



## A single-blind randomised controlled trial comparing clinical equivalence of Trulon® and Ethilon® polyamide sutures for the skin closure following laparotomy incisions

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### ABSTRACT

**Background:** Laparotomy is a common procedure to gain access to the peritoneal cavity, for obstetrics, gynecological, and digestive system-related surgeries. Wound infection is among other complications of laparotomy. This study compared the rate of wound infection post-laparotomy skin closure using Trulon® and Ethilon® polyamide sutures.

**Methods:** This multicentric, prospective, two-arm, parallel-group, randomized (1:1), single-blind study (CTRI/2020/09/027978) was conducted between January and July 2021, and included 102 women undergoing laparotomy-based obstetric/gynecological procedures. The primary endpoint, incidence of wound infection [superficial and deep surgical site infection (SSI)] occurring within 12 weeks of the surgery was compared between two treatment groups, Trulon® (n = 50) and Ethilon® (n = 52). The secondary endpoints, incidence of wound dehiscence, suture sinus, seroma, hematoma, skin disruption, suture loosening, re-suturing, duration of surgery, suture removal, hospital stay, intraoperative suture handling parameters, pain score, return to normal day-to-day activities, modified Hollander cosmesis score, subject satisfaction score, and adverse events were also evaluated.

**Results:** Non-significant differences were observed in the incidence of SSI, wound dehiscence, suture sinus, seroma, hematoma, skin disruption, suture loosening, re-suturing, intraoperative handling parameter (except ease of passage), operative time, hospital stay, suture removal duration, pain score, time to return to day-to-day activities, modified Hollander cosmesis score, and subject satisfaction score between the two groups.

**Conclusion:** Trulon® and Ethilon® polyamide sutures are clinically equivalent. For abdominal skin closure following laparotomy both the sutures deliver a lower chance of infection, minimal pain, higher satisfaction, and cosmesis score.

**Registration of research:** This trial is registered prospectively at Clinical Trial Registry of India (CTRI Reg. No: CTRI/2020/09/027978; Registered on: 23/09/2020).

### 1. Introduction

Laparotomy is the most popular technique for many obstetrics, gynecological, digestive, vascular, and abdominal trauma surgery [1]. In order to reduce hospital stay and to heal with an inconspicuous scar, a proper skin closure method is important, with a goal of the shorter operation time, rapid healing, cost-effectiveness, and minimal pain [2].

Sutures are one of the most implanted biomaterials in the human body [3] that are used to close surgical skin incisions with beneficial effects (lower dehiscence rates) compared to other closure methods [4]. Some complications following surgery may be directly attributable to the suture material itself [5]. Ideal suture material is characterized by good tensile strength and knot security along with excellent suture handling, low tissue reaction, and minimal infection [5,6]. Nylon (Polyamide) is a

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non-absorbable suture with a hydrolysis rate of 15–20%, good strength, and elasticity, easy to handle, and it glides easily through tissue without pre-mature breakage [7]. A previous study has reported excellent tensile strength of nylon suture, even after 2 weeks of use that was lost gradually over time (50% after 1–2 years) [8]. Due to its elasticity, it is usually recommended for epidermal and superficial surfaces [9].

Several clinical trials have used nylon sutures for skin closure [10, 11], and compared its functionality with staples [12], polybutester [13], and polydioxanone [14,15], but none compared two commonly used brands of non-absorbable polyamide sutures. Therefore, the present study compared skin closure with Trulon® or Ethilon® polyamide sutures following laparotomy-based obstetric/gynecological procedures.

## 2. Methods

### 2.1. Study design

This was a multicentric, prospective, two-arm, parallel-group, randomized (1:1), single-blind study, conducted at two different centers between January–July 2021. The primary objective of this study was to compare the rate of wound infection with Trulon® and Ethilon® polyamide sutures at 12 weeks' post-laparotomy. The secondary objectives were to compare the tissue reaction, wound dehiscence, skin disruptions, suture sinus, seroma, and hematoma, intraoperative handling, time to return to normal activities, adverse events, post-operative discomfort, pain, and overall subject satisfaction score, and the cosmesis score between the groups.

### 2.2. Ethical approval

The study was registered prospectively in the Clinical Trial Registry of India (CTRI/2020/09/027978; Registered on: 23/09/2020) and conducted in accordance with the Declaration of Helsinki. The institutional ethics committee of both centers approved the study, which was designed, conducted, recorded, and reported according to guidelines of ICH-GCP E6 R2, EN ISO 14155:2020, Indian MDR 2017, MDR (EU) 2017/745, and Indian New Drugs and CT rules 2019. The study was registered on Research Registry Platform [www.researchregistry.org](http://www.researchregistry.org) with a unique identification number of researchregistry8217. The study was reported in line with the 2010 Consolidated Standards of Reporting Trials (CONSORT) guideline for clinical trial <http://www.consort-statement.org>.

### 2.3. Study participants

Women (18–50 years) with good systemic or mental health and Centers for Disease Control and Prevention wound (CDC) classification of class I or II, who required laparotomy-based obstetric/gynecological procedures were included in this study after obtaining written informed consent.

Obese (body mass index  $>30 \text{ kg/m}^2$ ) and anemic (hemoglobin  $<7 \text{ g/dl}$ ) women with a history of any laparotomy procedure, previous (two weeks before the procedure) urogenital tract infection, active infection at the skin incision site, or allergic to nylon or similar products were excluded. Women, who required elective or emergency laparoscopic abdominal surgeries or prophylactic mesh augmentation after laparotomy were also excluded. Furthermore, subjects participating in another trial, unlikely to comply with the surgical procedure or complete the scheduled follow-up visit were excluded.

### 2.4. Study settings

This study was conducted at (i) Department of Obstetrics & Gynaecology, King George Hospital, Andhra Pradesh, India, and (ii) Department of Obstetrics & Gynaecology, Saphthagiri Institute of Medical sciences & Research, Bengaluru, Karnataka, India.

### 2.5. Intervention

Trulon® (Healthium Medtech Limited) is a sterile, monofilament, synthetic, non-absorbable, surgical suture composed of polyamide 6 and polyamide 6.6. Ethilon® (Ethicon-Johnson & Johnson) suture is a sterile, monofilament, synthetic, non-absorbable, surgical suture composed of polyamide 6 or polyamide 6.6. Both sutures are indicated for use in general soft tissue approximation and/or ligation.

### 2.6. Randomization and blinding

Prior to the study, a computer-based, automated randomization number was generated by an independent programmer using block sizes 4, 6 or 8. A total of 103 eligible subjects were randomized using block randomization to ensure an unbiased treatment assignment in a 1:1 ratio to receive either the Trulon® (n = 51) or Ethilon® (n = 52) suture. The sequentially numbered opaque sealed envelope technique was used to generate the randomization codes that were issued to the sites in sealed envelopes. This was a single-blind study and the subjects were kept blinded to the device allocation status.

### 2.7. Study procedure

The eligible subjects underwent laparotomy at the baseline visit (Day 0). After laparotomy, the abdominal fascia was sutured following the standard Institutional protocol. The abdominal skin was closed using one of the two sutures (Trulon® or Ethilon®). The primary dressing was removed after 24–48 h, and further wound care was done as per the Institutional protocol. Before the dressing, the subjects were inspected for any signs of infection and dehiscence, and put on antibiotics in case of infection. Skin sutures were removed in a conventional way between 7 to 14 days. The subjects were examined on Day 3, Day 7–14, Week 6, and Week 12.

### 2.8. Demographics and other relevant characteristics

Age, ethnicity, weight, height, vital signs, history of alcohol and tobacco use, along with the reason for laparotomy were recorded for both treatment groups. Medical/surgical history was also noted.

### 2.9. Study outcomes

#### 2.9.1. Primary endpoints

The primary endpoint was the incidence of wound infection, i.e., surgical site infection (SSI is defined as per the CDC for superficial, deep, and organ/space infections), occurring within 12 weeks of the surgery.

#### 2.9.2. Secondary endpoints

The secondary endpoints, incidence of wound dehiscence (post-operative disruption of all layers of the abdominal wall), skin disruption (spontaneous or iatrogenic separation of the skin wound edges of ~1 cm width), suture sinus, seroma and hematoma, suture loosening and re-suturing, intraoperative suture handling, operative time (skin incision to closure), time needed for suture removal, intensive care unit (ICU)/hospital stay, pain with visual analog scale (VAS), return to normal day-to-day activities, modified Hollander cosmesis score, subject satisfaction score, and adverse events were recorded.

Intraoperative handling characteristics, viz. ease of passage through tissue, first-throw knot holding, knot tie-down smoothness, knot security, stretch capacity, memory, and suture fraying was rated by the Investigator on a five-point scale as follows: 1 poor; 2 fair; 3 good; 4 very good; and 5 excellent, along with other suture related challenges. The subjects were asked to grade their post-operative pain, using VAS as follows: 0–4 no pain, 5–44 mild pain, 45–74 moderate pain, and 75–100 severe pain. Any untoward medical occurrence, unintended disease or injury, or untoward clinical signs, which were not reported as study

endpoints, were reported as adverse events. The cosmesis score was assessed using the modified Hollander Scale, which has 6 clinical variables step-off borders, edge inversion, contour irregularities, excess inflammation, wound margin separation, and good overall appearance, marked as satisfactory (0) or unsatisfactory (1). The subjects were also asked to grade the general appearance, location, and comfort of the scar using the subject satisfaction score (Likert scale 1–10, with 10 indicating very satisfied and 1 indicating very unsatisfied).

Other standard details about the type of laparotomy, suture size, length of incision, technique of skin suturing, number of blood transfusions, outcome of surgery, antibiotic prophylaxis, thrombosis prophylaxis, time of onset of post-operative pain, perioperative complications, pain at the time of suture removal, readmission, and post-operative other suture-related complications were recorded. In addition, principal medications prescribed to the subjects during the study period were also registered.

2.10. Sample size

A previous study reported laparotomy skin closure with nylon sutures that resulted in 6.27% infection at the end of 1.5 years [14]. Based on this evidence, the proportion of subjects having wound infection (SSI) in the standard Ethilon® arm was assumed to be 6.3%. Assuming type I error as 5%, power as 80%, and a difference of 0.5% for the proportion of subjects having wound infection (SSI) in the Trulon® arm with a margin of non-inferiority as 15% of the difference, a minimum sample size was worked out to be approximately 43 in each arm. Further, considering a dropout and post-randomization exclusion of 20% the required sample size was increased to 52 in each arm. So, a total of 104

subjects participated in this clinical study.

2.11. Statistical analysis

Primary analyses were performed based on the per-protocol or PP analysis set using SPSS version 25.0 (SPSS, Chicago, Illinois, USA). The PP set was comprised of all the subjects, who had complete data on the primary effectiveness parameter at 12 weeks of follow-up. All continuous variables were expressed as Mean and standard deviation (SD), and compared using the *t*-test (normally distributed data) or Mann-Whitney *U* test (distribution-free data). All qualitative variables were expressed as proportions/percentages and compared using Chi-square or Fisher's Exact test. The primary endpoint was summarized using proportions/percentages and compared using Fisher's Exact test. Secondary endpoints were expressed as Mean SD or as proportions/percentages based on quantitative or qualitative nature of a variable. An additional subgroup analysis was done using Fisher's Exact test. A *p*-value of  $\leq 0.05$  was considered statistically significant.

3. Results

Between January and April 2021, 104 women were screened, and follow-up of the last subject was completed in July 2021. One subject withdrew consent before randomization, and one subject from Trulon® group withdrew consent after randomization (after Day 3). All the 102 subjects in the PP analysis set received either Trulon® (n = 50) or Ethilon® (n = 52) suture (Fig. 1).

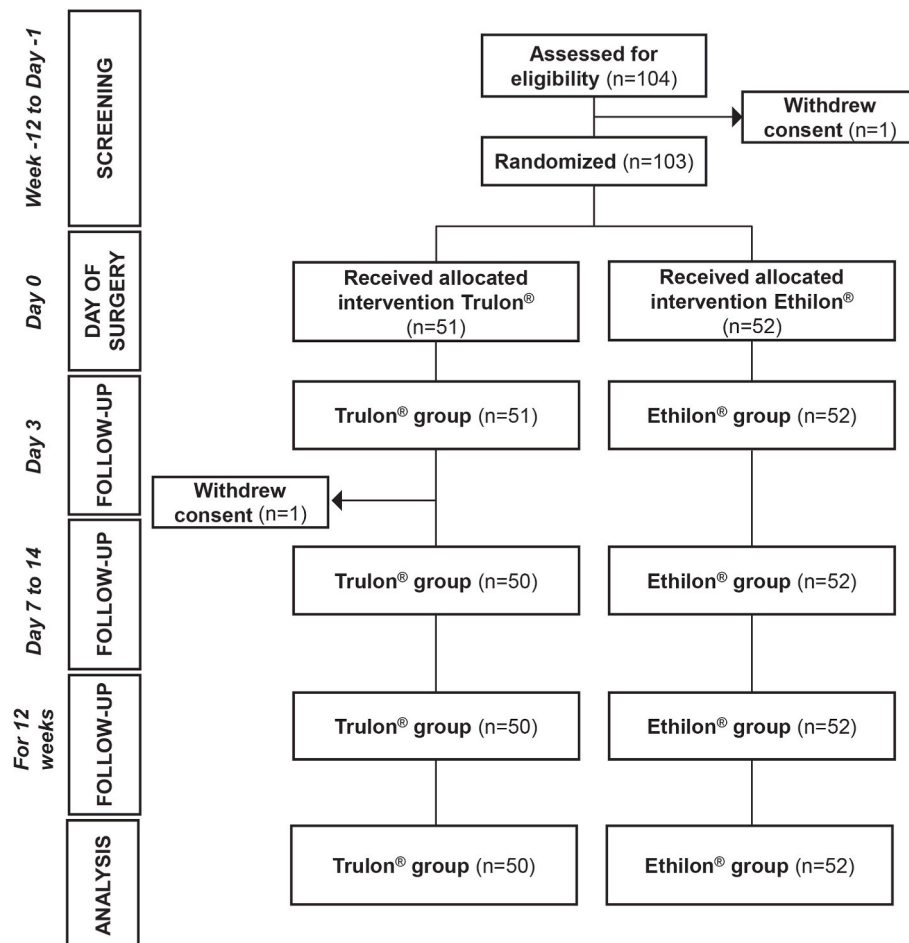


Fig. 1. CONSORT flow chart of the study participants.

### 3.1. Demographics and other relevant characteristics

All the participants were Indians, except one (2.00%) subject in the Trulon® group, who was Asian ( $p = 0.15$ ). None of the subjects had a history of alcohol or tobacco use. Baseline demographics (except age and height), vital signs and other characteristics were comparable between the groups (Table 1). The age ( $p = 0.02$ ) and height ( $p = 0.051$ ) of the subjects showed significant differences between the treatment groups, hence subgroup analysis was done. In Trulon® and Ethilon® group, 5 (10.00%) and 4 (7.69%) subjects respectively had medical/surgical history ( $p = 0.68$ ).

### 3.2. Primary endpoint analysis

Only one (2.00%) subject in Trulon® arm had serosanguinous discharge at skin incision site on day 8 post-laparotomy, which recovered after medical treatment. There was no significant difference in the findings of superficial SSI between the groups ( $p = 0.31$ ). Incidence of deep SSI was not recorded in any of the study participants.

#### 3.2.1. Subgroup analyses

Subgroup analyses for subjects showed non-significant differences ( $p > 0.05$ ) between the groups, regarding: SSI vs. age (subgroups:  $< 30$  and  $\geq 30$  years), and SSI vs. height (subgroups:  $< 156$  and  $\geq 156$  cm).

### 3.3. Secondary endpoint analysis

#### 3.3.1. Intraoperative profile

Antibiotic prophylaxis was given to all the subjects. All participants of Trulon® group received spinal anesthesia, whereas, 51 (98.08%) and 1 (1.92%) subjects of Ethilon® group received spinal and general anesthesia respectively ( $p = 0.32$ ). The measures used for skin suturing were either continuous or interrupted, with one suture of size 1. Post-partum hemorrhage occurred only in one subject of Ethilon® group, which was the only perioperative complication. Other intraoperative profile parameters are given in Table 2. The outcome of the surgery was

**Table 1**

Baseline demographic and vital signs of the study participants.

Subject Characteristics	Trulon® (n = 50)	Ethilon® (n = 52)	p value
<b>Baseline Characteristics</b>			
Age (years), Mean SD	31.52 SD7.76	27.81 SD7.40	0.02 <sup>a</sup>
Weight (Kg), Mean SD	61.09 SD7.27	59.22 SD6.14	0.16
Height (cm), Mean SD	159.37 SD4.82	156.23 SD10.19	0.051 <sup>a</sup>
Body mass index (Kg/m <sup>2</sup> ), Mean SD	24.02 SD2.40	24.56 SD4.94	0.48
<b>Vital Signs</b>			
Pulse rate (beats per minute), Mean SD	87.28 SD7.64	86.06 SD4.60	0.33
Respiratory rate (respiration per minute), Mean SD	15.82 SD1.61	15.73 SD1.56	0.78
Systolic blood pressure (mmHg), Mean SD	122.36 SD10.56	120.23 SD10.00	0.30
Diastolic blood pressure (mmHg), Mean SD	79.96 SD6.73	79.65 SD8.63	0.84
<b>Reason for Laparotomy</b>			
Cesarean section, n (%)	35 (70.00)	40 (76.92)	0.37
Abnormal uterine bleeding, n (%)	3 (6.00)	5 (9.62)	
Fibroid uterus, n (%)	4 (8.00)	0	
Hysterectomy, n (%)	5 (10.00)	6 (11.54)	
Ovarian cyst, n (%)	0	1 (1.92)	
Medical termination of pregnancy, n (%)	1 (2.00)	0	
Second-degree uterine prolapse, n (%)	1 (2.00)	0	
Secondary infertility with pain, n (%)	1 (2.00)	0	

<sup>a</sup>  $p < 0.05$ .

**Table 2**

Intraoperative and post-operative profile of the study participants.

Subject Profile	Trulon® (n = 50)	Ethilon® (n = 52)	p value
<b>Intraoperative Profile</b>			
Type of laparotomy, n (%)			0.49
Lower segment cesarean section	35 (70.00)	40 (76.92)	
Exploratory laparotomy	2 (4.00)	1 (1.92)	
Hysterectomy	10 (20.00)	11 (21.15)	
Myomectomy	3 (6.00)	0	
Length of incision (cm), Mean SD	7.52 SD2.61	7.81 SD2.46	0.57
Technique of Skin Suturing, n (%)			0.84
Continuous	26 (52.00)	28 (53.85)	
Interrupted	24 (48.00)	24 (46.15)	
Total operative time (minutes), Mean SD	82.90 SD42.04	72.44 SD25.65	0.13
Number of blood transfusions, Mean SD	0.20 SD0.70	0.13 SD0.44	0.55
Number of blood transfusions, n (%)			0.88
0	45 (90.00)	47 (90.38)	
1	2 (4.00)	3 (5.77)	
2	2 (4.00)	2 (3.85)	
3	0	0	
4	1 (2.00)	0	
<b>Post-operative Profile</b>			
Time of onset of post-operative pain at incision site (hours), Mean SD	2.45 SD0.89	2.51 SD1.22	0.78
Pain at the time of suture removal, n (%)	25 (50.00)	25 (48.07)	0.86
Hospital stay (days), Mean SD	5.84 SD2.47	5.23 SD2.18	0.19
Time needed for suture removal (days), Mean SD	7.44 SD3.03	7.29 SD2.80	0.80
Time taken to return to normal day to day activities (days), Mean SD	21.48 SD11.33	20.52 SD10.86	0.66

good for both groups.

Scores for intraoperative suture handling were favorable and not significantly different between the two suture groups for knot holding, knot security, knot tie-down, stretch capacity, memory, and suture fraying (Fig. 2). The “Excellent” scores for memory and suture fraying, and the “Very good” scores for ease of passage, knot tie-down, and stretch capacity were higher in the Trulon® group than Ethilon® group. The difference in scores for ease of passage between the groups was statistically significant ( $p = 0.04$ ). The Investigators showed dissatisfaction for knot holding (one subject), and for both knot holding and knot security (two subjects) of Trulon® suture. Similarly, the Investigators showed dissatisfaction for knot holding (one subject), for both knot holding and knot security (one subject), for both knot holding and knot tie-down (one subject), and for stretch capacity (one subject) of Ethilon® suture.

#### 3.3.2. Post-operative profile

None of the study participants of both groups were readmitted to the hospital during the study period. Incidence of dehiscence, skin disruption (at least 1 cm of width), hematoma, seroma, suture sinus, other suture related complications, suture loosening and requirement for re-suturing were not registered at any follow-up visit. Reduction in post-operative pain with each passing visit is evident through the findings of mean VAS score. No significant differences were found in terms of mean pain score and grade of pain (Fig. 3a & 3b). The mean Hollander cosmesis score was comparable between Trulon® and Ethilon® groups at week 6 (0.04 vs. 0.02,  $p = 0.27$ ) and week 12 (0 vs. 0.02,  $p = 0.30$ ). At week 6, unsatisfactory score was given for margin separation in 1 (2.00%) subject and edge inversion in 1 (2.00%) subject of the Trulon® group, compared to edge inversion in 1 (1.92%) subject of Ethilon® group ( $p = 0.91$ ). At week 12, unsatisfactory score was given for edge inversion in 1 (1.92%) subject of Ethilon® group ( $p = 0.99$ ). The mean subject satisfaction score of the two groups were comparable with no statistical differences (Fig. 3c). The other post-operative profile of the study participants is presented in Table 2.

In Trulon® group, non-serious adverse events viz. fever in 2 (4.00%) subjects, nausea and vomiting in 1 (2.00%) subject, headache in 1

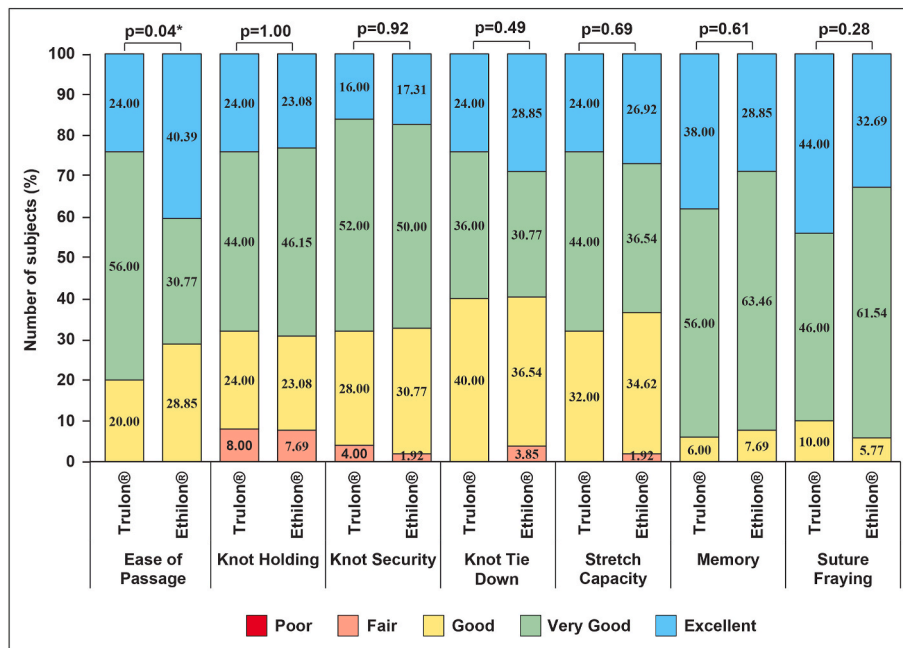


Fig. 2. Intraoperative suture handling parameters of the subjects randomized to Trulon® (n = 50) and Ethilon® (n = 52) group.

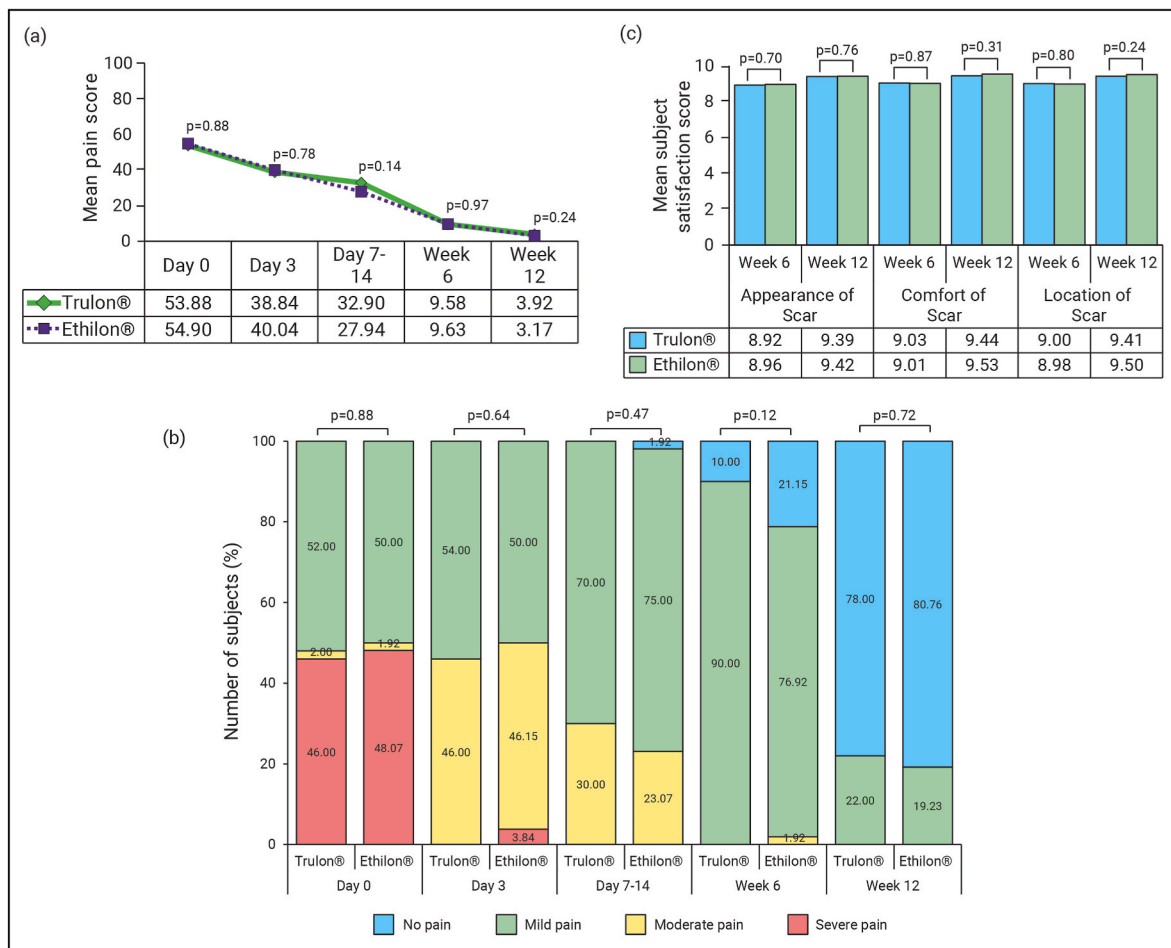


Fig. 3. Comparison of (a) mean pain VAS score and (b) grade of pain and (c) subject satisfaction score between Trulon® (n = 50) and Ethilon® (n = 52) groups.

(2.00%) subject, general body pains in 1 (2.00%) subject and upper respiratory tract infection in 1 (2.00%) subject were recorded. In Ethilon® group, 2 (3.84%) subjects had general body pains, and 1 (1.92%) subject had upper respiratory tract infection. The adverse events were not related to the medical device. During the study period, the medications prescribed to majority of the subjects are shown in Table 3.

#### 4. Discussion

In this study, both groups were comparable with respect to demographics and vital signs, except for age and height. This heterogeneity may have occurred due to the inclusion of subjects requiring a variety of laparotomy-based obstetric/gynecological procedures. However, this heterogeneity has not impacted the results of primary endpoint of this study as mandated by the subgroup analysis. Non-significant differences were observed in incidence of SSI, wound dehiscence, suture sinus, seroma, hematoma, skin disruption, suture loosening, re-suturing, intraoperative handling parameter (except ease of passage), operative time, hospital stay, suture removal duration, pain score, time to return to day-to-day activities, Modified Hollander cosmesis score, and subject satisfaction score between the two groups. This indicated clinical equivalence of Trulon® and Ethilon® suture.

Following laparotomy, proper skin closure is important to accomplish shorter hospital stay, better surgical outcomes, minimal pain, and patient's recovery and satisfaction. Use of suitable suture material can minimize the chances of post-operative complications [5]. Several studies have examined the role of nylon sutures [10–15], but none of them compared two commonly used brands of non-absorbable polyamide sutures. To our knowledge, this study for the first time compared the equivalence of Trulon® and Ethilon® non-absorbable polyamide sutures for skin closure after laparotomy-based obstetric/gynecological procedures.

The primary endpoint, incidence of wound infection did not differ significantly between the treatment groups. The SSI is one of the most common complications of surgery, associated with morbidity and mortality, compromising the health of the patient [16]. Previous studies reported occurrence rate of SSI as 38% in Asian population (35.7% in females) [16] and 12.5% in Indian population following laparotomy [17]. Many intrinsic and extrinsic factors are responsible for development for SSI, including patient's age, body mass index, lifestyle, pre-existing infection, diabetes or other comorbidities, and surgical history [18]. In this study, one subject of Trulon® group have developed SSI after removal of the suture, hence the incidence was not related to the studied intervention. The subject recovered after treatment and continued the study. The other post-operative complications, viz. incidence of dehiscence, skin disruption, hematoma, seroma, suture sinus, other suture related complications, suture loosening, and re-suturing has not occurred in any of the subjects. Hospital readmission affects patient's physical and mental health [19,20]. But subject readmission was also not recorded at any time point in this study.

The findings demonstrated that Trulon® is equivalent to Ethilon® suture in terms of overall intraoperative suture handling parameters.

**Table 3**

Concomitant or prescribed medication details in study participants during the study period.

Prescribed Medications	Trulon® (n = 50)	Ethilon® (n = 52)
<b>Analgesics</b>		
Diclofenac, n (%)	28 (56.00)	28 (53.85)
Paracetamol, n (%)	21 (42.00)	18 (34.62)
Injection Paracetamol, n (%)	19 (38.00)	18 (34.62)
Diclofenac + Serratiopeptidase, n (%)	26 (52.00)	24 (46.15)
<b>Antibiotics</b>		
Ceftriaxone, n (%)	47 (94.00)	49 (94.23)
Metronidazole, n (%)	48 (96.00)	51 (98.08)
Cefixime, n (%)	43 (86.00)	39 (75.00)

Although, a significant difference in scores for ease of passage was noted, but the change was not clinically significant, as both the groups were marked as "Excellent" (more subjects in Ethilon® group) and "Very good" (more subjects in Trulon® group) in similar proportion. Other intraoperative profile parameters such as length of surgery, suture size, number of sutures used, length of incision, total operative time, technique of skin suturing, antibiotic prophylaxis, and perioperative complications were comparable in both groups.

In terms of wound healing parameters, most of the subjects, who complained of post-surgery pain showed improvement with each follow-up visit. The cosmesis assessment after 6 and 12 weeks also provided satisfactory results for step-off borders, contour irregularity, excessive distortion and overall appearance of the wound in both groups. In addition, the general appearance, location and comfort of the scar have higher mean Likert scale score at the end visit, indicating satisfactory outcome. Modified Hollander cosmesis score is a good clinical index for scar evaluation that measures the healthcare quality and highlights the role of different repair interventions [21]. The present study found favorable outcomes in cosmetic score after post-laparotomy skin closure with Trulon® and Ethilon® non-absorbable polyamide sutures. Moreover, the type of adverse events recorded in both arms was mild in nature and not related to the suture material.

The limitations of the present study are: (i) the Investigators were not blinded and might have favored one suture over another; (ii) as laparotomy is a clean or clean-contaminated elective/emergency surgery, the SSI could only originate from contaminants in the operation room or from the surgical team, or most commonly from skin colonists. However, the key strengths of the study are it is methodologically robust to detect a difference for the primary and secondary outcomes, and the study is conducted in two different centers providing a geographically representative patient sample. Hence, the findings of the study can be generalized and validated to a wider population. This study not only supports the use of Trulon® non-absorbable polyamide suture for post-laparotomy skin closure, but also for all other surgeries, indicated for Ethilon® non-absorbable polyamide suture.

#### 5. Conclusion

The results indicated clinical equivalence of Trulon® and Ethilon® suture as non-significant differences were observed in primary and secondary endpoints (except ease of passage) of the study. Therefore, Trulon® and Ethilon® non-absorbable polyamide sutures can be safely and effectively used for skin closure, providing lower chance of infection, minimal pain, higher satisfaction and cosmesis score.

#### Ethical approval

The study was registered in Clinical Trial Registry of India (CTRI/2020/09/027978; Registered on: 23/09/2020) and conducted in accordance with the Declaration of Helsinki. Institutional ethics committee of both centers approved the study, which was designed, conducted, recorded, and reported according to guidelines of ICH-GCP E6 R2, EN ISO 14155:2020, Indian MDR 2017, MDR (EU) 2017/745, Indian New Drugs and CT rules 2019, and Consolidated Standards of Reporting Trials (CONSORT).

This study was conducted at (i) Department of Obstetrics & Gynaecology, King George Hospital, Andhra Pradesh, India, and (ii) Department of Obstetrics & Gynaecology, Sapthagiri Institute of Medical sciences & Research, Bengaluru, Karnataka, India.

The ethical committee approval details are provided below:

Institutional Ethics Committee, King George Hospital, Visakhapatnam

**Approval date:** 22/09/2020

Institutional Ethics Committee, Sapthagiri Institute of Medical sciences & Research, Center Bengaluru

**Approval date:** 24/12/2020

**Approval number:** SIMS&RC/IEC/AP-006/2020-21

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Authors AKM and DTS are the employees of Healthium Medtech Limited, India. They were part of Conceptualization, Methodology, Writing - original draft preparation, Writing - review and editing, Funding acquisition, Resources, and Supervision. They were not part of

### Formal analysis and investigation.

### Author contributions

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### Registration of research studies

This trial is registered prospectively at Clinical Trial Registry of India (CTRI Reg. No: CTRI/2020/09/027978; Registered on: 23/09/2020).

### Guarantor

Y. Aruna Subha Shree Rao, Padmasri R, Divya TK, Ashok Kumar Moharana, and Deepak TS.

### Consent

Written informed consent was obtained from the patient for participation in the study as well as for publication of this study results. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request.

### Provenance and peer review

Not commissioned, externally peer-reviewed.

### Data availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

### Declaration of competing interest

Authors AKM and DTS are the employees of Healthium Medtech Limited, India who are manufacturers of Trulon suture. The study was funded by Healthium Medtech Limited, India. Author ASSR, PR, and

DTK declares no conflict of interest.

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### Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ijso.2022.100534>.

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