swells; thus, the longer tent is recommended for most patients to insure that the internal cervical os is adequately dilated [35].

The greatest disadvantage of the older formulation of Dilapan<sup>™</sup> was its propensity to break during removal, increasing the risk of retained fragments. Dilator entrapment and fragmentation occurred in 4–12% of reported procedures using the older device [33,37,38]. In contrast, fragmentation is a rare complication of laminaria and has not been reported for Lamichel<sup>®</sup> [23,39]. The newer device, Dilapan-S<sup>™</sup>, was designed with a stronger core to decrease this problem. Although no published studies have addressed fragmentation and other complication rates in the reformulated product, there are anecdotal reports of fracture with Dilapan-S<sup>™</sup> [35].

### **Clinical questions and recommendations**

*1. Does use of osmotic dilators decrease the risk of complications with D&E?*

In a review of over 15,000 first-trimester abortions performed by multiple clinicians, Shulz et al. [40] showed

that preoperative cervical dilation with laminaria significantly reduced the risk of cervical injury requiring suture repair (RR=0.19; 95% CI: 0.07–0.52). Similarly, Peterson et al. [7] demonstrated the protective effect of laminaria in a review of over 11,000 second-trimester D&E procedures. In this prospective cohort study, the rate of cervical laceration in patients between 18 and 20 weeks of gestation declined from 5% to 1.6% ( $p=0.002$ ) when laminaria tents were placed 5–24 h preoperatively. Laminaria also decreased the rate of cervical laceration between 14 and 18 weeks from 0.8% to 0.4%; however, this result was not statistically significant due to the low laceration rate at earlier gestations.

## 2. What are the risks of using osmotic dilators before D&E?

Placement of osmotic dilators has a low risk of short-term complications [23]. Vasovagal symptoms may occur in 5–20% of women at the time of laminaria insertion [32,41]. Allergies and anaphylaxis have been reported to laminaria tents but not to synthetic dilators [23,42–44]. If dilators are not placed correctly, the internal cervical os may not dilate. Amniotic membranes may be inadvertently ruptured during insertion, though this occurs infrequently. Aggressive cervical preparation may lead to labor or precipitous delivery prior to the intended D&E. If placed with force, the dilators may create a false passage and perforate the cervix. The incidence at which these rare complications occur has not been reported.

Bacterial contamination from upward migration of vaginal and cervical flora remains a theoretical concern [45]. There are a few case reports of bacteremia and toxic shock syndrome following laminaria placement [22,45,46]. A fatal case report of *Clostridium perfringens* and *Escherichia coli* sepsis occurred 18 h after laminaria insertion in conjunction with a urea instillation abortion [47]. Despite these reports, medical evidence demonstrates that overall infectious morbidity is not increased when using osmotic dilators before D&E [13,20–23].

Cervical dilators are occasionally difficult to remove [39]. When Dilapan-S™ or laminaria swells within a noncompliant cervix, the portion within the canal may remain minimally dilated, while portions within the uterine cavity and the vagina swell significantly, creating an hourglass or “dumbbell” shape, resulting in inadequate dilation or difficult removal. Osmotic tents, especially Dilapan™, may fragment upon attempted removal when cervical dilation is inadequate. Osmotic dilators may also migrate into the uterine cavity. Whole or fragmented dilators may be removed from the uterus with suction or forceps. If fragments of or whole tents are inadvertently retained within the cavity, later complications, including pain and bleeding, may develop [39].

Although conflicting data exist in the medical literature on the potential impact of D&E on the outcome of future pregnancies, the increased future risk of preterm labor,

miscarriage and cervical incompetence shown in some studies were presumably due, in part, to cervical trauma from rapid dilation [8,9]. More recent studies demonstrate that midtrimester D&E, when preceded by osmotic dilation, does not increase the risk of future preterm birth or second-trimester miscarriage [48–50]. In a retrospective review of 600 patients undergoing D&E between 14 and 24 weeks, Kalish et al. [49] demonstrated that the overall rate of preterm birth in subsequent pregnancies was 6.5%; whereas the overall preterm birth rate is 12.5% in the United States [51]. Of note, subjects in the study who experienced future premature births underwent D&E at earlier gestations (16 vs. 19 weeks,  $p=0.02$ ) compared to women without premature births. The authors theorized that more aggressive cervical preparation at the later gestations may have resulted in less cervical trauma and potentially protected against future pregnancy complications. Though it remains unclear if preoperative cervical preparation offers protection against these potential complications, it seems prudent to minimize cervical trauma.

## 3. Which osmotic dilator is preferred for preparation of the cervix for D&E?

Few studies directly compare the effects of different osmotic dilators. Overall, Dilapan™ achieves greater cervical dilation in a shorter time interval than the other available tents. This shorter timeframe may avoid the need for overnight placement, allowing for single-day abortion procedures. Since Dilapan™ achieves greater dilation than Lamichel® and most laminaria, fewer may be inserted to achieve the same result [38]. Placement of fewer dilators decreases patient discomfort with insertion and potential expense [32,51]. Additionally, some clinicians report that Dilapan™ is easier to insert as it is smoother than laminaria [33,52].

The largest published study comparing osmotic dilators is a series of 1001 patients who underwent D&E at 13–25 weeks of gestation alternatively prepared with laminaria or Dilapan™ [38]. Subjects received a mean of 2 Dilapan™ vs. a mean of 3.7 thick laminaria tents placed 18–24 h preoperatively. Those receiving laminaria were more likely to require supplemental dilation even though more tents had been placed. Dilapan™ fragmented or was difficult to remove in 6% of subjects, whereas laminaria tents were difficult to remove in only 1 woman (0.2%). There were no differences in procedure time or blood loss.

A small randomized comparison ( $n=51$ ) between overnight use of a single Lamichel® or Dilapan™ at 13–16 weeks of gestation showed that significantly more dilation, as assessed with Pratt dilators, was achieved with Dilapan™ (39F vs. 50F;  $p<0.0001$ ) [33]. Dilapan™ was reported to fracture on attempted removal in 12.5% of women with no removal difficulties encountered with Lamichel®.

Overall, the choice of osmotic dilator will fall to individual clinician preference. Consideration should be made to gestational age and well as intended length of preparation.

For shorter intervals, Lamical<sup>®</sup> or Dilapan<sup>™</sup> are preferred as they act more rapidly. For later gestations, Lamical<sup>®</sup> is rarely used alone as greater dilation is achieved using multiple laminaria or Dilapan<sup>™</sup>. Dilapan<sup>™</sup> provides more rapid dilation and less insertion discomfort than laminaria since fewer dilators are needed [52] but may produce more cramping from rapid dilation [53]. Anecdotally, some clinicians combine laminaria and Dilapan<sup>™</sup> to achieve the greatest benefits from each while minimizing removal problems [3]; however, no research addresses this practice.

#### 4. Can misoprostol be used as an alternative or adjunct to osmotic dilators for cervical preparation prior to D&E?

While osmotic dilation is highly effective, it is viewed by many patients and clinicians as uncomfortable, invasive and inconvenient. The cervix may be prepared for second-trimester termination pharmacologically with prostaglandin analogues, specifically, the prostaglandin E<sub>1</sub> analogue misoprostol. Most research of prostaglandin or prostaglandin analogue use in the second trimester is in the setting of medical pregnancy termination via labor induction. Few studies address the use of vaginal and buccal misoprostol for cervical preparation prior to D&E, and there are no published studies using other prostaglandins or prostaglandin analogues for this purpose [54–57].

Adequate cervical preparation was achieved in 32 women between 14 and 16 weeks of gestation given 600 µg of buccal misoprostol 2–4 h prior to D&E [54]. In a demonstration project in one resource-poor setting with less experienced clinicians, buccal misoprostol was used successfully as a replacement for osmotic dilators in 439 women between 13 and 18 weeks; however, 9% of women required more than one dose of misoprostol over a 2-day interval to achieve adequate cervical preparation. The perforation rate was 0.45% [56].

Only one randomized trial compared the use of laminaria to misoprostol for cervical preparation before second trimester D&E. In a double-blind randomized trial, Goldberg et al. [55] compared 400 µg of vaginal misoprostol given 3–4 h before D&E to overnight laminaria in 84 women between 13 and 16 weeks of gestation. Although most subjects preferred a same-day regimen to overnight treatment, the investigators did not discriminate whether this preference was related to timing (3–4 h vs. overnight) or the agents (misoprostol vs. laminaria). Subjects in the misoprostol group avoided discomfort from laminaria insertion and overnight dilation but had more painful cramping after misoprostol administration. Greater preoperative dilation was achieved with laminaria than misoprostol (43F vs. 33F,  $p<.001$ ). Procedures in the misoprostol group took approximately 4 min longer ( $p=.01$ ), were more difficult and were more likely to require additional manual dilation (80% vs. 21%,  $p<.001$ ) than those in the overnight laminaria group. These differences were pronounced in nulliparous patients but not statistically significant in parous women. There was no significant difference in the physicians' ability to complete

the procedure on first attempt; however, their satisfaction with cervical preparation was lower with misoprostol alone (37% vs. 95%,  $p<.001$ ). Though the study is limited by small sample size, the safety of misoprostol as an alternative to laminaria is questioned, as one uterine perforation and two superficial cervical lacerations occurred in the misoprostol group with none in the laminaria group.

Patel et al. [58] reported a retrospective series of the experience from 19 planned parenthood centers using buccal misoprostol as an alternative or adjunct to overnight laminaria placement using various protocols that varied between centers. Buccal misoprostol was administered in doses of 400–800 µg 20 min to a few hours before D&E in women between 12 and 23 6/7 weeks of gestation. Almost two thirds of women received 400 µg of misoprostol at least 1.5 h preoperatively. Of the 2218 cases reported, 1268 (57%) women up to 18 weeks of gestation were treated with buccal misoprostol alone. The remaining women, all beyond 16 weeks of gestation, were treated with overnight laminaria followed by adjunctive buccal misoprostol on the day of surgery. Additional dilation was required in over 70% of those receiving misoprostol alone and 13% of those treated with laminaria and misoprostol ( $p<.0001$ ). Subsequent dilation was easily achieved in 75%; however, difficult or inadequate dilation was encountered in 2% and 18% of women who did and did not receive laminaria, respectively ( $p<.0001$ ). Thirty-one (1.3%) required additional doses of misoprostol or a second set of laminaria on the day of the procedure. The abortion was completed in 98.2% on the planned day of surgery. The rate of adverse events was statistically similar between treatment groups (1.9% receiving misoprostol alone vs. 1.5% receiving laminaria). The rates of uterine perforation (0.2%) and cervical laceration (1.3%) were not compared between treatment groups.

One randomized double-blind, placebo-controlled clinical trial examined the potential benefit of adjunctive preoperative buccal misoprostol in 125 women between 13 and 20 6/7 weeks of gestation prepared with overnight laminaria [57]. Subjects were treated with 400 µg of buccal misoprostol or placebo 90 min prior to D&E. Adjunctive misoprostol only increased preoperative cervical dilation as measured by Pratt dilators for subjects at 19 weeks of gestation and beyond (54F vs. 49F,  $p=.01$ ). Misoprostol significantly improved perceived ease of subsequent dilation at 16 weeks of gestation and above, as measured on a Visual Analogue Scale (37 vs. 57 mm,  $p<.001$ ); however, there was no difference in procedure time, estimated blood loss or complication rates between groups. Similar to the findings by Goldberg et al. [55], subjects receiving misoprostol reported more abdominal cramping while awaiting their procedure than those receiving placebo.

In summary, the only randomized trial comparing the efficacy of laminaria to misoprostol for cervical priming prior to midtrimester D&E demonstrated that vaginal misoprostol placed a few hours preoperatively was inferior to overnight laminaria [55]. A single large case series

showed that buccal misoprostol was less effective than overnight laminaria as well [58]. Adjunctive buccal misoprostol offers no benefit after overnight cervical tent placement in the early second trimester but may be of value at later gestational ages. The efficacy of buccal administration for cervical priming has not been compared directly to oral or vaginal use. No studies have compared the efficacy of misoprostol to Lamichel<sup>®</sup> or Dilapan-S<sup>™</sup> placed a few hours preoperatively.

All studies of cervical priming with misoprostol took place in settings with an immediate availability of procedure space and personnel; thus, none of the studies could address the effect of using misoprostol in the setting of a hospital operating room. The potential unpredictability of misoprostol effect in relation to timing (and need for doing the procedure sooner because of pain or bleeding) may not be practical in clinical settings where dilation and evacuation procedures are performed infrequently or when using hospital operating rooms with a predetermined schedule and where patients share preoperative space.

##### 5. How many osmotic dilators should be placed?

The number of dilators placed varies greatly amongst clinicians and depends on the choice of dilator used, desired preoperative dilatation, gestational age, parity and risk factors for cervical laceration. The package labeling for Lamichel<sup>®</sup> and laminaria refers to placement of a single tent but does not specifically preclude multiple tent placement [19,25]. The package labeling for Dilapan-S<sup>™</sup> recommends 2 tents between 13 and 15 weeks, 3 between 16 and 18 weeks, and 4 at 18 weeks of gestation and beyond; however, these recommendations are not based on published clinical trials [35].

A small study demonstrates effective cervical preparation for D&E up to 16 weeks of gestation with overnight use of a single Dilapan<sup>™</sup> [33]. In another case series of 80 women who received a single Dilapan<sup>™</sup> 6 h before D&E at 15–20 weeks of gestation, adequate cervical preparation was achieved in 97.5% [59]. Two subjects sustained cervical lacerations requiring suture.

Published reports demonstrate the safety of performing a D&E after preparation with single Lamichel<sup>®</sup> a few hours preoperatively in gestations up to 16 weeks [32,33] and after overnight placement in pregnancies up to 17 weeks [24]. Grimes et al. [32] conducted a double-blind randomized trial comparing the effect of a single Lamichel<sup>®</sup> to multiple laminaria (mean 5.4) placed a few hours before D&E at 14–16 weeks of gestation ( $n=219$ ). Significantly fewer subjects prepared with a single Lamichel<sup>®</sup> achieved a preoperative dilation of 43F (10% vs. 22%;  $p=.03$ ), as assessed by Pratt dilators. However, equal percentages reached 37F prior to surgery (47%). Subsequent manual dilation was subjectively easy in 95% of both groups. Subjects receiving Lamichel<sup>®</sup> were more comfortable and significantly less likely to have a vasovagal reaction with placement. Since fewer dilators

were used, Lamichel<sup>®</sup> was less expensive. The investigators concluded that Lamichel<sup>®</sup> was a favorable alternative to multiple laminaria tents prior to 16 weeks of gestation.

Textbooks and clinical experts offer guidelines based on provider experience [3,10,60]. These protocols recommend increasing numbers of dilators with increasing gestational age. While one osmotic dilator placed a few hours preoperatively is sufficient early in the second trimester, later gestations may require multiple tents placed overnight or serially for one or 2 days. Approximately half the number of Dilapan-S<sup>™</sup> compared to laminaria is needed due to the increased dilation achieved by the former [3,19,61]. Some providers may consider using more osmotic dilators in patients with no prior vaginal birth or other risk factors for challenging manual dilation. Importantly, specific protocols have not been compared in clinical trials, and none is clearly superior.

Though studies demonstrate that a single set of dilators is generally sufficient prior to 20 weeks of gestation [38,57,59], some clinicians place serial sets over 1–2 days [3,62,63]. More tents may be placed with each successive set due to increasing cervical dilation and softening. Stubblefield et al. [64] conducted a randomized study comparing a 1- (18–22 h) vs. 2-day (48 h) laminaria protocol prior to D&E between 17 and 19 weeks of gestation ( $n=60$ ). Greater dilation was achieved with the 2-day regimen than the overnight regimen (22.4- vs. 18.2-mm diameter;  $p<.001$ ), and subsequent dilation was subjectively easier in the 2-day group. However, the authors questioned whether the small clinical benefit of the 2-day regimen was outweighed by the additional patient inconvenience and discomfort entailed in placement of a second set of dilators the following day. The gestational age at which multiple sets of osmotic dilators should be placed has not been determined.

##### 6. How long should osmotic dilators be left in situ?

The length of time dilators should be retained varies depending on the dilator being used and the degree of dilation needed to complete the procedure. Early in the second trimester, overnight dilation is not required [32,33]. Though commonly recommended beyond 16 weeks of gestation [3], no controlled clinical studies clarify the gestation at which overnight dilation is beneficial.

Since Lamichel<sup>®</sup> and Dilapan<sup>™</sup> achieve their maximum effect within a few hours, overnight placement is usually unnecessary in gestations up to 20 weeks. A small comparative trial found no difference in cervical dilatation when Lamichel<sup>®</sup> was placed for 4 or 16 h [28]. Laminaria tents dilate more slowly and, for this reason, they are often left in place overnight. With shorter preparation (8 h), a single laminaria achieves less dilation than a single Lamichel<sup>®</sup> (7.5 vs. 4.7 mm;  $p<.001$ ) [31].

Laminaria tents and synthetic dilators have commonly been left in situ overnight. The package labeling indicate that they should not be left in place for more than 24 h [19,25,35].

However, Laminaria tents and synthetic dilators have commonly been left in situ for up to 24 h for continued priming effects without reports of infectious complications [33,38,52,65–67]. Hern and Oakes [66] reported a 2% postoperative infection rate in patients less than 20 weeks of gestation treated with serial laminaria for a median time of 41 h. Others reported no complications with tents in place for 48 h [65,67]. No studies directly compare infection rates by duration of cervical preparation.

When placing serial sets, some clinicians remove and replace all cervical tents, while others add additional dilators to those already in situ [3]. The risk of infection for both approaches is very low and has not been directly compared.

*7. What are the pregnancy outcomes if the patient chooses to continue her pregnancy after osmotic dilators or prostaglandin analogues are used for cervical preparation?*

Despite counseling prior to preoperative cervical preparation, some women may ultimately decide to continue their pregnancy after beginning the abortion process. In the largest published series evaluating outcomes in pregnancies continued after use of osmotic dilators, 14 of 515 women in their second trimester (2.7%) requested that cervical dilators be removed after placement, which was more than double the rate for women in the first trimester [68].

Limited data are available on pregnancy outcome subsequent to removal of laminaria tents with none available specifically for Dilapan™, Dilapan-S™ or Lamicel®. A small case series demonstrated that osmotic cervical dilation can reverse and that pregnancies may continue despite intentional dilation up to 2 cm [69]. The largest series of women who continued their pregnancies after laminaria removal includes only 17 women, of whom 14 (82%) delivered healthy term infants [68]. Two delivered prematurely and one miscarried 2 weeks after tent removal. With preterm cervical dilation, exposed membranes, and the presence of a foreign body, there is a theoretical increased risk of ascending infection. However, the miscarriage and preterm deliveries noted in this series were not attributed to infection. Of note, prophylactic antibiotics were administered at the time of dilator insertion and were continued after tent removal in most women [68,69].

If a woman decides to continue her pregnancy after misoprostol exposure, the potential for an increased risk of spontaneous abortion, preterm labor, and teratogenesis should be addressed. Misoprostol use in the first trimester of pregnancy may be associated with fetal anomalies, specifically Mobius' syndrome, a rare congenital facial paralysis, with or without limb defects [70,71]. In a retrospective case-control study, 96 infants with Mobius' syndrome were compared to 96 infants with neural tube defects [70]. Misoprostol exposure was noted in 49% of the Mobius' syndrome infants compared to 3% of the controls with neural tube defects (OR 29.7, 95% CI 11.6–76.0). No studies exist to confirm or exclude misoprostol as a teratogen beyond the first trimester.

*8. What are the relative risks of using osmotic dilators and misoprostol for cervical preparation between 14 and 20 weeks for women with a prior cesarean delivery?*

While studies involving D&E sometimes include women with prior cesarean sections, no one specifically examines the safety of dilator placement in these women. In a retrospective case control study, 70 women with a history of Cesarean delivery undergoing D&E at 14–22 weeks of gestation preceded by laminaria placement were compared to 994 with unscarred uteri [72]. Complication rates were not increased in subjects with a prior cesarean delivery. No uterine perforations or cervical lacerations occurred in either group. In contrast, Pridmore et al [73] reported a 19-fold higher risk of uterine perforation during D&E up to 20 weeks of gestation in women with prior cesarean deliveries. Three women amongst the sixty with a prior cesarean vs. three of the 1155 with an unscarred uterus sustained perforations (5% vs. 0.26%;  $p < .0001$ ). Osmotic dilators were not used in these patients, and the cervix was prepared with gemeprost, a prostaglandin analogue. The authors reported that, after conversion to use of osmotic dilators with adjunctive misoprostol, the perforation rate was zero.

Most data on the use of misoprostol beyond the first trimester comes from studies of labor induction. When used for third-trimester labor induction, misoprostol is associated with an increased risk of uterine scar rupture when compared to spontaneous labor or induction with oxytocin [74]. The literature regarding use of misoprostol for induction terminations in the second trimester suggests that misoprostol is relatively safe in women with a history of prior Cesarean delivery [75–79]. Only a few studies report outcomes in women with 2 or 3 prior cesarean sections [46,52,57]. Although the total number of women in these trials is small, no adverse outcomes have been noted. Rupture of a prior uterine scar has been reported in the second trimester after misoprostol use for labor induction; however, this outcome is rare [80].

Misoprostol administration prior to D&E typically involves one dose given on the day of surgery, whereas misoprostol for induction abortion involves multiple doses until vaginal delivery occurs. Theoretically, the lower cumulative misoprostol dose before D&E should decrease the chance of uterine scar rupture. A single case report of a uterine rupture during D&E preceded by overnight laminaria and two doses of preoperative misoprostol was found in the published literature [81]. This patient was 23 weeks gestation and had two prior cesarean deliveries. A few studies of misoprostol use prior to D&E include small numbers of women with prior cesarean section [55,57]. In the large review conducted at planned parenthood clinics described previously, 123 subjects with a prior cesarean delivery were given buccal misoprostol for cervical priming [58]. No uterine ruptures or scar dehiscences were reported.

Since uterine rupture is rare in the second trimester, no study has sufficient power to address the overall risk of this

complication and determine if risk is significantly increased by misoprostol administration. However, limited data suggest that misoprostol may be used for priming prior to midtrimester D&E for women with a prior cesarean section. No studies specifically address uterine scar location (i.e., low transverse vs. classical incision) or risk in subjects with a prior transmural myomectomy.

#### 9. Should cervical dilators be placed in the setting of ruptured membranes?

A retrospective case-control study of 34 women with midtrimester premature rupture of membranes showed that overnight laminaria placement prior to D&E did not result in increased rates of infection or complications in comparison to controls with intact membranes [82]. Of note, all subjects were treated with a 5-day course of broad-spectrum oral antibiotics.

#### 10. May dilators be placed in patients with a placenta previa?

Thomas et al [83] studied 131 women, 23 of whom had a low-lying placenta, partial previa or complete placenta previa, who underwent dilator placement and midtrimester D&E. Those with previa had an increased operative blood loss of approximately 20 cc, but there was no difference in operative time, hemorrhage, or infection. Safety was demonstrated up to 24 weeks of gestation in eight subjects with complete previa, with no increase in bleeding or transfusions [84]. Despite theoretical concerns, no significant bleeding was noted during or after laminaria placement in both studies. However, these studies do not address outcomes in the subset of women with placenta previa who are already bleeding prior to dilator insertion.

### Conclusions and recommendations

*Level A: The following recommendations are based on good and consistent scientific evidence*

- Cervical preparation is recommended prior to D&E between 14 and 20 weeks of gestation to decrease risk of cervical trauma.
- Osmotic dilators (laminaria, Lamichel<sup>®</sup> and Dilapan-S<sup>™</sup>) are safe and effective for preoperative cervical preparation prior to D&E.
- Use of osmotic dilators for second trimester D&E does not increase infectious morbidity.
- When dilator placement and D&E are to be performed on the same day, cervical preparation with Dilapan-S<sup>™</sup> or Lamichel<sup>®</sup> is preferred over laminaria tents as they achieve adequate priming more quickly.

*Level B: The following recommendations are based on limited or inconsistent scientific evidence*

- Prior to 20 weeks of gestation, cervical preparation may be achieved with a single set of osmotic dilators. Serial

sets of osmotic dilators over a 2-day interval are not routinely needed but may be considered based on patient risk factors and clinician experience.

- Routine use of misoprostol as an alternative to osmotic dilation prior to second-trimester D&E is not recommended due to increased risk of inadequate cervical dilation. Buccal or vaginal misoprostol use may be considered by experienced clinicians in lieu of osmotic dilation early in the second trimester (before 16 weeks) in women at low risk for cervical or uterine injury.
- Routine use of adjunctive buccal misoprostol in addition to osmotic dilators for preoperative cervical preparation is not recommended in the early second trimester (before 16 weeks) but may be considered at later gestational ages.
- Misoprostol may be given in the second trimester prior to D&E to women with a prior cesarean delivery, since uterine rupture or scar dehiscence occurs rarely in this setting.

*Level C: The following recommendations are based primarily on consensus and expert opinion*

- Overnight placement of osmotic dilators is recommended after 16 weeks of gestation.
- The choice of number and type of osmotic dilators and length of preoperative treatment depend on gestational age, clinical experience and individual patient risk. While increasing numbers of osmotic dilators are indicated for cervical preparation at greater gestational ages, no single protocol has been proven ideal.

### Important questions to be answered

Despite advances in second-trimester surgical abortion techniques over the past 3 decades, the ideal cervical preparation before second-trimester surgical abortion remains unknown. Future studies should focus on clarifying the gestational age at which overnight dilation is required. Studies are also needed to determine the gestational age at which serial sets of dilators over 1–2 days are needed.

Another question remaining is whether the reformulated Dilapan-S<sup>™</sup> resolves the removal and fragmentation problems of its predecessor. Prospective comparative trials comparing the newer formulation to laminaria and Lamichel<sup>®</sup> are needed to determine if the Dilapan-S<sup>™</sup> has a more favorable profile.

Finally, the use of misoprostol as an alternative or adjunct to osmotic dilators prior to D&E warrants further study. Limited published data demonstrate that misoprostol is inferior to overnight osmotic dilation with laminaria; however, in some circumstances, misoprostol may be more convenient than osmotic dilation. The common use of buccal misoprostol as a replacement for overnight osmotic dilation has not been subject to appropriate comparative trials.

Additionally, the efficacy of misoprostol has not been compared to single day protocols using the faster acting tents Dilapan-S™ and Lamichel®. Finally, the side-effect profile of misoprostol in comparison to osmotic dilation warrants further investigation.

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## Sources

The MEDLINE database was used to identify references published between 1966 and May 2007. The database was searched for the following terms: laminaria, Lamicel<sup>®</sup>, Dilapan<sup>™</sup>, second trimester pregnancy, dilation and evacuation, induced abortion, mifepristone and misoprostol. Only English-language abstracts were included. The abstracts were reviewed, and relevant articles were obtained. Additional references cited in these journal articles were reviewed. Additionally, contemporary textbooks and published women's health guidelines were consulted.

## Authorship

These guidelines were prepared by Michelle C. Fox, M.D., M.P.H., and Jennifer L. Hayes, M.D., M.P.H., and were reviewed and approved by the Board of the Society of Family Planning.

## Conflict of Interest Statement

Michelle C. Fox, M.D., M.P.H., and Jennifer L. Hayes, M.D., M.P.H., report no significant relationships with industry relative to these guidelines. The Society of Family Planning receives no direct support from pharmaceutical companies or other industries.

## Intended Audience

This guideline has been developed by the Society for Family Planning for its members and other clinicians who perform surgical second-trimester abortions. This guideline may be of interest to other professional groups that set practice standards for family planning services. The purpose of this document is to review the medical literature evaluating common means of cervical preparation for second-trimester surgical abortion prior to 20 weeks of gestation. This evidence-based review should guide clinicians in preparing the cervix prior to dilation and evacuation, though it is not intended to dictate clinical care.