# Comparison of Success Rate and Complications of Contour-Loop Excision of the Transformation Zone (C-LETZ) with Cold Knife Conization (CKC) in High Grade Lesion (HGL) from Colposcopic Impression

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**Objective:** To compare the complications and success rate of Contour-Loop Excision of the Transformation Zone (C-LETZ) with Cold Knife Conization (CKC) in High Grade Lesion (HGL).

*Material and Method:* Between April 1<sup>st</sup>, 2007 and November 30<sup>th</sup>, 2007, forty-five C-LETZs were performed in patients who had Pap smear result of High grade Squamous Intraepithelial Lesion (HSIL) or Squamous Cell Carcinoma (SCC) combined with colposcopic impression of satisfactory HGL by using the "See and Treat" approach. Success rate, tissue size, operating time, blood loss, intra-operative, and post-operative complications (2 weeks) were recorded to compare with the retrospective results from therapeutic CKC.

**Results:** Forty-five cases of C-LETZ and 50 cases of CKC were compared. Using the "See and Treat" approach, the over-treatment rate was 6.7% (3/45). The success rate and tissue size were not different between both groups. The operating time, blood loss, and post-operative infection were significantly less in the C-LETZ group.

**Conclusion:** The authors compared CKC with C-LETZ, which is a new method for the management of HGL of the cervix and found C-LETZ to be a favorable method with comparable efficacy but with significantly less morbidity, and suitable as a "See and Treat" method in a hospital outpatient clinic.

**Keywords:** Cold knife conization, CKC, Contour loop excision of the transformation zone, C-LETZ, Cervical intraepithelial neoplasia, Treatment outcome, Postoperative complications

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Cold Knife Conization (CKC) is the conventional technique for both diagnosis and treatment of cervical intraepithelial neoplasia (CIN), especially High Grade Lesion (HGL)*i.e.* CIN2 and CIN3. However, the use of conventional CKC usually required hospitalization, regional anesthesia, and high capital cost<sup>(1)</sup>. Loop Electrosurgical Excision Procedure (LEEP) or Large-Loop Excision of the Transformation Zone (L-LETZ) was introduced several years ago and has become an established method due to its lower cost, easy technique, equal success rate, and less morbidity compared to CKC<sup>(2-6)</sup>.

In most cases, L-LETZ can be performed on an out-patient basis in combination with colposcopic examination. For the management of HSIL cytology, many studies have shown a favorable outcome and acceptable over-treatment rate of the "See and Treat" approach<sup>(1,7-10)</sup>. Contour-Loop Excision of the Transformation Zone or C-LETZ with FINESSE<sup>TM</sup> electrosurgical unit (Utah Medical Product, Inc) has been established as a new electrosurgical conization

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technique with favorable clinical results<sup>(11)</sup>. The C-LETZ is performed with contoured loop electrodes for 360 degrees rotation during conization. These loop electrodes are available in several models with different radius and depth to match the size and shape of the cervical lesions. Currently, there is no published report available that describes the clinical comparison between CKC and the C-LETZ technique in terms of success rate, morbidity, and tissue size. In the present study, the authors reported not only the comparison of these parameters but also the pain score and thermal artifacts produced when using the C-LETZ technique.

The primary objective of the present study was to compare the operating times, blood loss, intraoperative complications, post-operative complications, tissue sizes in radius and depth, and the success rates, between C-LETZ and CKC in the management of colposcopic HGL of the cervix. The authors employed the "See and Treat" approach throughout for all of the C-LETZ procedures. The secondary objective was to ascertain the pain score during the C-LETZ procedure, the tissue thermal injury, and the accuracy of "See and Treat" approach in the authors' institute.

### **Material and Method**

Two groups of patients were recorded. The first group is the C-LETZ group, which included all women with HSIL or SCC PAP smear recorded at Songklanagarind Hospital between April 2007 and November 2007. Colposcopy and C-LETZ were performed in this group of patients by the "See and Treat" approach. Inclusion criteria were non-pregnant women with documented HSIL or SCC cytology but also with a satisfactory colposcopy with the colposcopic impression of HGL. Exclusion criteria were the suspicion of invasive cancer, previous cervical surgery or radiation, recent infection, coagulopathy, and immuno-compromised host. After informed consent, all of the patients underwent colposcopy and all the demographic data, colposcopic finding and Reid's colposcopic index (RCI) were recorded.

The C-LETZ procedure was performed under local anesthesia with 2 ml of 4% Xylocaine, injected at 2, 4, 6, 8, 10, and 12 o'clock peripheral to the lesion approximately 5 mm deep into the cervical parenchyma. The electrosurgical unit (ESU), FINESSE<sup>™</sup> from Utah Medical Products Inc was preset at the blended cut waveform-1 at 65 watts and at 60 watts for the coagulation waveforms. The C-LETZ loop electrodes (Fig. 1) are asymmetric and appropriate for conization of lesions with different degrees of ectocervical and



Fig. 1 C-LETZ electrodes, Radius (R) and Depth (D) in millimeter. No. DCE 110, DCE 115, DCE 120 and DCE 12 are 15 x 23, 11 x 18, 12 x 10 and 9 x 13 millimeters respectively

endocervical extensions and were selected as required by the extension of the lesions. The conization procedure was performed in four steps: 1) the tip of the electrodes was placed at the cervical os, with the electrode arm in the 12 o'clock position; 2) after activation of the ESU, the C-LETZ electrodes were pressed into the cervical os to its maximum depth; 3) the electrode was rotated 360 degree in the cervical os; 4) the electrode and the excised specimen were removed. Each excised specimen had a constant thickness and was removed in one piece. Haemostatic was achieved by fulguration using the ball electrode from the same supplier.

In the present study, all C-LETZ procedures were performed by the same physician throughout. The operating time, amount of bleeding, haemostatic, Visual Analogue Score (VAS) for the evaluation of pain level, and intra-operative complications were recorded. The sizes of the excised specimens were recorded before formalin fixation and finally transferred for pathological examination. Only one pathologist examined and reported the final pathological results, which included diagnosis, marginal status, and thermal artifact. Clinical-Pathologic-Correlation was routinely done once a week. The first follow-up was 2 weeks after C-LETZ including vaginal examination and recording of the patient history concerning any complications such as pain, infection, bleeding, and intestinal or urinary complications. Appropriate treatments were initiated in case of complications, positive margin, or invasive cancer. Six months follow-up for the next cytological study was scheduled in patients with no complications and in which the conization had been performed with a free resection margin.

The second group was the patients who fulfilled the inclusion criteria and underwent CKC by

the physician (Residents and fellowship residents) at Songklanagarind Hospital between January 1<sup>st</sup>, 2002 and December 31<sup>st</sup>, 2006. The inclusion criteria were HSIL or SCC PAP smear cytology, and satisfactory high-grade colposcopic impression with colposcopic directed biopsy confirmed as CIN2, 3, or carcinoma in situ (CIS). Exclusion criteria were previous cervical surgery or radiation, recent infection, coagulopathy and immuno-compromised host. Demographic data, colposcopic impression, RCI, operating time, anesthesia, amount of bleeding, haemostatic, operative complications, size of specimen, final diagnosis, marginal status, and two weeks complications such as pain, infection, bleeding, and intestinal or urinary complications were all reviewed and recorded.

The sample size in each group was calculated by two-proportion differences of infection complication. The authors hypothesized that the two-week infection rate in the C-LETZ group should be lower than that in the CKC group for at least two-thirds; therefore, the 42 samples of each group was needed with the power of 80%. The continuous data were analyzed by pair t-test or Wilcoxon Rank Sum test as appropriate. The categorical data were analyzed by Chi-square or Fisher exact test as appro priate. The p-value of 0.05 was considered as statistical significance. All data were entered into EpiData 2.0 and the statistical analysis was done using R statistical software packages version 2.6.1 (The R Foundation for Statistical Computing (ISBN 3-900051-07-0) and Epicalc package version 2.6.1.6 (Chongsuvivatwong V, copyright 2007). The present study was approved by the Institute Ethics Committee of the Faculty of Medicine at Prince of Songkla University, Hat Yai, Songkhla, Thailand.

# Results

Forty-five and fifty patients were included in the C-LETZ group and CKC group, respectively. The demographic data are shown in Table 1. There were no differences in mean age, religion, reproductive period, parity, co-factor of persisted HPV infection, and RCI between the two groups. As seen in Table 2, neither the size of the excised specimens nor the frequency of free margins was significantly different between the groups. The median operating times and median amounts of blood loss were significantly less in the C-LETZ group. Injury to the vaginal wall occurred in one case in the C-LETZ group without severe

Table 1.	Demographic data of	patients undergoing CKC	(group-1) and C-LETZ (Group-2)

	Group-1 (CKC) n = 50	Group-2 (C-LETZ) n = 45	p-value
	11 – 50	11 – 43	
Mean age (SD)	41.4 (6.8)	44.2 (8.4)	NS
Religions			NS
Buddism	46 (92%)	37 (82.2%)	
Muslim	4 (8%)	8 (17.8%)	
Reproductive			NS
Premenopause	44 (88%)	35 (77.8%)	
Menopause	6 (12%)	10 (22.2%)	
Parity			NS
Nulliparous	6 (12%)	2 (4.4%)	
Multiparous	44 (88%)	43 (95.6%)	
OCP* used	13 (26%)	10 (22%)	NS
Coitache < 20 years	18 (36%)	20 (44.4%)	NS
Multiple partner	15 (30%)	12 (26.7%)	NS
Previous STD**	4 (8%)	4 (8.9%)	NS
Smoking	2 (4%)	5 (11.1%)	NS
Reid colposcopic index (RCI)			NS
3-5	4 (8%)	9 (20%)	
> 5	46 (92%)	36 (80%)	

\* OCP = oral contraceptive pill

\*\* STD = sexually transmitted disease

NS = no statistical significance different

	Group-1 n = 50	Group-2 n = 45	p-value
	n = 50	11 – 45	
Tissue size			
Mean radius (mm)	9.8	10.4	0.264
Median depth (mm)	10	13	0.236
Median operative time (min)	40	3	< 0.001
Median blood loss (ml)	85	5	< 0.001
Hemostatic methods			
Electric fulguration	14	22	0.06
Monsel's paste	13	45	< 0.001
Vaginal packing	30	3	< 0.001
Intra-operative complications	0	1	0.474
Marginal status			0.174
Free margin	37	32	
Positive ectocervical margin	4	2	
Positive endocervical margin	9	7	
Positive both margins	0	4	
Two week complications			
Infection	18 (36%)	3 (6.6%)	0.001
Secondary hemorrhage	1	1	1

**Table 2.** Comparison of specimen size, operative time, and morbidity obtaining from Cold Knife Conization, CKC, (Group-1) and Contour Loop Excision of the Transformation Zone, C-LETZ, (Group-2)

complications. The Sturmdorf tracheloplasty was used in most cases of the CKC group (41/50) but not in any of the C-LETZ group. Haemostasis in the C-LETZ group was achieved by the combination of electrofulguration and applications of Monsel's paste. Pathological examination proved that all C-LETZ specimens were without significant thermal artifacts and all of them could thus be evaluated for the marginal status. The mean thermal artifacts of excised lesions located in the ectocervix and endocervix were  $0.17 \pm 0.085$  mm (0-0.5 mm) and  $0.34 \pm 0.21$  mm (0.01-1.6 mm), respectively. The first postoperative appointment, 2 weeks after the excision procedure, revealed a significant increase in the rate of infection in the CKC group compared with the C-LETZ group (18/50 vs. 3/45, p=0.001).

The over-treatment rate in the C-LETZ group, *i.e.* absence of CIN, was 6.7% (3/45). The final histological results are shown in Table 3. The Visual Analogue Score (VAS) was evaluated for all patients in the C-LETZ group and the results are shown in Table 4. Nearly half of the patients had no or only mild pain (score 0-3) whereas the rest of the patients had moderate pain (score 4-7). A more detailed analysis of the moderate pain score showed that, of the 45 patients, 15 (33.33%) scored VAS = 4, eight (17.8%) scored VAS = 5, and only one patient scored VAS = 7.

None of the patients in the present study reported intolerable pain or discomfort during the C-LETZ procedure.

#### Discussion

The excision procedure is the management of choice in pre-cancerous lesions of the cervix, especially in CIN2, CIN3 and CIS. Several studies have reviewed the usefulness and complications of L-LETZ.

The present study revealed significantly reduced morbidity in the C-LETZ group, shorter operating time, reduced blood loss, reduced infection rate at post-operative 2 weeks, reduced secondary hemorrhage, and with similar marginal status as reported in previous studies<sup>(3-5)</sup>. The frequencies of a complete excision according to histological results were similar in the two groups of patients, 71% of the cases in the C-LETZ group vs. 74% of the cases in the CKC group. The cases that showed a positive margin could be managed by standard therapy such as re-excision, hysterectomy or other clinical procedures for the case of pre-invasive or invasive lesion, respectively. It has been reported previously that the long-term outcome in similar cases was without adverse effect<sup>(11)</sup>.

The overall complication rate in the C-LETZ group was 11.1% (5/45) compared to 38% (18/50) in

Final histology	Group-1 Group-2		
	n = 50	n = 45	
Negative/chronic inflammation/no residual	17	3	
CIN 1/ Koilocytosis	2	2	
CIN 2	2	3	
CIN 3	6	13	
CIS	21	15	
Microinvasive carcinoma	2	7	
Invasive carcinoma	0	2	

 Table 3. Final histology report in each group, CKC (group-1) and C-LETZ (group-2)

Table 4. Visual Analogue Score (VAS) in C-LETZ group

No.	Percent
9	20
12	26.7
24	53.3
-	-
45	100
	9 12 24

the CKC group. One case of minor lateral vaginal laceration was controlled by simple electro-fulguration during the out-patient procedure and can be prevented in the future by using the lateral vaginal retractor. There was no postoperative primary hemorrhage within 24 hour compared with a reported incidence of 0.7-2.3% in other studies<sup>(6,12-14)</sup>. The incidence of secondary hemorrhage in the present study was 2.2%, which was comparable to the 0.6-6.4% reported in previous studies. Furthermore, all cases with secondary hemorrhage in the present study could be managed on an out-patient basis with Monsel's paste. There were cases of heavy bleeding that required suturing and hospitalization in other reports<sup>(11,15-16)</sup>. Prophylactic and postoperative antibiotics had to be prescribed in all cases in the CKC group but not in the C-LETZ group. The post operative infection rate of 6.6% in the C-LETZ group was similar to those previously reported  $(0.8-14.4\%)^{(4,11,12,17-19)}$ , whereas the infection rate in the CKC group was considerably higher at 36%. The low postoperative infection rate in the C-LETZ group might be explained by a shorter operating time, decreased blood loss and no need for suturing. A certain electro-fulguration at the excision site and the antiseptic effect of Monsel's paste might also have influenced the lower infection rate.

In the present study, both ESU (FINESSE<sup>TM</sup>) and the 0.3 mm tungsten wire (C-LETZ electrode) were produced by Utah Medical Products, USA. The ESU is equipped with a microprocessor ensuring that the voltage at the cutting wire is constant during the operation in order to avoid any peak voltage and thus minimize the electro-coagulation at the incision site. The FINESSE<sup>™</sup> electrosurgical generator has previously been evaluated with good results in a study of thirteen different brands of ESU<sup>(20)</sup>. All of the excised C-LETZ specimens in the present study showed a narrow thermal coagulation artifact zone both at the ectocervical and endocervical margins and all of them were accepted for evaluation by the pathologist. The mean thermal artifacts at the ectocervical and endocervical margin were 0.17 and 0.34 mm respectively. These artifacts were similar to those previously reported in the literature, 0.396 mm<sup>(21)</sup>, 0.187 mm<sup>(22)</sup>, and less than 0.1 mm<sup>(23)</sup>. The small thermal artifacts, which may be related to the choice of ESU as well as the size and material of the loop electrode wire, ensured a correct pathological diagnosis of the C-LETZ specimens.

In the present study, the authors also reported the VAS for the C-LETZ procedure. Most of the patients tolerated the C-LETZ well and postoperative analgesic drugs were needed only in a few cases. Only one patient (2.2%) scored a VAS in the higher range of 5-10 compared to11% as previous reported<sup>(24)</sup>. The authors believe that a detailed preoperative disclosure to the patient about the procedure, supportive care, and local cervical anesthesia were important factors that contributed to a low VAS.

In the present study, the authors compared the two study groups between prospective data of C-LETZ and retrospective data of CKC group. Some data may not be precisely accurate because of the retrospective characteristic and the procedure that is sometimes performed by different operators. The randomized controlled trial should be performed for more complete results.

The "See and Treat" approach was used in all of the C-LETZ cases. The over-treatment rate in this group was 6.7% compared with the maximum of 10% recommended by the 2004 NHS cancer-screening program<sup>(25)</sup>. The over-treatment reported in previous studies ranged between 2-30%<sup>(1,8,10)</sup>. Three cases of over-treatment in the C-LETZ group were negative for CIN whereas two cases were diagnosed as koilocytosis. The authors reviewed the cases of over-treatment in detail and found that the missed interpretation was mostly in case of CIN2/HSIL PAP smear and/or in cases where the acetowhite epithelium was located inside the endocervical canal. This suggested that such cases should be evaluated with great care in future procedures and, if possible, the cytological slides should be re-examined by the cyto-pathologist prior to the "See and Treat" procedure in every case of CIN2/HSIL PAP smear. There were two invasive cancer cases previously reported as HSIL and SCC PAP smear and RCI of 7. When considering this over-treatment rate with the advantage of the "See and Treat" approach, the authors still support the "See and Treat" strategy especially in some special circumstances such as poor patient compliance, patients living in the area of terrorism. The feasibility and effectiveness of this approach favor a continuing use of the "See and Treat" strategy in the future. It has previously been shown in a Swedish study<sup>(11)</sup> that substantial cost savings may be obtained by using the C-LETZ method in an outpatient setting compared with CKC. The costeffectiveness of the authors' "See and Treat" patients by using C-LETZ procedure will be further evaluated.

In conclusion, comparing with CKC in the management of HGL of the cervix, C-LETZ is lesstraumatic, yields a comparable efficacy, and much faster to perform with significantly less morbidity. This method is gentle to the patients, evidenced by the result from the VAS, and can generally be performed in an outpatient setting with only local anesthesia. This is in contrast to the CKC, which has to be done under general anesthesia. The C-LETZ method enabled the authors to design the better size and shape of the conization specimens, which come in only one-piece before being transferred for histological examination. Furthermore, the C-LETZ method seems to be safe and economically appropriate for use as a "See and Treat" procedure in the authors' hospital outpatient setting.

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ผลสำเร็จและผลข้างเคียงในการใช้ห่วงไฟฟ้าแบบบังคับรูปร่าง (C-LETZ<sup>®</sup>) เปรียบเทียบกับ การตัดปากมดลูกเป็นรูปกรวยโดยใช้มีด (CKC) ในผู้ป่วยที่ผลการส่องกล้องปากมดลูกเป็น รอยโรคภายในเยื่อบุปากมดลูกชนิดขั้นสูง (HGL)

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**วัตถุประสงค**์: เปรียบเทียบผลสำเร็จการรักษาและผลข้างเคียงการใช้ C-LETZ<sup>®</sup> เมื่อเปรียบเทียบกับ CKC ในผู*้*ป่วย ที่ผลการส่องกล<sup>้</sup>องปากมดลูกเป็นรอยโรคเยื่อบุปากมดลูกชนิดขั้นสูง

**วัสดุและวิธีการ**: ผู้ป่วย 45 คน ที่ผลการคัดกรองมะเร็งป<sup>้</sup>ากมดลูกเป็น HSIL หรือ SCC และตรวจสองกล้องปากมดลูก เป็นรอยโรคเยื่อบุปากมดลูกชนิดขั้นสูง รับการตัดปากมดลูกใช้ C-LETZ® ข้อมูลด้านผลการรักษา ลักษณะชิ้นเนื้อ และผลข้างเคียงได้รับการบันทึกเพื่อเปรียบเทียบข้อมูลจาก CKC

**ผลการศึกษา**: ผลสำเร็จของการรักษาและลักษณะชิ้นเนื้อไม่มีความแตกต่างกันขณะที่ผลข้างเคียงจากการผ่าตัด C-LETZ<sup>®</sup> พบน้อยกว่า

**สรุป**: ห่วงไฟฟ้าแบบบังคับรูปร่าง (C-LETZ<sup>®</sup>) เป็นเครื่องมือใหม่สำหรับการรักษารอยโรคภายในเยื่อบุปากมดลูก ชนิดขั้นสูงโดยผลสำเร็จไม่แตกต่างจากการตัดปากมดลูกเป็นรูปกรวยโดยใช้มีด (CKC) โดยมีผลข้างเคียงน้อยกว่า