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The effect of triclosan-coated sutures in wound healing. A double blind randomised prospective pilot study

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Summary *Background:* Wound infection and dehiscence are both major contributors to post-operative morbidity. One potential cause or co-factor is the use of suture material. A recently introduced subcutaneous suture is coated with triclosan (TC), an antiseptic drug. It is suggested to reduce wound complications.
Methods: To investigate the effect of TC on wound healing a double blind prospective pilot study in women undergoing a breast reduction was performed. Each patient was her own control. After randomisation the TC-coated sutures were used either on the left or right side. The contralateral side was used as the control. The incidence of dehiscence was studied.
Results: Twenty-six patients were included. In the TC breasts there was a wound dehiscence in 16 cases, whereas in the control breasts in seven cases a dehiscence was observed ($P = 0.023$).
Conclusion: These results suggest that TC-coated sutures should be used with caution. These sutures have already been introduced on to the market without good clinical studies and might have potential adverse effects as shown by these data.

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Wound infection and dehiscence are two of the most important factors in postoperative morbidity in surgical patients. In addition to delayed healing and increased costs, they are also related to impaired scar quality and cosmetic

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outcome. The cause of wound infections is multifactorial. Co-morbidity, malnutrition, and nicotine, for example, are important risk factors.[1] However, suture material might also play a significant role. Excessive inflammatory responses can be provoked by suture material. To reduce the effect of suture material on the risk of developing an infection a polygalactin 910 suture coated with triclosan (Vicryl plus, Ethicon Inc., Sommerville, NJ, USA) was recently introduced. Triclosan (TC) is an antiseptic drug mainly used in dentistry and in several antiseptic soaps. The safety of TC has already been investigated in several experimental studies.[2] The clinical efficacy however has not been studied yet. In this pilot study we investigate the effect of TC-coated suture material on wound healing.

Patients and methods

A pilot study of 26 patients was performed at the Viecuri Medical Centre in Venlo, the Netherlands, during the second half of 2006. Patients who were operated on for breast hypertrophy were asked to participate in the study.

A double blind randomised design in which each patient was their own control was used to evaluate the effect of TC-coated subcutaneous sutures. Inclusion criteria were women between 16 and 65 years of age with bilateral breast size higher than cup DD and clinical complaints such as intertrigo, head neck and/or shoulder complaints. Patients with diabetes, skin diseases, history of keloid formation, use of corticosteroids and other immunosuppressive medication, metabolic and/or degenerative diseases were excluded. Patients were informed about the study and written informed consent was obtained. Breast reduction was perfomed using the Strombeck technique modified with a mediocranial pedicle, which is standard in our clinic. Three different surgeons with comparable experience were involved in the study. In each patient both breasts were operated on by the same surgeon. There was no prophylactic use of antibiotics. Patients were randomly allocated to be treated with the TC-coated suture on the left or right side. The control suture was polygalactin 910 (Vicryl, Ethicon Inc., Sommerville, NJ, USA) which cannot be distinguished from the TC-coated polygalactin 910 suture. The circulating nurse obtained an envelope in which the side that would receive the TC-coated sutures was written. Subsequently she prepared the sutures for the control and experimental side on the table of the scrub nurse. Thus, scrub nurse and surgeon were blinded. A suction drain was left in both breasts and skin was sutured in both breasts with an intradermal soluble suture (Monocryl Ethicon Inc., Sommerville, NJ, USA). Distance between jugulum and nipple as an indicator for preoperative breast anatomy, data on the condition of the patient (body mass index, smoking, age) and surgical data (reduction weight, number of sutures) were collected. After being discharged 1 day after surgery, patients were seen at the outpatient clinic at fixed postoperative days (1 week, 2 weeks, 4 weeks) and more frequently if necessary. The clinical outcome was evaluated. Dehiscence was defined as a spontaneous disruption of the wound with or without infection occurring during 3 weeks postoperatively. Each wound dehiscence, independent of size, was registered. In case of clinical signs of infection (secretion, fever, erythema) antibiotics were given. There were no routine cultures taken. Drain production and day of removal of the drain was also noted. Using the statistical software SAS (version 9.1), an exact McNemar test has been used to compare the proportion dehiscence between both groups. The reported *P*-value is two-sided and considered significant if smaller than 0.05.

Results

Twenty-nine patients were seen during the study period. Three patients were excluded because of diabetes, or use of corticosteroids. Twenty-six patients were thus included. Clinical follow up was obtained in these 26 patients. Mean age was 36 (range 17–65 median: 35) years. Body mass index was between 21 and 31 (median 25.9). There were nine smokers included. The data on resection, sutures used and anatomy of the breast are presented in Table 1. There was a wound dehiscence in seven breasts treated with standard suture material. In the TC-treated breasts there was a dehiscence in 16 cases ($P = 0.023$), Fig. 1. Of all patients there was bilateral dehiscence in five cases. There was no difference in the incidence of wound dehiscence between the different surgeons. Wounds were locally treated with dry gauzes and/or povidone iodine solution and generally healed within 4 weeks. Antibiotic therapy was started in two bilateral dehiscent cases, and in four unilateral dehiscent cases in the TC group. In one case there was no dehiscence, but antibiotics were started because of redness of the breast. In the smokers group (nine patients), there was a bilateral dehiscence in three cases and a unilateral dehiscence in four cases. The unilateral dehiscences were all in the TC-coated site. Wound dehiscence occurred in both cases at day 21 in the control breasts. In the TC group dehiscence was seen at day 7 until day 21 (median 11).

Table 1 Distance between jugulum and nipple (in cm), reduction weight (in grams), the number of different sutures sizes used, and postoperative suction (in ml) in breasts treated with standard polygalactin and those with triclosan. Ranges (min-max) and medians are given

	Control		TC coated	
	Range	Median	Range	Median
Jugulum nipple distance (cm)	22–39	27	22–37	28
Resection weight (g)	76–720	460	190–970	435
Sutures 2.0	1–16	1	1–10	1
Sutures 3.0	4–24	11	8–25	11
Sutures 4.0	0–7	3	0–9	3
Suction production (ml)	5–85	20	5–100	25
Removal of suction (postop day)	1–3	1	1–3	1

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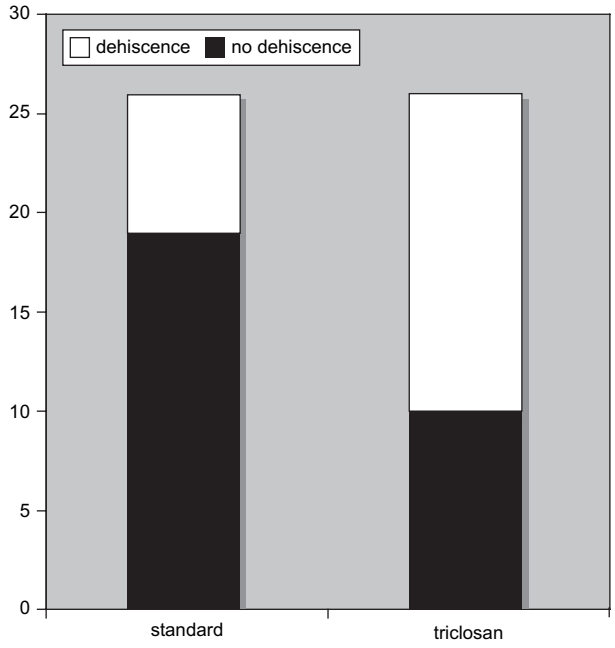

Figure 1 Incidence of dehiscence in the two groups including bilateral cases ($p = 0{,}023$).

Discussion

This pilot study shows that there is no evidence for any effectiveness of TC coating. Even more, TC coating seems to have adverse effects on wound healing.

TC is an antiseptic drug that has been used since the 1970s mainly in disinfecting soaps and dentistry. Safety studies have been performed in the past, mainly focusing on systemic toxicity and local adverse reactions. Overall, these studies concluded that TC has no carcinogenic, genotoxic, pyrogenic, or teratogenic effects. In addition, systemic levels of TC are extremely low due to the use in these products.[2] Recently, however, concern ensued after reports of the formation of toxic byproducts of TC-containing soaps in household conditions.[3] Laboratory and modelling studies indicate that the formation of chloroform and other chlorinated daughter products can occur when triclosan-containing antimicrobial products react with free chlorine and that these reactions can potentially lead to enhanced chloroform exposures.[3] The use in suture material has been tested in animal and in vitro experiments. Handling and tension force of the sutures was found to be comparable to standard suture material. The antimicrobiotic effect was shown to be significant without any negative effect on wound healing.[4–6] In the only clinical study TC-coated sutures had a positive effect on postoperative pain. No effect on wound healing was observed.[6]

Although our group is small we think this study is of value because each patient is her own control. This excludes the effect of confounding factors such as smoking. The difference with our study and previous, experimental results can be due to several reasons. First, the wounds tested until now were linear wounds, which have a tendency to heal well. This is different in our situation where flaps were sutured with tension and, consequently, the blood supply due to the extreme undermining is decreased. This is demonstrated in the control site where a high incidence of wound dehiscence was found, in agreement with reported data in the literature.[7] As this incidence is high, the breast reduction model is very suitable to find positive but also negative effects of new suture material. In addition to the decreased blood supply and tension, we used subcutaneous knots instead of a continuous subcutaneous suture as in other studies. Although TC is relatively non-toxic in classical toxicological terms, negative effects such as dermatitis, skin irritation, and allergic reactions have been described.[8] Potential formation of toxic products due to chemical reactions has to be elucidated.[3]

In conclusion, our observation, together with the lack of evidence illustrating the efficacy of triclosan-containing suture material, suggests that more research is needed before this product is generally introduced to the market.

The findings in this study also contribute to the discussion on whether the introduction of new suture materials, but also new wound-mediating products, should be evaluated and tested in the same way as new medication. As TC-containing sutures have already been introduced and are used on a large scale, marketing seems to be more important than clinical evidence and may potentially put our patients at an unnecessary risk.

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