International Journal of Medical and Health Research
ISSN: 2454-9142
www.medicalsciencejournal.com
Volume 1; Issue 5; December 2015; Page No. 23-27

A comparative clinical study of post- operative wound complications using Prolene, PDS ll and PDS plus

Dr. Puneet Tyagi, Dr. Mohammed Raza
JSS Medical College, Mysore.

Abstract
Approximately 700,000 open abdominal procedures are performed annually in Germany and 4,000,000 in the United States. Incidence (annual) of abdominal surgery around the world is 25 per 10000. Development of incisional hernia remains the major postoperative wound complication after open abdominal surgery with a stable incidence of 5% to 24% over the last decades. Prolene is amongst the common materials used for closure of abdominal incision. The introduction of PDS and PDS plus for closure of abdominal incisions has completely changed the scenario in form of surgical site infections. The study aims to identify the best suture material with least post-operative wound complication. Selection of patients was on basis of inclusion and exclusion criteria. Patients who undergo elective and emergency abdominal surgeries were taken in the study and compared based on the type of suture material used from post-operative day one, patient accessed for complications related to incision like Infection, dehiscence, sinus, incisional hernia and pain. Examination of wound on fifth post-operative day, stitch removal on 9 day with follow up on first month, second month and sixth months. In our study the result were compared with previous studies done. Prolene, PDS II and PDS plus were equally effective for closure of midline wound following laparotomy closed by continuous running technique except the rate of infection with PDS plus due to presence of antiseptic (3.3% in PDS plus and 26.7% in PDS II). However use of PDS plus is not cost effective and therefore requires further studies to be conducted to evaluate the availability, cost effectiveness and measurement of health related quality of life.

Keywords: clinical study, abdominal surgery, post- operative wound, Prolene, PDS ll, PDS

Introduction

Approximately 700,000 open abdominal procedures are performed annually in Germany and 4,000,000 in the United States [1]. Incidence (annual) of abdominal surgery around the world is 25 per 10000 [2]. Development of incisional hernia remains the major postoperative wound complication after open abdominal surgery with a stable incidence of 5% to 24% over the last decades. [3, 4] 52% of incisional hernias occur within 6 months post operatively, burst abdomen occurs within 6 to 8 days after surgery and infections are excess in the early days of post op. The ideal method of abdominal wound closure should be technically simple and should be free from the post-operative wound complications like wound infection, wound dehiscence, incisional hernia, suture sinus formation and should leave a reasonably aesthetic scar. Closure of abdominal incision with different suture materials has been a matter of great controversy. Prolene is amongst the common materials used for closure of abdominal incision.

The introduction of PDS and PDS plus for closure of abdominal incisions has completely changed the scenario in form of surgical site infections. Both the techniques of abdominal closure and the suture material to be used, continue to excite debate. Like many others we employ interrupted two-layered closure, but the best suture material to be used is debatable.

The study aims to identify the best suture material with least post-operative wound complication.

Materials and methods

The study was conducted on 90 patients undergoing elective and emergency laparotomy, 30 cases each underwent midline mass continuous running closure with Prolene No I, PDS II, No.1. PDS plus No.1. The post-operative complications in the patients were noted.

Patients of elective and emergency laparotomies are selected in the study the operating surgeon, assistant and assisting nurse should take proper aseptic precautions during scrubbing, gowning and gloving. Skin is prepared by betadine solution and spirit. Antibiotic prophylaxis at induction of anaesthesia. Cefotaxime 1gm intravenous (should be same for all groups and switched to oral ones as oral feeding started) for all the groups. In all the groups classification of the wounds is carried out in four types:

Type I – clean wound
Type II – clean contaminated wound
Type III- contaminated wound
Type IV – dirty wound

Suturing done by continuous running method in two layers for all vertical incisions, skin being the second and all other layers as first. While suturing suture property and knot technique assessed. Examination of wound is carried out on fifth postoperative day, (in case of soakage, fever and tachycardia then examination is done earlier). Stitch removal on eight post-operative day.

From post-operative day one patient accessed for complications related to incision:
Early complications
- Surgical site infection
- Wound dehiscence

Late complications
- Sinus
- Incisional hernia
- Chronic pain

Abdominal belt for three months (advised only for those who have obesity, chronic constipation, and chronic obstructive airway disease).

Follow up visit for patient:
First month
Second month
Sixth month
Twelve month

Suture material used includes Prolene,
PDS II
PDS plus in 30 patients each

Inclusion criteria
Either sex: Male or female
Age: above 15 years
Abdominal surgery: Emergency
Incision: Vertical midline
Closure: En mass continuous running technique of suturing.

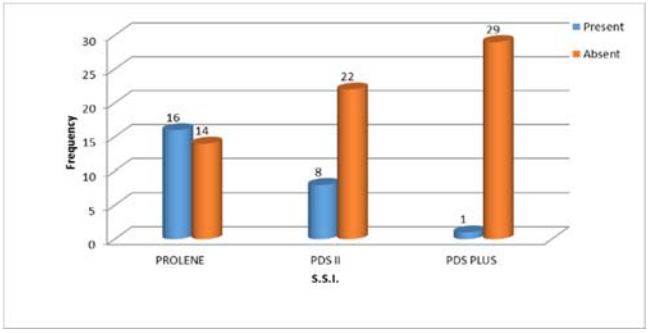
Exclusion criteria
1. Comorbid conditions
   a. Chronic obstructive pulmonary diseases
   b. Immunocompromised state
   c. Uncontrolled diabetes mellitus
2. Paediatric age groups
3. Peritonitis
4. Post-operative patients presenting with incisional hernia for which elective abdominal surgery planned.

Statistical Analysis
- Using SPSS for windows (version 16.0).

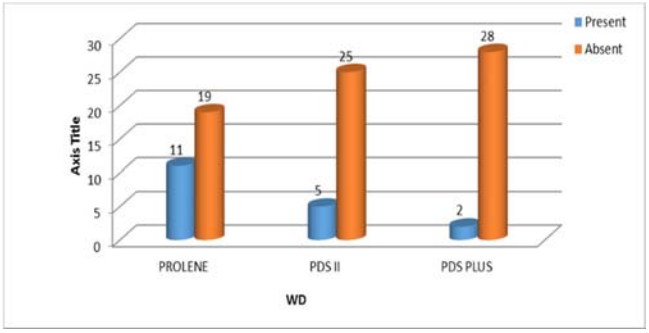
Results
This study was undertaken from October 2013 to October 2015.
The observations of our study were as follows:
Total patients –90
All patients were operated in an elective and emergency setup, with use of midline incision for exploration and sutured with en mass continuous running technique.
En mass closure was done with the use of Prolene, PDS II and PDS Plus with 30 patients for each in a randomized way. M:F ratio of 1.9:1.
The p value was found to be 0.165 for association between gender and complication which indicates no significant association between gender and complication. Complications after midline closure by continuous running technique with prolene, PDSII and PDS Plus were seen to be present more after age of 50. Incidence of complication is 50% (51-60), 63.2% (61-70) and 60% (70-80) age groups. The p value 0.053 which indicates no significant association between increasing age and complication.

All the patients were assessed post operatively for complications such as surgical site infection, wound dehiscence, chronic pain, sinus formation and incisional hernia.

Surgical Site Infection
In present study the percentage of SSI in Prolene is 53.3%, PDS II is 26.7% And PDS Plus is 3.3%. The above table indicates association between suture material used and SSI. The p value was found to be 0.00, which indicates a significant association between suture material used and SSI.

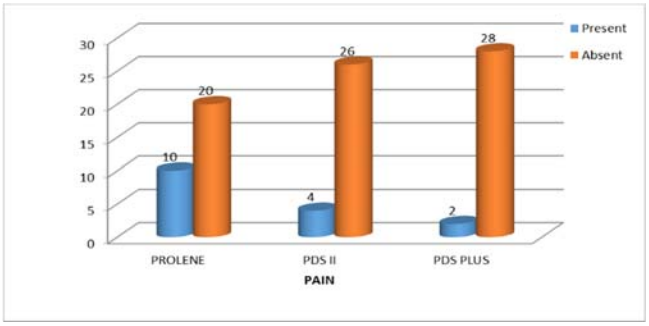


Wound dehiscence
Wound dehiscence is an early complication seen in 5 out of 30 patients in PDSII, 11 out of 30 patients in prolene and 2 in PDS Plus in present study. The rate being 36.7% in Prolene 16.7% in PDSII and 6.7% in PDS Plus. The above table indicates associations between suture material used and wound dehiscence. The p value was found to be 0.013, which indicates a significant association between suture material used and wound dehiscence.



Graph 5: Wound dehiscence according to suture material

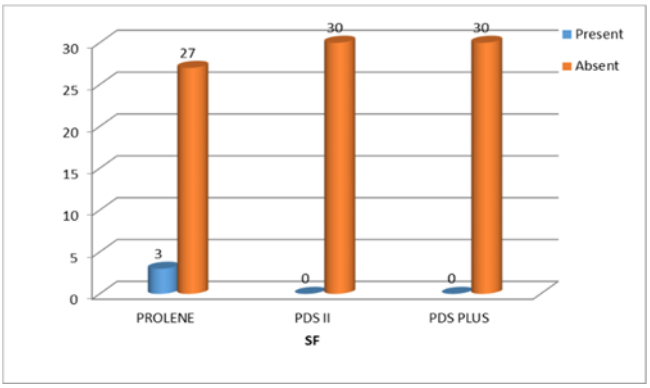
Chronic pain
Chronic pain in prolene is 33.3%, PDS is 13.3% and PDS plus is 6.7%. The above table shows association between suture material used and chronic pain. The p value is <0.05, which indicates a significant association between suture material used and chronic pain.



Graph 6: Chronic pain according to suture material

Sinus formation

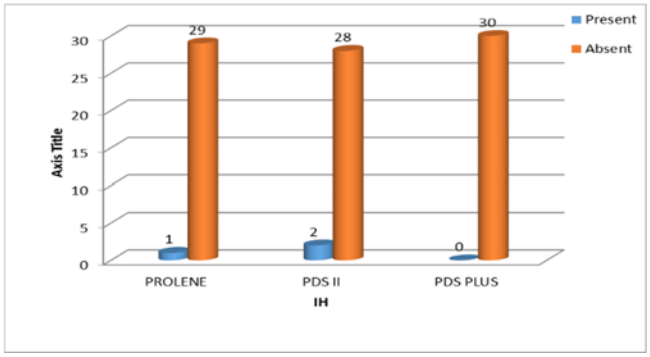
Sinus formation was observed in present study only in3 cases all were sutured with prolene. The rate of sinus formation being 10.0%. The above table shows association between suture material used and sinus formation. The p value <0.05 indicates a significant association between suture material used and sinus formation.



Graph 7: Sinus formation according to suture material

Incisional hernia

Incisional hernia is a late complication seen in 2 out of 30 patients in PDSII, 1 out of 30 patients in prolene and none in PDS Plus in present study. The rate being 3.3% in Prolene and 6.7% in PDS. The above table indicates associations between suture material used and Incisional hernia. The p value was found to be 0.355, which indicates no significant association between suture material used and Incisional hernia.



Graph 8: Incisional hernia according to suture material

Complications according to type of wound

All the operated cases in present study are included in Type I, Type II and Type III surgical wounds. Out of 10 Type I cases 1(10.0%) case had complication, out of 32 Type II cases 18 (56.2%) cases had complication and out of 48 Type III cases 19(39.6%) cases had complication.

Table 10: Distribution of cases according to type of wound

Type of wound		infection		Total
		Absent	Present	
Type I	Count	9	1	10
	% within TOW	90.0%	10.0%	100.0%
Type II	Count	14	18	32
	% within TOW	43.8%	56.2%	100.0%
Type III	Count	29	19	48
	% within TOW	60.4%	39.6%	100.0%
Total	Count	52	38	90
	% within TOW	57.8%	42.2%	100.0%

Table 11: Distribution according to suture material used and wound complications

Suture	Wound complications(percentage)				
	Wound dehiscence	SSI	Chronic pain	Sinus Formation	Incisional Hernia
Prolene	36.7%	53.3%	33.3%	10.0%	3.3%
PDS	16.7%	26.7%	13.3%	0	6.7%
PDS Plus	6.7%	3.3%	6.7%	0	0

Table 12: Distribution of complications according to Intraoperative diagnosis

Diagnosis	Total patients	Wound dehiscence	SSI	Pain	Sinus	Incisional Hernia
CA Rectum	15	4	5	4	1	0
CA Sigmoid colon	8	1	3	3	0	0
CA Ascending colon	10	3	3	2	0	1
Blunt trauma abdomen	6	1	2	0	0	0
Intestinal obstruction	25	5	8	5	2	2
Gastric outlet obstruction	5	0	1	0	0	0
Chronic calcific pancreatitis	5	1	0	1	0	0
Mesenteric cyst	6	1	1	1	0	0
CA Stomach	4	1	1	0	0	0
CA Head of pancreas	2	0	0	0	0	0
CA 1/3rd lower esophagus	1	0	0	0	0	0
GIST	3	1	1	0	0	0

Discussion

Approach to abdominal cavity, the techniques used for abdominal closure and the various materials to be used in emergency and elective exploratory laparotomies continue to excite the debate amongst surgical fraternity. The best suture material which can be used is still debatable. Materials such as absorbable suture materials are found to higher rate of wound failure than non-absorbable suture materials, but the later also causes wound pain, knot palpability and sinus formation with infection. So we compared prolene, PDS II and PDS plus in a randomized trial.

Ideal suture material should be sufficient to hold the parts together, get absorbed as soon as its work is finished, be non-irritant and free from any complications. There is a tendency of knot slippage and occasionally fracture of suture with Prolene. Prolene can also causes palpable knot below, the skin becoming the source of wound pain and sinus. The wounds closed with PDS II suture material were more comfortable, with fewer knots palpable and very less patients experienced wound pain.

Suture materials used for the closure of abdominal incisions in presence of infection has more chances of complications in

terms of post-operative wound infection, wound dehiscence and burst abdomen. SSI being the third most common hospital acquired infection accounts for 14-16% of all such infections. The surgical complications depends on extent of surgical trauma, colonization and additional co-morbid conditions.

In present study comparison between PDS II (uncoated) and PDS Plus (coated) was carried out and after analysis a significant difference was found in favour of PDS Plus (SSI rate 3.3% Versus 26.7%). In present study the total sample size was 90 patients out of which 30 patients each were sutured using Prolene, PDS II and PDS plus.

Table 13: Comparison of studies related to surgical site infection

Study	Prolene		PDS		PDS Plus	
	Total patients	Infected cases	Total patients	Infected cases	Total patients	Infected cases
Cameron 1987 [5]	141	21(14.8%)	143	12(8.39%)	0	0
Krukowsi 1987 [6]	383	27(7.04%)	374	13(3.47%)	0	0
Mirza 2003 [7]	85	10(11.7%)	79	8(10.1%)	0	0
Justinger *et al.* [8]	0	0	371	42(11.35)	485	31(6.4%)
Present study	30	16(53.3%)	30	8(26.7%)	30	1(3.3%)

In the studies done by Cameron 1987(44), Krukowski 1987(45), Mirza 2003 comparing Prolene and PDS as in table it was found that SSI was 14.8%, 7.04% and 11.7% in Prolene as compared to PDS in which infection rate was 8.39%, 3.47% and 11.3%. All these studies showed higher rate of infection of Prolene was compared to with PDS II for closure.

In the study of Justinger *et al.* out of 485 patients in whom PDS plus was used 31 patients (6.4%) had SSI when compared with PDS in which out of 371, 42(11.3%) patients had SSI. In present study the rate of SSI in Prolene, PDS II and PDS plus was 53.3%, 26.7% and 3.3% respectively. Incidence was less with PDS plus an antiseptic coated suture material being 1 out of 30, and high with Prolene and PDS. The p value was approximately 0.00 which indicates a significant association between suture material used and surgical site infection in present study.

Table 14: Comparison of studies related to wound dehiscence

Study	Prolene		PDS	
	Total patients	Infected cases	Total patients	Infected cases
Cameron1987	141	9(6.3%)	143	1(0.69%)
Krukowsi1987	383	7(1.8%)	374	3(0.8%)
Mirza2003	85	2(2.3%)	79	1(1.26%)
Present study	30	11(36.7%)	30	5(16%)

In present study 11 (36.7%) cases of Prolene, 5 (16.7%) of PDS II and 2(6.7%) cases of PDS Plus developed wound dehiscence. SSI delays the normal process of wound healing, disintegrating the aponeurosis and sutures placed before the wound has gained its own tensile strength resulting into wound dehiscence. In present study, out of 18 patients with wound dehiscence 14 cases had SSI. The p value was found to be 0.013, which indicates a significant association between suture material used and wound dehiscence.

Table 15: Comparison of studies related to sinus tract formation

Study	Prolene		PDS	
	Total patients	Infected cases	Total patients	Infected cases
Cameron1987	141	1(0.7%)	143	0
Krukowsi1987	383	1(0.26%)	374	0
Mirza2003	85	11(12.9%)	79	2(2.53%)
Wissing1987	299	23(7.69%)	281	11(3.91%)
Present study	30	3(10%)	30	0

In present study sinus tract formation was seen only in Prolene (10%) versus PDS II being 0 and PDS Plus being 0.0. The p value was found to be 0.045 *which* indicates a significant association between suture material used and sinus formation. In all the studies mentioned in above table 15 sinus formation was seen in Prolene with rates as 0.7%q 0.26%J2.9% and 7.69% while for PDS II the rate 0 in *two* studies and 2.53% and 3.9 1% in other two studies. With PDS plus the rate of sinus formation in present study was 0.

Table 16: Comparison of studies related to incisional hernia

Study	Prolene		PDS	
	Total patients	Cases with hernia	Total patients	Cases with hernia
Cameron1987	141	11(7.8%)	143	10(6.99%)
Bloemen2011[9]	256	45(17.6%)	374	58(21.7%)
Mirza2003	85	4(4.7%)	79	5(6.3%)
Wissing1987[10]	299	31(10.36%)	281	37(13.16%)
Present study	30	1(3.3%)	30	2(6.7%)

In present study we noted only 3 cases of incisional hernia 2 in PDS II (6.7%) and 1 in Prolene (3.3%). The p value was found to be 0.355, which indicates a no significant association between suture material used and incisional hernia. There is not a much statistical difference in incidence of incisional hernia in the above studies. The rate of occurrence of incisional hernia is 7.8%, 17.6%, 4.7% and 10.36% with Prolene in studies conducted by Cameron, Bloemen (46), Mirza and Wissing (47) and the rates are 6.99%, 21.7%, 6.3% and 13.16% with PDS II.

Chronic pain after use of prolene, PDS II and plus

Slowly absorbable materials are designed in a way to approximate the fascia in the critical early period of healing and it subsequently undergo absorption to avoid chronic pain. With a non-absorbable suture the cause of pain is the persistent suture knot. The incidence of chronic suture site pain is less with absorbable material. Meta analyses of three randomized trial with one year follow up revealed 40(4.5%) of 891 patients in the PDS group had chronic pain as compared to 70(8.7%) patients out of 912 in whom non absorbable suture. In present study the p value was found to be 0.019 which indicates a significant association between suture material used and chronic pain.

Distribution of complications according to age and sex

With increasing age the chances of wound infection increases. In present study with increase in age there is increase in the occurrence of complications and it is maximum in the age group of 50 and above. The p value was found to be 0.053, which indicates no significant association between increasing age and complications.

Distribution of wound complications according to gender

In present study men (47.5%) are affected more than females (32.3%) but the p value was found to be 0.165, which indicates no significant association between sex and complications. This possibly could be because of less number of females in our study.

Conclusion

In present study the results were compared with the studies done previously. In the fixed effect model the comparison between Prolene, PDS II and PDS Plus was carried out in terms of risk of post-operative complications like SSI, wound dehiscence, risk of incisional hernia, suture sinus formation and post-operative chronic wound pain.

Prolene, PDS II and PDS Plus were equally effective for closure of midline wound following laparotomy closed by continuous running technique.

There are no significant differences between PDS II and PDS Plus except the rate of infection being less with PDS Plus due to the presence of antiseptic (3.3% in PDS Plus and 26.7% in PDS II).

However use of PDS Plus is not cost effective and so it requires further studies to be conducted to evaluate the availability, cost effectiveness and measurement of health related quality of life, instead of analyzing their effectiveness in laparotomy closure. PDS Plus and PDS II use was favoured over Prolene to avoid the palpability of knot beneath the skin, chronic pain due to irritation and subsequent sinus formation, prolene being non absorbable synthetic material. There was statistically significant higher risk of knot palpability, chronic pain and suture sinus development following the use of prolene compared to PDS II and PDS Plus.

In present study it was found that wounds closed with PDS II and PDS Plus were more comfortable, fewer knots were palpable and vey less patients experienced wound pain. Therefore PDS Plus and PDS II have advantage over Prolene.

PDS II and PDS Plus retains its strength for a considerable time and is eventually absorbed. PDS Plus is coated with Triclosan antiseptic which inhibits the growth of common bacteria implanted in the laparotomy wound, which brings down the overall rate of post-operative wound infection, therefore decreasing the hospital stay, use of sophisticated dressings, need of isolation of bacteria by culture and sensitivity test and overall morbidity.

The incidence of post-operative abdominal wound infection can be significantly reduced by prophylactic use of antiseptic coated suture material like PDS Plus. Therefore PDS Plus should be given preference in the closure of laparotomy wounds especially when colorectal surgeries have been carried out. If cost effectiveness is the issue then PDS II should be preferred over Prolene.

No further trials are required for the evaluation of suture materials in laparotomy wound closure according to the results of outcomes of our study. Further randomized trials may be directed to evaluate variables such as availability, cost effectiveness, health related quality of life measurement, duration of hospital stay, operative time, long term follow up and readmission rate due to post-operative adhesion formations.

In conclusions PDS Plus and PDS II may be an alternative suture to Prolene for midline laparotomy incisions using continuous running closure technique.

References

1. Knowler WC, Barret Connor E, Conze J, Klinge U, Schumpelick V. Incisional hernia. Chirurg, 2005; 76(9):897-909.
2. Statistics of abdominal surgery updated 2008 June 16; cited 2008 November 9 available from URS: http://www.ncbi.nlm.nihgovt/pubmed/1634942152.
3. LA, Jonsson T. Incisional hernia after midline laparotomy: a prospective study. Eur J Surg. 1996; 162:125-129.
4. Hoer J, Lawong G, Klinge U, Schumpelick V. Factors influencing the development of incisional hernia. A retrospective study of 2983 laparotomy patients over a period of 10 years. Chirurg, 2002; 73:474-480.
5. Cameron AEP, Parker CJ. A randomized comparison of polydioxanone (PDS) and polypropylene (Prolene) for abdominal wound closure.
6. Krukoswki Z. Cusick EL. Pollydioxanone or polypropylene for closure of midline abdominal incision: A prospective comparative clinical trial. The British Journal of Surgery. 1987; 74:828-30.
7. Sajid UMS, Parampalli MK, Baig MR, Mcfall. A systemic review on the effectiveness of slowly-absorbable versus non-absorbable sutures for abdominal fascial closure following laparotomy. International journal of surgery. 2011; 9(8):615-25
8. Justinger C, Slotta JE, Ningel S, Gräber S, Kollmar O, Schilling MK. Surgical-site infection after abdominal wall closure with triclosan-impregnated polydioxanone sutures: results of a randomized clinical pathway facilitated trial Surgery 2013; 154(3):589-95.
9. Bolemen A, Van Dooren P HB. Randomized clinical trial comparing polypropylene or pollydioxanone for midline abdominal closure. British Journal of Surgery. 2011; 98:633-9.
10. Wising J, Van Vroon Hoven TJ. Fascial closure after midline laparotomy: result of a randomized trial. The British journal of surgery. 1987; 74:738-41.