Loop Electrocurgical Excision Procedure (LEEP) and Cold Knife Conization

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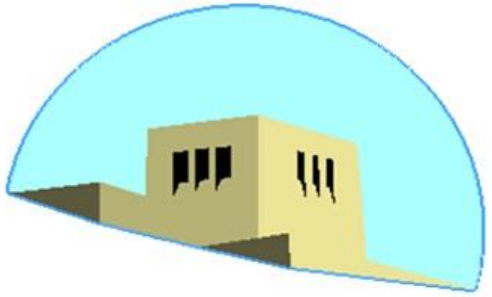


Objectives

- Review the indications and techniques of LEEP and cold knife cone
- Compare risks of LEEP vs. cold knife cone
- Review the failure rates and risk factors for recurrence of disease after LEEP and cone

Summary

- Excision is widely used as treatment for HSIL of the uterine cervix (CIN2 and CIN3)*.
  - Preferred over ablation with large lesions (>75% of cervix area), lesions extending into the endocervical canal, or if the transformation zone is not fully visualized
  - LEEP is usually an office procedure performed under local anesthesia
  - Cold knife conization (CKC) is performed in the operating room usually with general or regional anesthesia

*LAST terminology is used in this module (See Darragh et. al. J. Low Genit Tract Dis 2012 ;16:205-42.)

Summary

- Excision provides tissue for histologic examination
  - Reduces risk of missing occult invasive cancer
  - Allows assessment of surgical margins
- Success rates high with both LEEP and cold knife cone. Risk of recurrence lower with cold knife cone.
- Perinatal risks in subsequent pregnancy higher with cold knife cone.

Treatment Terminology

- Ablation
  - Destruction of the entire transformation zone
- Excision (LEEP and cold knife cone)
  - Removal of the transformation zone
  - Provides tissue for histopathology evaluation

Indications for LEEP

- HSIL when not good candidate for cryotherapy
  - Lesion too large (3 quadrants of cervix)
  - Lesion extends into canal or SCJ not fully visualized
- Histologic specimen needed

Indications for Cold Knife Cone

- Same as indications for LEEP

  plus

- Suspected microinvasive squamous carcinoma
- Rule out adenocarcinoma in situ
  - Requires deep cylindrical endocervix conization
- Distorted cervical or vaginal anatomy
  - Cervix fixed in downward pointing position
  - External os obliterated or flush with vaginal apex
- High grade lesion extends deep into canal
  - Cone vs LEEP with top hat

General Principles of Treatment

- HSIL (CIN2, CIN3) begins at squamocolumnar junction
  - If colposcopy adequate, squamous lesions do not begin de novo within the endocervical canal
- Most severe area of lesion is usually most central
- Treat the transformation zone (TZ) 360 °
  - Excise circumferentially to a distance at least 2-3 mm beyond width of lesion
  - Higher failure rates if treat only the lesion
- Excise to depth of at least 5-7 mm
  - 99% of endocervical gland involvement to depth <5 mm

Wright and Davies, 1983

Excision Procedures: Contraindications

LEEP

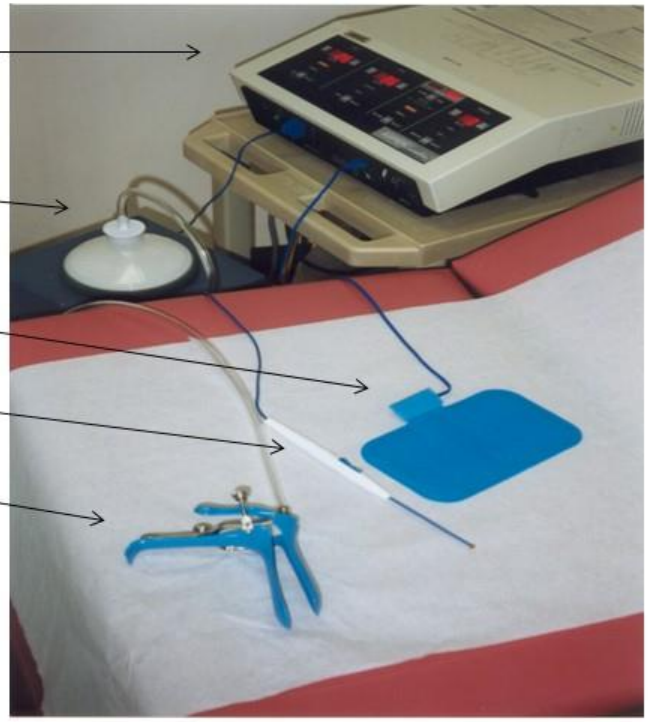
- Severe cervicitis
- Pregnancy
- Allergy to local anesthetic
- Hemorrhagic disorder/anticoagulant therapy
- Demand type cardiac pacemaker
- Suspected microinvasive or invasive cancer (relative)
  - Risk of thermal artifact
- Suspected adenocarcinoma or adenocarcinoma in situ (relative)
  - Risk of thermal artifact

Cold Knife Cone

- Severe Cervicitis
- Pregnancy (relative)
- Contraindications to anesthetic
- Hemorrhagic disorder/ anticoagulant therapy

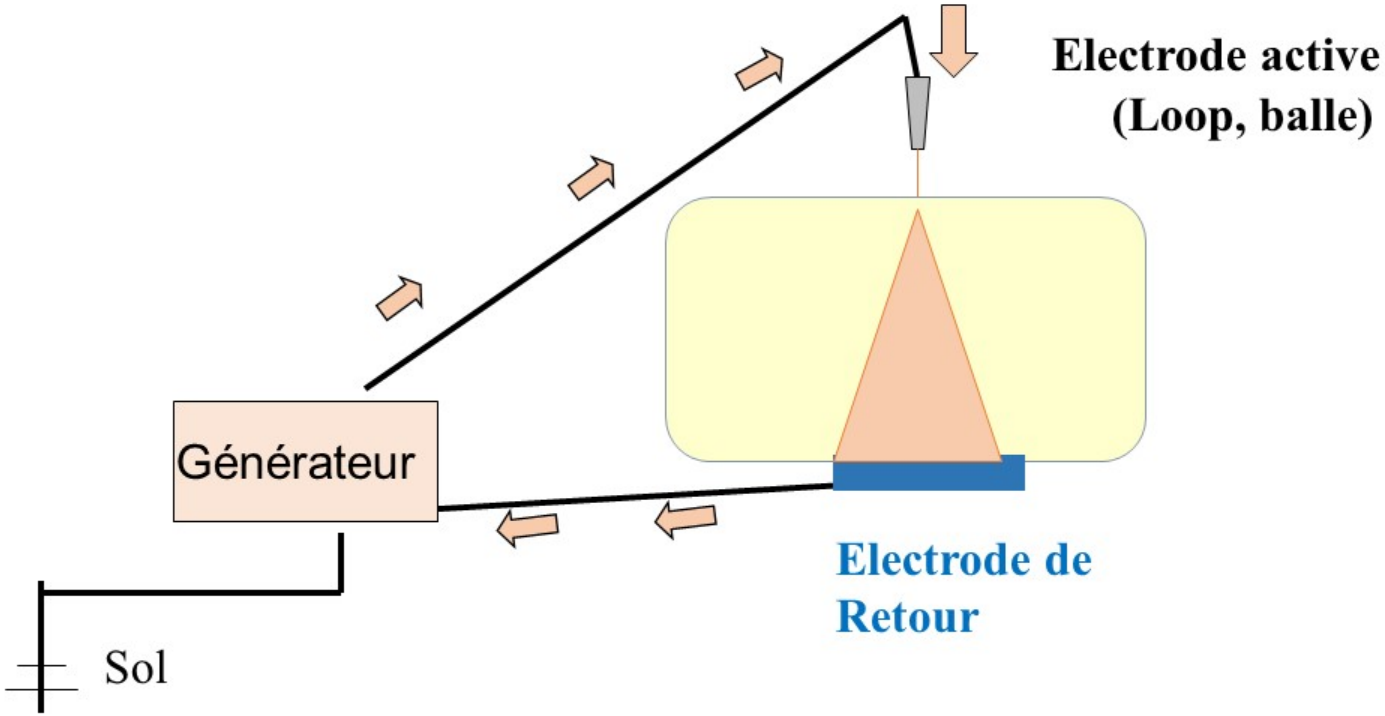
Elements of electrosurgical system for LEEP

- Monopolar electrosurgical generator (ESU) with isolated circuitry and monitoring system
- Smoke evacuator
  - May be separate or built in
- Return electrode (dispersive pad)
- Active tissue electrode
  - Loop and ball electrodes
- Insulated speculum with smoke evacuation port
- Insulated vaginal sidewall retractor (often helpful)



Circuit électrochirurgical

- Le courant circule de générateur à l'électrode de tissu actif (haute densité de courant) à travers le patient à dispersif pad (faible densité de courant) et retour vers le générateur.

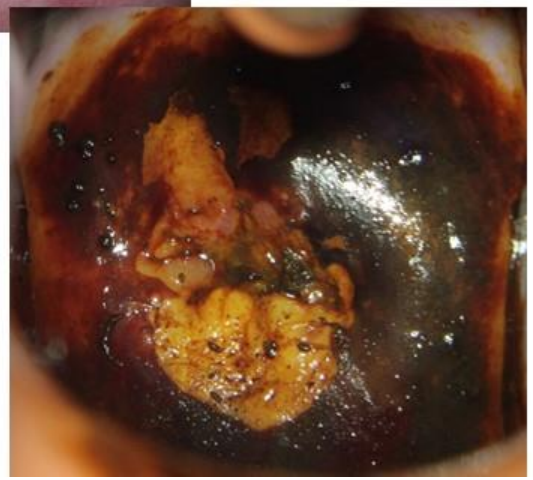


Safety precautions: LEEP

- Remove metal jewelry from patient
- Avoid grounding to metal equipment
    - Metal stirrups, instrument trays, IV poles
- Dispersive pad (return electrode) must be in complete contact with patient near operative site
- Inspect return electrode and generator for frayed wires
- Avoid alcohol, flammable liquids near electrode
- Patient should not have cardiac pacemaker
- Ask about allergies to anesthesia or iodine

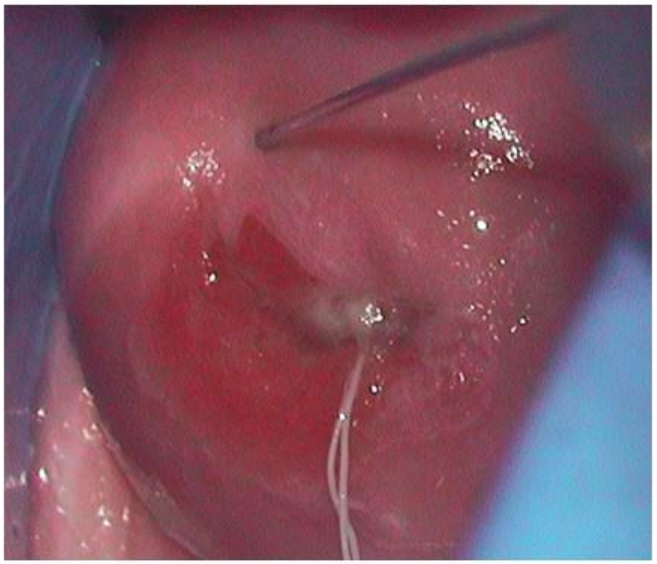
LEEP Technique

- Review Pap and Colposcopy
- Informed consent
- Repeat colposcopy to identify lesion
- Lugols to outline lesion and area of transformation zone to be removed



LEEP Technique: Anesthesia

- Submucosal intracervical field block
  - 1-2% lidocaine with epinephrine or pitressin
    - One approach: 5 cc 2% lidocaine with epinephrine follow with additional 1% or 2% lidocaine without epinephrine
  - Injected at multiple sites
    - Small gauge spinal needle
  - Wait several minutes
  - Transient tachycardia normal

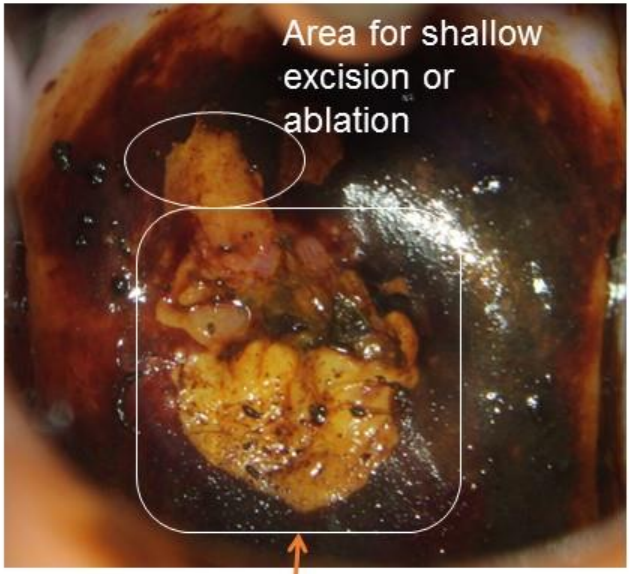


LEEP Technique

- LEEP should be performed through the colposcope for precision.
- LEEP will remove 360 degrees of transformation zone to 2-3 mm beyond lesion
- Practice pass with current turned off
- Start blended or cutting current prior to touching tissue
  - Current setting depends on generator and size of Loop

LEEP Technique

- Perform LEEP in a single smooth movement
  - Side to side preferred
  - Convexity of loop through center of cervical canal
- Endocervical top hat extension if indicated
- Shallow excision or ablation with cautery if part of lesion remains beyond excision margins
- Endocervical curettage

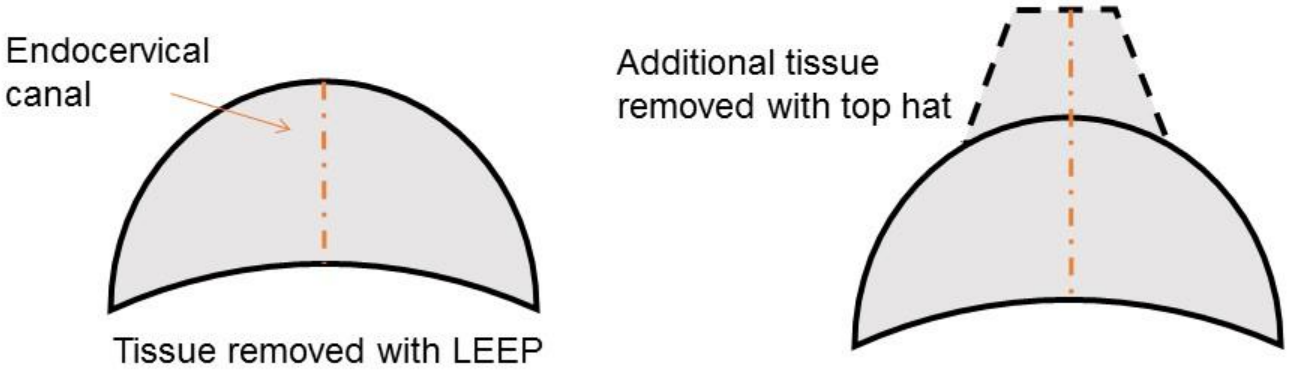


LEEP Technique

- Cauterize base with ball electrode
  - Avoid os to decrease stenosis
- Monsel's may be needed
- Pin out specimen –orient ectocervical vs endocervical margin

The Top Hat

- Add a deeper 1cm x 1cm extension after the initial LEEP excision
- Indications
  - Suspected disease in canal above depth of LEEP
- Increased risk of thermal artifact

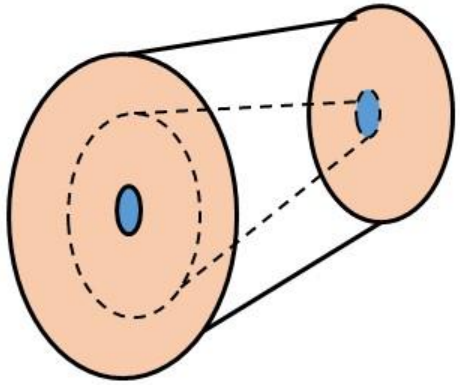


Cold Knife Cone: Technique

- General or regional anesthesia in operating room
- Identify transformation zone with colposcopy and /or Lugol's iodine
- Anterior lip of cervix stabilized with tenaculum
- Cervix may be injected with dilute vasopressin for hemostasis
- Stay sutures near level of internal os at 3:00 and 9:00
  - 2-0 delayed absorbable sutures
  - Hemostatic, useful for traction, may be loosely tied together to hold Surgicel at conclusion of case

Cold Knife Cone: Technique (2)

- Using straight or angled scalpel with #11 blade, perform cone shaped excision
  - Remove 360^0 of transformation zone beginning 2-3 mm beyond lesion
  - Remove endocervical canal to depth of cone
- Base excised with curved scissors



Hemostasis

Running locking suture (2-0 or 3-0 delayed absorbable) around excised edge
Alternately cautery may be used same as LEEP
Accessories for hemostasis

Cold Knife Cone: Technique (3)

- Hemostasis
  - Running locking suture (2-0 or 3-0 delayed absorbable) around excised edge
  - Alternatively, cautery may be used same as LEEP
  - Accessories for hemostasis
    - Monsels
    - Surgicel in cone bed loosely tied in place with stay sutures previously placed at 3:00 and 9:00

Discharge Instructions: LEEP and Cold Knife Cone

- Ibuprofen or tylenol usually sufficient for pain – expect mild cramping
- Back to work one to two days for LEEP, may be 1-2 days longer for cold knife cone
- Patient will have discharge for several days to weeks
- Avoid intercourse X 4 wks
- Avoid heavy lifting or vigorous exercise X 2 weeks
- RTC or call for heavy bleeding, fever, severe abdominal pain

Complications of LEEP and Cone

- Bleeding
  - Intraoperative blood loss: Cone > LEEP
  - Delayed bleeding risk comparable between LEEP and cone
- Stenosis
  - More likely with deep excision (>2 cm) or totally endocervical lesion
- Thermal artifact with LEEP
  - May obscure margins
- Unintentional burns with LEEP
  - Vaginal sidewall
  - Under return electrode or alternate ground
    - Uncommon with modern generators

Obstetric Outcomes after LEEP vs CKC: 2 meta-analyses

M Kyrgiou, et al. Lancet 2006;367:489-498
M Arbyn et.al. BMJ 2008;337: a1284

LEEP

Statistically significant increase

- Late preterm births (>32 / 34 wks)
- pPROM
- Low birth weight infants

No statistically significant increase

- Preterm births <32/34 weeks
- Cesarean section
- NICU admissions
- Perinatal mortality

CKC

Statistically significant increase

- Late preterm births (>32 / 34 wks)
- Preterm births <32/34 weeks
- Low birth weight infants
- Cesarean Section

No statistically significant increased risk of preterm birth after LEEP compared with women with cervical dysplasia but no excision.

S Conner et al Obstet Gynecol 2014;123:752-61

Risk of Recurrence after Treatment

- Retrospective study of 37,142 women treated for CIN
  - Compared Cryo, Laser, Cone, LEEP with negative margins
- Recurrence of CIN 2,3 in first 6 yrs after Tx
  - Higher with older age
  - Higher with more severe dx at treatment
    - CIN 3> CIN 2> CIN 1
  - Varies with treatment modality
    - Cryo > LASER> LEEP > Cone
  - Rate of CIN 2,3 diagnosis after treatment of CIN 3
    - Age 30-39: CKC 6.3% LEEP 9.6%
    - Age 40-49: CKC 8.5% LEEP 12.9%

Melnikow, et al J Natl Cancer Inst 2009;101:721-728

Risk of Recurrence if Margins Involved

- Meta analysis of 25 studies
  - RR of CIN 2+ after incomplete excision 6.09 (CI 3.87-9.60) compared with complete excision
  - Frequency of post –treatment CIN 2+
    - Clear margins - 3%
    - Margins involved - 18%

Ghaem-Maghami et al Lancet-oncol 2007:8:895-93

ASCCP Guidelines for Follow-up After Treatment of CIN 2 and CIN 3

- Cotesting at 12 and 24 months
  - Results negative for both cytology and HPV X 2 → cotesting in 3 years – if negative, return to routine screening
  - If any test positive → colposcopy with endocervical sampling
- CIN 2 + identified at surgical margins or on immediate post- procedure ECC
  - Repeat cytology and ECC in 4-6 months (preferred)
  - Repeat excision (acceptable)
    - Hysterectomy acceptable if re-excision not feasible

Massad et al J Low Genit Tract Dis 2013;17(5S):S1-17

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