

Trushield NXT Non Adherent Wound Dressing versus Standard of Care Dressing among Women Undergoing Obstetric and Gynaecological Surgeries: A Randomised Clinical Study

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ABSTRACT

Introduction: Surgical Site Infection (SSI) is the most frequently reported postsurgical wound complication worldwide. Trushield NXT is a non adherent dressing with a unique non leaching physical mechanism of action antimicrobial property, whereas the Standard of Care (SOC) dressing is made with cotton, povidone, and leucoplast which is primarily used as a barrier dressing.

Aim: To compare the effectiveness of Trushield NXT non adherent wound dressing over SOC dressing (cotton+povidone+leucoplast) in postoperative wound management of obstetric and gynaecological surgeries.

Materials and Methods: This was an investigator-initiated, single-centre, prospective, two-arm, parallel-group, randomised (1:1) clinical study conducted in the Department of Obstetrics and Gynaecology, Institute of Post-Graduate Medical Education and Research and Seth Sukhlal Karnani Memorial Hospital, Kolkata, West Bengal, India, between 7th February 2022 and 18th May 2022. A total of 114 patients were screened but finally 111 were selected for the study and randomised to Trushield NXT non adherent wound dressing (n=56) and SOC (n=55) groups. Women in the age group of 18-65 years, undergoing obstetric and/or gynaecological surgeries at the site were enrolled in the study after fulfilling the inclusion and exclusion criteria. Patients underwent surgery (caesarean section/hysterectomy) as per the standard

institutional practice and were followed-up on day 3±1, day 8±1, day 42±7. The primary endpoint was the evaluation of SSI using the Additional treatment, Serous discharge, Erythema, Purulent exudate, Separation of deep tissues, Isolation of bacteria and Stay (ASEPSIS) scoring system, along with dressing time and the number of dressing changes. The secondary endpoints include assessment of pain using a Visual Analog Scale (VAS), and pain during dressing removal, evaluation of ease of application/usage/removal of the dressing, modified Hollander wound score scale, wound healing score, and patient satisfaction of wound dressing and wound healing. Statistical analysis was done using Student's t-test or Mann-Whitney U test for continuous variables or Moses' test for extreme reaction. A p-value of ≤0.05 was considered significant.

Results: Statistically significant difference favouring Trushield NXT was observed between the two groups of Trushield NXT and SOC in terms of asepsis scoring (6.97±0.63 vs. 7.04±0.61; p-value <0.0001), dressing time (39.16 vs 101.07 secs; p-value <0.0001), pain score (3.28 vs 3.82; day 8), pain during dressing removal (30.63 vs 59.2; p-value <0.0001) and patient satisfaction (3.71 vs 3.24; p-value <0.0001).

Conclusion: Trushield NXT was found to be superior to SOC for postoperative wound management in obstetric and gynaecological surgeries.

Keywords: ASEPSIS score, Cotton dressing, Pain, Surgical site infection

INTRODUCTION

The Center for Disease Control and Prevention (CDC) defines Surgical Site Infection (SSI) as an infection related to a surgical procedure that occurs near the surgical site within 30 days following surgery (or up to 90 days following surgery where an implant is involved) [1]. Among hospital-acquired infections in lower-income and middle-income countries, SSI is the most frequently reported one, accounting for approximately 11.8% cases [2,3]. For postoperative morbidity and mortality, SSI is one of the major contributors in India, and the range varies from 1.6-3.8% depending on the surgery type, hospital setting, administration of the perioperative or prophylactic antibiotics, and patient co-morbidities [4,5]. A meta-analysis emphasises the explicit relationship between wound dressing and SSI. As a surgical incision site is at high risk of microbial colonisation, in such cases, a wound dressing with additional infection-preventing properties may prevent such infections and protect the wound from microbial contamination [6].

Trushield NXT non adherent wound dressing is a 3-Dimensional (3D) knitted hydrocellular textile substrate made of Polyethylene

Terephthalate (PET) and Polyurethane (PU), which is permanently bound and cross polymerised, cross-linked with "Dimethyl Tetradecyl {3-(trimethoxysilyl) propyl} Ammonium Chloride" (DTAC) that is immobilised on the substrate and does not leach out of the dressing [7]. It is already a marketed product with evidence of comparative benefits, generated based on the theoretical properties and personal experience of its use by surgeons. Standard of Care (SOC) dressing includes povidone-iodine solution and cotton gauze which is secured in place by a leucoplast adhesive pad. An in-vitro study conducted to assess the antimicrobial properties of the Trushield NXT dressing, suggests that it shields against a wide range of microorganisms over a time period of one minute to 28 days thus supporting effective and significant wound healing [8]. Till now, there is no randomised clinical trial conducted with Trushield NXT non adherent wound dressing. Hence, there is a need to generate robust, unbiased evidence on Trushield NXT over SOC in routine practice.

The primary objective of the study was to evaluate the effectiveness of Trushield NXT non adherent wound dressing over the standard of care dressing in postoperative wound management of obstetric

and gynaecological surgeries. The secondary objectives include evaluation of the pain scores via a Visual Analog Scale (VAS) as well as the comfort and ease, cosmetic appearance of the wound using a modified Hollander wound score scale [9], wound healing using photographs using Early Wound Healing Scale (EHS) [10], patient satisfaction on wound dressing and wound healing and evaluation of material problems and other Adverse Events (AE) among the two groups.

To aim of the present study was to compare the effectiveness of Trushield NXT non adherent wound dressing over SOC dressing (cotton+povidone+leucoplast) in postoperative wound management of obstetric and gynaecological surgeries. The exploratory objective of the present study was to evaluate different bacterial species in the wound site after the removal of first dressing.

MATERIALS AND METHODS

This was an investigator-initiated, single-centre, prospective, two-arm, parallel-group, randomised (1:1), study conducted in the Department of Obstetrics and Gynaecology, Institute of Post-Graduate Medical Education and Research and Seth Sukhlal Karnani Memorial (IPGMER and SSKM) Hospital, between 7th Feb 2022 and 18th May 2022. The study was approved by the Institutional Ethics Committee. Prior to randomisation, written informed consent was obtained from every subject who participated in the study. The study was conducted in accordance with the Declaration of Helsinki and prospectively registered on 21/12/2021 in the Clinical Trial Registry of India with Ref No. CTRI/2021/12/038800. The study findings are reported as per Consolidated Standards of Reporting Trials (CONSORT).

Inclusion criteria: Women aged 18-65 years undergoing uncomplicated obstetric and gynaecological surgeries {caesarean section (n=107)/hysterectomy (n=4)}, with hemoglobin more than/equal to 7 gm/dL, and ready to provide written informed consent were included in the study.

Exclusion criteria: Women based on the presence of condition/comorbidity that could compromise wound healing, including varicose eczema, peripheral vascular disease, receiving immunosuppressive medications, corticosteroid abuse, and having uncontrolled diabetes, a systemic infection not controlled by suitable antibiotic treatment, an active neoplastic condition, being treated by radiotherapy, chemotherapy, hormone therapy or immunosuppressant agents, treated for a chronic disease requiring high doses of systemic corticosteroids (≥ 40 mg/day of prednisolone or equivalent), a severe illness that might lead to premature withdrawal from the trial, or women participating in another clinical trial less than 30 days before participation in this trial or based on Investigator's discretion were excluded from the study.

Sample size calculation: In a study, hydro fibre dressing was found to be 5.8 times more effective than traditional dressing with an adhesive border [11]. Based on this evidence, superiority trial sample size calculation formula was used for the study with a power of 80%, and two-sided α of 0.1, and the sample size was estimated to be 94. Considering randomisation failure and loss to follow-up of 20%, sample size was increased to 114 with 57 subjects in each group.

Study Procedure

Trushield NXT non adherent wound dressing (Intervention group): 3-D Spacer fabric made of PET (90% w/w) and Polyurethane (10% w/w) + 1% w/w of DTAC; Dimethyl Tetradecyl {3-(trimethoxysilyl) propyl} ammonium chloride (non leaching, permanently bound). The DTAC enables infection control by continuously inhibiting the growth of pathogens without depletion of the kill mechanism (without a decrease in the quantity of DTAC), since DTAC is permanently bound to the dressing fabric without leaching out in the skin or out of the dressing [8].

Mechanism of action: Trushield NXT non adherent wound dressing consists of cationic sites bound to it permanently. The

cationic sites are present in all directions and attract negatively charged pathogens. The cationic sites attract pathogen cells and bind rapidly to the cellular envelope and physically disrupt the cell wall structures. This leads to lysis and disruption of cells leading to the killing of pathogens [7,8,12].

Standard of care dressing (Comparator group): Dressing used in SOC group is povidone-iodine solution, cotton gauze pad and a leucoplast adhesive pad to secure the cotton gauze pad.

All subjects who participated in the study underwent designated surgeries as per the standard institutional practice. After skin closure, either Trushield NXT or SOC dressing was used as per the randomisation. Randomisation was done to avoid bias while assigning the dressings. Initially, the patient was blinded as they came to know about the type of dressing used postsurgery only. The dressing was changed on day 3 as per hospital practice.

Randomisation

All women who participated in the study were randomly assigned in a 1:1 ratio to either Trushield NXT non adherent dressing or SOC dressing. The randomisation sequence was created independently using computer-generated randomisation (blocks of 4,6 and 8 was used). The randomisation code and the study arm details were concealed in opaque envelope which was opened on Day 0 when the patients were taken to the operation theatre for surgery.

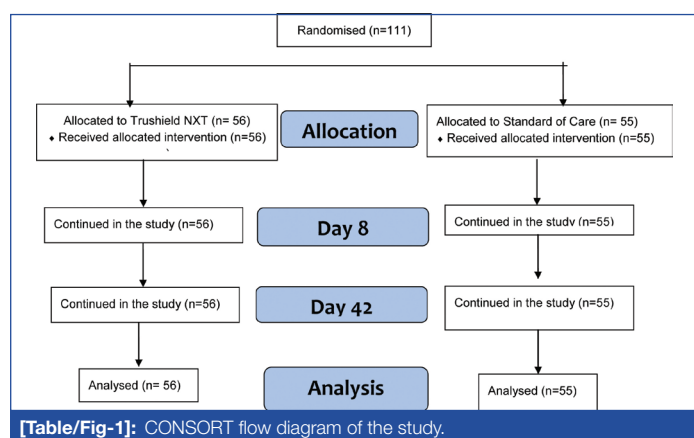
Study Endpoints

Primary endpoints: The primary endpoints for the study were dressing application time, the number of dressing change, and evaluation of SSI using the Additional treatment, Serous discharge, Erythema, Purulent exudate, Separation of deep tissues, Isolation of bacteria, and Stay as an inpatient prolonged over 14 days (ASEPSIS) scoring system on day 3 ± 1 , day 8 ± 1 and day 42 ± 7 . The score is calculated based on the percentage of the wound affected by serous exudate (0-5), erythema (0-5), purulent exudate (0-5), and separation of deep tissues (0-5). If none of the mentioned daily wound characteristics is present in a wound, then the scores for all four parameters are zero. In case the proportion of wounds affected is 20% then the score is 1, 20-39% then the score is 2, and similarly, a score of 3, 4, and 5 respectively for 40-59%, 60-79%, and >80% proportion of wound affected. Additional ten points each are awarded for antibiotic treatment, debridement of the wound under general anaesthesia, and isolation of bacteria whereas five points each are awarded for drainage of pus under local anaesthesia and stay as an inpatient for prolonged over 14 days [13].

Secondary endpoints: The secondary endpoints included pain scores on the VAS on day 0, 3 ± 1 , day 8 ± 1 , day 42 ± 7 , pain during dressing removal, evaluation of ease of application, usage, removal of the dressings using a product usage assessment scale (with a score of 1 to 5, where a score of 5 being excellent, and a score of 1 being poor) [14]. Cosmetic appearance assessed using modified Hollander wound score on day 8 ± 1 , day 42 ± 7 , evaluation of wound healing score on day 8 using wound photograph by an independent assessor on day 8 ± 1 [15]. Patient satisfaction of wound dressing and wound healing was assessed using 5 point scale on day 8 ± 1 , day 42 ± 7 . The end of study visit was conducted on day 42 ± 7 where the patient's vitals, pain score, ASEPSIS score, Modified Hollander score, patient satisfaction on wound healing were evaluated apart from clinical investigation of the wound. The scoring for modified Hollander score is given as zero (absence) or one (presence) for characteristics of the wound like step-off borders, contour irregularities, margin separation, edge inversion, excessive distortion, and overall appearance. A total score of zero is best and score 6 is worst. The exploratory endpoint was the comparison of the presence of different bacterial species in the wound swab collected from the wound site while first dressing change in both groups. Occurrence of any Adverse Effects (AE)/ Serious Adverse Events (SAE) were also recorded.

The patient demographics, vitals, medical, surgical history, and physical examination data were recorded on the screening visit. Participants were interviewed for dressing removal and re-application on day 3 and day 8. A wound swab was collected for isolation of bacteria from the wound site on day 3. Also, an image of the stitch line was captured for all patients irrespective of study arm during dressing change for each patient on day 8, and later wound healing score was given for each photograph by a surgeon who is independent of the study. To secure an unbiased assessment of the wound healing score, the surgeon who evaluated the photographs was blinded to the treatment allocation. Patients of both arms were discharged from the hospital on day 8 after the removal of the dressing.

A total of 114 women were screened between 7th Feb, 2022 and 31st March 2022, and were randomly assigned to two groups Trushield NXT and SOC arm. Three women were excluded from the study due to the appearance of exclusion criteria postconsenting and they did not receive any study intervention. The follow-up of the last recruited subject was completed on 18th May, 2022. Hence, 111 subjects were randomised into two groups; 56 subjects in Trushield NXT arm and 55 subjects in SOC [Table/Fig-1].



STATISTICAL ANALYSIS

Continuous variables were assessed using Student's t-test or Mann-Whitney U test or Moses' test for extreme reaction and results were given as mean, and standard deviation as appropriate. Categorical variables were assessed using Pearson's Chi-square test. Calculations were performed with a confidence interval of 95% wherever applicable and a p-value ≤ 0.05 was considered statistically significant. All statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) software version 28.0.

Parameters		Trushield NXT (n=56)	SOC (n=55)	p-value*	
Demographics	Age (Mean \pm SD)	28.38 \pm 4.97	27.28 \pm 6.03	0.31	
	Weight (Mean \pm SD)	60.94 \pm 10.95	62.61 \pm 9.2	0.38	
	Height (Mean \pm SD)	156.80 \pm 4.90	156.993 \pm 3.991	0.83	
	Ethnicity (n)	Indian	57	56	1.00
Vital characteristics	Temperature ($^{\circ}$ F) (Mean \pm SD)	97.80 \pm 0.44	97.93 \pm 0.47	0.13	
	Systolic blood pressure (mmHg) (Mean \pm SD)	116.84 \pm 10.91	117.21 \pm 11.14	0.77	
	Diastolic blood pressure (mmHg) (Mean \pm SD)	77.19 \pm 8.42	75.89 \pm 6.86	0.32	
	Pulse rate (beats/minute) (Mean \pm SD)	82.08 \pm 3.82	82.80 \pm 4.42	0.75	
	Respiratory rate (cycles/min) (Mean \pm SD)	20.31 \pm 12.69	17.90 \pm 0.92	0.16	
Surgery	Type of surgery	Caesarean section n (n)	53	54	0.34
		Laparoscopic hysterectomy y (n)	1	0	
		Total abdominal hysterectomy y (n)	2	1	
Medical history	Obstetric history	Yes (n)	40	40	0.95
		No (n)	16	15	

[Table/Fig-2]: Baseline demographic and vital characteristics.

*p-value was measured using Student's t-test; SD: Standard deviation; SOD: Standard of care dressing

RESULTS

A total of 114 women were screened between 7th Feb, 2022 and 31st March 2022, and were randomly assigned to two groups Trushield NXT and SOC arm. Three women were excluded from the study due to the appearance of exclusion criteria postconsenting and they did not receive any study intervention. The follow-up of the last recruited subject was completed on 18th May, 2022. Hence, 111 subjects were randomised into two groups; 56 subjects in Trushield NXT arm and 55 subjects in SOC [Table/Fig-1].

Baseline demographics (age, weight and height) and vital characteristics (temperature, blood pressure, pulse rate and respiratory rate) were comparable between the two groups [Table/Fig-2].

Primary Endpoint Analysis

SSI using ASEPSIS score: Superficial serous discharge was observed in one patient (1.78%) of the Trushield NXT group whereas Standard of care dressing group reported 13 (23.6%) cases, among which one sample from Trushield NXT and two samples from SOC tested positive for the presence of a microorganism. The mean ASEPSIS SCORE for Trushield NXT and SOC was 6.97 \pm 0.63 vs. 7.04 \pm 0.61 which was found to have statistically significant p-value $<$ 0.0001 via Moses test for extreme reaction. Trushield NXT group has 21.4% of patients with ASEPSIS score of more than 10, while SOC had 27.3% of patients with score more than 10 [Table/Fig-3].

Time required for application of dressing: The mean time of dressing was 39.16 seconds vs 101.07 seconds in Trushield NXT and SOC respectively (p-value $<$ 0.0001) [Table/Fig-4].

Number of dressing changes: Patients in both groups needed two dressing changes on day 3 and day 8, respectively postsurgery. Only four SOC patients needed three dressing changes on day 3, day 6 and day 9, respectively. The results were not statistically significant for the number of dressing changes (p-value=0.68). Trushield NXT outperformed SOC in the primary endpoint analysis parameters for SSI and dressing application time, and the values were statistically significant.

Secondary Endpoints Analysis

Intraoperative profile: A total of 107 of the 111 study participants had caesarean deliveries, three had hysterectomies, and one had a laparoscopic hysterectomy. All patients who were enrolled received spinal anaesthesia and antimicrobial prophylaxis, which are standard procedures at the site (p-value=1.00). No dressing related challenges were reported for dressings used in the study. As shown in [Table/Fig-4], Trushield NXT was discovered to be more stretchable and easier to apply than SOC.

Parameters		Trushield NXT	SOC	p-value	
ASEPSIS score	Day 3±1 n (%)	Score ≥10	12 (21.4)	15 (27.3 %)	<0.0001*
		Score <10	44 (78.6%)	40 (72.7%)	
	Day 8±1 n (%)	Score ≥10	4 (7.14%)	8 (14.5%)	<0.0001*
		Score <10	52 (92.8%)	47 (85.4%)	
	Day 42±7 n (%)	Score ≤10	56 (100%)	55(100%)	1.00
	Day 3±1 (Mean±SD)		10.68±1.59	10.89±1.58	<0.0001*
	Day 8±1 (Mean±SD)		9.23±0.63	9.24±0.49	0.111
	Day 42±7 (Mean±SD)		0	0	1.00
Average		6.97±0.63	7.04 ±0.61	<0.0001*	
Pain score	Day 0 (Mean±SD)		7.68±0.25	7.96±0.67	<0.0001*
	Day 3±1 (Mean±SD)		5.44± 0.12	6.67±0.49	<0.0002*
	Day 8±1 (Mean±SD)		3.28±0.18	3.82±0.42	<0.0003*
	Day 42±7 (Mean±SD)		0	0	1.00
Modified hollander score	Day 8±1 (Mean±SD)		0.08±0.3	0.14±0.31	<0.0001*
	Day 42±7 (Mean±SD)		0.06±0.28	0.13±0.29	<0.0001*
	Average		0.07±0.29	0.13 ±0.3	<0.0001*
Patient satisfaction score	Day 8±1 (Mean±SD)		3.75±0.48	3.11±0.83	<0.0001*
	Day 42±7 (Mean±SD)		3.69±0.57	3.57±0.57	<0.0001*
	Average		3.71±0.52	3.34±0.7	<0.0001*

[Table/Fig-3]: ASEPSIS score, mean pain score and Modified Hollander score in the study arms.

*p-value <0.05 was considered statistically significant (Moses test of extreme reaction)

Parameters	First dressing (Day 0)		Second dressing (Day 3)		Average	
	Trushield NXT (Mean±SD)	SOC (Mean±SD)	Trushield NXT (Mean±SD)	SOC (Mean±SD)	Trushield NXT (Mean±SD)	SOC (Mean±SD)
Ease of application	4.11±0.48	3.08±0.45	3.98±0.36	2.83±0.47	4.04±0.46	2.95±0.46
	p-value <0.0001*		p-value <0.0001*		p-value <0.0001*	
Stretch ability	3.74±0.46	2.46±0.54	3.41±0.65	2.36±0.522	3.57±0.56	2.41±0.53
	p-value <0.0001*		p-value <0.0001*		p-value <0.0001*	
Dressing time (seconds)	37.61±25	103.02±24.99	40.83±22.72	98.11±15.01	39.16±21.96	101.07±16.50
	p-value <0.0001*		p-value <0.0001*		p-value <0.0001*	
Exudate management	First dressing (Day 3)		Second dressing (Day 8)		Average	
	3.69±0.54	2.77±0.57	3.67±0.51	2.76±0.54	3.68±0.52	2.72±0.56
p-value <0.0001*		p-value <0.0001*		p-value <0.0001*		
Breathability of skin	3.48±0.63	2.38±0.56	3.56±0.63	2.39±0.56	3.53±0.63	2.38±0.56
	p-value <0.0001*		p-value <0.0001*		p-value <0.0001*	
Conformance to skin	3.78±0.66	2.62±0.52	3.72±0.59	2.56±0.63	3.75±0.63	2.46±0.50
	p-value <0.0001*		p-value <0.0001*		p-value <0.0001*	
Stickiness of adhesive layer	2.43±0.79	3.98±0.46	2.28±0.68	4±0.67	2.35±0.73	3.99±0.56
	p-value <0.0001*		p-value <0.0001*		p-value <0.0001*	
Water proofing	3.65±0.55	2.42±0.60	3.81±0.55	2.52±0.69	3.73±0.55	2.47±0.64
	p-value <0.0001*		p-value <0.0001*		p-value <0.0001*	
Ease of removal	3.94±0.68	2.02±0.53	3.94±0.76	2.06±0.59	3.94±0.72	2.04±0.56
	p-value <0.0001*		p-value <0.0001*		p-value <0.0001*	
Non adherence to wound	3.24±0.95	1.64±0.52	3.24±0.93	1.83±0.72	3.24±0.94	1.73±0.62
	p-value <0.0001*		p-value <0.0001*		p-value <0.0001*	

[Table/Fig-4]: Surgeon's opinion on dressing application and properties (5 being excellent, 1 being poor).

Average: Mean of scores for ease of application, stretchability and dressing time (seconds) on day 0 and day 3 were added and the result was divided by 2 to get an average of the scores for dressing application. Similar process was followed for exudate management, the breathability of skin, conformance to skin, stickiness of adhesive layer, water proofing, ease of removal, and non adherence to wound scores taken on day 3 and day 8.

*p-value<0.05 was considered statistically significant (Mann-Whitney U test).

SOD: Standard of Care Dressing; SD: Standard Deviation

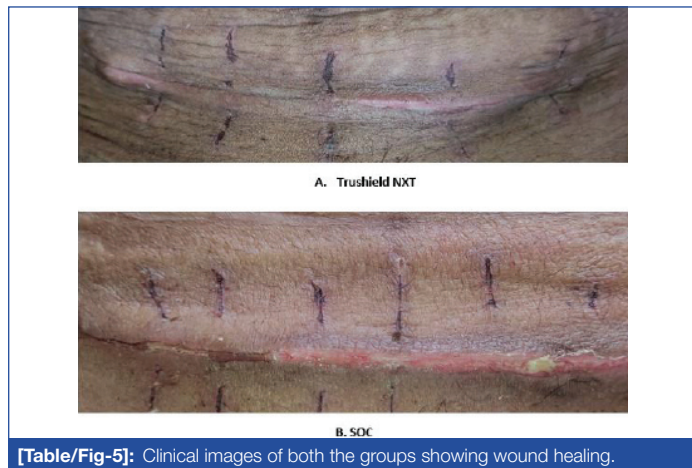
Postoperative profile: The postoperative pain started between 2-3 hours postsurgery. The intensity of pain can be seen to decrease with each follow up visit along with the number of analgesics used as represented in [Table/Fig-3]. Wound healing score was 82.57±8.83 vs 73.36±7.56 in Trushield NXT and SOC respectively

with statistically significant p-value of <0.0001 by Mann-Whitney U Test [Table/Fig-5].

In case of usability assessment also Trushield NXT performed better than SOC as summarised in [Table/Fig-4]. The patient's comfort in application, usage and pain during removal are

summarised in [Table/Fig-6]. Trushield NXT was observed to have more comfort and less pain with statistically significant p-values. The average patient satisfaction score on wound healing was 3.71 ± 0.52 in Trushield NXT arm and 3.34 ± 0.70 in SOC arm (p-value < 0.0001).

The average modified Hollander score was 0.07 ± 0.29 vs 0.13 ± 0.3 in Trushield NXT and SOC, respectively with p-value < 0.0001 by Moses' test of extreme reaction, once again establishing Trushield NXT to be more effective than SOC in postoperative wound healing, management and cosmesis. The details of dressing removal



[Table/Fig-5]: Clinical images of both the groups showing wound healing.

Parameters	Day 3 \pm 1		Day 8 \pm 1		Average	
	Trushield NXT (Mean \pm SD)	SOC (Mean \pm SD)	Trushield NXT (Mean \pm SD)	SOC (Mean \pm SD)	Trushield NXT (Mean \pm SD)	SOC (Mean \pm SD)
Comfort during application of dressing	2.48 \pm 1.85	2.02 \pm 1.29	3.30 \pm 1.04	2.42 \pm 0.87	2.89 \pm 1.44	2.22 \pm 1.08
	p-value $< 0.0001^*$		p-value $< 0.0001^*$		p-value $< 0.0001^*$	
Comfort in use	3.74 \pm 0.82	1.96 \pm 0.64	4.07 \pm 0.57	2.94 \pm 0.96	3.90 \pm 0.69	2.45 \pm 0.80
	p-value $< 0.0001^*$		p-value $< 0.0001^*$		p-value $< 0.0001^*$	
Comfort in removal	3.84 \pm 0.92	1.87 \pm 0.84	3.85 \pm 0.78	2.11 \pm 0.88	3.84 \pm 0.85	1.99 \pm 0.86
	p-value $< 0.0001^*$		p-value $< 0.0001^*$		p-value $< 0.0001^*$	
Pain during removal (100 point scale)	27.67 \pm 17.80	54.00 \pm 31.12	33.59 \pm 15.22	64.41 \pm 13.53	30.63 \pm 16.51	59.2 \pm 22.32
	p-value $< 0.0001^*$		p-value $< 0.0001^*$		p-value $< 0.0001^*$	

[Table/Fig-6]: Patients' opinion on dressing application, usage, and removal (5 being excellent, 1 being poor).

*p-value < 0.05 was considered statistically significant (Mann-Whitney U test)

parameters with significant p-value indicating Trushield NXT to be superior to SOC. The pain during dressing removal was significantly less in Trushield NXT arm than that in SOC [Table/Fig-6].

Exploratory Endpoint Analysis

As a part of exploratory outcome bacterial analysis from wound swab was performed on day 3. *Enterobacter cloacae*, *Acinetobacter baumannii* and *Proteus mirabilis* organism was reported in swab collected from three patients, one in Trushield NXT arm and two in SOC arm. This result was not statistically significant (p-value=1.000 calculated using Mann-Whitney U Test). The number of adverse events reported in Trushield NXT group was 4 (Fever, cough, cold and headache) and that in SOC was 5 (Fever, cough, cold, headache and stomach infection). All adverse events reported were not related to the dressings used. There were no SAE reported during the study.

DISCUSSION

For SSI prevention, early detection of risk factors like diabetes, obesity, and immunosuppression is beneficial whereas for management of SSI, it is suggested by CDC that the incision site should remain covered by sterile dressing for at least 24-48 hours postsurgery [16]. National Institute for Health and Care Excellence (NICE) guidelines updates team reports that in obstetric and gynaecological surgeries wound complications account for 2-30%

[17]. Another study reports the clinical safety and effectiveness of new antimicrobial dressings designed to manage exudate, which shows a lower rate of infection when compared to that of SOC [18]. An ongoing study assessing the effectiveness of Dialkyl Carbamoyl Chloride (DACC) coated dressing versus SOC (the dressing trial) considered ASEPSIS score < 10 to be indicative of satisfactory wound healing while that between 10-21 indicates impaired wound healing [13]. In the present randomised control trial, Trushield NXT had more percentage of patients with < 10 ASEPSIS score than SOC, once again establishing the effectiveness of Trushield NXT over SOC. It was also noted that all patient's wound was completely healed on Day 42 \pm 7 and their ASEPSIS and pain scores were calculated as 0.00.

The observed evidence of 1.78% vs 23.6% superficial serous discharge in Trushield NXT and SOC respectively is similar to results (2.8% vs 9.8%) observed in a pilot study, efficacy and cost-effectiveness of DAAC dressing over standard surgical dressing in managing SSI in a randomised controlled trial conducted on cesarean delivery patients, which emphasises the need for advanced dressings to prevent and manage SSI in postsurgical wound management [19]. The result of the present study also indicates the same.

A study on chlorhexidine containing antimicrobial bandage highlighted the importance of antimicrobial bandage for postoperative wound management which is in terms with the results shown by our study while comparing Trushield NXT and SOC [20].

The patient satisfaction score analysis in the current study shows Trushield NXT performed better than SOC (3.71 vs 3.24; p-value < 0.0001) which matches with the findings of randomised control trial on antimicrobial dressings versus SOC dressing with a patient satisfaction score of 52 vs 49 (p-value=0.002) respectively in obese women undergoing caesarean delivery [21]. Evidence from a meta-analysis suggests hydro fibre dressings have fewer wound complications which was also witnessed in the current study with a relatively lower number of SSI in Trushield NXT than that of SOC [22,23].

The basic parameters for an effective postoperative wound healing like ASEPSIS score < 10 , application, usability and removal satisfaction from patient and provider along with less pain score, pain during removal and dressing time make Trushield NXT non adherent wound dressing a more potent choice of dressing than SOC in obstetric and gynaecological surgeries.

Limitation(s)

The study was performed in a single-centre with a relatively small patient population. If it was performed across different hospitals with varied settings and patient pools, the results would have been more enriching and generalisable. Also, the surgical procedures conducted are clean surgeries with less incidence of SSI.

CONCLUSION(S)

In obstetric and gynaecological surgery, it was found that Trushield NXT non adherent wound dressing performed better in postoperative wound management than SOC with not only superior provider and patient satisfaction but also in wound healing, a sepsis score, and pain management.

Acknowledgement

The authors are grateful to Healthium Medtech Limited for providing the Trushield NXT dressings and funding in the form of educational grant for conducting the study.

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AUTHOR DECLARATION:

- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. Yes

PLAGIARISM CHECKING METHODS: [Jan H et al.]

- Plagiarism X-checker: Aug 25, 2022
- Manual Googling: Oct 13, 2022
- iThenticate Software: Oct 17, 2022 (11%)

ETYMOLOGY: Author Origin

Date of Submission: **Aug 18, 2022**
Date of Peer Review: **Sep 19, 2022**
Date of Acceptance: **Oct 26, 2022**
Date of Publishing: **Dec 01, 2022**