THE SEARCH FOR THE IDEAL METHOD OF ABDOMINAL FASCIAL CLOSURE: A META-ANALYSIS, A PROVINCIAL SURVEY AND A RANDOMIZED CONTROLLED TRIAL PROPOSAL

By

Nicole Christina Fink Hodgson

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ABSTRACT

Objective: The ideal suture for abdominal fascial closure has yet to be determined. Part I: a meta-analysis of randomized trials was conducted to determine which suture material and technique reduces the odds of incisional hernia. Part II: to determine the current practice of abdominal fascial closure in Ontario and Part III: a randomized controlled trial proposal.

Methods: Part I: Two databases were searched for articles in English published from 1966-1998. Randomized controlled trials and trials with a Jadad Quality Score $\geq$3, comparing suture materials and/or technique were included. The primary outcome was postoperative incisional hernia

Part II: A provincial survey of general surgeons was conducted. A mailed questionnaire containing common surgical scenarios was developed.

Part III: A randomized controlled trial proposal incorporating results from the meta-analysis and the provincial survey.

Results: Part I: Incisional hernias were significantly lower in the nonabsorbable group, with an odds ratio of 0.68 (95% CI 0.52 to 0.87), and relative risk reduction (RRR) of 33%. Suture technique favored nonabsorbable continuous closure with an odds ratio of 0.61 and RRR of 36%.

Part II: Most surgeons (86%) chose an absorbable suture for abdominal fascial closure.

Conclusions: Part I: Abdominal fascial closure with a continuous nonabsorbable suture had a significantly lower rate of incisional hernia. Part II: Current practice of abdominal fascial closure among Ontario general surgeons is discordant to this meta-analysis. A randomized controlled trial comparing a continuous nonabsorbable closure versus a continuous absorbable closure is warranted.

KEY WORDS: surgery, sutures, meta-analysis

This thesis is dedicated

An meine Eltern, Monika und Peter

"Immer weiter Hilfsarbeiter"

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CO-AUTHORSHIP

The following thesis contains information that will be submitted for publication in Annals of Surgery and the Canadian Journal of Surgery. Dr. Ostbye and Dr. Malthaner, advisors of this work, are listed as secondary authors.

Chapter 1. Introduction

1.1 Definition of Surgical Laparotomy

Surgical methods for entering the abdominal cavity are numerous. Incisions traverse the skin, subcutaneous tissues and fascial tissues. The incision used is technically known as a "celiotomy" but most commonly referred to as a "laparotomy". Laparotomy incisions are commonly employed for gastric, hepatobiliary, vascular, and colorectal surgery. It is a surgical approach employed for both elective and emergency operations. Many anterior abdominal wall incisions exist (Appendix I). The midline incision permits expeditious abdominal entry, access to both sides of the abdomen and a strong, rapid closure. For these reasons this incision has become the standard surgical approach to enter the abdomen.

1.2 Wound Complications

Wound complications following laparotomy can be divided into early and late complications. Early complications include: wound infection, burst abdomen (evisceration of bowel/abdominal contents) and wound dehiscence (fascial disruption without evisceration). Burst abdomen occurs after 1-3% of operations, has a high mortality rate of 15-20%, and requires immediate reoperation (1). Late complications include chronic wound pain, suture sinus, and incisional (ventral) hernia. Any protrusion of abdominal cavity contents through a defect in the fascial wall may be defined as a hernia (2). They are classified as congenital

or acquired. Acquired incisional hernias are iatrogenic hernias resulting from a prior surgical procedure.

The etiology of wound failure is multifactorial with contributions from patient, local and technical factors. Patient factors include malignancy, steroid use, pulmonary disease, obesity and age. Local factors: such as emergency surgery, degree of operative contamination, antibiotic prophylaxis and technical factors such as suture material, suture technique and type of incision are all contributory. Suture material is one of the few controllable factors in preventing postoperative wound failure. The quest for an ideal suture material has been an objective of surgeons since before the 1500s. Suture materials are broadly classified into absorbable and nonabsorbable sutures (Appendix II). The characteristics of an ideal suture material include: retention of tensile strength, lack of tissue reactivity, and facility of handling. Aponeurotic incisions of the abdominal wall are much less vascular and heal more slowly than skin incisions (3). They require about 120 days to retain strength (3).

1.3 The Definition of Meta-analyses

The term "meta-analysis" was coined by Glass in 1976 from the Greek prefix "meta" meaning "transcending" and the root, analysis (4). Meta-analysis is a quantitative approach that employs statistical methods for systematically combining the results of previous research in order to arrive at a conclusion about the body of research (5). It relies on quantitative methods and proceeds in a strict sequence of retrieval of eligible studies and data extraction, assessment

of the degree of concordance between the reports, and either examines the reasons for disagreements between the studies, or combines the results if indicated.

A meta-analysis of all completed randomized controlled trials (RCT) has been proposed as an alternative to the conduct of a large definitive RCT. Most trials are not large enough to reliably answer questions about moderate treatment effects. To detect modest, but clinically significant effects, thousands of patients are often needed (5).

Meta-analyses of the literature have many potential advantages. The results of several studies can be combined to obtain a more precise estimate of the treatment effect. They can be used to combine small studies to achieve sufficient statistical power. The effects in subgroups can be examined. Meta-analyses can aid in generating new hypotheses from existing research. They are inexpensive and may help determine when another trial is no longer necessary.

1.4 Design Issues in Meta-analysis

A meta-analysis is a retrospective systematic review and subject to the same biases that affect other retrospective studies. Many authors have provided guidelines for conducting and publishing meta-analyses (6,7). A consensus conference for methodologic guidelines for systematic reviews and meta-analyses have been developed and summarized (8).

Qualitative and quantitative elements are important components to the analysis of a systematic review. The qualitative elements deal with 1) formulating the question; 2) developing a search strategy to retrieve all published studies; 3) selecting studies for inclusion in the analysis; 4) extracting the data from each study; and 5) assessing the validity (quality) of the studies. Currently, there is only one scale that has been validated for assessing the quality of randomized controlled trials (9,10). The Jadad scale is a five point scale which assesses: 1) the presence of randomization; 2) the method of randomization; 3) blinding; 4) if the blinding was appropriate; and 5) the handling of withdrawals or dropouts in a trial. An example of the Jadad scoring instrument is shown in Appendix III.

The quantitative (statistical) elements of a systematic review can be summarized as 1) choice of a summary statistic; 2) evaluating homogeneity; 3) estimating a common effect; 4) resolving heterogeneity if it exists; 5) assessing the potential for bias; and 6) presenting the results (11).

1.5 Study Objective

The overall objective of this study is to determine the ideal method of abdominal fascial closure. This study is divided into three parts.

Part I

In this study, a meta-analysis of randomized controlled trials was applied to assess the role of suture materials and suture technique in reducing postoperative incisional hernia rates.

Part II

The second part of the study addressed the current suture materials and techniques employed by general surgeons for common clinical scenarios. A random sample of provincial general surgeons will be utilized.

Part III

A definitive RCT design is proposed in an attempt to reconcile the discordance between the evidence from the literature and current traditional practice.

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PART I

Manuscript #1

Search for the Ideal Method of Abdominal fascial closure: A Meta-analysis

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A version of this chapter has been submitted for publication.

INTRODUCTION

The ideal suture for closing abdominal fascia has yet to be determined. Surgical tradition, prejudice, familiarity and personal conviction tend to dictate surgical procedures rather than evidence-based medicine. The reported cumulative incidence of incisional hernia varies from 5 -19% (1,2,3). Incisional hernias often require repair, with postoperative recurrence rates as high as 45% (4), further contributing to patient morbidity.

Previous randomized controlled trials (RCT) of abdominal fascial closure have failed to determine the best technique and the ideal suture. Many of these trials had small sample sizes and lacked sufficient power to show significant treatment differences. Results were often conflicting and have left many surgeons uncertain about the ideal suture and technique for abdominal fascial closure.

A meta-analysis is a statistical compilation of studies performed to address a treatment effect (5). It attempts to summarize knowledge by rigorous and explicit methodology (6). A recent meta-analysis by Weiland et al. (7), attempted to address the question of fascial closure. Unfortunately, it contains numerous omissions and raises certain methodological concerns. It should

therefore be interpreted with caution. A more thorough and rigorous meta-analysis to determine the ideal suture is warranted.

METHODS

Literature Search

Computer searches of the MEDLINE, for the years 1966-1998 and Cochrane Library (1998, Volume IV) databases were performed using the keywords "abdominal surgery," "sutures" and "randomized clinical trials" or clinical trial (pt) or controlled clinical trial (pt). A manual search of the bibliographies of the identified papers was carried out to identify any additional trials. Finally, expert academic surgeons in Ontario, Canada, were asked if they knew about any unpublished data.

Inclusion and Exclusion Criteria

All randomized clinical trials comparing at least two different suture materials or techniques for abdominal fascial closure were included. Trials using vertical midline, paramedian, oblique or transverse incisions were included. Other criteria included patients > 15 years of age and a Jadad Quality Score of $\geq$ 3 (8). Gynecologic surgery trials and trials of infants/children < 15 years were excluded. Trials comparing two sutures of the same category (i.e., absorbable versus absorbable) and with the same technique, were excluded since relevant comparisons could not be applied to our clinical question.

Data Extraction

Two reviewers blinded to journal, authors and publication dates, performed independent data extraction. Study quality was assessed using the Jadad Quality Scale (8). Discrepancies were resolved by discussion and consensus.

Analyses

The primary outcome was postoperative incisional hernia. Definitions of incisional hernia, wound dehiscence, wound infection, wound pain and suture sinus were accepted as reported. Based on *a priori* criteria, the primary comparison was nonabsorbable versus absorbable sutures, and continuous versus interrupted techniques. Further comparisons included continuous nonabsorbable versus continuous absorbable and interrupted nonabsorbable versus interrupted absorbable. Studies were assessed for homogeneity both qualitatively and quantitatively. Statistical homogeneity of study data was confirmed using the chi square test of heterogeneity (9). All analyses were conducted utilizing Review Manager 3.1 (The Cochrane Collaboration, Software Update, Oxford).

The Mantel-Haenszel (9) fixed-effects method was used to summarize dichotomous outcomes of pooled studies. The odds ratio (OR) was used as the summary statistic, with 95% confidence intervals (CI). Absolute risk reduction

(ARR), relative risk reduction (RRR), and number-needed-to-treat (NNT) were also calculated. Sensitivity analyses were performed by serially omitting each trial and omitting trials with follow-up periods < 1 year. Comparisons of trials using only midline incisions were also carried out. A reanalysis utilizing the random-effects model was also performed to assess the robustness of the results.

Subgroup analyses of individual suture types (i.e., polydioxanone-PDS® *versus* polypropylene- Prolene®) were also examined.

Results:

Thirty-two studies that evaluated suture material and/or technique for abdominal fascial closure were identified. Nineteen trials were excluded for the following reasons: poor quality (10-19), gynecologic surgery only (20, 21), pediatric trial (22), nonrandomized trials (23-26), and comparison exclusions (i.e., studies assessing absorbable versus absorbable sutures) (2, 27,28). Study characteristics are displayed in Table 1. No unpublished data were identified.

Data extraction revealed no interobserver variation, with 100% agreement between the two reviewers for all outcomes.

Nonabsorbable versus Absorbable

The trials appeared to be clinically homogenous with the possible exception of one trial that compared polydioxanone versus polypropylene in very high risk morbidly obese patients (39). The test for heterogeneity was not significant ($\chi^2 = 21.16$, $p > 0.05$) indicating that the studies were homogenous and statistical combination was appropriate. The pooled odds ratio (OR) for all outcomes comparing nonabsorbable versus absorbable sutures (13 studies) (28-40) are summarized in Figure 1. An OR < 1 favors nonabsorbable and an OR >1 favors absorbable. For the primary outcome, incisional hernia, the OR was 0.68 and 95% CI 0.52 to 0.87 (Figure 2). This means that the odds of incisional hernia was significantly lower in the nonabsorbable group by 32%. The calculated cumulative incidence of incisional hernias across all studies was 5%.

The OR of wound infection in the nonabsorbable group versus the absorbable group was 0.90 (95% CI 0.73 to 1.12) and the OR of wound dehiscence was 1.25 (95% CI 0.78 to 2.01), both not statistically significant. Suture sinuses and wound pain were significantly more frequent in the nonabsorbable group (OR 2.18, 95 %CI 1.48 to 3.22, and OR 2.05, 95% CI 1.52 to 2.77, respectively).

Continuous versus Interrupted

In the trials (n=6) comparing continuous versus interrupted technique (irrespective of suture type) the OR for incisional hernia was significantly lower

for continuous closure (OR 0.73, 95% CI 0.55 to 0.99). These results are summarized in Figure 3. There was no statistical difference in wound infection and wound dehiscence.

Continuous Nonabsorbable versus Continuous Absorbable

In the trials (n=9) comparing continuous nonabsorbable versus continuous absorbable suture technique (see Figure 4), incisional hernias were significantly lower in the continuous nonabsorbable group (OR 0.61, 95% CI 0.46 to 0.80). Table 2 summarizes OR, CI, relative risk reduction (RRR), absolute risk reduction (ARR), and number-needed-to-treat (NNT).

Interrupted Nonabsorbable versus Interrupted Absorbable

There was no statistical significant difference in incisional hernia rates between these two comparisons (n=2 trials).

Sensitivity Analyses

A reanalysis of only the trials using vertical midline incisions (omitting trials using paramedian or transverse incisions), the rate of incisional hernia was still significantly lower in the nonabsorbable group, OR 0.64 (95% CI 0.48 to 0.86). Further sensitivity analyses included: reanalyzing the data using the random-effects model, including poor quality trials, including gynecologic trials, excluding all small trials, excluding the obesity trial and omitting all trials < 1 year follow-up. These analyses did not substantially change the summary statistic.

Subgroup Analyses

The subgroup analyses are summarized in Table 3. Polydioxanone (PDS®) compared to polypropylene (Prolene®) did not have a significant increase in the risk of incisional hernia, OR 0.65 (CI 0.21 to 2.01). In contrast, use of polyglactin (Vicryl®) compared to nonabsorbable sutures resulted in increased wound failure. Nylon compared to Polyglycolic acid (Dexon®) demonstrated a lower rate of incisional hernia, with an OR of 0.30 (95% CI 0.13 to 0.68). There was no statistical difference between polyglycolic acid (Dexon®) and polypropylene (Prolene®).

DISCUSSION

Incisional hernias contribute significantly to patient morbidity and once repaired have a high recurrence rate (4). Wound dehiscence, infection, pain and suture sinus formation, are also important contributors to postoperative morbidity.

A meta-analysis, when including a series of satisfactory trials and rigorously performed, is high quality Level I evidence (29). The recent meta-analysis by Weiland et al. (7) failed to meet most of the methodological requirements supported by a recent consensus (6). The search strategy was less than explicit, nonrandomized trials, and poor quality studies were included in their analyses, decreasing the validity of their results. The quality of RCTs included in their analysis was not assessed. Interpretation of their results was

difficult since individual study characteristics were not described. There was an absence of clinically useful outcome measures, with odds ratios, numbers-needed-to-treat, and relative risk reductions not reported. The method of combining p-values used in their report has two important drawbacks. First, it does not weigh the studies according to their uncertainties or sample sizes. Second, it does not give any estimates of the magnitude of the effects. For these reasons, combining p-values is not recommended as a meta-analytic tool (43).

Poor quality in the reporting of surgical trials appears to be common (44). A recent meta-analysis of drainage of colorectal anastomoses also reported overall poor quality of the surgical trials included in their analyses (45). The Jadad Quality Scale (8) is the only validated instrument available to assess RCT quality. Incorporation of poor quality trials into a meta-analysis has been shown to increase the estimate of benefit by 34% and may produce discordant results (46). In our review, 10 trials (31%) were excluded for poor quality (Jadad score < 3) in order to enhance validity.

Qualitative and quantitative homogeneity was confirmed and statistical combination was appropriate. Multiple sensitivity analyses confirmed the robustness of our summary statistic. Inclusion or exclusion of the morbidly obese trial (39) did not alter the results. Gynecologic trials (20,21) were omitted in order to focus results to a general surgical practice and inclusion of these trials did not appreciably change the summary statistic.

For the primary outcome for this study, the pooled odds ratio for incisional hernia with nonabsorbable versus absorbable sutures, was 0.68, with 95% CI of 0.52 to 0.87. The fact that the point estimate <1, and the 95% CI both yielded a statistically significant result, favouring the nonabsorbable group (refer to Figure 2). Clearly, the evidence supports a significant benefit in using nonabsorbable suture. With a relative risk reduction (RRR) of 32%, using a nonabsorbable suture lowers the risk of incisional hernia formation by 32%. A more clinically useful measure is the number-needed-to-treat (NNT). The NNT was 50, which means only 50 patients need to undergo nonabsorbable fascial closure to prevent one incisional hernia.

For continuous nonabsorbable versus continuous absorbable the relative risk reduction was even greater (36%) and the NNT was 40 patients. These results are intuitive and biologically plausible. Nonabsorbable sutures are permanent and retain tensile strength for the duration of fascial healing (4). The continuous suture technique also has the added benefit of being easier and less time consuming (33).

A potential benefit of meta-analysis is the ability to perform subgroup analyses (47, 48). Our subgroup analyses demonstrated that polydioxanone (PDS®), unlike all other absorbable sutures, did not have an increased risk of incisional hernia. However, this may be soley due to the small number of trials.

Our meta-analysis is limited by the absence of unpublished literature and other potential sources of heterogeneity. Unpublished studies are more likely to have "negative results" and, therefore, a meta-analysis of only published studies may have publication bias. A survey of experts in Ontario did not yield any unpublished data. Extraction bias was minimized by blinding reviewers to publication date, authors and journal. Other sources of heterogeneity include: patient factors (malignancy, steroid use, pulmonary disease, obesity, age), local factors (emergency surgery, degree of contamination, antibiotic prophylaxis) and technical factors (surgical experience, type of incision). These factors may theoretically have been unequally distributed between treatment groups or between studies, but this is unlikely. The location of the incision may be instrumental in incisional hernia formation. A prospective study described lower incisional hernia rates in paramedian incisions as compared to midline incisions (28). Studies of transverse incisions have been inconclusive (49-51). The randomized trials included in this study did not stratify based on type of incision. For example, no direct comparisons of midline versus transverse incisions were done. The question of the role of incision type in the development of incisional hernias is therefore impossible to answer by this meta-analysis.

The follow-up of patients for individual studies was highly variable and only 7 (54%) studies followed patients for one year or more. This may explain why our cumulative incidence of incisional hernia across studies was only 5%.

This incisional hernia rate at one year does not reflect the true incidence of this outcome. Mudge et al. (1) followed a cohort of patients prospectively for 10 years and noted that 35% of all incisional hernias actually occurred after three years.

This meta-analysis serves to synthesize some of the information of the effect of suture choice on wound failure. Given the high number of poor quality trials, short follow-up and variable patient factors, a large definitive trial of nonabsorbable continuous closure versus the current surgical practice with a longer follow-up period is warranted. With incisional hernia being an infrequent outcome, very large sample sizes are required in order to determine a difference between suture materials (nonabsorbable versus absorbable) or technique (continuous versus interrupted). If we assume an incisional hernia rate of 10% over 5 years (1) in a control group and we would like to reduce this rate to 7% (30% RRR) in the intervention group with 80% power and a significance level of 5%, we would require 860 patients in each treatment arm in a traditional randomized controlled trial. Such a trial does not exist. This meta-analysis is the best evidence to date.

In conclusion, we report high quality Level I evidence that the ideal suture in reducing incisional hernia rates is a nonabsorbable suture material and a continuous technique.

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Table 1. Summary of Trials

Study	Participants	# of patients	Intervention	Outcome
Irvin et al. (29)	adults, age group < 60 years matched for age, sex and type of operation	109	polyglactin (Vicryl®) versus polyglycolic acid (Dexon®) polypropylene (Prolene®) all continuous	no statistically significant difference in incisional hernia rate between comparisons
Corman et al. (30)	adults colorectal surgery	161	nylon vs polypropylene (Prolene®) versus polyglactin (Vicryl®) all interrupted	no significant difference in rate of incisional hernias between comparison groups

Wissing et al. (31)	adults midline incisions excluded patients in which skin was not primarily closed	1491	continuous polyglactin (Vicryl®) interrupted polyglactin (Vicryl®) continuous polydioxanone(PDS®) continuous Nylon	statistically significant difference with fewer incisional hernias in the nylon group versus the continuous polyglactin ($p < 0.009$); no significant difference between other comparisons
Carlson et al. (32)	adults vertical midline incisions only	225	polyglyconate (Maxon®) versus nylon both continuous	no significant difference in incisional hernia rate between groups
Richards et al. (33)	adults stratified by degree of contamination	571	interrupted (Dexon®) versus continuous (Prolene®)	no statistical difference in rate of incisional hernia between comparisons
Leaper et al. (34)	midline and transverse incisions	204	continuous polydioxanone (PDS®) versus continuous Nylon	only 1 incisional hernia (in polydioxanone group) non significant difference

Larsen et al. (35)	adults midline, paramedian, transverse or oblique incisions	238	continuous Dexon® continuous Surgilon interrupted Dexon®	no significant difference between all three comparisons
Kronborg (36)	adults, excluded patients with previous laparotomy and inoperable cancers	326	interrupted polyglycolic acid (Dexon®) versus interrupted Silk	no incisional hernias developed in either group
Cameron et al. (37)	age >15 years midline vertical incisions 6 month follow up	361	polyglactin (Dexon®) polypropylene (Prolene®)	incisional hernias: polyglactin: 8 (6.1%) polypropylene: 7 (5.2%) not significant p>0.05
Krukowski et al. (38)	vertical midline incisions elective & emergency procedures	757	continuous polydioxanone (PDS®) versus continuous (Prolene®)	incisional hernia: polydioxanone: 3.5% polypropylene: 4.7% not statistically significant
Cleveland et al. (39)	adults	250	part I: continuous	no statistical difference in

	midline incisions morbidly obese patients		versus interrupted (Vicryl®) part II: polydioxanone (PDS®) versus polypropylene (Prolene®)	incisional hernia rate between comparisons
Lewis et al. (40)	adults, mean age 56 years median, paramedian incisions	200	interrupted polyglycolic acid (Dexon®) versus continuous polypropylene (Prolene®)	incisional hernias were more frequent in the absorbable (Dexon®) group, statistically significant ($p < 0.05$)
Bucknall et al. (41)	adults, mean age 56 years median, paramedian incisions	200	continuous nylon versus continuous polyglycolic acid (Dexon®)	incisional hernia: nylon: 4 (3.8%) Dexon®: 12 (11.5%) $p < 0.0.5$, significant

Table 2. Clinical Outcome Measures of Incisional Hernia across Comparison Groups

Comparison	OR 95% CI	ARR	RRR (%)	NNT
nonabsorbable vs absorbable	0.68 [0.52, 0.87]	0.02	33	50
continuous vs interrupted	0.73 [0.55, 0.99]	0.024	28	42
continuous nonabsorbable vs continuous absorbable	0.61 [0.46, 0.80]	0.025	36	40

* OR Odds ratio

† ARR (absolute risk reduction): the absolute arithmetic difference in event rates, control event rate minus experimental event rate. For our calculations, event of incisional hernias in absorbable group minus the event rate in the nonabsorbable group.

‡ RRR (relative risk reduction: the proportional reduction in rates of adverse events between control event rate (CER) and experimental event rate (EER). It is calculated as CER-EER/ CER (52).

§ NNT (number-needed-to-treat): the number of patients who need to be treated to achieve one additional favorable outcome or the prevention of one adverse event; calculated as 1/ARR, rounded up to the next highest whole number (52).

Table 3. Subgroup Analysis of Individual Suture Types

Suture Type	**Number of studies (n)**	**Favours**	**Odds Ratio (95% CI)**
Nylon Versus Polyglycolic acid (Dexon®)	3	Nylon	0.30 [0.13, 0.68]
polypropylene (Prolene®) versus polydioxanone (PDS®)	2	No difference	0.65 [0.21, 2.01]
polypropylene (Prolene®) versus polyglycolic acid (Dexon®)	4	No difference	0.78 [0.43, 1.42]
Nonabsorbable Versus polyglactin (Vicryl®)	3	Nonabsorbable	0.57 [0.41,0.77]

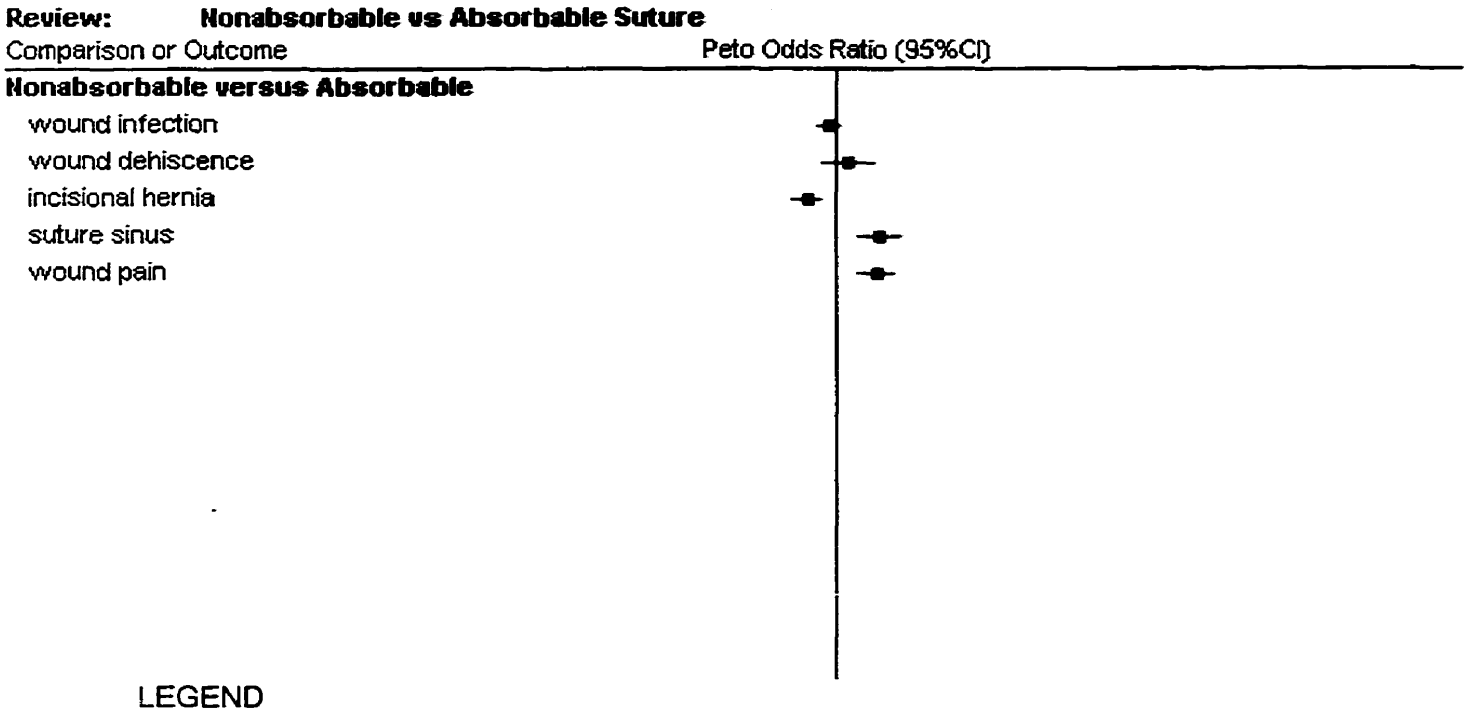

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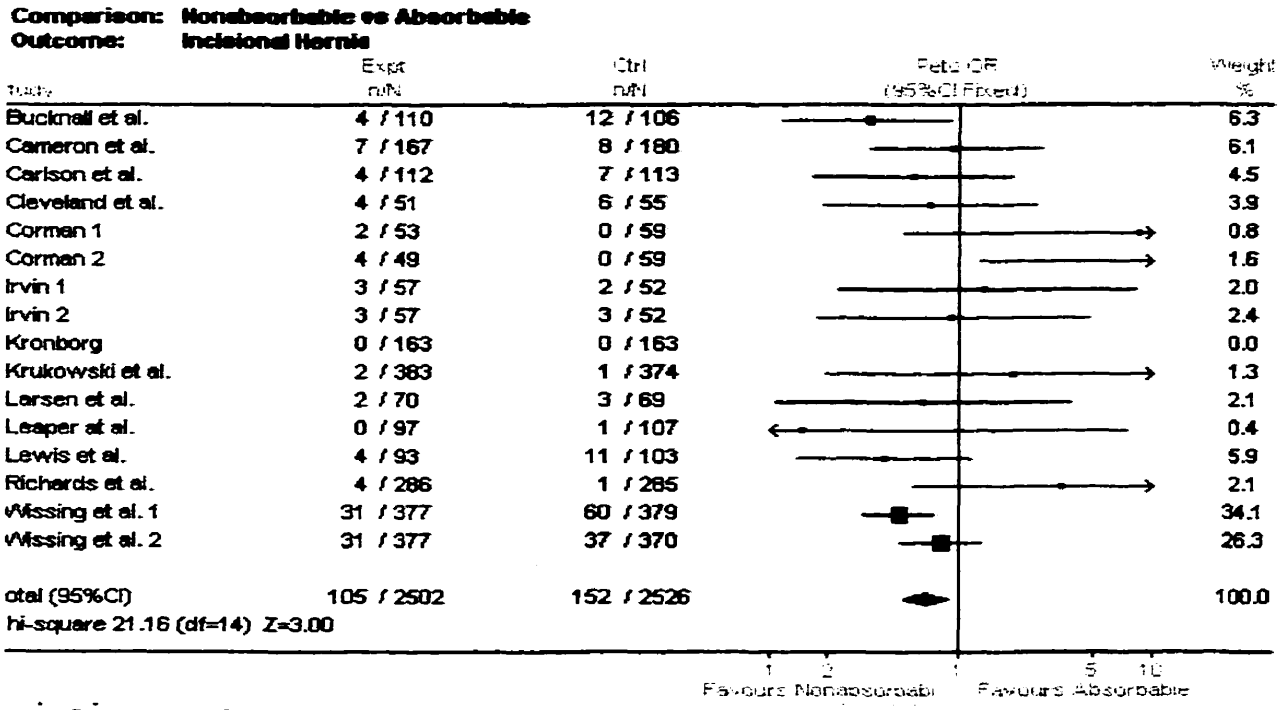
Figure 1. Meta-analysis of all outcomes comparing absorbable versus nonabsorbable sutures. Squares indicate point estimates of odds ratio and horizontal bars signify 95% confidence intervals. Values < 1 favor the nonabsorbable group and values > 1 favor the absorbable group. Point estimates are significant at the $p < 0.05$ level if their confidence intervals exclude the vertical line at 1 ("no effect").



Summary Statistic: OR= 0.68 [0.52,0.87]

Figure 2. Pooled estimates of risk of incisional hernia comparing absorbable versus nonabsorbable. The weight attributed to a particular study is represented by the size of the square on the point estimate of each odds ratio, the width of the horizontal bars reflects the 95% CI. Point estimates crossing the vertical bar represent statistically nonsignificant results, with 95% CIs that include 1. An odds ratio (OR) < 1 favors nonabsorbable suture and OR > 1 favors absorbable suture

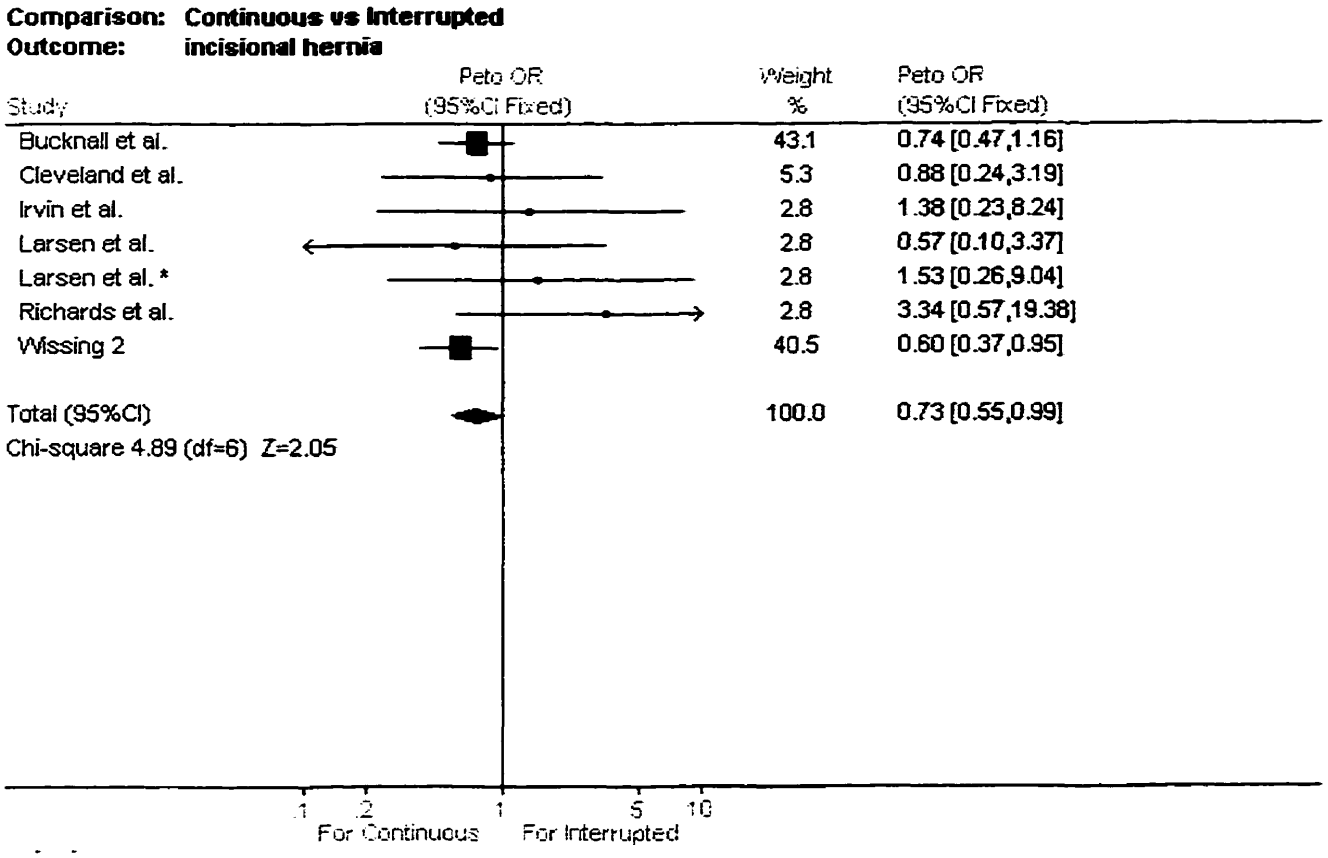


Figure 3. Pooled estimates of continuous versus interrupted suture technique. Squares indicate point estimates of odds ratios and horizontal bars represent 95% confidence intervals. Values < 1 favor the continuous group and values > 1 favor the interrupted group.

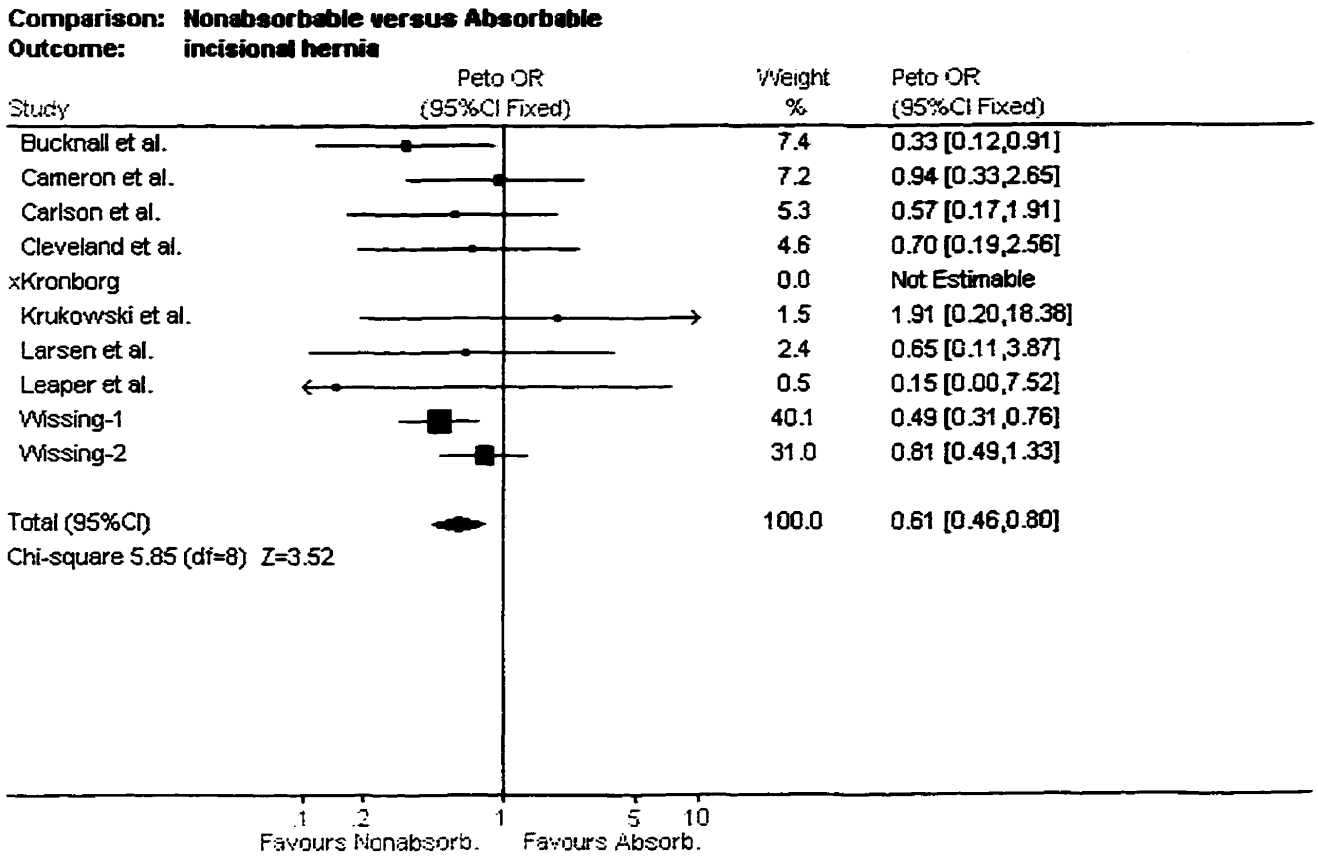


Figure 4. Pooled estimates of incisional hernia comparing continuous nonabsorbable versus continuous absorbable closure. The summary odds ratio is represented by the diamond, values to the left of the vertical bar favor the continuous nonabsorbable group and values to the right favor continuous absorbable.

PART II

Manuscript #2

Current practice of Abdominal Fascial Closure:

A Survey of Ontario General Surgeons

A version of this chapter has been prepared for publication.

INTRODUCTION

The method of abdominal fascial closure elicits strong opinions among surgeons. The ideal suture is yet to be determined. Many factors such as patient, local and technical factors influence wound healing. Suture material and/or technique of abdominal fascial closure is one of the few controllable factors in reducing postoperative wound complications. Wound infection, dehiscence, incisional hernia, suture sinus formation and chronic wound pain continues to be a source of patient morbidity. The incidence of incisional hernias range from 5-19% (1-3), with a recurrence rate as high as 40% post repair (4).

To date, randomized controlled trials comparing suture materials and or technique have been largely inconclusive as a result of small sample sizes and insufficient power (5-8). A recent meta-analysis of randomized controlled trials concluded that a nonabsorbable suture is the ideal suture material and that the ideal technique is continuous in reducing incisional hernia rates (9).

Much of surgical practice is based on tradition, familiarity and/or personal preference rather than evidence. The current practice of abdominal fascial closure among Ontario general surgeons is not known. The purpose of this study was to conduct a provincial survey of academic and community general surgeons in order to determine what suture material and technique they employ for abdominal fascial closure. Secondary objectives included: determining

surgeon's attitudes to and knowledge of evidence based medicine, to detect any differences in practice patterns between community and academic surgeons and to determine the effect of potential independent predictors (e.g. surgical training, age etc.) on suture use.

METHODS

A provincial survey of Ontario general surgeons was conducted between February and May 1999. The Canadian Medical Directory 1998 was utilized as the sampling frame to identify Ontario general surgeons (10). This list identified 535 general surgeons in Ontario, approximately 60% were academic/university based and 40% were community surgeons. A computer generated random number sequence was utilized to generate a random sample stratified for community and academic general surgeons. As, there is no literature on current practice patterns of surgeons for fascial closure, for convenience, 100 surveys were mailed for this descriptive study. As no sample size calculation could be performed *a priori* for the primary objective, *a posteriori* power calculation was calculated. For the secondary objective it was estimated that a sample of 88 surgeons would be necessary to detect a 30% clinically significant difference in practice patterns between community and academic surgeons (Appendix VII).

A questionnaire was developed consisting of 23 questions. The questions were compiled by consensus (surgical content experts) and were developed according to the Dillman Survey Methods (11). It was composed of three parts:

1) clinical scenarios requiring responses on choice of absorbable or nonabsorbable suture, continuous or interrupted suture technique and specific type of suture used (i.e. polydioxanone [PDS®]). A total of four clinical scenarios ranging from elective to emergent abdominal cases requiring a laparotomy were described. Patient and local factors were varied throughout the scenarios (refer to Textbox 1).

Textbox 1. Description of Clinical Scenarios

Clinical Scenario	***Description***
#1 elective clean-contaminated	54 year old man undergoes elective right hemicolectomy for colon cancer.
#2 emergent-clean	24 year old healthy male involved in MVC requires a laparotomy for a ruptured spleen.
#3 High risk clean	A 36 year old female with Crohn's disease on steroid treatment develops a small bowel obstruction. An enterolysis is performed, there is no contamination of the abdominal cavity.
#4 High risk contaminated	A 64 year old female 2 years post liver transplantation presents with perforated diverticulitis, laparotomy reveals gross fecal contamination.

2) knowledge and attitudes of evidence based medicine.

3) demographic and practice information including: age, site of residency training, number of laparotomies performed per year and approximate percentage of elective/emergent laparotomies.

The questionnaire was pretested on a sample of 10 surgeons and it was determined that it would take approximately 15 minutes to complete. Postage paid return envelopes were used and respondents who did not return the first questionnaire were sent a second copy.

Descriptive statistics and the Chi square test for difference in proportions were used for the univariate analyses. For each scenario, the proportions of continuous versus interrupted technique and absorbable versus nonabsorbable suture materials were compared. The responses of academic versus community surgeons were also compared.

A logistic regression model was also formulated such that the dependent variable was defined as the choice of suture material (absorbable or nonabsorbable). The independent predictor variables were defined as number of years in surgical practice, age category (< 45 years and > 46 years), number of laparotomies per year and site of residency training. A p value of < 0.05 was considered statistically significant. Data management and statistical analyses were performed using Statistical Analysis System version 6.07 for Sun OS (Unix).

RESULTS:

PART A : Practice Patterns of Abdominal Fascial Closure

The response rate was 72%, with 63 of 88 completed surveys returned. One hundred questionnaires were distributed initially with 75 returned. Of these twelve questionnaires were excluded as recipients were either deceased (n=2), retired (n=8), or not general surgeons (n=2). The first and second mailings yielded 48 and 15 returned surveys, respectively. The demographic profile of the surgeons who participated is outlined in Table 1.

Academic and community surgeons were similar with respect to age, sex, years in practice and # of laparatomies performed per year. There were slightly more academic surgeons (56%) than community surgeons. The majority of surgeons sampled 77% (49 of 63 surgeons) performed more than 50 laparotomies per year.

Of the respondents, 85-87% utilized an absorbable suture for fascial closure for scenarios 1-3 (Table 2). A nonabsorbable continuous closure was more commonly chosen for scenario 4, (high risk contaminated case). A continuous suture technique was the preferred method of closure with 75%, 76%, 73% for scenarios 1-3 while slightly more than half (53%) of surgeons chose a continuous technique for scenario 4 (high risk contaminated). The primary

outcome per clinical scenario is displayed in Graph 1 with percentages described in Table 2b.

The responses were not significantly different between academic and community surgeons with the exception of scenario 2 (emergent-clean case) where community surgeons were more likely to use a continuous suture technique ($p=0.015$). Most surgeons (65%) consistently used the same suture for all scenarios. Thirty-five percent (22 surgeons) used a different suture material throughout the scenarios with 91% (20 of 22) solely changing their choice of suture for scenario 4 (high risk contaminated).

For specific suture types, polyglactin (Vircyl®) was the most commonly chosen suture (39-44%), followed by polydioxanone (PDS®) (24-26%) then polypropylene (Prolene®) (14-16%) for scenarios 1-3. Polypropylene (Prolene®) was chosen most often (44%) for scenario 4 (Graph 2) followed by Vicryl®.

Self reported rankings of wound complications are displayed in Table 3. Wound pain (chronic) was the most common complication followed by wound infection. No surgeons reported wound dehiscence as their most common wound complication.

Descriptive analysis of site of residency training on choice of suture technique and material is displayed in Table 4. Surgeons consistently chose a

continuous absorbable suture irrespective of site of training with the exception of surgeons trained at the University of Western Ontario (UWO). UWO trained surgeons were more likely to choose an interrupted (7/11- 64%) suture technique.

Four potential independent predictor variables for choice of suture material were assessed (Tables 5a-d). These included: number of years in surgical practice, number of laparotomies per year, age category of the surgeon and site of residency training. None of the variables reached statistical significance except for number of laparotomies in Scenario 3 (high risk clean) with a p value of 0.027 (Table 5c). Examples of standard 2X2 contingency tables for dichotomous data and descriptive analyses are displayed in Appendix VI.

PART B: Knowledge & Attitudes of Evidence relating to Abdominal fascial closure

Eighty-one per cent of surgeons who participated in this survey were aware of published literature on abdominal fascial closure. Literature on abdominal fascial closure, however, had only influenced 38% of surgeons' current practice. When asked if surgeons' would change their current practice if there was evidence that certain sutures had a lower incidence of wound failure, 85% responded that they would change their practice. The levels of evidence that would influence this change in practice: 59% of surgeons would change based on a large randomized controlled trial (RCT), 22% based on a meta-

analysis of RCTs and the remainder based on cohort, case control studies and case series (Graph 3).

DISCUSSION:

The current practice of abdominal fascial closure is predominantly a continuous technique and an absorbable suture material. There appears to be little difference between academic and community surgeons. Varying patient and wound factors appeared to have minimal influence as most surgeons (65%) consistently used the same suture material and technique irrespective of clinical scenario.

The most commonly reported suture in this random sample of surgeons was polyglactin (Vicryl®). Polypropylene was the most common suture chosen by 34% of surgeons for fascial closure in scenario 4, an immunocompromised patient with gross fecal contamination. This suggests that surgeons recognize that a nonabsorbable suture is superior in the high risk patient in reducing wound failure. Why surgeons choose not to use nonabsorbable sutures in the elective scenarios is unknown. It can be postulated that the poor handling characteristics of Prolene® may come into play.

The majority of surgeons (85%) surveyed indicated that they would be willing to change their practice of abdominal fascial closure based on evidence. More than half of surgeons (59%) would change their current practice based on results of a large randomized controlled trial and 22% based on results of a meta-analysis of RCTs. Therefore, Level I evidence would influence 81% of surgeons sampled. In contrast, why 19% of surgeons sampled would believe Level III, IV and V evidence is disturbing.

Self- reporting of complications, moderate sample size and non-response bias are potential limitations of this study. However, the 72% response rate for a survey of surgeons is excellent; recent other surveys of surgeons have reported much lower response rates of 49-56% (12,13).

The reported rank of incisional hernias was low, only 5.1% surgeons indicated that this was their most common complication. It was reported as the second most common complication by 27% of surgeons. The accuracy of these rankings may be unreliable due to self-reporting or that patients are lost to follow-up or seen by other surgeons. A more standardized study evaluating wound complications following laparotomy is warranted.

The multivariate logistic regression model, a secondary analysis, is strictly exploratory. The results should be interpreted with caution as re-coding of the data to dichotomous variables yielded low numbers in some of the cells. A

posteriori power calculation (Appendix VII) yielded a power of 69% in order to detect a difference between absorbable and nonabsorbable suture choice at a significance level of 0.025 (2-sided). The study primarily aimed to explore current opinions and practice patterns of Ontario general surgeons. There are certainly other factors such as cost and hospital administrative factors that may influence a surgeon's choice of suture material. For example, some hospitals only stock sutures manufactured by a certain company. More questions exploring why surgeons chose certain sutures could have been added to the survey.

The meta-analysis of randomized controlled trials (from Part I) found a 32% risk reduction in the rates of incisional hernias when a nonabsorbable continuous closure rather than an absorbable continuous closure was employed (9). In contrast, the most common practice of fascial closure among Ontario general surgeons is an absorbable continuous technique. As incisional hernias contribute significantly to patient morbidity with recurrence rates as high as 45% post repair (8), a large definitive RCT with adequate follow-up is warranted. This may be instrumental in changing current surgical practice and ultimately reduce patient morbidity and re-operation.

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Table I. Demographic Information of Surgeons Surveyed

	All Surgeons Sampled	Academic Surgeons	Community Surgeons
Age			
25-35	3	2	1
36-45	19	10	9
46-55	21	12	10
> 56	16 *	9	8
Sex			
Males	59	33	26
Females	4	2	2
# years in practice			
1-5	10	8	2
6-10	6	3	3
11-15	15	8	7
16-20	13	4	9
21+	17 **	10	7
# laparotomies per year			
0-10	0	0	0
11-50	12	6	6
51-100	17	8	9
>101	33	20	13

*, ** 2 missing values

Table 2. Suture material and technique employed by general surgeons for the outlined clinical scenarios

Clinical Scenario	All Surgeons	Academic	Community
Scenario 1†	**% responses, #**	**number**	**number**
Continuous	75% (48)	28	20
Interrupted	25% (14)	6	8
Absorbable	87% (53)	30	23
Nonabsorbable	13% (8)	4	4
Scenario 2‡			
Continuous	76% (49)	30	19
Interrupted	24% (13)	4	9
Absorbable	85% (52)	28	24
Nonabsorbable	15% (9)	5	4
Scenario 3†‡			
Continuous	74% (46)	28	18
Interrupted	26% (16)	6	10
Absorbable	85% (52)	28	24
Nonabsorbable	15% (9)	5	4
Scenario 4†			
Continuous	53% (35)	19	16
Interrupted	48% (27)	14	13
Absorbable	42% (26)	15	11
Nonabsorbable	58% (36)	19	17

† 1 missing value
‡ 2 missing values

Table 2b: Primary Outcome: Proportion of Absorbable versus Nonabsorbable

Scenario/ Case	**Absorbable**	**Nonabsorbable**
Elective Clean contaminated (Scenario 1)	87%	13%
Emergent- Clean (Scenario 2)	85%	15%
High risk Elective Clean (Scenario 3)	85%	15%
High risk Contaminated (Scenario 4)	42%	58%

Table 3. Most Common Wound Complications as reported by Surgeons

Wound Complication	*Most Common Complication*	*Second Most Common Complication*
Wound Infection	39%	47.5%
Wound Dehiscence	-	1.7%
Incisional Hernia	5.1%	27.1%
Suture Sinus	1.8 %	7%
Chronic Wound Pain	54.4%	14%

Table 4: Site of Residency Training

Site of residency training	Continuous	Interrupted	Absorbable	Nonabsorbable
U of T	82% (14)	18% (3)	76% (13)	24% (4)
U of Ottawa	100% (6)	0	83% (5)	17% (1)
U WO	36% (4)	64% (7)	91% (10)	9% (1)
McMaster	60% (3)	40% (2)	75% (3)	25% (1)
Queen's	67% (2)	33% (1)	67% (2)	33% (1)
Atlantic	100% (4)	0	100% (4)	0
Quebec	0	0	0	0
Western provinces	83% (5)	17% (1)	83% (5)	17% (1)
Other	80% (8)	20% (2)	50% (4)	0

Table 5a. Multiple Logistic Regression of Independent Predictor Variables: Scenario 1

Variable	Wald Chi-square	Odds Ratio
# of years in surgical practice	0.1189	1.623 [0.104,27.4]
# of laparotomies/year	0.725	0.580 [0.166,2.03]
Age	0.1168	1.370 [0.225,8.33]
Site of Residency Training	0.2762	0.820 [0.195,16]

Table 5b: Logistic Regression: Scenario 2

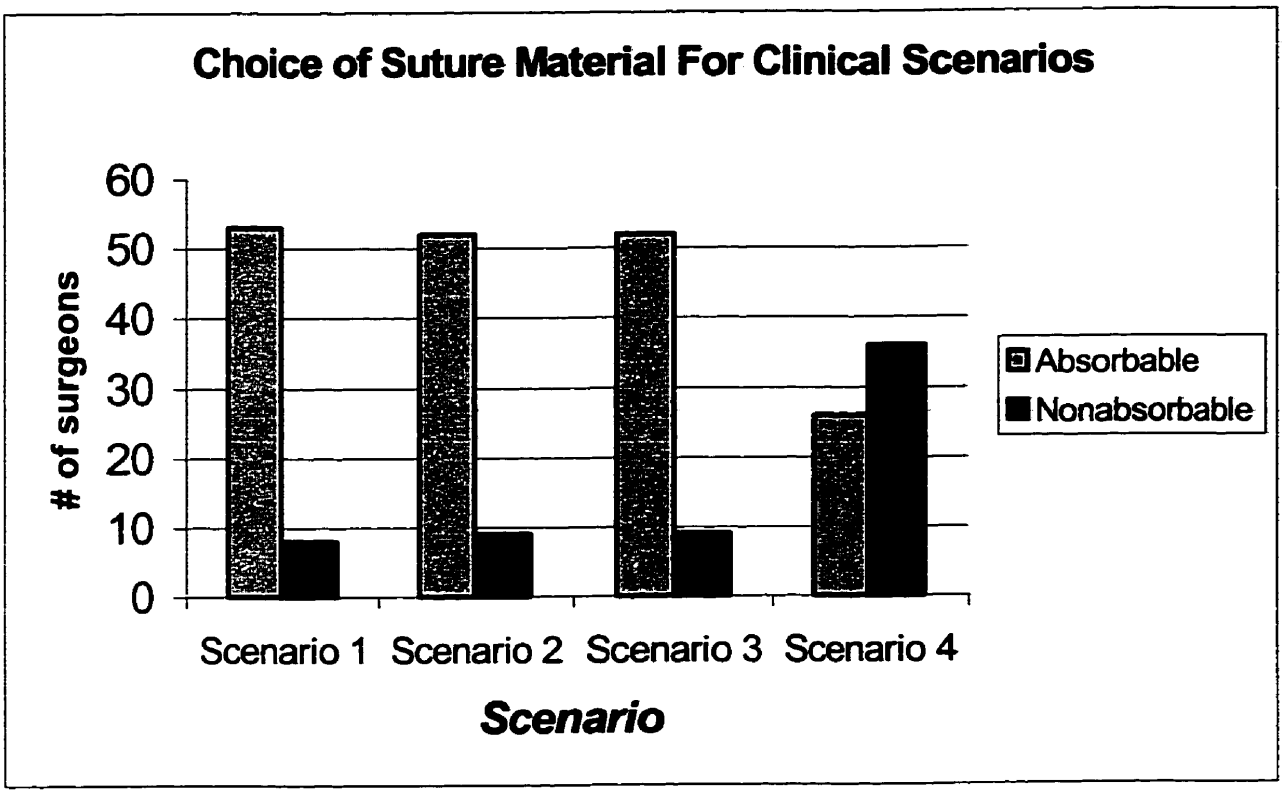
Variable	Wald Chi-square	Odds Ratio
# of years in surgical practice	0.1504	1.7 [0.180,27.5]
# of laparotomies/year	1.763	0.44 [0.28,1.483]
Age	0.044	1.21 [0.2,7.38]
Site of Residency Training	1.065	3.01 [0.37,24.4]

Table 5c: Logistic Regression: Scenario 3

Variable	Wald Chi-square	Odds Ratio
# of years in surgical practice	0.4789	2.345 [0.143,5.86]
# of laparotomies/year	3.6949	0.355 [0.124,1.02]
Age	0.0792	1.25 [0.264,5.9]
Site of Residency Training	2.1224	3.86 [0.627,23.8]

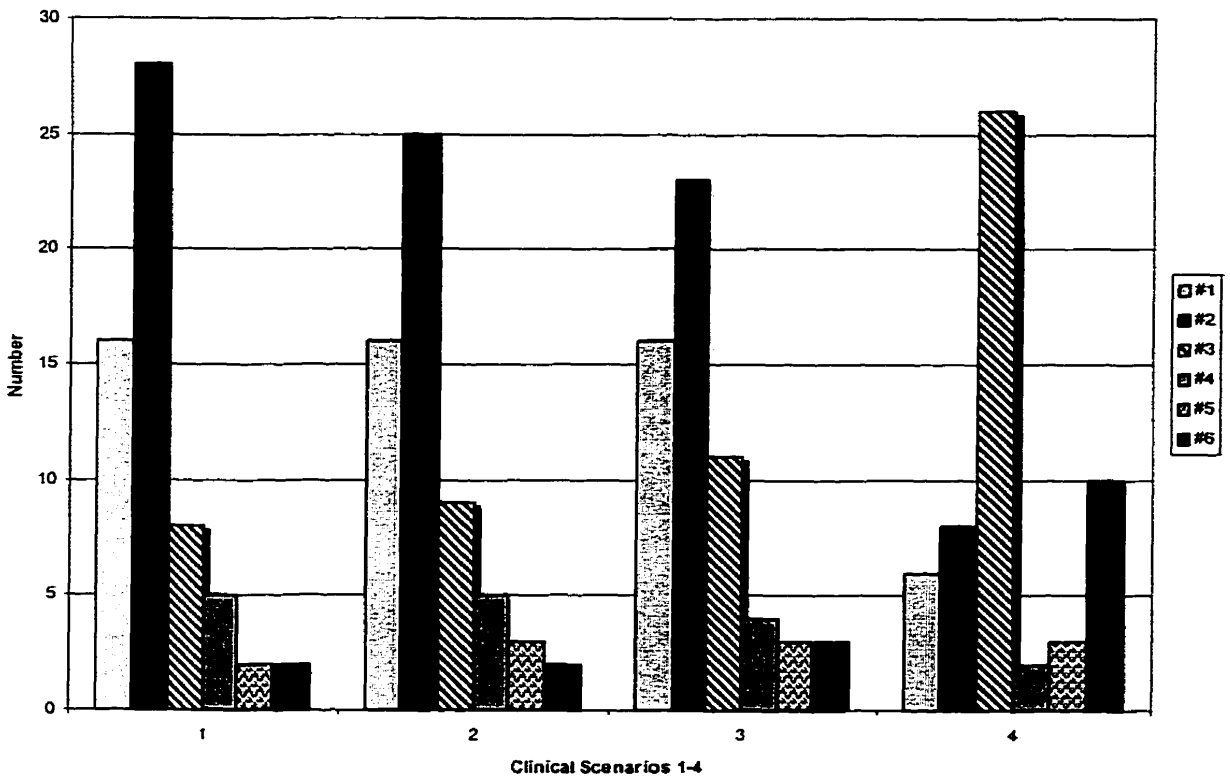
Table 5d: Logistic Regression: Scenario 4

Variable	Wald Chi-square	Odds Ratio
# of years in surgical practice	0.5172	0.320 [0.01,6.433]
# of laparotomies/year	1.354	0.621 [0.35,1.58]
Age	1.392	2.069 [0.54,5.83]
Site of Residency Training	2.41	3.22 [0.74,1.162]



Graph 1. Bar graph of primary outcome: Absorbable versus nonabsorbable suture material as chosen by surgeons for common surgical scenarios. Absorbable sutures were consistently chosen for scenarios 1-3. Nonabsorbble sutures were preferred for scenario 4 (high risk contaminated).

Specific Suture Materials Chosen per Clinical Scenario



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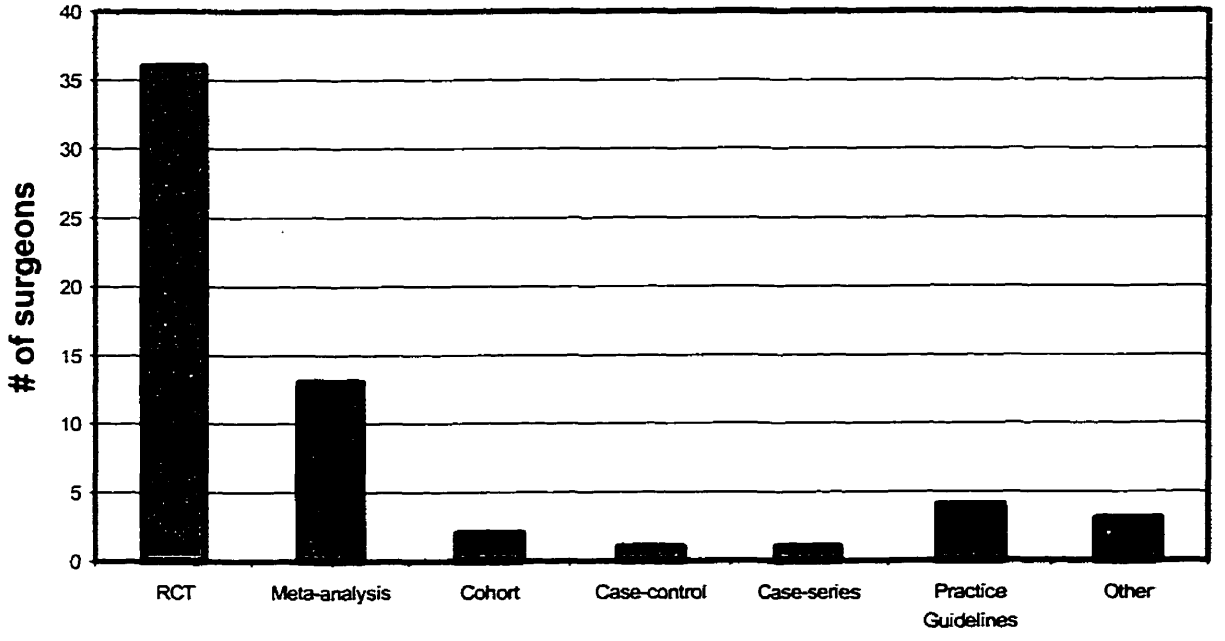
Graph 2. Specific Suture Materials
#1- polydioxanone (PDS®), #2- polyglactin (Vicryl®), #3-polypropylene (Prolene®), #4-polyglycolic acid (Dexon®), #5-polyglyconate (Maxon®) and #6-other.
Vicryl® was the preferred suture for scenarios 1-3 followed by PDS®.
Prolene® followed by Vicryl® was preferred for scenario 4.

Levels of Evidence that would influence a Surgeon's Change in Current Practice for Abdominal Fascial Closure



Graph 3. Levels of Evidence Influencing a Change in Surgical practice Patterns for Abdominal Fascial Closure.

Most surgeons would change their practice based on a large RCT (randomized controlled trial)

PART III

A RANDOMIZED CONTROLLED TRIAL PROPOSAL FOR POLYGLACTIN VERSUS POLYPROPYLENE IN THE CLOSURE OF VERTICAL MIDLINE ABDOMINAL INCISIONS

INTRODUCTION

Much of surgical practice continues to rely heavily on tradition, personal conviction and prejudice rather than good evidence-based practice.
A recent meta-analysis of randomized trials (Part I) has suggested a continuous closure with a nonabsorbable suture as the best method for abdominal fascial closure. The use of meta-analysis as a substitute for a randomized controlled trial in establishing a causal relationship remains controversial. A meta-analysis of 10 studies of 100 patients each is not equivalent to a single randomized controlled trial enrolling 1 000 patients (1). The enthusiasm for meta-analyses expressed by their proponents is not always shared by the entire clinical community. It is unrealistic to think that a meta-analysis will provide simple statistical conclusions to complex clinical problems. They are however, useful in formulating broad decision-making and aid in the design of randomized trials.

As aforementioned, tradition has largely dictated surgical practice. Reassuringly, the results of the provincial survey indicate that the majority of surgeons would change their current practice based on the results of a randomized controlled trial (59%), whereas 22% indicated willingness to change based on a meta-analysis (Part I).

The purpose of this study is to compare two different suture materials in reducing postoperative incisional hernias.

BACKGROUND and RATIONALE

Review of the literature revealed 23 randomized controlled trials (RCTs) comparing suture materials and or technique. Of these 13 were determined to be good quality trials (score ≥3) based on the Jadad Quality Scale, the only validated quality score (2,3-15). These RCTs (4,3-15) were largely inconclusive due to small sample sizes and insufficient power. Poor quality surgical trials are a common phenomenon, with the majority hampered by inappropriate randomization methods and analyses (16). Our meta-analysis (Part I) of these trials revealed that a nonabsorbable continuous fascial closure resulted in a 30% risk reduction in incisional hernia rates, as compared to absorbable sutures (17). This meta-analysis has some limitations. The RCTs had only 6 month to one-year patient follow-ups. In contrast, a prospective cohort study supports that many incisional hernias do not present until after one year and the majority by 3 years (18).

Nonabsorbable suture materials may be less ideal with respect to other late complications, as they have a higher frequency of wound sinuses and wound pain (17). With the development of new absorbable sutures with longer retention of tensile strength, surgeons now have a wide armamentarium of suture materials with which to close abdominal wounds. These include polydioxanone

(PDS) and polyglycolic acid (Dexon), which have fueled the continuing debate over the ideal suture material.

Moreover, a survey of provincial Ontario surgeons (Part II) identified that absorbable continuous suture is the current practice of abdominal fascial closure. This is different than the results of the meta-analysis. Specifically, polyglactin (Vicryl®), was consistently preferred by surgeons for common surgical scenarios. The most common nonabsorbable sutures chosen by provincial surgeons was polypropylene (Prolene®). A definitive RCT is warranted, comparing nonabsorbable continuous (control) versus absorbable continuous closure (intervention).

Specific Aims

Hypothesis

A continuous nonabsorbable (polypropylene) reduces the rate of incisional hernia at 3 years for midline abdominal incisions as compared to an absorbable (polyglactin) suture material.

Objectives

Primary Objective: The primary objective is to determine the rate of postoperative incisional hernia at 1 and 3 years. Incisional hernia is defined as a

palpable defect (regardless of size) in the abdominal fascia with or without protrusion of abdominal contents.

Secondary Objectives: Secondary objectives include occurrences of postoperative wound infection, wound dehiscence, suture sinus formation and wound pain (persistent beyond 3-month postoperative recovery period). Another exploratory objective, time-to- event with respect to incisional hernias, will also be assessed between the two groups.

Population

Inclusion Criteria: All patients > 18 years of age, undergoing elective or emergency abdominal operations requiring a midline laparotomy incision will be included for study.

Exclusion Criteria: Patients with previous laparotomy incisions, patients with umbilical hernias, unresectable cancer, and morbidly obese patients will be excluded. Trauma patient swill aslo be excluded since obtaining informed consent may prove difficult for this patient population. Morbid obesity is defined as 2 times ideal body weight. These clinical scenario will be evident prior to randomization in the operating room.

Patients scheduled for elective surgery will be recruited in the clinic usually 1-2 months prior to surgery. Informed consent will be obtained along with consent for the elective procedure. Routinely type of suture materials does not involve patient consent. Ethics review approval will be obtained.

Patients will be enrolled from various sources. Surgical clinics receive patient referrals from family physicians, gastroenterologists and other specialists. These patients will be enrolled in the preoperative surgical clinics. Informed consent will be sought from all eligible patients and/or family members by the surgeon and/or surgical resident.

DESIGN

Multi-center randomized controlled trial encompassing 3 academic centers and 3 community hospitals stratified by surgeon. Block randomization to ensure equal numbers per surgeon.

Patient Registration: A registration log book and randomization log book will be located at each clinical center. All patients who meet the inclusion criteria must be entered into the registration logbook. For an excluded patient, the reason for exclusion must be entered into the log book.

Randomization process: Prior to randomization, the patient's history, physical examination, bloodwork and consent form must be completed. Randomization will be stratified by surgeon. Block random computer generated trial cards indicating the intervention will be kept in sequentially numbered sealed

opaque envelopes in a locked box in each operating suite. To minimize post-randomization dropouts, trial cards will be drawn in the operating room prior to abdominal closure.

TIMETABLE

Total trial time will require approximately 5 to 6 years from start-up to final analysis. Six months will be allocated for patient recruitment, however, many patients will be recruited during the active trial period given the nature of surgical patient referral. Often patients are referred 2 weeks – 3 months prior to requiring a procedure depending on the urgency of the operation. Trauma patients comprise 10-20% of all abdominal procedures and study enrollment for this population is independent of formal recruitment processes. It is anticipated that all abdominal operations will occur in a one- year period. Each patient will require 3 years of follow-up (refer to Figure 1) from time of operation.

PRE-OPERATIVE PATIENT EVALUATION AND MANAGEMENT

Surgical Treatment Arms

All patients will receive standard prophylactic antibiotics prior to the operative procedure and 2 doses postoperatively. Patients requiring longer

doses (i.e. patients with perforated bowel) will be recorded, dose and duration of antibiotic treatment.

Patients will undergo a midline abdominal incision followed by the abdominal procedure required for that patient (i.e., splenectomy, colectomy, gastrectomy etc). Trial cards will be drawn in the operating room just prior to abdominal fascial closure. Patients in the control group will have abdominal fascial closure with continuous nonabsorbable polypropylene (Prolene®) and the intervention group will undergo fascial closure with continuous absorbable polyglactin (Vicryl®). The specific technical details of abdominal fascial closure will be outlined in detail with each participating surgeon and an illustrative video will be shown to each participating surgeon. Fascial closure will consist of at least 2 cm tissue bites from the fascial edge with at least 3 knots for polyglactin closure and a minimum of 6 knots for the polypropylene closure

The patients will be blinded to the treatment as will the physician performing clinical postoperative assessments. The surgeons performing the surgery cannot be blinded as the two suture materials have distinctive colours and textures, which cannot be masked. They are coated with specific synthetic polymers, which reduce the coefficient of friction and hence cannot be altered.

POST-OPERATIVE PATIENT EVALUATION AND MANAGEMENT

Patients will receive routine post-operative management with attention to analgesia, fluid and electrolyte management and wound assessment. A physician or nurse practitioner blinded to suture material and technique will

perform wound assessment. Post-operative assessment will be from Day 1 until discharge. Follow-up appointment will be scheduled for 2 and 6 weeks, 3 and 6, months followed by 1,2, 3, -year follow-ups. Please refer to Figure 1. Appendix B. Wound pain evaluation will commence at the 6 month postoperative visit and a standard form will be used. (Figure 2).

CLINICAL SITES each clinical site must comprise a clinical investigator (CI), a surgeon and study coordinator (SC).

SAMPLE SIZE CALCULATION

Assuming a 10% cumulative incidence of incisional hernias (18) over 3 years and aiming for a 30% risk reduction, to 7% in the intervention group at 5% significance level (2-sided) and 80% power will require 841 patients per surgical treatment arms. Accounting for 10% loss to follow-up / year will require 1201 patients per group (2402 patients for the total study). A sensitivity analysis of potential sample sizes is displayed in Table 1(Please refer to Appendix A).

Justification of Sample Size Determination: Precedence has been set to use a composite endpoint, incisional hernia. The risk reduction (30%) is high but not out of keeping with the risk reduction demonstrated in the recent meta-analysis comparing suture materials. A poll of expert opinions of general surgeons from the London Health Sciences Centre indicated that the 3% difference in incisional hernia rates was considered clinically significant.

ANALYSES

Descriptive analyses. The control and intervention groups will be compared based on their demographic characteristics, which include gender, age, weight, comorbid illnesses (pulmonary /heart disease). The primary endpoint is a postoperative incisional hernia at 1 year and 3 years. This is a dichotomous outcome and the Pearson chi square test will be utilized. Clinical useful outcome measures including odds ratios with 95% confidence intervals will be calculated (19). These outcome measures are displayed in Table 2. All tests will be two-sided at 5 % significance level. An intention-to-treat analysis will be performed such that all patients will be analyzed by initial group assignment. There will be no cross-over.

Multiple logistic regression will be used to control for the influence of potential confounders namely: degree of operative contamination, steroid use, jaundice, weight, pulmonary disease, and diabetes. These variables will be measured and recorded at baseline. Another potential covariate, level of surgical experience/training is controlled for in the design by stratifying for surgeon.

Secondary outcomes are also dichotomous and will be analyzed using the Pearson chi square test. Time-to-event (incisional hernia) between the two groups will be analyzed using a Cox regression model.

Given the multicenter trial design, tests for qualitative interaction will be conducted on any divergent centers.

INTERIM MONITORING

A safety committee will meet after the first 6 months of the study. The proportion of burst abdomens (evisceration) requiring urgent surgical repair will be determined. Even though, patients at high risk for this complication are outlined I the exclusion criteria, burst abdomens do occur as a result of a technical failure (i.e., slipped knot) irrespective of the patients risk factor. An incidence of greater than 5% would warrant study termination. The safety committee will have the authority to terminate the study if warranted.

ADVERSE EVENT DATA

An adverse event data form will be completed for all deaths, major complications or re-admission to hospital. Detailed information on the cause of the event will be forwarded to the external Safety and Efficacy Monitoring Committee.

DATA COLLECTION AND ORGANIZATION

All study data will be collected on case report forms and a study file will be created for every patient. A copy of the consent form will be maintained in each patient's study file. An operative report will be dictated for each study file, this report will omit mention of suture material used in order to maintain blinding of investigators. Baseline information will be recorded after consent is obtained (Figure 1, Appendix B). One copy will be kept at the research site and the original mailed to the Data Centre. Data will be electronically scanned into the database. Double data entry will be employed to check for data entry errors. Data forms with errors or missing values will be returned to the research site for correction and/or completion. All patient study files will be maintained in a secure environment and retained for the period of time mandated by the hospital/institution after completion of the study. Steering and data monitoring committees will comprise of a surgeon, biostatistician, epidemiologist and data manager. The data manager will be responsible for data base management, as well as overseeing and ensuring the accuracy of all data entered. The data manager will prepare monthly reports of accrual rates, noting also withdrawal rates.

FEASIBILITY

Ability to reach the specified recruitment goal is feasible. The average general surgeon performs in excess of 50 laparotomies per year, with more than half of surgeons performing greater than 100 laparotomies (Part II). Since each academic hospital usually employs 6 general surgeons. Community hospitals in southwestern Ontario average approximately 4-5 surgeons/hospital. As we require 1200 patients per surgical treatment arm (2400 total), approximately 24 surgeons will be required to meet this recruitment goal. Therefore 3 academic hospitals and 3 community hospitals, for a total of 6 clinical centres will be recruited.

LIMITATIONS

The large sample size requirement may result in a longer recruitment period than anticipated. Non-participation is expected to be minimal since both suture materials are already routinely used in surgical practice, therefore patient fears/safety concerns that are common with novel procedures is negligible. Loss to follow-up and dropouts may be more prevalent after the first year postoperative year. Cancer patients and inflammatory bowel disease patients are highly motivated populations and it is anticipated that loss to follow-up will be minimal in this population. Sources of competing mortality other than the patient's diagnosis at operation will also contribute to loss-to-follow-up. Heart disease, the leading cause of death in Ontario, may be a major contributor of competing mortality especially in the over 60 age category of this study. It is

anticipated that the sample size corrected for a loss to follow-up of 10% /year will account for these potential sources of patient loss.

Although the randomized controlled design will minimize bias there are factors which are difficult to control. In any surgical trial, individual surgical skill may play an important part in outcome. Although, the general approach to fascial closure is standard, variation between individual surgeons clearly exists. Although it is practical to set standards for surgical techniques in the study protocol, it is impractical to believe that these will be adhered to either in the trial or in subsequent practice.

Generalizability of study results can be applied to academic and community centres. However, results will not be generalizable to patients meeting the exclusion criteria. These patients are considered high risk for wound failure and constitute a small fraction of general surgical practice.

Potential Significance

Surgical practice is largely based on surgical tradition and familiarity rather than evidence –based practice. Surgical trials of abdominal fascial closure to date have largely been inconclusive. More importantly results of a provincial survey also indicated that general surgeons are willing to change their current

practice of abdominal fascial closure based on a definitive large randomized controlled trial. The morbidity of incisional hernias is compounded since most patients will require surgical repair at some stage. In defining the ideal suture material for reducing the rate of incisional hernias, hospital procedures and health care costs will ultimately be reduced. The impact on current surgical practice also has the potential to influence education of General Surgical Residents.

APPENDIX A Sample Size Calculation

Using comparison of two proportions:

Sample Size

$$n=\frac{(Z_\alpha + Z_\beta)^2 \ [P_E(1-P_E) + P_c(1-P_c)]}{(P_E-P_c)^2}$$

$$= \frac{(1.96 +0.84)^2 \ [.07)(.93) +.10)(.90)\ ]}{(.10-0.07)^2}$$

n= 841 per treatment arm

Study size = 2n= 1682

Accounting for loss to follow-up of 10% X 3 years

N= N/ (1-L) =(1682)/ 1-0.3 =2402 patients

Table 1.

Sensitivity Analysis of Varying Incidence of Incisional Hernia in Experimental Group

PE (Experimental)	PC (Control)	Sample Size	Sample size Accounting for Loss to follow-up
.08	0.10	6412	9160
.07	0.10	1682	2402
.06	0.10	1434	2050
.05	0.10	862	1232

Table 2. Clinical Outcome Measures of Incisional Hernia across Comparison Groups

Comparison	OR 95% CI	NNT
Group 1		
(age<60) nonabsorbable vs absorbable		
Group 2		
(age ≥ 60) nonabsorbable vs absorbable		

* OR Odds ratio

APPENDIX B Figure 1: **Patient Baseline Characteristics Form**

Parameter	
Weight	
Height	
BP	
HR	
Temperature	
Laboratory values CBC	
Electrolytes	
BUN/Creatinine	
Bilirubin	
Blood gases	
Medications	
Previous Surgery	
History of other Hernia Surgery (i.e inguinal)	
Type of Surgery Planned Gastric Colorectal Hepatobiliary Vascular Other	

Figure 2.

POSTOPERATIVE PATIENT EVALUATION

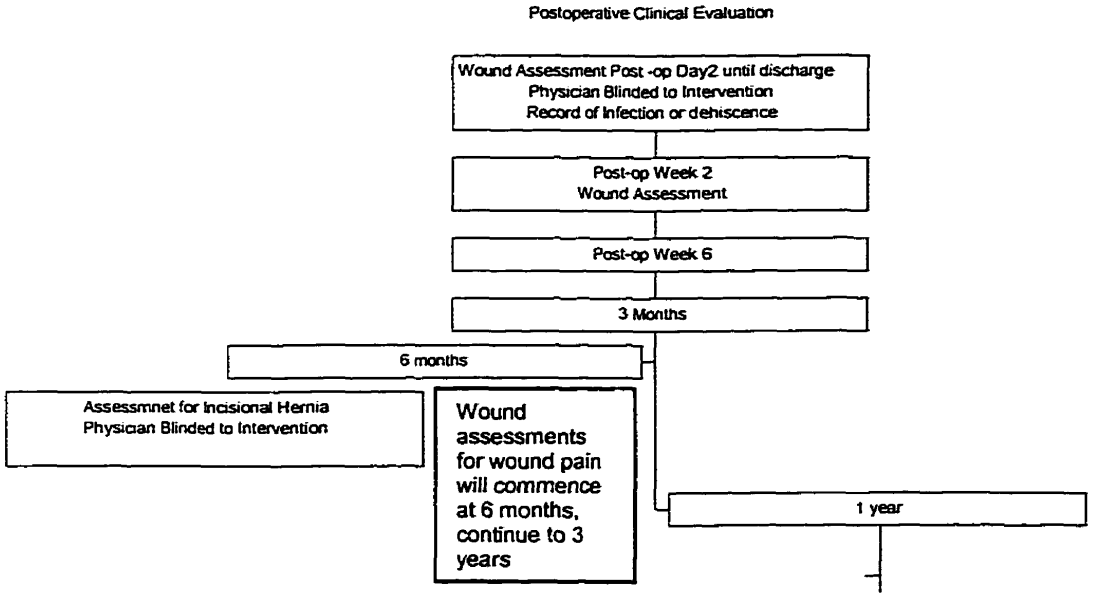


Figure 3. Wound Pain Assessment Form

Which one of the following best describes the pain and discomfort the patient experienced during the specified recall period?

1. Free of pain and discomfort
2. Mild to moderate pain or discomfort that prevented no activities.
3. Moderate pain or discomfort that prevented a few activities.
4. Moderate to severe pain or discomfort that prevented some activities.
5. Severe pain or discomfort that prevented most activities.

Patient Group	Post –op: 6 Months	Post-op: 1 Year	Post-op: 2 Years	Post-op: 3 Years
Group 1 (Age <60)				
Group 2 Age ≥ 60				

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Chapter 5. Discussion

5.1 Summary of the Results

In Part I, the meta-analysis provided some insight into the role of suture materials and suture technique in reducing the rate of postoperative incisional hernia. The meta-analysis found that a nonabsorbable continuous closure is best. Interpretations of results require caution. However, a meta-analysis can produce clinically meaningful results only if it is based on high quality RCTs of similar treatments in similar patients and in similar medical contexts (1). The meta-analysis included only high quality trials and the results are therefore valid.

In contrast, the results of the provincial survey in Part II revealed that general surgeons are choosing a continuous absorbable suture technique most often for abdominal fascial closure. The most common suture was polyglactin (Vicryl®). Surgeons consistently chose an absorbable suture material for elective and clean cases, but were more likely to choose a nonabsorbable suture for contaminated cases. The most common nonabsorbable suture was polypropylene (Prolene®). The majority of surgeons sampled (85%) indicated that they would be willing to change their current practice of abdominal fascial closure based on Level I evidence.

Randomized controlled trials are generally considered the *sine qua non* when answering questions about therapeutic efficacy. The etiology of

postoperative wound failure is multifactorial with multiple potential factors. Randomization is the only way to control unknown or unmeasured confounders. A RCT is proposed to compare the best suture determined by the literature (Part I) versus the most common sutures chosen by Ontario surgeons (Part II)

5.2 Limitations of the Study

Part I

The limitations of meta-analyses include publication bias and the limitation of individual trials. Studies with negative results are more likely to remain unpublished because investigators, reviewers and editors are not enthusiastic about publishing "negative" information. (2,3). The problem of publication bias will be solved only when investigators submit and editors accept all well-conducted studies of important questions regardless of their results. Limitations of the trials included: short follow-up periods (one year or less) and failure to randomize by individual surgeon.

Part II

Survey research is subject to sampling and nonsampling biases. Nonresponse bias is considerably higher in mailed questionnaires. However, given the nature of our sampling unit (surgeons), a 72 % response rate was higher than anticipated. Again, the overall-sampling fraction was just under 20%

and the power of the study was almost 70%. This was respectable yet limited our ability to detect small statistical differences.

5.3 Implications for Practice and Future Research

Abdominal fascial incisions are basic fundamental procedures used by surgeons in their daily practice. To be able to reduce postoperative complications and ultimately patient morbidity by simply selecting a different suture material appears pragmatic. Initiation of a randomized controlled trial is imperative and the next step in determining the ideal method of abdominal fascial closure. Clinical management involves values, the recognition of a patient's unique circumstances, and information. Evidence-based clinical management requires that we take account of the whole spectrum of available evidence, not a potentially biased "biopsy" of it. " The next RCT comparing a nonabsorbable suture versus an absorbable suture with a longer patient follow-up and adequate power is warranted. As the ideal suture has yet to be developed, further research into suture technology and additional clinical trials are needed.

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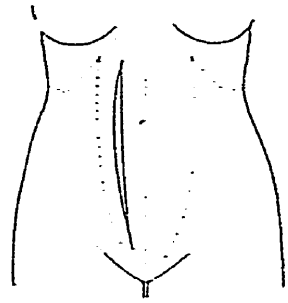
Appendix I

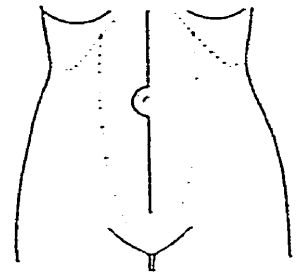
Common Surgical Abdominal Incisions

Common Surgical Abdominal Incisions



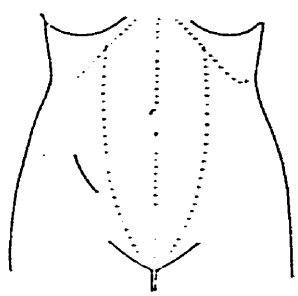
A

Paramedian



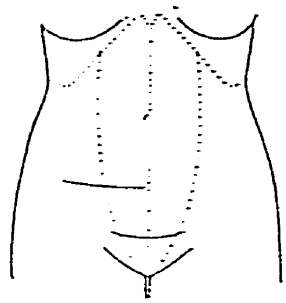
B

Midline



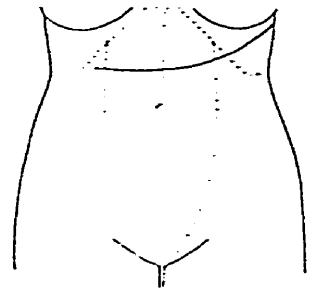
C

McBurney



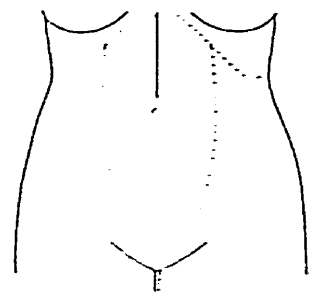
D

Transverse



E

Subcostal



F

Upper Midline

APPENDIX II

Characteristics of Surgical Sutures

. Characteristics of Suture Materials

Suture Name	**Category**	**Tensile Strength**	**Absorption/Tissue Reactivity**
Polyglactin (Vicryl®)	Absorbable	60% retained at Day 14	Absorption complete by 60-90 days
Polyglycolic Acid (Dexon®)	Absorbable	65% retained at Day 14	Completely absorbed by Day 56-70
Polydioxanone (PDS®)	Absorbable	70% retained at Day 28	Minimal absorption until about the 90th day post-op, completely absorbed by 6 months
Polyglyconate (Maxon®)	Absorbable	70-75% retained at Day 30	Absorbed by 6 months
Polypropylene (Prolene®)	Nonabsorbable	Retained indefinitely (> 2 years)	Nonabsorbable Low tissue reactivity
Nylon (Nurolon, Surgilon, Ethilon)	Nonabsorbable	Retained for 2 years (Loses 15-25%/year)	Degrades in vivo by hydrolysis at a rate of 12.5%/yr
Silk	Nonabsorbable	Retained for 1 year	Increased tissue reactivity

Appendix III

Jadad Instrument for Study Quality

Jadad Instrument for Study Quality

Study Number	1. Was the study described as randomized	2. Was the Method of randomization described and was it appropriate?	3. Was the study described as double-blind?	4. Was the method of double-blinding appropriate?	5. Was there a description of withdrawals and dropouts?	QUALITY SCORE

Other factors:

Study Number	Was there adequate concealment of treatment allocation	Was the crossover design appropriate	Was there sponsorship by a pharmaceutical company?

Scoring the items:

Give a score of 1 point for each "yes" and 0 points for each "no". There are no in-between marks.

Guidelines for Assessment

1. A method to generate the sequence of randomization will be regarded as appropriate if it is allowed each study participant to have the same chance of receiving each intervention and the investigators could not predict which treatment was next.

2. Methods of allocation using date of birth, date of admission, hospital numbers, or alternation should not be regarded as appropriate.

3. A study must be regarded as double-blind if the word "double-blind" is used.

4. The method will be regarded as appropriate if it is stated that neither the person doing the assessments nor the study participant could identify the intervention being assessed, or if in the absence of such a statement, the use of active placebos, identical placebos, or dummies is mentioned.

5. Participants who were inlcuded in the study but did not complete the observation period or who were not included in the analysis must be described. The number and the reasons for withdrawal in each group must be stated. If there were no withdrawals, it should be stated in the article. If there is no statement on withdrawals, the item must be given no points.

APPENDIX IV

Data Extraction Forms

DATA EXTRACTION FORM

Study #_____ Abstracter_____

Participants

Inclusion criteria

Exclusion criteria

Age (mean, median)			
Weight			
% Malignancy			
Males/Females			

Intervention Data

	Group A	**Group B**	**Group C**
Number of patients randomized			
Type of suture			
Type of closure (interrupted vs Continuous)			
Type of incision			
% Prophylactic Antibiotics Steroids			
Emergency Surgery/ Elective			
# of patients lost to follow-up			
# of patients evaluated			
Type of Surgery Hepatobiliary Gastric Colorectal Other (vascular)			

OUTCOME DATA

	Group A	Group B	Group C
Early- Wound dehiscence			
Burst Abdomen			
% wound infection			
Suture Sinus			
Chronic Wound Pain			
Incisional Hernia 3 months 6 months (early)			

I

APPENDIX V

Copy of Mailed Questionnaire

Current Surgical Practice of Abdominal Fascial Closure

Q-1 Are you a surgeon in current practice?

1. Yes--- Go to Question Two.
2. No--- Thank you and Quit.

Initially we would like to ask you a few questions regarding clinical cases that represent scenarios requiring abdominal fascial closure.

For each scenario there are three parts, each part requires that you circle **one** answer.

Q- 2 A 54 year old gentleman undergoes elective right hemicolectomy for colon cancer. Please choose how you would close the abdominal fascia.
(Circle **ONE** answer for each part - A,B,C)

A.
1. Continuous
2. Interrupted

B.
1. Absorbable
2. Nonabsorbable

C. Please select which type of suture you most likely would choose.
1. Polydioxanone (PDS ®)
2. Polyglactin (VICRYL®)
3. Polypropylene (PROLENE ®)
4. Polyglycolic acid (DEXON®)
5. Polyglyconate (MAXON®)
6. Other _____

Q-3

A 24 year old male,previously healthy, was involved in a motor vehicle collision and requires a laparotomy for a ruptured spleen. Please choose how you would close the abdominal fascia after splenectomy.
(Circle **ONE** answer for each part - A,B,C)

A.
1. Continuous
2. Interrupted

B.
1. Absorbable
2. Nonabsorbable

C. Please select which type of suture you most likely would choose.
1. Polydioxanone (PDS ®)
2. Polyglactin (VICRYL®)
3. Polypropylene (PROLENE ®)
4. Polyglycolic acid (DEXON®)
5. Polyglyconate (MAXON®)
6. Other _____

Q-4

A 36 year old female with Crohn s disease on steroid treatment develops a small bowel obstruction. After enterolysis, what would your method of abdominal fascia closure be? There is no contamination of the abdominal cavity.
(Circle **ONE** answer for each part - A,B,C)

A. 1. Continuous
2. Interrupted

B. 1. Absorbable
2. Nonabsorbable

C. Please select which type of suture you most likely would choose.
1. Polydioxanone (PDS ®)
2. Polyglactin (VICRYL®)
3. Polypropylene (PROLENE ®)
4. Polyglycolic acid (DEXON®)
5. Polyglyconate (MAXON®)
6. Other _____

Q-5

A 64 year old woman 2 years post liver transplantation presents with perforated diverticulitis. Laparotomy reveals gross feculent contamination of the abdominal cavity. Please choose how you would close the abdominal fascia.
(Circle **ONE** answer for each part - A,B,C)

A. 1. Continuous
2. Interrupted

B. 1. Absorbable
2. Nonabsorbable

C. Please select which type of suture you most likely would choose.
1. Polydioxanone (PDS ®)
2. Polyglactin (VICRYL®)

3. Polypropylene (PROLENE ®)
4. Polyglycolic acid (DEXON®)
5. Polyglyconate (MAXON®)
6. Other _____

Q-6

Please rank the following complications post abdominal fascial closure from most common to least common in your current practice.
(1 = most common and 5 = least common)

___ Wound infection
___ Incisional hernia
___ Suture sinus
___ Wound dehiscence
___ Wound pain

Another important aspect of clinical practice is your opinion about the importance of research. The next few questions will inquire about this matter.

Q-7

Have you changed your practice of abdominal fascial closure since you first were trained as a general surgeon?
(Circle **ONE** answer)

1. YES
2. NO

Q-8

Are you aware of any published literature on abdominal fascial closure?

1. YES----- Go to Question 9
2. NO-----Go to Question 10

Q-9

Has published literature on abdominal fascial closure influenced your current surgical practice?
(Circle **ONE** answer)

1.YES
2. NO

3. Do Not Know

Q -10 Would you be willing to participate in clinical research addressing abdominal fascial closure?

(Circle **ONE** answer)

1. Yes
2. No
3. Do not know

Q-11 Would you participate in the development of guidelines regarding abdominal fascial closure?

1. Yes
2. No
3. Do not know

Q-12 Would you change your current practice of abdominal fascial closure, if there was evidence that certain sutures had a lower incidence of wound failure?

1. Yes
2. No
3. Do not know

Q-13 Would published literature change your current surgical practice of abdominal fascial closure?

1. Yes---- Please go to Question 14
2. No-----Please go to Question 15
3. Do not know----Please go to Question 15

Q-14 What level of evidence would change your current surgical practice of abdominal fascial closure?

(Circle **ONE** answer)

1. Single large randomized control trial (RCT)
2. Meta-analysis of RCTs
3. Cohort study
4. Case control study
5. Case series
6. Practice Guidelines
7. Do not know

We would like to ask you a few confidential questions about yourself for statistical purposes.

Q-15

How would you describe your surgical practice?
(Circle **ONE** answer)

1. COMMUNITY-BASED
2. UNIVERSITY-BASED
3. BOTH 1 & 2

Q-16

How many years have you been in active surgical practice?
(Circle **ONE** answer)

1. 1- 5 years
2. 6 – 10 years
3. 11- 15 years
4. 16 – 20 years
5. > 21 years

Q-17 Are you presently performing laparotomies/celiotomies in your practice?

1. Yes
2. No

Q-18

On average how many laparotomies/ celiotomies do you perform in one year?
(Circle **ONE** answer)

1. 0 - 10
2. 11 - 50
3. 51 - 100
4. > 101

Q-19

Of the number of laparotomies/ celiotomies that you performed in an average year, please indicate the percentage of elective and emergent cases.
(Write in percentage)

1. ELECTIVE _____
2. EMERGENT _____

Q-20

What age category applies to you?
(Circle **ONE** answer)

1. 25 - 35
2. 36 - 45
3. 46 - 55
4. > 56

In addition to current status, for general group comparison purposes we would like to ask you questions about your surgical training.

Q-21

What year did you graduate from medical school?

1. YEAR _____

Q-22

Please indicate where you completed your general surgery training.
(Circle **ONE** answer, if other please fill in the specific institution)

1. UNIVERSITY OF TORONTO
2. UNIVERSITY OF OTTAWA
3. UNIVERSITY OF WESTERN ONTARIO
4. MCMASTER UNIVERSITY
5. QUEENS UNIVERSITY
6. ATLANTIC PROVINCES
7. QUEBEC
8. WESTERN PROVINCES
9. OTHER _____

Q-23

Did you complete any specialty training?
(Circle **ONE** answer)

1. YES--- PLEASE GO TO QUESTION 24
2. NO

Q-24

Which area of specialty training did you complete?
(Circle **ONE** answer)

1. Hepatobiliary
2. Colorectal
3. Surgical Oncology
4. Vascular
5. Cardiothoracic
6. Pediatric
4. Other _____

Finally, any comments you wish to make regarding abdominal fascial closure can be written in the following space, or in a separate letter.

Your contribution to this investigation is greatly appreciated. If you would like a summary of results, please print your name and address on the back of the return envelope. We will make sure you will receive a copy once the results have been tabulated.

APPENDIX VI

Examples of Contingency Tables: Scenarios1-4

Descriptive Analysis of Independent Variables: Scenario 3

Independent Predictor Variables	**Continuous**	**Interrupted**	**Absorbable**	**Nonabsorbable**
Years of surgical practice				
1-10 years	76% (13)	24% (4)	81% (13)	19% (3)
> 10 years	73% (32)	27% (12)	86% (38)	14% (6)
# of laparotomies/ year				
1- 50	91% (10)	9% (1)	91% (10)	9% (3)
> 50	69% (33)	31% (15)	88% (42)	12% (6)
Age Category				
25-45	86% (18)	14% (3)	81 % (17)	19% (4)
46 +	66% (25)	34% (13)	87 % (33)	13% (5)
Site of residency training				
Ontario	69% (29)	31% (13)	82% (37)	18% (8)
Other	85% (18)	15% (3)	93% (13)	7% (1)

Contingency Table: Scenario #1 Question b

	Absorbable	Nonabsorbable
< 50 laparotomies	10	1
≥ 50 laparotomies	43	6

Odds Ratio = 1.40
95% CI= [0.5,13.1]

Contingency Table: Scenario #2 Question b

	Absorbable	Nonabsorbable
< 50 laparotomies	10	1
≥ 50 laparotomies	41	7

Odds ratio = 1.7

95%CI=[0.19,15.5]

Contingency Table: Scenario #3 Question b

	Absorbable	Nonabsorbable
< 50 laparotomies	10	1
≥ 50 laparotomies	42	6

Odds Ratio = 1.43
95% CI= [0.15,13.36]

Contingency Table: Scenario #4 Question b

	Absorbable	Nonabsorbable
< 50 laparotomies	9	2
≥50 laparotomies	26	22

Odds Ratio = 3.80
95% CI= [0.79,18.29]

APPENDIX VII

Power and Sample Size Formulas

POWER CALCULATION

= Pr(Reject H_0 given H_1 true)

$$= \left[\frac{p_1 - p_2}{(p_1q_1/n_1 + p_2q_2/n_2)^{1/2}} - z_{1-\alpha/2} \frac{[\text{p bar q bar}(1/n_1 + 1/n_2)]^{1/2}}{(p_1q_1/n_1 + p_2q_2/n_2)^{1/2}} \right]$$

where = Pr ($X \leq x$) where X is a standard normal distribution.

P1= 0.85 (% absorbable)
P2= 0.15 (% nonabsorbable)
N1= 52
N2= 9

Sample Size Calculation

$$= \frac{(Z_\alpha + Z_\beta)^2 \, [(P1)(1-P1) + P2(1-P20]}{(\Delta)^2}$$

where P1= 0.60 (proprtion of academic surgeons)
and P2 =0.40 (proportion of community surgeons)

and Δ= 30%(0.30) clinically significant difference

Pagano M. Principles of biostatistics. Belmont, Ca. Wadsworth Inc. 1993.