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Intraoperative Handling and Wound Healing: Controlled Clinical Trial Comparing Coated VICRYL® Plus Antibacterial Suture (Coated Polyglactin 910 Suture with Triclosan) with Coated VICRYL® Suture (Coated Polyglactin 910 Suture)

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ABSTRACT

Background: **Coated polyglactin 910 suture with triclosan was developed recently in order to imbue the parent suture, coated polyglactin 910, with antibacterial activity against the most common organisms that cause surgical site infections (SSI). Because such alterations could alter the physical properties of the suture, this study sought to compare the intraoperative handling and wound healing characteristics of coated polyglactin 910 suture with triclosan and traditional coated polyglactin 910 suture in pediatric patients undergoing various general surgical procedures.**

Methods: **This was a prospective, randomized, controlled, open-label, comparative, single-center study. Pediatric patients (age 1–18 years) undergoing various surgical procedures were randomized in a 2:1 ratio to treatment with either coated polyglactin 910 suture with triclosan or coated polyglactin 910 suture. The primary endpoint was the surgeon's assessment of the overall intraoperative handling of coated polyglactin 910 suture with triclosan and traditional coated polyglactin 910 suture without triclosan. The secondary endpoints included specific intraoperative suture handling measures and wound healing assessments. The suture handling measures were (1) ease of passage through tissue; (2) first-throw knot holding; (3) knot tie-down smoothness; (4) knot security; (5) surgical handling; (6) surgical hand; (7) memory; and (8) suture fraying. Assessment of wound healing included the following: Healing progress, infection, edema, erythema, skin temperature, seroma, suture sinus, and pain. Adverse events were recorded.**

Results: **Scores for intraoperative handling were favorable and not significantly different for both sutures, although coated polyglactin 910 suture with triclosan received more "excellent" scores (71% vs. 59%). Wound healing characteristics were comparable for both sutures except for pain on postoperative day 1. Significantly fewer patients treated with polyglactin**

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910 suture with triclosan reported pain on day 1 than patients who received the other suture (68% vs. 89%, p = 0.01). The overall incidence of adverse events was 18%; none was device-related.

***Conclusions*: Coated polyglactin 910 suture with triclosan performed as well or better than traditional coated polyglactin 910 suture in pediatric patients undergoing general surgical procedures. The incidence of postoperative pain was significantly less in patients treated with coated polyglactin 910 suture with triclosan than the traditional suture. We speculate that polyglactin 910 suture with triclosan, by inhibiting bacterial colonization of the suture, reduced pain that can be an indicator of "subclinical" infection. Coated polyglactin 910 suture with triclosan may be a useful alternative in patients at increased risk of developing SSI.**

Surgical site infections (SSI) remain a pervasive problem in the surgical community. Of the nearly 27 million surgical procedures performed annually in the United States, SSIs occur in 2–3% [1,2], with the majority (60%) of these infections being confined to the incision [3]. Evidence suggests that the suture knot may be the central repository for bacteria that contaminate the wound. As such, it provides a nidus or scaffold for bacterial colonization and replication that can ultimately result in SSI. The most common organisms responsible for SSI include *Staphylococcus aureus*, *Staphylococcus epidermidis*, methicillin-resistant *S. aureus* (MRSA), and methicillin-resistant *S. epidermidis* (MRSE) [1,4]. Therefore, active inhibition of these organisms at the surgical site may help reduce the overall rate of postoperative infections.

Coated polyglactin 910 suture (Vicryl®, ETHICON, Inc., Somerville, NJ) is the most frequently used suture material in the world [5,6]. Because the suture knot is believed to be the principal site of bacterial colonization in the wound, coated polyglactin 910 suture with triclosan (Vicryl Plus Antibacterial Suture®, ETHICON) was developed in order to imbue the suture material with antibacterial activity against the most common putative pathogens that cause SSI. The active component in coated polyglactin 910 suture with triclosan is triclosan itself (Irgacare MP, Ciba-Geigy, Basel, Switzerland), a broad-spectrum antiseptic agent. Triclosan has been used as a safe and effective antimicrobial agent for more than 30 years. During this time, it has been proved to be effective against both methicillin-sensitive and methicillin-resistant *S. aureus* (MSSA, MRSA); furthermore, triclosan-resistant populations have not been encountered [7]. Coated polyglactin 910 suture with triclosan has demonstrated antibacterial activity in vitro against *S. aureus*, *S. epidermidis*, MRSA and methicillin-resistant *S. epidermidis* (MRSE). In vivo, coated polyglactin 910 suture with triclosan demonstrated antibacterial activity against *S. aureus*, resulting in a statistically significant 30–fold reduction in the number of organisms [8]. Furthermore, triclosan has been proved to be nontoxic in a variety of test systems, and does not affect tissue reaction, healing response, or the absorption profile of coated polyglactin 910 suture with triclosan, compared to the traditional coated polyglactin 910 suture without triclosan [9].

The intraoperative and postoperative performance characteristics of coated polyglactin suture have been well established. Because tactile considerations are important, improvements made in one aspect of a surgical product should ideally preserve its expected "feel" and reliability. Prior studies have documented the physical and functional comparability of coated polyglactin 910 suture with triclosan and traditional coated polyglactin 910 suture [5,6]. Surgeons specializing in general, orthopedic, plastic, or gynecologic surgery evaluated the suture materials in an in vivo porcine model with regard to (1) ease of passage through tissue; (2) first throw knot holding; (3) knot tie-down smoothness; (4) knot security; (5) surgical handling; and (6) an overall evaluation. They found that both sutures performed favorably and similarly. In fact, surgeons could not reliably make a distinction with regard to handling between the two sutures. There was also no difference in breaking strength retention and absorption rate between the sutures [5]. The present blinded, randomized, con-

trolled trial was conducted to characterize further the clinical performance of coated polyglactin 910 suture with triclosan and traditional coated polyglactin 910 suture in pediatric patients undergoing various general surgical procedures.

MATERIALS AND METHODS

Study design

This was a prospective, randomized, controlled, open-label, comparative, single-center study. Pediatric patients (age 1–18 years) undergoing various general surgical procedures were randomized in a 2:1 ratio to treatment with either coated polyglactin 910 suture with triclosan or traditional coated polyglactin 910 suture.

Inclusion criteria

Patients of the stated age were enrolled if they were scheduled for clean or clean-contaminated surgical procedures. Written informed consent was obtained from all patients or their legal guardians.

Exclusion criteria

Reasons for excluding patients included contaminated wound sites; use of retention sutures; inappropriate age; evidence of malnutrition or debilitation; coexisting conditions that may impair wound healing including acquired immunodeficiency syndrome (AIDS); incision sites prone to expand, stretch, distend, or require support; ophthalmic, cardiovascular, or neurologic surgical sites; a need for more than one surgical procedure; prior participation in this study; or allergy to triclosan.

Suture material

The test suture was coated polyglactin 910 suture with triclosan. The control suture was traditional coated polyglactin 910 suture. Various suture sizes were employed for both test and control sutures.

Primary endpoint

The primary endpoint was the surgeon's blinded assessment of the *overall* intraoperative handling characteristics of each suture (Table 1).

Secondary endpoints

Secondary endpoints included assessment of wound healing and of specific intraoperative suture handling characteristics. The intraoperative suture handling characteristics evaluated included: Ease of passage through tissue; first-throw knot holding; knot tie-down smoothness; knot security; surgical "hand," memory, and degree of fraying. These are described in Table 1. The handling characteristics of all test sutures were rated on a five-point scale as follows: 1 = poor; 2 = fair; 3 = good; 4 = very good; and 5 = excellent. Wound healing assessments included healing progress; infection; edema; erythema; skin temperature; seroma; suture sinus; pain (nonverbal infants were scored on the FLACC [face, legs, activity, cry, consolability] scale (Tables 2 and 3). Adverse events were recorded and classified according to severity and whether they were device-related.

Evaluation timeline

Suture handling was evaluated at the time of implantation. Wound healing was evaluated during follow-up visits at 1–2 days, 14 ($\pm$ 2) days, and 80 ($\pm$ 5) days post-implantation. The incidence of adverse events and the use of antibiotics or medications that could impair wound healing were recorded at each visit.

Statistical analysis

Logistic regression analysis was used to evaluate intraoperative suture handling techniques. The Fisher exact test (two-sided) was used for wound assessment data. A commercial software package, SAS 8.02 (SAS Institute Inc, Cary, NC), was used to calculate statistics and generate the randomization schedule. Significance was accepted at alpha of 0.05.

RESULTS

Patient population

One hundred fifty-one patients were enrolled and randomized. Two patients from

Table 1. Intraoperative Suture Evaluation Criteria

Primary endpoint	
Overall evaluation	The composite evaluation of the suture on all characteristics rated. This evaluation takes into consideration the relative importance of all the different characteristics.
Secondary endpoints	
Ease of passage through tissue	The ease with which a suture passes through the tissue into which it is being implanted. The relative lack of "drag," absence of friction, or lack of sawing or cutting of the tissue as the suture passes through.
First-throw knot holding	Holding opposing tissue edges together with the first throw. The opposing tissue edges must remain together and no loosening of the knot is observed before the second knot is thrown.
Knot tie-down smoothness	The capacity of a suture that allows a throw or knot to be tied at some distance from its final location and then slide into place with the next throw.
Knot security	The quality of a suture that allows it to be tied securely with a minimum number of throws per knot.
Surgical hand	The surgeon's gloved feel or tactile reaction to handling suture. This characteristic is comprised of good pliability (lack of stiffness) and softness.
Memory	The capacity of a suture to assume a relatively stable linear configuration after removal from packaging and after stretching. The capacity of a suture to remain relatively free of kinking, curling, and other contortions which may interfere with surgical handling and use.
Lack of fraying	Capacity of the suture to resist shredding or unraveling.

The handling characteristics of all test sutures were rated on a 5-point scale as follows: 1 = poor, 2 = fair, 3 = good, 4 = very good, and 5 = excellent.

each group withdrew prior to treatment, leaving 98 patients in the triclosan suture group and 49 patients in the traditional suture group, for a total of 147 treated patients. These 147 patients provided the basis for baseline data, safety assessments, the primary endpoint of overall intraoperative handling, and secondary endpoints of specific intraoperative handling

Table 2. Wound Healing Assessments

Assessment	*Outcome measurements*			
Healing progress, apposition	Complete	Incomplete		
Infection[a]	No	Yes		
Seroma requiring drainage	No	Yes		
Suture sinus, culture-negative	No	Yes		
Erythema	0 (none)	+ (closure line redness)	++ (redness <2 mm)	+++ (redness >2 mm)
Edema	0 (none)	+ (slight increase in firmness)	++ (skin dimples with pressure)	+++ (tense firmness)
Pain	0 (none)	+ (with pressure)	++ (with touching)	+++ (constant)
Skin temperature increase	0 (none)	+ (slight)	++ (definite)	+++ (hot, radiating)

[a]Defined as observed redness >3–5 mm from the wound margins, edema, purulent discharge, pain, and increased skin temperature were considered evidence of infection; a confirmatory culture was not required.

Table 3. FLACC Scale (Face, Legs, Activity, Cry, Consolability)

Face	0 No particular expression or smile	1 Occasional grimace or frown, withdrawn, disinterested	2 Frequent to constant frown, clenched jaw, quivering chin
Legs	0 Normal position or relaxed	1 Uneasy, restless, tense	2 Kicking or legs drawn up
Activity	0 Lying quietly, normal position, moves easily	1 Squirming, shifting back/forth, tense	2 Arched, rigid, or jerking
Cry	0 No cry (awake or asleep)	1 Moans or whimpers, occasional complaint	2 Crying steadily, screams or sobs, frequent complaints
Consolability	0 Content, relaxed	1 Reassured by occasional touching, hugging, or "talking to"; distractible	2 Difficult to console or comfort

The FLACC is a behavior pain assessment scale for use in non-verbal patients unable to provide reports of pain. Instructions: 1. Rate patient in each of the five measurement categories. 2. Add together. 3. Document total pain score.

measurements. The patient population for the secondary endpoints of wound healing was slightly diminished at each assessment period due to voluntary withdrawal or loss to follow-up. At the first postoperative evaluation (day 1–2) the groups consisted of 88 and 45 patients; on day 14 the groups had 91 and 44 patients; and finally on day 80 the groups comprised 76 and 38 patients, respectively.

There were no differences in baseline demographic variables between the treatment groups. The mean age for the patients was 9.8 years (range 1–18 years), the mean height was 137.2 cm (range 67–191 cm), and the mean weight was 41.3 kg (range 8–130 kg). Most patients were Caucasian (85%) or African-American (11%); about half (52%) were male. There was no difference in the types of surgical procedures between groups.

Risk factors that could affect wound healing adversely were present in similar proportion in both groups, 29% versus 33% (triclosan suture vs. traditional suture). The most common risk factors were chemotherapy and obesity. Sixty-five percent of patients in the triclosan suture group received intravenous antibiotics compared to 82% of patients in the traditional suture group. In addition, 5% of the triclosan suture group and 10% of the traditional suture group were also taking other medications.

Overall intraoperative handling

For the primary endpoint, overall intraoperative handling, "excellent" scores were recorded for the coated polyglactin 910 suture with triclosan in a mean of 71% of cases compared with 59% for the traditional sutures, respectively (Fig. 1). More than 94% of the responses rated the handling as "very good" or "excellent" for both sutures. The difference between groups was not statistically significant.

Specific intraoperative handling

The scores for the secondary endpoint, specific intraoperative handling characteristics, are shown in Figure 1. "Excellent" scores were recorded for the coated polyglactin 910 suture with triclosan (mean "excellent" rating of 75%) compared with 62% for the traditional suture. Both sutures performed well, with $\geq 94\%$ of the responses rating the sutures "very good" or "excellent" on all measures. The difference between the groups was not statistically significant.

Wound healing

The scores for wound healing parameters are shown in Table 4. Significantly fewer patients in the coated polyglactin 910 suture with tri-

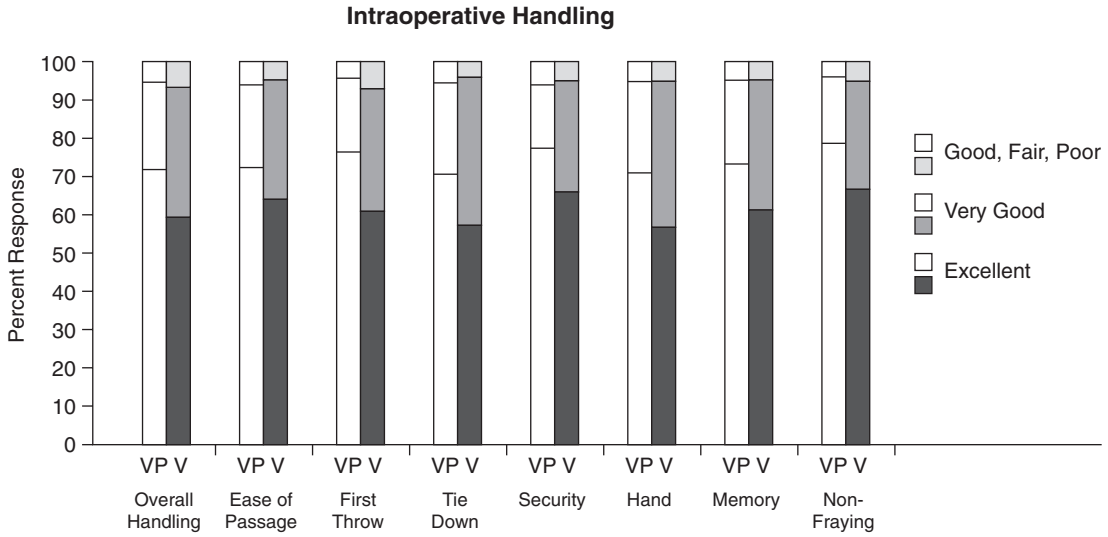

FIG. 1. Intraoperative handling. The primary endpoint of overall intraoperative handling is shown in the first set of bars. Secondary endpoints for individual aspects of intraoperative handling comprise the remaining bars. Values for good, fair, and poor handling were small and combined into one measurement. V, coated polyglactin 910 suture; VP, coated polyglactin 910 suture with triclosan.

closan group reported pain on day 1 than in the traditional suture group (68% vs. 89%, p = 0.01). Subset analysis revealed an even greater difference between the groups, with only 23% of patients in the triclosan suture group reporting "pain with touching" compared to 49% in the traditional suture group. The incidence of pain decreased to approximately 10% by day 14 in both groups. There was no relationship between perceived pain and the patient's age or length of incision (data not shown). All other wound healing parameters were similar between groups. Erythema, present in a small number of patients, was generally mild. Edema, characterized by increased tissue firmness, occurred in 10% of the triclosan suture group versus 18% of the traditional suture group. Twenty-four percent of patients in the triclosan suture group, and 31% of patients in the traditional suture group, received peri-operative antibiotics. On day 14, 13% versus 23% had taken antibiotics for various reasons, whereas by day 80 the rates were 22% versus 29%, respectively. Other medications that could impede wound healing were administered to 10% of patients in the triclosan suture

TABLE 4. WOUND HEALING SCORES

	Day 1		*Day 14*		*Day 80*	
	VP (n = 88)	*V (n = 45)*	*VP (n = 91)*	*V (n = 44)*	*VP (n = 76)*	*V (n = 38)*
Apposition, %	100	100	99	98	100	100
Infection, %	0	0	2	0	1	0
↑ Skin temp, %	0	2	0	0	0	0
Seroma, %	0	0	0	0	0	0
Suture sinus, %	0	0	0	0	0	0
Edema, any, %	10	18	3	2	0	3
Erythema, %	9	7	9	2	1	3
Antibiotics, %	24	31	13	23	22	29
Other meds, %	10	13	14	14	12	21
Pain, any, %	68[a]	89[a]	12	9	3	0

[a]p = 0.01.
V, coated polyglactin 910 suture; VP, coated polyglactin 910 suture with triclosan.

group and 13% of patients in the traditional suture group on day 1 (no significant difference). At day 14 the rates were 14% and 14%, and by day 80 the rates were 12% and 21%, respectively. Three patients developed infections that were judged not to be related to the suture. On day 14, a 13-year-old male who had undergone a pilonidal cystectomy developed a new sinus tract that was related to the location of the cyst, not the suture. Also on day 14, a 14-year-old female who had undergone a laparoscopic cholecystectomy developed a superficial fungal rash around the umbilicus that was believed to be due to body habitus. On day 80, a 14-year-old female patient who underwent a pilonidal cystectomy developed a new sinus tract distal to the original site of excision that was filled with hair, which most likely represented a new lesion.

Adverse events

Adverse events were reported in 17% of patients treated with coated polyglactin 910 suture with triclosan and 20% of patients treated with traditional coated polyglactin 910 suture (Table 5). None of the adverse events were device-related, and there was no difference between treatment groups. The most common events consisted of admissions for chemotherapy.

DISCUSSION

Coated polyglactin 910 suture with triclosan was developed in order to imbue the suture material with antibacterial activity against the most common organisms that cause SSI, *S. aureus, S. epidermidis*, MRSA, and MRSE [7,9]. The active component in coated polyglactin 910 suture with triclosan is Irgacare MP (triclosan), a broad-spectrum antiseptic agent that has been shown to be efficacious against these putative pathogens without inducing resistance [11–15]. Triclosan has been used as a safe, non-toxic, and effective antimicrobial agent for more than 30 years. Because the addition of triclosan could impact the overall performance of coated polyglactin 910 suture adversely, it was important to evaluate thoroughly the physical and functional properties of coated polyglactin 910 suture with triclosan, especially in comparison with traditional coated polyglactin 910 suture, to determine if the suture's familiar characteristics would change measurably by the addition of the antimicrobial agent.

Sutures are distinguished by four measurable traits: Physical and mechanical properties, biocompatibility, biodegradation, and handling [16]. These properties are directly related to the physical and mechanical characteristics of the suture and can be measured in experimental animal models and by instrumentation [16–19]. Indeed, previous studies in animal models have shown that the handling properties of coated polyglactin 910 suture and coated polyglactin 910 suture with triclosan were indistinguishable [5,6]. Additionally, the breaking strength retention and absorption profiles of both sutures were similar over a 70–day time course [5]. There was also no significant difference in wound healing between the sutures, whether measured in terms of tissue reaction or bursting strength [6]. The addition of triclosan did, however, provide an antimicrobial effect sufficient to prevent colonization by *S. aureus* and *S. epidermidis*, as well as MRSA and MRSE [4]. This effect was both durable and robust, as it persisted even after immersion of the sutures in saline for 24 h or

Table 5. Adverse Events

	Adverse events, n, *(%)*				
	Any	*Severe*	*Serious*	*Requiring surgery*	*Device-related*
VP (n = 98)	17 (17)	1 (1)	13 (13)	17 (17)	0 (0)
V (n = 49)	10 (20)	1 (2)	8 (16)	10 (20)	0 (0)
All patients (n = 147)	27 (18)	2 (1)	21 (14)	27 (18)	0 (0)

V, coated polyglactin 910 suture; VP, coated polyglactin 910 suture with triclosan.

after passage through porcine skin [4]. The present randomized, blinded, controlled study examining handling and wound healing characteristics in a pediatric population confirms the earlier preclinical studies in vitro, and in large animal models in vivo, in that there were no statistically significant differences in handling or wound healing characteristics between coated polyglactin 910 suture with triclosan and traditional coated polyglactin 910 suture. The primary endpoint of overall intraoperative handling was comparable and favorable for both sutures. Individual aspects of intraoperative handling were also similar. The incidence of adverse events between groups was also similar, and none was judged to be related to the suture material.

The only significant difference observed between treatment groups was pain on postoperative day 1. Fewer patients in the coated polyglactin 910 suture with triclosan group reported pain compared to patients in the traditional coated polyglactin 910 suture group ($p = 0.01$). Although not statistically significant, the incidence of "edema," which could be attributed to increased inflammation at the wound site, was lower in the coated polyglactin 910 suture with triclosan group than in the traditional coated polyglactin 910 suture group. To investigate this finding further, a post-hoc logistic analysis was performed in which the incidence of pain on day 1 was compared against treatment by either suture; edema on day 1; risk factors at baseline; use of prophylactic antimicrobial agents in the first two days after surgery; and the use of therapeutic antimicrobial agents in the first two days after surgery. Two of these parameters were found to affect the incidence of pain significantly. Treatment with coated polyglactin 910 suture with triclosan was associated with significantly less pain and prophylactic antimicrobial use was associated with significantly more pain. It is possible that the decrease in postoperative pain in patients who received coated polyglactin 910 suture with triclosan was the result of diminished inflammatory reaction resulting from "subclinical" infection in the tissue, owing to a reduction in bacterial colonization of the suture afforded by the antimicrobial agent. This is supported by the trend toward a lower incidence of wound edema in the triclosan suture group (Table 4), which may be an indirect measure of inflammatory infiltrates in the tissue. However, our data do not explain the observation that the use of prophylactic antibiotics was associated with significantly more postoperative pain, as this finding was unrelated to the presence of surgical site infection, the length of the incision, or the type of operation performed. Confirmation and explanation of these findings will require further study.

CONCLUSION

Our study in pediatric patients undergoing general surgical procedures demonstrates that the intraoperative handling of coated polyglactin 910 suture with triclosan was similar to that of traditional coated polyglactin 910 suture. There was no significant difference in wound healing parameters between the sutures, except for pain, which was significantly less frequent in patients treated with coated polyglactin 910 suture with triclosan. It is possible that polyglactin 910 suture with triclosan, by inhibiting bacterial colonization of the suture, reduced pain that can be an indicator of inflammation or "subclinical" infection. Thus, polyglactin 910 suture with triclosan may be a useful alternative to traditional coated polyglactin 910 suture, particularly in surgical patients at increased risk of developing SSI.

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