



## Systematic review

# **Polylactic-Glycolic Acid Absorbable Synthetic Suture (PglA) Plus Antibacterial: A Systematic Review**

**September 2012**



Regione Umbria

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# Systematic review

## Poly(lactic-Glycolic Acid Absorbable Synthetic Suture (PglA) Plus Antibacterial: A Systematic Review

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## Foreword

This year Agenas produced on behalf of the Ministry of Health (Direzione generale dei dispositivi medici, del servizio farmaceutico e della sicurezza delle cure), a systematic review on the efficacy and cost-effectiveness of "Polylactic-Glycolic Acid Absorbable Synthetic Suture (PGLA) Plus Antibacterial".

These devices are already marketed with indication of "reduction of the risk of post-operative infection".

The need to investigate the efficacy arose from the awareness that the post-surgical infections are a main problem for the NHS in terms of quality of health, and additional costs that may result.

The systematic review, like all products of the Agency, is the result of a long and laborious process of consultation with experts, auditors and other stakeholders.

This systematic review is also one of the first experiences in analysis and synthesis of evidence, carried out by Agenas, in collaboration with the Italian regions in the context of the Italian Network for Health Technology Assessment (RIHTA) or Italian HTA network.

The activity was aimed to identify, evaluate and synthesize the currently available evidence on the efficacy and cost-effectiveness of suture plus antibacterial compared with sutures without antibacterial, which are, to date, the most frequently used devices.

It is hoped that the document will provide useful information for the proper use of the devices in question.

Fulvio Moirano

Executive Director Agenas



## Premessa

Quest'anno l'Agenas ha prodotto, su mandato del Ministero della Salute (Direzione generale dei dispositivi medici, del servizio farmaceutico e della sicurezza delle cure), una revisione sistematica sull'efficacia e costo-efficacia delle "Suture sintetiche assorbibili in acido poliglicolico con Antibatterico".

Tali dispositivi sono già commercializzati con l'indicazione della "riduzione del rischio di infezione post-operatoria".

La necessità di indagarne l'efficacia nasce dalla consapevolezza che le infezioni post-chirurgiche costituiscono un problema rilevante per il Servizio sanitario nazionale sia in termini di qualità delle prestazioni erogate, sia di costi aggiuntivi che ne possono derivare.

La revisione sistematica, come tutti i prodotti dell'Agenzia, è il frutto di un lungo e laborioso processo di consultazione con esperti, revisori e altri stakeholders.

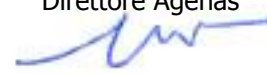
Questa revisione sistematica rappresenta inoltre una delle prime esperienze nella realizzazione di un'attività di analisi e sintesi dell'evidenza, svolta da Agenas in collaborazione con le Regioni Italiane, nell'ambito della Rete Italiana di Health Technology Assessment (RIHTA) o Italian HTA network.

L'attività è stata finalizzata ad identificare, valutare e sintetizzare l'evidenza attualmente disponibile sull'efficacia e costo-efficacia delle suture con antibatterico comparate con le suture senza antibatterico, che rappresentano, ad oggi, i dispositivi più frequentemente utilizzati.

Si auspica che il documento possa fornire utili informazioni per l'appropriato utilizzo dei dispositivi in esame.

Fulvio Moirano

Direttore Agenas





# Executive Summary

## Introduction

Surgical site infections (SSIs) represent a common postoperative complication with a great impact in terms of morbidity, mortality and hospital costs.

The development of SSIs is influenced by a multitude of risk factors directly linked to patient (including diabetes, nicotine use, steroid use, malnutrition, obesity, etc.) or connected to pre and post-intervention phases (prolonged preoperative stay, perioperative transfusion, etc.). Further risk factors that should happen during the pre and post-intervention are represented by an inappropriate use of antimicrobial prophylaxis, infection at remote site not treated prior to surgery and improper skin preparation and surgical team hand preparation.

Besides, no healing or different wound closure could increase the risk of infection and excessive scar formation which can lead to a poor cosmetic outcome. Wound closure using suture materials is an ancient art and the research and application of suture techniques and methods have progressed greatly with the development of bio-technology and the increasing sophistication of new suture materials. Suture materials should produce minimal tissue reaction, primary wound healing, good cosmetic results and avoid scarring.

## Objectives

The aim of this systematic review is to identify, appraise and synthesize the available evidence about the effectiveness, safety and economic data of sutures (PGLA) plus antibacterial compared to standard sutures (PGLA) without antibacterial.

## Methods

We identified, assessed and synthesized effectiveness, safety and economic evidence of suture plus antibacterial compared to standard sutures according to following inclusion criteria:

- Population: patients of any age undergoing surgical intervention for any specialty with PGLA sutures with antibacterial compared to standard sutures.
- Intervention: PGLA sutures plus an antibacterial substance.
- Comparator: PGLA sutures.
- Outcomes:
  - Primary outcomes: Wound infection incidence - Rate of wound healing, Time to closure or Mean Operation Time.
  - Secondary outcomes: Cosmetic outcomes - Rate of wound healing, Time to closure, Mean Operation Time, Visible scars.

- Study design: we included Comparative Studies: Randomized Clinical Trials (RCTs), Controlled Clinical Trials (CCTs), Cohort Studies, Case-control Studies.

We ran searches on five electronic bibliographic databases (Medline, EMBASE, Cochrane Library, CINAHL and Web of Science) and included clinical efficacy and safety studies published from 2000 to February 2012 in English and Italian languages. We also considered information from "grey literature" and we searched the Clinicaltrials.gov website for the ongoing studies. A specific search was performed to identify economic evidence and applied to EMBASE, Cochrane Library, Medline and Econlit from 2000 to February/March 2012.

Independently, three reviewers extracted, quality assessed and synthesized the data, for clinical efficacy and safety evidence, while two reviewers extracted, quality assessed and synthesized the data for economic evidence. Disagreements were resolved by another reviewer. Data extraction was performed using an ad hoc form.

## Results

We included eight clinical efficacy and safety studies. All included studies were randomized controlled trials testing efficacy of PGLA/Triclosan (Vicryl® Plus) suture compared with PGLA suture (Vicryl®). The trials reported different outcomes in different periods of follow up and the heterogeneity of data did not allow us to perform a meta-analysis.

About efficacy results seven of eight studies included reported the primary outcome while none studies included reported our secondary outcome. About safety results five of eight studies included reported data on. Regarding the economic evidence none studies met our inclusion criteria. Regarding the safety of the technology, included studies did not report significant adverse events, concluding that the PGLA/Triclosan suture seems to be safe to date. Harms from the added use of Triclosan should also be observed and reported in a standardized manner.

## Conclusions

In the studies included, different outcomes and age groups and heterogeneous follow up time coupled with unclear reporting led to a considerable loss of data.

Since the available evidence is scarce and heterogeneous there is a need of a large multicenter study to test the equipoise currently visible in the data presented in this review. Until such time clear evidence of dominance of Triclosan coated sutures is not available.

Besides, given the higher cost of suture plus antibacterial compared to standard suture, economic studies should be performed to have clear and useful evidence for decision making.

# Sintesi

## Introduzione

Le infezioni del sito chirurgico rappresentano una complicanza postoperatoria abbastanza comune che registra un impatto rilevante in termini di morbidità, mortalità e di costi ospedalieri.

L'insorgenza delle infezioni del sito chirurgico è influenzata da una moltitudine di fattori di rischio, collegati direttamente al paziente (il diabete, l'uso di nicotina, l'uso di steroidi, la malnutrizione, l'obesità, ecc.) o connessi alla fase pre e post operatoria (la degenza pre-intervento prolungata, le trasfusioni pre-intervento, ecc.). Ulteriori fattori di rischio che possono intervenire nella fase che precede o in quella che segue l'intervento chirurgico sono rappresentati da una inadeguata profilassi antimicrobica, dal mancato trattamento del sito chirurgico prima dell'intervento e dalla preparazione inappropriata sia dell'epidermide del paziente che della pulizia delle mani del team sanitario coinvolto nell'intervento.

Inoltre, la non perfetta cicatrizzazione o le diverse modalità di sutura della ferita possono aumentare sia il rischio di infezione sia favorire la formazione di cicatrici con risultati estetici non soddisfacenti.

L'arte di suturare una ferita chirurgica, attraverso l'utilizzo di diversi materiali, è molto antica e la ricerca di tecniche e metodologie si sono nel tempo sempre più sviluppate andando di pari passo con il progresso bio-tecnologico e con l'utilizzo di materiali sempre più nuovi ed innovativi. I materiali utilizzati per la sutura dovrebbero produrre reazioni primarie minime sul tessuto epidermico della ferita con conseguenti risultati clinici e cosmetici ottimali.

## Obiettivi

Lo scopo di questa revisione sistematica è identificare, valutare e sintetizzare le evidenze disponibili sui dati di efficacia e sicurezza e sui dati economici delle suture con antibatterico comparati con le suture standard senza antibatterico.

## Metodi

Abbiamo identificato, valutato e sintetizzato le evidenze sull'efficacia e sicurezza e le evidenze economiche delle suture con antibatterico comparate con le suture standard senza antibatterico sulla base dei seguenti criteri di inclusione:

- Popolazione: pazienti di tutte le età, sottoposti a qualsiasi procedura chirurgica, suturati con suture PGLA con antibatterico comparate con le suture PGLA senza antibatterico.
- Intervento: suture PGLA con l'aggiunta di antibatterico.

- Comparatore: suture PGLA senza antibatterico.
- Outcomes:
  - Outcome primario: Incidenza delle infezioni della ferita chirurgica: - Tasso di guarigione/chiusura della ferita, Tempo di chiusura della ferita, Tempo medio dall'incisione alla sutura della ferita.
  - Outcome secondario: Outcome cosmetic - Tasso di guarigione/chiusura della ferita, Tempo di chiusura della ferita, Tempo medio dall'incisione alla sutura della ferita, Cicatrici visibili.
- Disegno di studio: abbiamo incluso Studi Comparativi: Trial Clinici Randomizzati (RCTs), Trial Clinici Controllati (CCTs), Coorti, Casi-controllo.

Abbiamo condotto le ricerche bibliografiche su cinque database elettronici (Medline, EMBASE, Cochrane Library, CINAHL e Web of Science) e abbiamo incluso gli studi di efficacia e sicurezza pubblicati in lingua Inglese e Italiano dal 2000 a Febbraio 2012. Abbiamo considerato la "letteratura grigia" e abbiamo cercato sul sito Clinicaltrials.gov gli studi in corso. Una ricerca ad hoc è stata condotta per identificare le evidenze di natura economica su EMBASE, Cochrane Library, Medline e Econlit dal 2000 a Febbraio/Marzo 2012.

Tre revisori, indipendentemente, hanno estratto, valutato la qualità e sintetizzato i dati di efficacia e sicurezza, mentre due revisori hanno estratto, valutato la qualità e sintetizzato i dati di evidenza economica. Eventuali disaccordi sono stati risolti da un altro revisore. Per l'estrazione dei dati è stata creata una scheda di estrazione ad hoc.

## Risultati

Gli studi inclusi, per l'efficacia e per la sicurezza, sono stati otto. Tutti gli studi inclusi sono trial clinici randomizzati che comparano l'efficacia delle suture PGLA con l'aggiunta dell'antibatterico Triclosan (Vicryl® Plus) con le suture standard PGLA (Vicryl®) senza antibatterico. I trial riportano differenti outcome con differenti periodi di follow up e, tale eterogeneità dei dati, non ha consentito di condurre una meta-analisi.

In merito ai risultati di efficacia sette degli otto studi inclusi hanno riportato l'infezione del sito chirurgico come outcome primario mentre nessuno studio ha riportato il nostro outcome secondario. Cinque studi hanno riportato dei dati sulla valutazione della sicurezza. In merito all'evidenza economica nessuno studio è stato incluso, poiché non rispondente ai nostri criteri di inclusione. Infine, nessuno degli studi inclusi ha riportato eventi avversi significativi, concludendo che le suture PGLA/Triclosan sembrano, ad oggi, essere sicure; tuttavia gli eventi avversi dovrebbero essere riportati ed osservati in maniera più standardizzata.

## Conclusioni

Negli studi inclusi gli outcome diversi, con gruppi di età dei pazienti differenti e con follow up diversi, hanno generato una considerevole mancanza di dati per poter condurre una meta-analisi.

Poiché l'evidenza disponibile è scarsa e molto eterogenea risulta necessario uno studio multicentrico più ampio in grado di fornire dati valutabili. Ad oggi l'evidenza sulla dominanza delle suture con l'aggiunta del Triclosan non è, quindi, disponibile.

Inoltre, dati i costi maggiori delle suture con antibatterico comparate con le suture standard, dovrebbero essere condotti studi economici al fine di disporre di evidenze chiare ed utili per prendere decisioni.



# 1. Introduction

## Epidemiological data

Wound closure using suture materials is an ancient art found in Egyptian scrolls dating back to nearly 3500 BC. Animal hair, vegetable fibers, silk, leather, and gut have all been used with varying degrees of success [1]. The research and application of suture techniques and methods have progressed greatly with the development of bio-technology and the increasing sophistication of new suture materials. Suture materials should produce minimal tissue reaction [2], primary wound healing, good cosmetic results and avoid scarring [3].

Poor wound closure can increase risk of infection and excessive scar formation which, in turn, can lead to a poor cosmetic outcome [4]. The most common and internationally used definition of a wound infection as surgical site infection (SSI) was made in 1992 by the US Centre for Disease Control and Prevention (CDC) to prevent confusion between the infection of a surgical incision and the infection of a traumatic wound [5]. SSI is defined as an infection within 30 days of surgery (or within a year in case of prosthetic surgery) and can be classified as incisional and organ/space manipulated during an operation. Incisional infections are further divided in superficial (skin and subcutaneous tissue) and deep (deep soft tissue muscle and fascia). Deep incisional and organ/space are the types causing the most morbidity.

Causes of SSIs can be endogenous (i.e. bacteria on the patient's skin) or exogenous (i.e. personnel, the environment or materials used for surgery). Most SSIs are caused by the patient's own bacterial flora. The most common bacteria causing surgical site infection are *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Enterococcus* spp [6].

SSIs represent a common postoperative complication with a great impact in terms of morbidity, mortality and hospital costs [7, 8]. The development of SSIs is influenced by a multitude of risk factors including diabetes, nicotine use, steroid use, malnutrition, obesity, prolonged preoperative stay, preoperative nares colonization and perioperative transfusion [9]. Other preoperative and intraoperative risk factors for SSIs are represented by an inappropriate use of antimicrobial prophylaxis, infection at remote site not treated prior to surgery and improper skin preparation and surgical team hand preparation [10].

Data presented in a retrospective review of reported SSI rates in Europe show an estimated range varying widely from 1.5-20%. Due to a high rate of under-reporting, the true rate of SSIs is currently unknown. Consequently, the associated economic burden is also likely to be underestimated [11].

In Italy, since 2006, a National Surveillance on Surgical Site Infections has been implemented. It collects data on SSIs coming from voluntary participation of Regions as well as Local Health Units.

Furthermore the annual rate of SSIs has been estimated locally in many hospital-based studies as well as regional surveys. Incidence rates vary in accordance to types of surgical interventions, but are broadly consistent with estimates from European studies [12].

### **Description of technology**

The sutures can be composed of several types of materials, also combined themselves in different alternatives. In Italy polylactic-glycolic acid absorbable synthetic sutures (PGLA) are frequently used in surgical practice. PGLA is a braided synthetic absorbable sterile surgical suture composed of copolymers made from 90% glycolide and 10% L-lactide.

To improve the tensile strength, the polymeric structure includes the presence of dodecanol, a lubricant coating mixture composed of equal parts of a copolymer of glycolide and lactide (Polyglactin 370) and calcium stearate that facilitate the sliding of the wire during the use.

Absorption of the suture is produced by hydrolysis with degradation in glycolic acid and lactic acid metabolized into water and carbon dioxide. Absorption is minimal until day 40 and complete between days 56 and 70.

In the last years new sutures, which present the addition of an antibacterial to the composition of polyglycolic and lactic acid, have been introduced in the market.

The antibacterial is represented by an antimicrobial agent with broad spectrum activity towards Gram+ and Gram– included *Pseudomonas Aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis* and their mutants resistant to methicillin (MRSA, MRSE). To date the antibacterial used is Triclosan with a concentration not exceeding 275 µg/ml.

PGLA plus antibacterial is intended to be applied to skin, subcutaneous tissue, muscle planes, band peritoneum, gastrointestinal anastomosis. It is used in soft tissue approximation and/or ligation but not in cardiovascular and neurological tissue and in ophthalmic surgery because safety and efficacy have not yet been well defined.

To date the only polylactic-glycolic acid absorbable synthetic suture with antibacterial present on the market is the Vicryl® Plus (Ethicon, A division of Johnson & Johnson SpA). This technology received the approval certificate CE in September 2004 and a premarket notification from Food and Drug Administration (FDA) in December 2002.



## **2. Rationale**

The use of PGLA sutures plus antibacterial is based on assumed higher effectiveness at the expense of higher cost. However the evidence basis for these assumptions is unclear and to our knowledge it has never been assessed.



### 3. Objectives and research questions

The objectives of this review are:

- to systematically identify, appraise and synthesize the clinical evidence, effectiveness and safety, of sutures plus antibacterial;
- to systematically identify, appraise and synthesize economic data from the scientific literature on sutures plus antibacterial.

The research questions are:

- do the PGLA sutures plus antibacterial compared to standard sutures (PGLA) reduce wound surgical infections?
- are the PGLA sutures plus antibacterial cost-effective compared to standard sutures (PGLA)?



## 4. Methods

We carried out a systematic review according to the following methodological steps considering the effectiveness, safety and economic issues.

### 4.1 Systematic Review of Effectiveness and Safety Evidence

We carried out searches of the available evidence to identify and assess the effectiveness and safety of PGLA sutures plus antibacterial according to following inclusion criteria:

- Population: patients of any age undergoing surgical intervention for any specialty with PGLA sutures with antibacterial compared to standard sutures.
- Intervention: PGLA sutures plus an antibacterial substance.
- Comparator: PGLA sutures.
- Outcomes:
  - Primary outcomes: Wound infection incidence - Rate of wound healing, Time to closure or Mean Operation Time.
  - Secondary outcomes: Cosmetic outcomes - Rate of wound healing, Time to closure or Mean Operation Time, Visible scars.

Adverse events:wound bleeding, dehiscence, hematoma (local collection of clotted blood), formation of granuloma, incisional hernia, pain or suture sinus (cavity) formation; in addition, the adverse events related to the resistance to antibacterial will be taken into account.

- Study design: we included Comparative Studies: Randomized Clinical Trials (RCTs), Controlled Clinical Trials (CCTs), Cohort Studies, Case-control Studies carried out from 2000 to the date, reported in the English and Italian languages.

We searched the main electronic databases: EMBASE, Cochrane Library, Medline, CINHALL and Web of Science (Science Edition). Search strategies were conducted, from 2000 to the present date (February 2012), to identify studies published in English and Italian languages. The time frame has been chosen to identify unpublished pre-marketing studies since the first suture with antibacterial to be marketed gained the CE mark in 2004.

Search strategies were constructed by appropriate combinations of the following keywords: Surgery, Surgical, Suture, Absorbable synthetic sutures, Polyglycolic acid, Polylactic acid, Poliglactin, Poly (lactic-co-glycolic acid), PGLA, Vicryl<sup>®</sup>, Antibacteric, Triclosan, Surgical wound infection. Detailed description of the searches is reported in Appendix 1.

We also considered information from “grey literature” (conference proceedings, websites, ongoing clinical studies, unpublished work, data from national and international registries).

We searched the *Clinicaltrials.gov* website combining the words “suture” and “antimicrobial”.

Authors of trials reporting incomplete information were contacted to provide the missing information.

The title and abstract of records, identified from our literature search, were examined for relevance and the full text of any potentially relevant record was assessed for inclusion by three reviewers independently. If it was unclear, from an abstract, whether a study should be potentially relevant or not, the whole text of the study was obtained for further information. Studies which met the inclusion criteria, defined above, were included. Disagreements were resolved by a fourth reviewer. Excluded studies were tabulated together with reasons for exclusion.

Data extraction from included studies was performed by three reviewers using a standard form. The studies were distributed among the authors and each one extracted the part of them. The data extraction was checked by a fourth reviewer.

The data extraction standard form included details of the study design, participant characteristics, intervention, comparator, outcomes, duration of follow-up, sample size, number of patients lost to follow-up, randomization, allocation concealment, blinding, statistical analyses and reporting (See Appendix 2).

The risk of bias was assessed by one review author (AM) according to the Cochrane Collaboration criteria for assessing risk of bias (Higgins 2011). Trials that met the eligibility criteria were assessed for random sequence generation and allocation concealment (selection bias), blinding of patients and investigators (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias) and freedom from other biases.

Quality of evidence of primary studies included, for each outcome, was appraised according to the criteria suggested by the Cochrane Handbook [13], synthesised according to GRADE method [14,15] and reported in the Summary of Findings.

In particular, randomized controlled trials were downgraded if any of the following situations occurred: Risk of bias; Indirectness of results; Inconsistency of results; Imprecision of results.

Data synthesis and analyses were done using the Cochrane Review Manager software, RevMan 5.

## 4.2 Systematic Review of Economic Evidence

We carried out searches of the available evidence from literature to identify and assess the economic data of PGLA synthetic sutures plus antibacterial according to the following inclusion criteria:

- Population: patients of any age undergoing surgical intervention for any specialty with PGLA sutures with antibacterial compared to standard sutures.
- Intervention: PGLA sutures plus an antibacterial substance.
- Comparator: PGLA sutures.
- Outcome: Costs for treated case.
- Study design: Cost Minimisation Analysis, Cost effectiveness analysis, Cost utility analysis.

We searched the main electronic databases: EMBASE, Cochrane Library, Medline and Econlit. Search strategies were conducted from 2000 to present date (February/March 2012). We considered studies published in English and Italian languages.

The search terms were combined with the following keywords to search economic evidence: cost analysis, CMA, cost effectiveness, CEA, cost utility, CUA, health care costs, economic evaluation, economic analysis, economic aspect, economic assessment. The search strategy is reported in details in Appendix 3.

In particular, reference lists of all relevant papers were searched and authors of relevant papers and manufactures were contacted regarding any further published or unpublished work.

We considered information from "grey literature" (conference proceedings, websites, ongoing clinical studies, unpublished work, data from national and international registries).

Titles and abstracts of all studies identified from our search were examined by two reviewers independently. Full text of any potentially relevant study was assessed for inclusion by the same two reviewers.

Studies which met the inclusion criteria were selected. If it was unclear from titles and abstracts whether a study should be potentially relevant or not, whole text of the studies was obtained for further information. Disagreements were resolved by discussion. Excluded studies were listed together with reasons for exclusion.

We intended to extract data related to the costs of sutures with and without antibacterial from included studies by two reviewers independently using an ad hoc form (see Appendix 4).

The results of analysis were planned to be graphically presented.





## 5. Results

### 5.1 Effectiveness and Safety Evidence

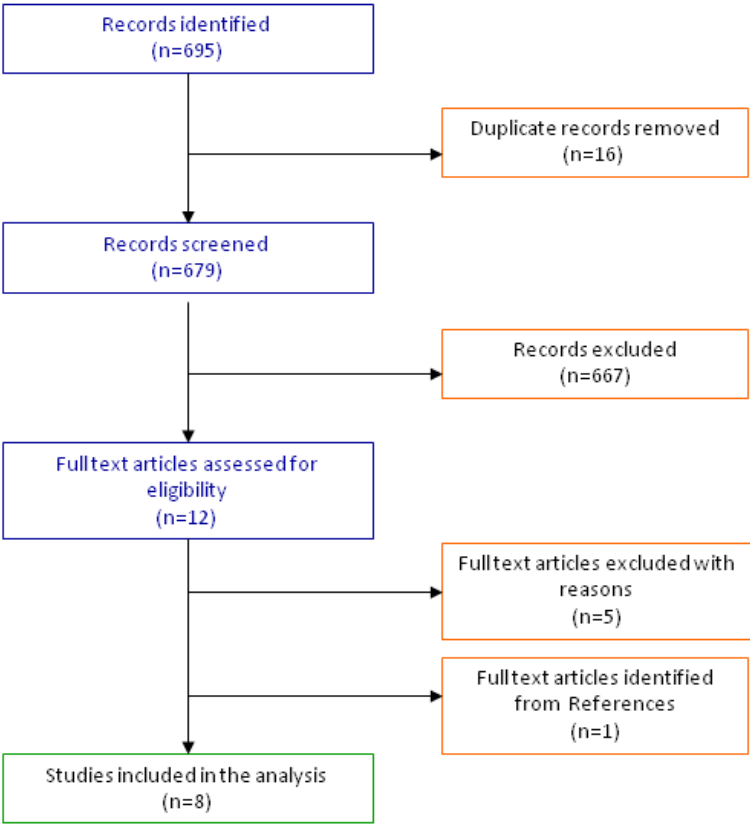
Through electronic searches we identified 695 titles and selected 8 as relevant to our review.

Three authors (CR, EF and EG) immediately excluded 16 records as they were duplicates. Then, from 679 publications by title and abstract, EG and EF selected 15 studies while CR selected 12 studies. The disagreement was solved by TJ. We excluded in total 667 publications as they were not relevant. Twelve relevant publications were retrieved for further assessment of the full text.

After reading the full text of the studies, we included 8 randomized controlled trials. Four studies were excluded for different reasons (See Appendix 5 - Included studies, and Appendix 6 - Excluded studies). Scanning the references lists of several studies included we found one potentially relevant article (*Fleck*); we retrieved the full text of this article for further assessment. From reading of full text it was unclear if this study met our inclusion criteria. The study design was unclear. For this reason we contacted the author who was unable to clarify our doubts. The study was excluded (*See Figure 1*).

We searched the Clinicaltrials.gov website combining the words "suture" and "antimicrobial" on the 10<sup>th</sup> May, 2012. We found 16 trials of which only 11 were pertinent for our review. In particular, 3 trials were in "Recruiting status", 1 trial was in "Not yet recruiting", 1 trial was in "Enrolling by invitation", 1 trial was in "Unknown recruitment status" and 5 trials were "Completed". As regards the Completed trials, 3 trials did not provide publications, 2 trials (Trial Registration number: NCT00768222 and NCT00932503) were published and they were included in our search but we excluded them because did not meet our inclusion criteria (respectively Zhang Z T et al, 2011 and Justinger C et al, 2009). We reported the summary of results in the Appendix 7.

Figure 1: Flow-chart of Effectiveness and safety evidence



**5.1.1. Description of Included Studies**

All 8 included studies were randomized controlled trials, comparing the use of PGLA/Triclosan suture (Polylactic-Glycolic Acid absorbable synthetic suture plus antibacterial) with the use of standard PGLA suture (Polylactic-Glycolic Acid absorbable synthetic suture) for surgical site closure.

**Chen et al. (2011)** performed a prospective randomized control trial, in one centre, from January 2007 to December 2009, with 241 patients enrolled. All patients, divided in two groups by flip of a coin, underwent a simultaneous exploration of the cervical area, either for radical neck lymph-node dissection or a vascular examination for microsurgical anastomoses. The “Triclosan group” (intervention group) contained 112 patients, whose surgical wounds were closed with Triclosan-coated sutures (Vicryl® Plus). The Control group included the remaining 129 patients, whose surgical wounds were closed with standard sutures. There were no statistically significant differences between the groups in sex, age, tumour stage, history of previous head and neck reconstructive surgery, preoperative radiotherapy,

prevalence of diabetes, flap type (free flap or local flap), flap size, or the length of hospital stay. No patients was lost to follow-up or was excluded (post-randomization) from outcomes analyses. After the removal of stitches, the authors assessed the healing of intra-oral wound. Infection of cervical wounds was defined as local erythematous change in the sutured wound with purulent discharge, cervical wound dehiscence, or neck skin necrosis. In the Intervention group, the subcutaneous layer was sutured with 3-0 Triclosan-coated polyglactin 910 sutures (Vicryl<sup>®</sup> Plus, 70 cm); in the Control group, the subcutaneous layer was sutured with 3-0 polyglactin 910 sutures (Vicryl<sup>®</sup>, 70 cm). The skin layer was closed with 5-0 nylon sutures in both groups. All patients were administered prophylactic antibiotics intravenously after the ablation of their head or neck cancer and subsequent reconstruction. The study received governmental funding and the authors declared no conflict of interest.

**Deliaert et al. (2009)** reported the results of a double blind randomized, single centre, pilot study. Patients, who were operated for breast hypertrophy during the second half of 2006, were asked to participate in the study. Twenty-six patients (range 17-65) were included. In this study each patient was their own control. In each patient both breasts were operated on by the same surgeon. PGLA/Triclosan suture was compared with standard PGLA suture. The duration of follow-up was 4 weeks: 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. There was no prophylactic use of antibiotics. Primary outcome was to investigate the effect of TC-coated suture material on wound healing (the dehiscence, 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. Funding and potential conflict of interest were not reported.

In a prospective, randomized, controlled, open-label, comparative, single-centre study **Ford et al. (2005)** allocated a total of 151 paediatric patients (age 1-18 years) in an Active group (n=100), treated with PGLA/Triclosan suture and in a Control group (n=51), treated with PGLA suture. Patients, undergoing various general surgical procedures, were enrolled if scheduled for clean or clean-contaminated surgical procedures. There were no statistically significant differences in demographic characteristics (age, gender, height, and weight), type of surgical procedures or risk factors that could affect wound healing adversely (i.e., chemotherapy, obesity, other medications, etc.) between the two groups of patients. The primary endpoint of this study was to investigate the overall intraoperative handling characteristics of each suture. The secondary endpoints included the wound healing and specific intraoperative suture handling characteristics (ease of passage through tissue; first-throw knot holding; knot tie-down smoothness; knot security; surgical "hand"; memory and degree of fraying). In the assessment of wound healing, the authors reported the SSI at day 1, 14 and 80 too. Two patients from each group withdrew prior to treatment, leaving a total of 147 treated patients. The patient population for the endpoint 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 (Intervention

Group) and 45 patients (Control Group); on day 14 the groups had 91 (Intervention Group) and 44 patients (Control Group); and finally on day 80 the groups comprised 76 (Intervention Group) and 38 patients (Control Group). 65% in the Active group and 82% in the Control group received intravenous antibiotics. The study received industry funding and supporting (Ethicon); besides the authors do not report potential conflict of interest.

**Galal et al. (2011)** performed a prospective, randomized, double-blind, controlled, multicentre study performed in Cairo (this article cites the results of the Cairo University centre only). The objective was to assess the incidence of SSI (defined according to the Centres for Disease Control and Prevention) using Triclosan-coated polyglactin 910 antimicrobial sutures (Vicryl<sup>®</sup> Plus) compared with the conventional polyglactin 910 suture (Vicryl<sup>®</sup>). The study enrolled 450 patients (Active group n=230; Control group n=220) who underwent surgery by the same team of surgeons, in each specialty, and in the same operating room. No patients was lost to follow-up or excluded (post-randomization) from outcome analysis. All patients of different age, sex, and risk factors who were candidates for surgical intervention during the study period were included; however, patients with an established preoperative infection at the surgical site were excluded. The duration of follow-up was over a period of 30 days (or 1 year in case of prosthetic surgery). After surgery, patients were followed up daily during their stay at the hospital by a trained physician and nurse. After discharge, patients were requested to return to the outpatient clinic weekly for 30 days (then monthly until the end of the first year in the case of prosthetic surgery). It's important to notice that investigators followed the local protocol of the infection control unit at their institute, as preoperative preparation procedures to prevent SSI, which may deviate from current modern practices. Data about antibiotic prophylaxis are not reported. Funding and potential conflict of interest were not reported.

A prospective, randomized, controlled, double blind, comparative, single-center study was performed at Department of Surgery, Faculty of Medicine, Thammasat University, Pathumthani, (Thailand) between August 2006 and March 2007, by **Mingmalairak et al (2009)**. A total of 100 adult patients (15-60 years old) undergoing appendectomy were enrolled: Active group (n=50) treated with PGLA/Triclosan suture compared with Control group (n=50) treated with standard PGLA suture. Both sutures were similar in physical properties and used to close the abdominal sheath. The appendectomy was done with standard technique. The primary outcome was to evaluate the efficacy of coated polyglactin 910 with Triclosan (Vicryl<sup>®</sup> Plus) in reducing the SSI appendectomy compared to traditional polyglactin 910 (Vicryl<sup>®</sup>). The secondary goal was to analyze the safety and physical properties of Vicryl<sup>®</sup> Plus. Prophylactic antibiotics were given intravenously 30-60 minutes before surgery. The duration of follow-up was 12 months. No patients was lost to follow-up or was excluded (post-randomization) from outcomes analyses. All patients completed the study. Sample size was calculated. There were no statistically significant differences in demographic characteristics (age, gender, height, weight), preoperative information (pain, temperature, WBC count, etc.) and operative information (type of appendicitis, degree of

microbial contamination) between the two groups of patients. The study received governmental funding and the authors declared no potential conflict of interest.

**Rasic et al. (2011)** in a single centre (University Hospital, Zagreb, Croatia), randomized clinical trial, enrolled a total of 184 adult patients diagnosed with colo-rectal cancer scheduled for elective surgery (with closure of abdominal wall) from September 2008 to September 2009. The Active group (n=91) was treated with PGLA/Triclosan suture and the Control group (n=93) was treated with standard PGLA suture. There was no statistical difference between the two groups in demographic and preoperative data. No data were reported about co-morbidity or tumour stage. The duration of follow-up was restricted to hospital stay (the mean hospitalization period was  $13.2 \pm 1.3$  days in Active group and  $21.4 \pm 2.8$  in the Control group). No patients was lost to follow-up or was excluded (post-randomization) from outcomes analyses. The patients were carefully followed throughout their hospitalization. Prophylactic antibiotics were given intravenously during induction of anaesthesia to all patients. Wound closure was performed with a continuous single-layer mass technique (peritoneum, muscle, and fascia). The running sutures were 1 cm apart and 1.5 cm from the wound edge. Skin was closed with polyamide. The aim of this study was to compare the effect of Triclosan coated polyglactin 910 suture (Vicryl<sup>®</sup> Plus) or polyglactin 910 suture (Vicryl<sup>®</sup>) on abdominal wall healing. Funding and potential conflict of interest were not reported.

**Rozzelle et al. (2008)** reported the results of a single centre, prospective, double-blind, placebo controlled, randomized clinical trial performed at Women and Children's Hospital of Buffalo, between April 2005 and December 2006, to determine whether the antimicrobial suture reduces the risk of subsequent shunt infection. A total of 84 shunt procedures were performed in 61 patients requiring cerebrospinal fluid (CSF) shunt implantation or revision surgery because of hydrocephalus. Forty-six patients in Active group were treated with PGLA/Triclosan suture, and 38 patients in Control group received PGLA suture for closure of the galea and fascia. Shunts were performed in 48 male and 36 female patients, who ranged in age from 1 day to 48 years (median 6.3 years). Shunt procedure types consisted of 40 implants and 44 revisions. The most common type was the Ventriculo-Peritoneal shunt (used in 68 operations, 81%). The duration of follow-up was 6 months. No patients was lost to follow-up or was excluded (post-randomization) from outcomes analyses. There was no statistical difference between the two groups in demographic and preoperative data, i.e., age, gender, prematurity, weight, hydrocephalus origin, shunt type, recent shunt infection, shunt procedure time. All shunt procedures were performed by one of the two attending paediatric neurosurgeons. All participants received preoperative chlorhexidine skin cleansing, betadine<sup>®</sup> skin preparation, preoperative intravenous antibiotics, iodine-impregnated adhesive drapes, and antibiotic wound irrigation prior to closure. Silicone shunt components were soaked in bacitracin solution before implantation. No antibiotic-impregnated shunt components were used in this study. Skin closures for all procedures were performed with poliglecaprone 25 sutures (Monocryl; Ethicon, Inc.). The primary outcome measure was the

incidence of shunt infection within 6 months of cerebrospinal fluid shunt placement surgery. As secondary outcome they considered the Mean Operation Time. This study was designed and conducted with no extramural research funding or commercial relationships. Curtis J. Rozzelle, M.D., has subsequently served on a medical advisory board for Ethicon/ Johnson & Johnson. The other authors have no commercial or current research relationship with Ethicon/Johnson & Johnson.

**Williams et al.(2011)** performed a single-center, double blinded, randomized, clinical trial, from November 2008 to February 2011, at the Department of Surgery and the Department of Wound Healing and Dermatology of the Cardiff and Vale National Health Service (NHS) Trust (single center) – Cardiff (UK). The objective was to compare Triclosan-coated polyglactin 910 and poliglecaprone 25 sutures (Vicryl<sup>®</sup> Plus for subcutaneous suture and Monocryl Plus for subcuticular suture) with polyglactin 910 and poliglecaprone 25 sutures (Vicryl<sup>®</sup> for subcutaneous suture and Monocryl for subcuticular suture). A total of 150 adult women having breast cancer and undergoing primary elective surgery were randomized, using random computer numbers, in two groups: 75 in the Active and 75 in the Control group. None of the parameters of the enrolled patients (age, weight, type of operation) was significantly different. The duration of follow-up was 6 weeks. The patients were evaluated (for wound infections incidence) at 2 and 6 weeks from intervention. Two patients in each group were excluded from wound infections incidence analysis at two weeks; while 7 patients in Active and 12 patients in Control group at 6 weeks. In conclusion nine and fourteen respectively in Active and Control group were excluded from the six weeks wound infections incidence assessment. In both groups, wounds were dressed with Steri-Strips<sup>®</sup> (3M, St. Paul, MN) and Tegaderm<sup>®</sup> (3M) or Cosmopore<sup>®</sup> (Hartmann USA, Rock Hill, SC) or Primapore<sup>®</sup> (Smith and Nephew, Hull, UK), or Cosmopore<sup>®</sup> alone, again at the discretion of the surgeon. Eight patients (five having antimicrobial sutures, three control subjects) received a single intravenous dose of 1g of Augmentin<sup>®</sup> (amoxicillin clavulanate) antibiotic prophylaxis for surgery considered at risk (high body mass index, mastectomy, or axillary clearance). As primary outcome the authors reported the incidence of SSIs (CDC criteria). It's important to notice that Sample size was inappropriate: to show a statistically difference in SSIs incidence at two and six weeks is necessary 2,000 and 400 patients respectively. The study was supported by an investigator-initiated grant from Ethicon: one author (Prof. Leaper DJ) has been a consultant for the Ethicon; the remaining authors declared no conflict of interest. Table 1 reports all included studies focusing on main data presented (methods, participants, interventions, outcomes).

**Table 1 Evidence synthesis**

STUDY	METHODS	PARTICIPANTS	INTERVENTION AND COMPARATOR	OUTCOMES (Primary: SSI Secondary: Cosmetic) and Other outcomes	OTHER INFORMATION/NOTE
<b>Chen et al. (2011)</b>	Single-center, prospective, randomized clinical trial, between January 2007 and December 2009. Follow up: unclear Sample size calculations: no Contemporary group: yes	Diagnosis: wide excision of a head or neck cancer and reconstructive procedures. Participants: 241 (Active: 112; Control: 129). Lost to follow-up: 0 Excluded post-randomization: no Inclusion criteria: patients also underwent a simultaneous exploration of the cervical area, either for radical neck lymph-node dissection or a vascular examination for microsurgical anastomoses. Exclusion criteria: patients who underwent tumour ablation without neck exploration (12 patients excluded prior randomization).	PGLA/Triclosan suture (Vicryl®Plus-Ethicon, J&J SpA)  vs  PGLA suture (Vicryl®-Ethicon, J&J SpA)	<u>Primary</u> Active: 17/112 (14.9%); Control: 19/129 (14.7%) Total: 36/241 (14.9%) <u>Secondary</u> : nr  <u>Other outcomes</u> - Wound healing: considered as an independent risk factor for cervical wound infection	- No use prophylactic antibiotic. - Specific characteristics of surgical wounds: the wounds created by head and neck cancer surgery are at high risk of contamination compared with other surgical wounds because they are potentially contaminated by the normal flora of the oral cavity. - Tumour stage and delayed intra-oral wound healing were independent risk factors for wound infection after head and neck reconstruction. - None conflict of interest
<b>Deliaert et al. (2007)</b>	Double blind randomized pilot study. Follow-up: 4 weeks Intention to treat: yes Sample size calculation: no Contemporary group: yes	Diagnosis: bilateral hypertrophy undergoing breast reduction. Each patient was her own control. Participants: 26 (Active: 26; Control:26)(16 and 65 years of age). Lost to follow up: 0 Exclusion after randomization: 0 Inclusion: women with bilateral breast size higher than cup DD and clinical complaints such as intertrigo, head neck and/or shoulder complaints. Exclusion: diabetes, skin diseases, history of keloid formation, use of corticosteroids and other immunosuppressive medication, metabolic and/or degenerative diseases.	PGLA/Triclosan suture (Vicryl®Plus-Ethicon, J&J SpA)  vs  PGLA suture (Vicryl®-Ethicon, J&J SpA)	<u>Primary</u> : nr <u>Secondary</u> : nr  <u>Other outcomes</u> - Wound healing (considering the incidence of wound dehiscence): Active Group: 16/26 have had dehiscence; Control Group: 7/26 have had dehiscence.	- No use prophylactic antibiotic

STUDY	METHODS	PARTICIPANTS	INTERVENTION AND COMPARATOR	OUTCOMES (Primary: SSI Secondary: Cosmetic) and Other outcomes	OTHER INFORMATION/NOTE
<b>Ford et al. (2005)</b>	Single-center randomized, open-label, clinical trial. Follow up: day 1, 14 and 80 Sample size calculations: no Contemporary group: yes	Diagnosis: various general surgical procedures for paediatric patients. Participants: 151 (Active:100; Control:51) (age 1-18 years).  Lost to follow up or voluntary withdrew their participation: Active: 9;Control: 7 (day 14)  Inclusion: scheduled for clean or clean-contaminated surgical procedures. Exclusion: contaminated wound sites; use of retention sutures; inappropriate age; evidence of malnutrition or debilitation; coexisting conditions that may impair wound healing including 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.	PGLA/Triclosan suture (Vicryl®Plus-Ethicon, J&J SpA)  vs  PGLA suture (Vicryl®-Ethicon, J&J SpA)	<u>Primary:</u> (related to wound healing) 1 day: 0/88 Active, 0/45 Control; 14 days: 2/91 Active, 0/44 Control; 80 days: 1/76 Active, 0/38 Control.  <u>Secondary:</u> nr  <u>Other outcomes</u> - Overall assessment intraoperative handling of each suture measurable through a five point scale reported. - Wound healing and specific intraoperative suture healing characteristics assessed through the following parameters: Apposition, Infection, Skin temp., Seroma, Suture sinus, Edema, Erythema, Antibiotics, Other meds, Pain.	The most common events consisted of admission for chemotherapy.
<b>Galal et al. (2011)</b>	Multicenter, randomized, double-blind, clinical trial. Follow up: 30 days or 1 year in case of prosthetic surgery Intention to treat: yes Sample size calculation: no Contemporary group: yes Exclusion post-randomization:0	Diagnosis: various general surgical procedures. Participants: 450 (Active:230; Control:220) (age: 21-60). Lost to follow-up: 0 Inclusion: nr Exclusion: nr	PGLA/Triclosan suture (Vicryl®Plus-Ethicon, J&J SpA)  vs  PGLA suture (Vicryl®-Ethicon, J&J SpA)	<u>Primary:</u> Active: 17/230 (7%); Control: 33/220 (15%).  Total: 50/450 (11%)  <u>Secondary:</u> nr	



STUDY	METHODS	PARTICIPANTS	INTERVENTION AND COMPARATOR	OUTCOMES (Primary: SSI Secondary: Cosmetic) and Other outcomes	OTHER INFORMATION/NOTE
Mingmalairak et al. (2009)	<p>Single-center randomized double blind, clinical trial between August 2006 and March 2007.</p> <p>Follow up: up to 12 months</p> <p>Sample size calculation: yes</p> <p>Intention to treat: yes</p> <p>Contemporary group: yes</p>	<p>Diagnosis: appendectomy.</p> <p>Participants: 100 (Active:50; Control:50) (age 15-60).</p> <p>Lost to follow-up:0</p> <p>Exclusion post-randomization:0</p> <p>Inclusion: both sexes, appendicitis was diagnosed by intra-operative who operated with right lower quadrant incision and included both acute and ruptured appendix.</p> <p>Exclusion: patient with diabetes, immunocompromised host, HIV, on immunosuppressive drug, malignancy, missed diagnosis intra-operative, history of allergy to this substance, or pregnancy.</p>	<p>PGLA/Triclosan suture (Vicryl®Plus-Ethicon, J&amp;J SpA)</p> <p>vs</p> <p>PGLA suture (Vicryl®-Ethicon, J&amp;J SpA)</p>	<p><u>Primary</u></p> <p>Active: 5/50 (10%); Control: 4/50 (8%).</p> <p>Total: 9/100 (9%)</p> <p><u>Secondary:</u> nr</p> <hr/> <p><u>Other outcomes:</u></p> <p>- to analyze the safety and physical properties of Vicryl Plus through the following indicators:</p> <p>Mean operation time: same for both groups (min)</p> <p>Pre-op time: A=275; C=305</p> <p>Op time: A=41; C=45</p> <p>Handling suture: no differences</p> <p>Clinical data: Pain; Anorexia; Nausea vomiting.</p>	<p><u>Other information</u></p> <p>- Prophylactic use of antibiotics was performed</p> <p>Adverse events, allergy and complications: not recorded linked to suture.</p>

STUDY	METHODS	PARTICIPANTS	INTERVENTION AND COMPARATOR	OUTCOMES (Primary: SSI Secondary: Cosmetic) and Other outcomes	OTHER INFORMATION/NOTE
<b>Rasic et al. (2011)</b>	<p>Single center randomized clinical trial</p> <p>Follow-up: restricted to hospital stay (the mean hospitalization period was 13.2±1.3 days in the Vicryl®Plus (Active) group and 21.4±2.8 in the Vicryl® (control) group.</p> <p>Intention to treat: yes</p> <p>Sample size calculation: no</p> <p>Contemporary group: yes</p>	<p>Diagnosis: colo-rectal cancer scheduled for elective surgery (with closure of abdominal wall).</p> <p>Participants: 184 (Active:91; Control:93).</p> <p>Lost to follow-up: 0</p> <p>Exclusion post-randomization: 0</p> <p>Inclusion: colo-rectal, cancer scheduled for elective surgery (with closure of abdominal wall)</p> <p>Exclusion: nr</p>	<p>PGLA/Triclosan suture (Vicryl®Plus-Ethicon, J&amp;J SpA)</p> <p>vs</p> <p>PGLA suture (Vicryl®-Ethicon, J&amp;J SpA)</p>	<p><u>Primary</u></p> <p>Active: 4/91 (4.3%)</p> <p>Control: 12/93 (13.2%)</p> <p><u>Secondary: nr</u></p> <p><u>Other outcomes</u></p> <p>Mean operation time is: A=95.5±17.3; C= 91.3±18.6.</p> <p>Inflammatory biochemical parameters.</p> <p>Wound complications:</p> <ul style="list-style-type: none"> <li>- Inflammatory reactions to skin sutures: Active= 7.5%; Control=17.5%.</li> <li>- Dehiscence: Active=1.1%; Control=7.7%.</li> <li>- Re-operations: Active=1.1%; Control=8.8%.</li> <li>- Incisional hernia: Active=2.2%; Control=5.5%.</li> </ul>	

STUDY	METHODS	PARTICIPANTS	INTERVENTION AND COMPARATOR	OUTCOMES (Primary: SSI Secondary: Cosmetic) and Other outcomes	OTHER INFORMATION/NOTE
<b>Rozzelle et al. (2008)</b>	Single center, double-blind, placebo controlled, randomized clinical trial, between April 2005 and December 2006. Follow-up: 6 months Intention to treat: yes Sample size calculation: no Contemporary group: yes	Diagnosis: CSF shunt implantation or revision surgery because of hydrocephalus. Participants: 61 (Active: 46; Control:38) underwent 84 shunt procedures. Lost to follow-up: 0 Exclusion post-randomization: 0 Inclusion: patients (paediatric) of all ages requiring CSF shunt implantation or surgery. Exclusion: patients receiving ventricular access devices or ventriculo-subgaleal shunts, patients with active shunt infections, immunocompromised patients.	PGLA/Triclosan suture (Vicryl®Plus-Ethicon, J&J SpA)  vs  PGLA suture (Vicryl®-Ethicon, J&J SpA)	<u>Primary</u> Total: 10 patients Active: 2/46; Control: 8/38.  <u>Secondary: nr</u>  <u>Other outcomes</u> Mean Operation time: A= 71.7±22.9; C=68.3±23.1	No Adverse event recorded.

STUDY	METHODS	PARTICIPANTS	INTERVENTION AND COMPARATOR	OUTCOMES (Primary: SSI Secondary: Cosmetic) and Other outcomes	OTHER INFORMATION/NOTE
<b>Williams et al. (2011)</b>	<p>Single-center, double blinded, randomized, clinical trial, from November 2008 to February 2011.</p> <p>Follow-up: 2 weeks and 6 months</p> <p>Intention to treat: no</p> <p>Sample size calculation: yes</p> <p>Contemporary groups: yes</p>	<p>Diagnosis: breast cancer.</p> <p>Participants: 150 (Active:75; Control:75)(older than 18 years).</p> <p>Withdrawal:</p> <p>1) Loss to follow-up: - two weeks: Active= 0; Control=1. - six weeks: Active=1; Control=2.</p> <p>2) Patient request: -two weeks: Active= 1; Control=1. - six weeks: Active=1; Control=0.</p> <p>3) Need for further surgery: -two weeks: Active= 1; Control=0. - six weeks: Active=5; Control=10.</p> <p>Exclusion post-randomization: 0</p> <p>Inclusion: women having breast cancer and undergoing primary elective surgery under the care of two breast surgeons.</p> <p>Exclusion: inflammatory breast cancer or skin ulceration; neo-adjuvant chemotherapy or radiotherapy; surgery for benign or reconstructive reasons; known immune deficiency or allergy to Triclosan; inability to give consent or suspicion that the patient was unlikely to comply with follow-up.</p>	<p>PGLA/Triclosan suture (Vicryl®Plus) + Monocryl® Plus Ethicon, J&amp;J SpA</p> <p>vs</p> <p>PGLA suture (Vicryl®) + Monocryl® Plus (Ethicon, J&amp;J SpA)</p>	<p><u>Primary:</u></p> <p>Two weeks – Overall: 13.7% Active: 9/73 (12.3%) Control: 11/73 (15.1%)</p> <p>Six weeks – Overall: 18.9% Active: 10/66 (15.2%) Control: 14/61 (22.9%)</p> <p><u>Secondary:</u> nr</p>	- Some patients received antibiotic therapy.

*nr: not reported*

## 5.1.2. Risk of Bias and Methodological Quality

### Risk of Bias

#### *Random sequence generation (selection bias)*

Most of the included studies used low risk of bias methods of sequence generation. Computerised random number generators or random number tables were used in five studies (*Ford 2005, Galal 2011, Mingmalairak 2009, Rasic 2011, Williams 2011a*), one study (*Chen 2011*) used flip of a coin and in one study (*Rozzelle 2008*) randomization was performed by the assignment of letter codes to study and placebo suture types (in addition, a sort of "minimization" was done to avoid uneven distribution of implant versus revision procedures). In Deliaert 2009 there was insufficient information about the sequence generation process to permit judgement of low or high risk of bias.

#### *Allocation concealment (selection bias)*

Most of the trials were judged with an unclear risk of bias method of allocation concealment: Deliaert 2009; Ford 2005; Galal 2011; Mingmalairak 2009; Rozzelle 2008; Williams 2011. Only one study (*Rasic 2011*) reported a low risk of bias method of allocation concealment (sealed, numbered and assigned in order opaque envelopes containing suture packets). High risk of bias was found in Chen 2011 where the flip of a coin was used; although this method is considered an adequate method of a random sequence generator it makes impossible to perform a subsequent low risk of selection bias method for allocation concealment.

#### *Blinding of patients and/or investigators (performance bias)*

In five studies (*Deliaert 2009, Galal 2011, Mingmalairak 2009, Rozzelle 2008, Williams 2011*) there was a low risk of bias method for the blinding of patients and investigators. Chen 2011 and Rasic 2011 reported insufficient information to allow the appraisal of risk of bias. Ford 2005 was at high risk of performance bias because the authors reported it as an open label trial.

#### *Blinding of outcome assessors (detection bias)*

Most of the trials were with an unclear risk of bias for blinding of outcome assessors: Chen 2011; Deliaert 2009; Ford 2005; Mingmalairak 2009; Rasic 2011; Rozzelle 2008. In only two studies (*Galal 2011; Williams 2011*) outcome assessors were blinded.

### *Incomplete outcome data (attrition bias)*

Most of the included studies were at low risk of attrition bias (*Chen 2011; Deliaert 2009; Galal 2011; Rasic 2011; Mingmalairak 2009; Rozzelle 2008*). The remaining two studies were deemed at high risk of bias: in Ford 2005 there were voluntary withdrawals and the proportion of missing outcomes compared with observed event risk is enough to induce clinically relevant bias in intervention effect estimate; in Williams 2011 four patients were excluded from a two-week assessment of Surgical Site Infection (SSI) incidence and further 19 patients from a six-week assessment.

### *Selective reporting (reporting bias)*

Studies were at unclear risk of reporting bias, due to insufficient information to permit a judgement, with the exception of Deliaert 2009 that was deemed at high risk because not all of the study's pre-specified primary outcomes have been reported and Galal 2011 judged at low risk of selective reporting bias: the protocol is available and all study pre-specified outcomes that are of interest in the review have been reported in the pre-specified way.

### *Other potential sources of bias*

Two studies appear to be free of other sources of bias (*Chen 2011 and Mingmalairak 2009*). Four studies (*Deliaert 2009, Galal 2011, Rasic 2011, Rozzelle 2008*) having insufficient information to assess whether an important risk of bias exists, were judged as unclear. The remaining studies were at high risk: Ford 2005 and Williams 2011 received industry funding and/or supporting (ETHICON).

### *Summary of Risk of Bias*

We present the assessment of risk of bias using two figures: a Risk of Bias graph (Figure 2) that illustrates the proportion of studies with each of the judgments for each entry in the tool; a Risk of Bias Summary figure (Figure 3), which presents all of the judgements in a cross-tabulation of study by entry.

Figure 2: Risk of Bias graph: review authors' judgments about each risk of bias item presented as percentages across all included studies

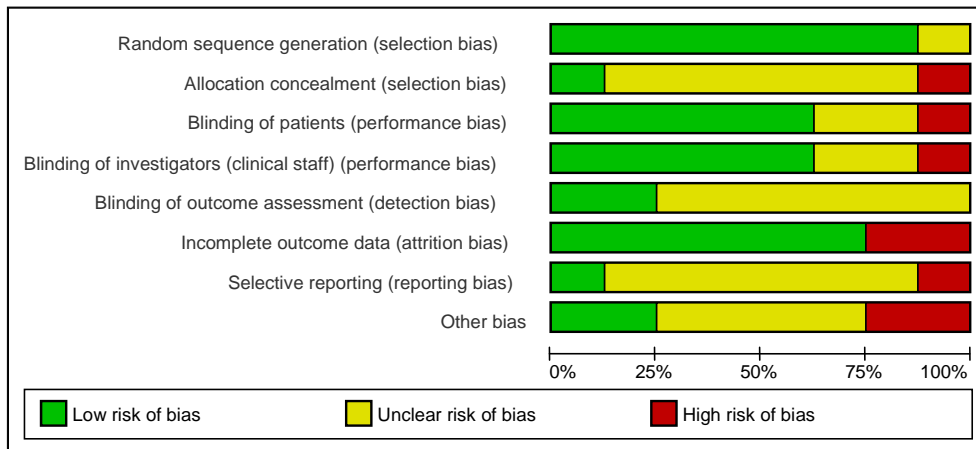


Figure 3: Risk of bias summary: review authors' judgments about each risk of bias item for each included study

Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of patients (performance bias)	Blinding of investigators (clinical staff) (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Chen 2011	+	-	?	?	?	+	?	+
Dellaert 2009	?	?	+	+	?	+	-	?
Ford 2005	+	?	-	-	?	-	?	-
Galal 2011	+	?	+	+	+	+	+	?
Mingmalairak 2009	+	?	+	+	?	+	?	+
Rasic 2011	+	+	?	?	?	+	?	?
Rozzelle 2008	+	?	+	+	?	+	?	?
Williams 2011	+	?	+	+	+	-	?	-

### Methodological Quality

We reported in the following "Quality of Evidence tables", for each outcome of interest for this review, the results of quality assessment according to GRADE criteria.

### *Outcome: Surgical Site Infections (SSIs) incidence*

For the outcome Surgical Site Infections incidence no study result was assessed of high quality and only two (*Chen 2011; Galal 2011*) were judged of moderate quality (See Table 2).

### *Other Outcomes including harms*

#### **Dehiscence incidence**

Only two studies (*Deliaert 2007; Rasic 2011*) reported Dehiscence incidence. Evidence in both studies was judged to be of low quality (See Table 3).

#### **Incisional hernia incidence**

Only one study (*Rasic 2011*) reported Incisional hernia incidence; study result was assessed of low quality (See Table 4).

#### **Time to closure or Mean Operation Time**

Three studies (*Mingmalairak 2009; Rasic 2011; Rozzelle 2008*) reported Time to closure. Evidence in these studies was judged to be of low or very low quality (See Table 5).



Table 2: Quality of evidence – Outcome: Surgical site Infections (SSIs) incidence

**Population:** Patients of any age undergoing surgical intervention for any specialty  
**Intervention:** Polylactic-glycolic acid absorbable synthetic suture (PGLA) plus antibacterial  
**Comparators:** Polylactic-glycolic acid absorbable synthetic suture (PGLA)  
**Outcome:** Surgical Site Infections (SSIs) incidence

Ref.	No. of patients	Study design	Risk of bias	Indirectness	Inconsistency	Imprecision	Outcome measure : intervention vs comparator	Quality of evidence
Chen 2011	241	RCT	Serious	No	No	No	Rate 17/112 VS 19/129 P= 1.00 (two weeks)	Moderate
Ford 2005	151	RCT	Very Serious	No		Serious	Rate 2/91 VS 0/44 (day 14) 0/88 VS 0/45 (day 1) 1/76 VS 0/38 (day 80)	Very low
Galal 2011	450	RCT	Serious	No		No	Rate 17/230 VS 33/220 P=0.011 (day 30)	Moderate
Mingmalairak 2009	100	RCT	Serious	No		Serious	Rate 5/50 VS 4/50 (p= 0.727) (day 30)	Low
Rasic 2011	184	RCT	Serious	No		Serious	Rate 4/91 VS 12/93 (p<0.05) (hospitalization period)	Low
Rozzelle 2008	84 shunt procedures in 61 patients	RCT	Serious	Serious		Serious	Rate 2/46 VS 8/38 ; p=0.038 (6 months)	Very Low
Williams 2011	150	RCT	Serious	No		Serious	Rate 9/73 VS 11/73 (two weeks) 10/66 VS 14/61 (six weeks)	Low

Table 3. Quality of Evidence - Outcome: Dehiscence incidence

**Population:** Patients of any age undergoing surgical intervention for any specialty  
**Intervention:** Polylactic-glycolic acid absorbable synthetic suture (PGLA) plus antibacterial  
**Comparators:** Polylactic-glycolic acid absorbable synthetic suture (PGLA)  
**Other Outcome:** Dehiscence incidence

REF.	NO. OF PATIENTS	STUDY DESIGN	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	IMPRECISION	OUTCOME MEASURE (INTERVENTION VS COMPARATOR)	QUALITY OF EVIDENCE
Deliaert 2007	26	RCT	Serious	No	No	Serious	Rate 16/26 VS 7/26 (P=0.023) (three weeks)	Low
Rasic 2011	184	RCT	Serious	No		Serious	Rate 1/91 VS 7/93 P: 0.027 (hospitalization period)	Low

Table 4: Quality of Evidence; Outcome: Incisional hernia incidence.

**Population:** Patients of any age undergoing surgical intervention for any specialty  
**Intervention:** Polylactic-glycolic acid absorbable synthetic suture (PGLA) plus antibacterial  
**Comparators:** Polylactic-glycolic acid absorbable synthetic suture (PGLA)  
**Other Outcomes:** Incisional hernia incidence

REF.	NO. OF PATIENTS	STUDY DESIGN	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	IMPRECISION	OUTCOME MEASURE (INTERVENTION VS COMPARATOR)	QUALITY OF EVIDENCE
Rasic 2011	184	RCT	Serious	No	Not applicable	Serious	2/91 VS 5/93 P: 0.235 (hospitalization period)	Low

Table 5: Quality of Evidence - Outcome: Time to closure (mean difference)

**Population:** Patients of any age undergoing surgical intervention for any specialty  
**Intervention:** Polylactic-glycolic acid absorbable synthetic suture (PGLA) plus antibacterial  
**Comparators:** Polylactic-glycolic acid absorbable synthetic suture (PGLA)  
**Other Outcomes:** Time to closure (in min)[mean diff.]

REF.	NO. OF PATIENTS	STUDY DESIGN	RISK OF BIAS	INDIRECTNESS	INCONSISTENCY	IMPRECISION	OUTCOME MEASURE (INTERVENTION VS COMPARATOR)	QUALITY OF EVIDENCE
Mingmalairak 2009	100	RCT	Serious	No	Not applicable	Serious	41 VS 45 P:0.356	Low
Rasic 2011	184	RCT	Serious	No		Serious	95.5 +17.3 VS 91.3 + 15.3 P: 0.8933	Low
Rozzelle 2008	84 shunt procedures in 61 patients	RCT	Serious	Serious		Serious	71.7 + 22.9 VS 68.3 + 23.1 P: 0.495	Very Low

### 5.1.3. Efficacy Results

The eight included studies were randomized controlled trials testing efficacy of PGLA/Triclosan (Vicryl® Plus) sutures compared with PGLA suture (Vicryl®). The trials reported different outcomes in different periods of follow up. The heterogeneity of data did not allow us to perform a meta-analysis.

#### *Primary outcome: Surgical Wound infection*

**Chen et al. (2011)**, compared PGLA/Triclosan sutures vs standard PGLA sutures in head and neck surgery. The primary outcome was measured after 2 weeks post-surgical intervention: in the Active group, in 17 out of 112 patients that received the PGLA sutures with Triclosan were observed infections; in the Control group, 19 patients out of 129 have had infections in cervical wounds. There was prophylactic use of antibiotics. The authors concluded that PGLA sutures with Triclosan did not reduce the infection rate of cervical wounds after head or neck cancer surgery.

**Ford et al. (2005)** performed a comparison of PGLA/Triclosan sutures vs standard PGLA sutures in pediatric patients underwent different surgical procedures. The authors assessed wound healing and specific intraoperative suture handling characteristics, as secondary outcome. The authors measured the wound healing through several parameters, among them they reported the incidence of SSIs. The infection rates were observed at day 1 (0 cases both in Active than in Control group); at day 14 (2/91 patients in Active group, 0 cases in Control group); at day 80 (1/76 patients in Active group, 0 cases in Control group). At day 14, patients of Control group (Vicryl® suture) had a not statistically significant lower incidence (0/44) compared with Intervention Group (Vicryl® Plus suture) (2/91). The study specified that the infections were judged not to be related to the suture.

In the **Galal et al. (2011)** study, 450 patients randomly divided in Active group n=230 and Control group n=220, underwent various general surgical procedures by the same team of surgeons in each specialty in the same operating room. The study compares PGLA/Triclosan suture with standard PGLA suture and Poliglecaprone 25 was used in skin closure. The primary outcome was the overall incidence of SSI, defined as a surgical site infection within 30 days of surgery (or within a year in case of prosthetic surgery) according to the Centers for Disease Control and Prevention criteria. The follow up was 1 month for the different surgical procedure analyzed and 1 year in case of prosthetic surgery. The authors concluded that PGLA/Triclosan suture (Vicryl® Plus) leads to a statistically significant decrease in the incidence of SSI: patients using Vicryl® Plus suture had a statistically significant lower incidence (rate: 17/230) compared with Vicryl® suture (rate: 33/220).

**Mingmalairak et al. (2009)** analyzed the data from 100 patients undergoing appendectomy: 50 patients in the Active group treated with PGLA/Triclosan suture and 50 patients in the Control group treated with PGLA suture not containing Triclosan antibacterial. Primary outcome was the incidence of SSIs evaluated with a follow up of 30 days, 6 months and 1 year. The results showed that patients using Vicryl Plus suture (5/50) had a not statistically significant higher incidence compared with Vicryl suture (4/50) ( $p= 0.727$ ).

**Rasic et al. (2011)** studied the effect of Triclosan coated polyglactin 910 (Vicryl<sup>®</sup> Plus) or polyglactin 910 (Vicryl<sup>®</sup>) on abdominal wall healing in patients with colorectal carcinoma being operated on electively. A total of 184 adult patients were enrolled, divided in Active group ( $n=91$ ) and Control group ( $n=93$ ). Primary outcome was the incidence of SSI during hospital stay. In the Active group they have 4/91 infections, while 12/93 infections occurred in Control group. Patients using coated Vicryl<sup>®</sup> Plus had a statistically significant lower incidence of wound infection compared with patients treated with Vicryl<sup>®</sup> suture ( $p=0.035$ ).

**Rozzelle et al. (2008)** studied 84 shunts procedures in 61 patients requiring cerebrospinal fluid (CSF) shunt implantation or revision surgery because of hydrocephalus. The PGLA/Triclosan (Vicryl<sup>®</sup> Plus) suture was compared with PGLA suture not containing Triclosan (Vicryl<sup>®</sup>) for closure of the galea and fascia. Primary outcome of the study was the incidence of shunt infections within 6 months: in the Active group, 2/46 patients were infected; in the Control group, 8/38 patients recorded infections ( $p=0.038$ ). The authors concluded that shunt infections incidence within 6 months is statistically significant lower in patients using coated Vicryl<sup>®</sup> Plus suture compared with Vicryl<sup>®</sup> suture. Results support the suggestion that the use of antimicrobial suture for wound closure in CSF shunting surgery is effective and may be associated with a reduced risk of postoperative shunt infection. The authors conclude that a larger randomized controlled trial is needed to confirm this association.

**Williams et al. (2011)** reported the results of a comparison between Triclosan-coated sutures (Vicryl<sup>®</sup> Plus for subcutaneous suture and Monocryl<sup>®</sup> Plus for subcuticular suture) with standard sutures (Vicryl<sup>®</sup> for subcutaneous suture and Monocryl<sup>®</sup> for subcuticular suture) in primary elective surgery for breast cancer. A total of 150 adult women were randomized in two groups: 75 in the Active and 75 in the Control group. The primary outcome of this study was the SSIs (CDC criteria) incidence at two and six weeks. In the Active group (Vicryl<sup>®</sup> Plus + Monocryl<sup>®</sup> Plus group), at two weeks, the study reported 9 cases of infections among the 73 patients involved; in the Control group (Vicryl<sup>®</sup> + Monocryl<sup>®</sup>) 11 out of 73 patients involved reported infections. The follow up at six weeks showed 10 cases of infection on a total of 66 patients of the Active group and 14 cases of infections on a total of 61 patients of the Control group. Wound infections incidence at two

weeks and at six weeks showed a no statistically significant reduction in the antimicrobial coated sutures compared with conventional sutures. Authors state that antimicrobial sutures may become part of a surgical site infection prevention bundle but further evaluation will need a larger cohort to show a statistically significant difference for skin closure after breast cancer surgery.

#### *Secondary outcome: Cosmetic outcomes*

None of the included studies reported data about our secondary outcome.

#### *Other outcomes including harms*

##### *Wound healing*

**Chen et al. (2011)** concluded that delayed intra-oral wound healing was an independent risk factor for cervical wound infection because they observed that the delayed healing of the intra-oral flap leads to bacterial translocation from oral cavity to the neck area.

In the **Deliaert et al. (2007)** study, 26 women with bilateral hypertrophy underwent breast reduction. All women were their own control. Patients were randomly allocated to be treated with the Triclosan-coated (TC) suture on the left or right side. The outcome was the wound healing considering the incidence of wound dehiscence (defined as a spontaneous disruption of the wound with or without infection occurring during 3 weeks postoperatively). In the breast group treated with Triclosan-coated suture, 16 on a total of 26 breasts have had dehiscence; in the breast group treated with polylactic-glycolic acid absorbable synthetic suture, 7 have had dehiscence on a total of 26. Of all patients there was bilateral dehiscence in 5 cases. This pilot study shows that there is no evidence for any effectiveness of TC suture. Even more, TC suture seems to have adverse effects on wound healing. Results suggest that Triclosan-coated sutures should be used with caution.

The **Rasic et al. (2011)** study reported results on dehiscence incidence in patients electively operated for colorectal carcinoma. In the 91 patients treated with Vicryl® Plus, 1 case of dehiscence (1.1%) occurred, while among the 93 patients treated with Vicryl® 7 cases of dehiscence (7.7%) were reported, showing that there is a statistically significant lower incidence ( $p=0.027$ ) of dehiscence in active group. The authors concluded that PGLA/Triclosan presents an opportunity to improve the postoperative wound healing process.

##### *Mean Operation time or Time to closure*

In the study of **Mingmalairak et al. (2009)**, the mean operating time or the time to closure the surgical wound, after appendectomy was considered as an indicator of the physical properties of Vicryl® Plus suture. The time to closure was 41 minutes in the active

group (n=50), treated with Polyglactin 910 Suture Coated with Triclosan (Vicryl® Plus) and 45 minutes in the control group (n=50) treated with Polyglactin 910 (Vicryl®), showing no statistical differences (p=0.356).

In the study of **Rasic et al. (2011)**, as regards the mean operation time or time to closure, defined as time from incision to wound closure, there was no statically significant difference between group treated with Vicryl® Plus suture (95.5±17.3 minutes) compared with group treated with Vicryl® suture (91.3±15.3) (p=0.8933).

**Rozzelle et al. (2008)** reported results of the Mean shunt procedure time (in minutes): patients using coated Vicryl® Plus suture had a not statistically significant higher mean time (71.7±22.9) compared with Vicryl® suture (68.3±23.1) (p=0.495).

#### *Safety Results reported in the studies*

##### *Adverse Events*

The analysis of the included studies shows that the polyactic-glycolic acid absorbable synthetic suture Plus antibacterial is generally safe. Few studies reported adverse events. No life-threatening events were reported.

The studies of Chen, Galal, Williams didn't mention somewhat relating to adverse events.

**Deliaert et al. (2007)** reported that in their pilot study there is no evidence for any effectiveness of TC suture: in their surgical operation for the breast reduction, each patient is her own control. There was a statistically higher incidence of wound dehiscence in breasts treated with suture material Plus antibacterial than in breast treated with standard suture, so the authors concluded that "... TC coating seems to have adverse effects on wound healing."

**Ford et al. (2005)** reported a 17% of adverse events occurring in their pediatric patients treated with coated polyglactin 910 sutures with Triclosan and a 20% of adverse events occurring in their pediatric patients treated with traditional coated polyglactin 910 sutures. This difference was not statistically significant. The authors stated that none of the adverse events (not described) were device-related. The most common events consisted of admission for chemotherapy.

**Mingmalairak et al. (2009)** reported as secondary goal the safety (and physical properties) of Vicryl® Plus. After follow-up of 1 year, the authors found no allergy or adverse effects, indicating that it is safe to be used in patients.

**Rasic et al. (2011)** reported significantly less postoperative inflammatory reactions to the skin sutures in the Vicryl® Plus group (7.5%), compared with the Vicryl® group (17.5%),

significantly less SSIs (4.3% in the Vicryl<sup>®</sup> Plus group compared with 13.2% in the standard Vicryl<sup>®</sup> group); with less dehiscence events (4.3% Vicryl<sup>®</sup> Plus patients compared with 13.2% in Vicryl<sup>®</sup> group). In 8.8% of the Vicryl<sup>®</sup> group patients, re-operation was necessary (in 7 patients because of wound dehiscence and in one patient because of peritonitis) whereas only 1% needed re-operation in the Vicryl<sup>®</sup> Plus group (wound dehiscence). These differences in complication rates between groups were statistically significant ( $p < 0.05$ ). The difference between incisional hernia incidence was not statistically significant (5.5% in Vicryl<sup>®</sup> group compared with 2.2% in Vicryl<sup>®</sup> Plus group;  $p = 0.235$ ).

**Rozzelle et al. (2008)** evaluated the incidence of CSF shunt infection following shunt procedures performed using either antimicrobial suture or conventional suture, with a 6-months surveillance period. No suture-related adverse events were reported in either group.

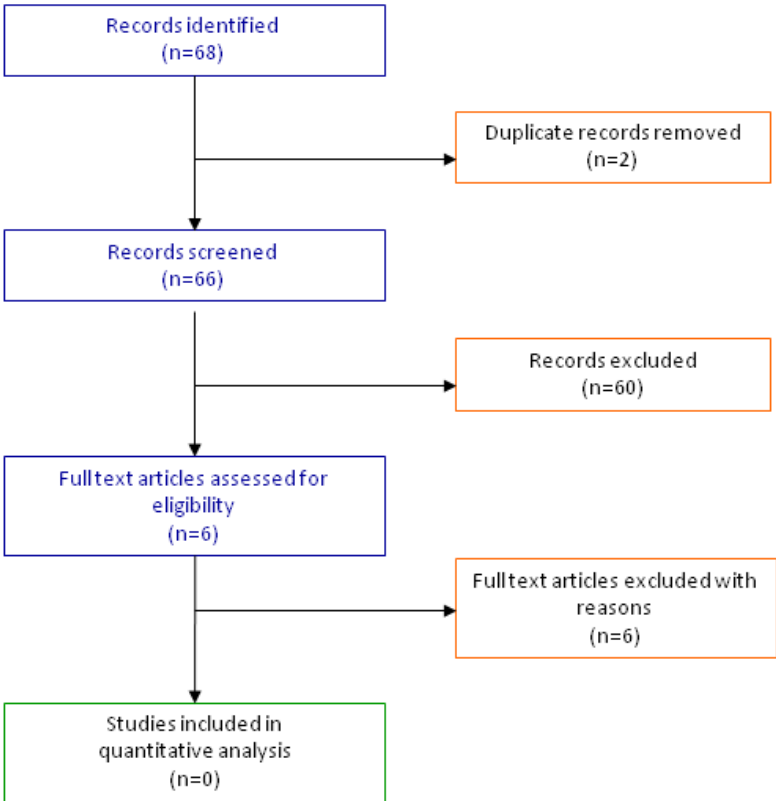


## 5.2 Economic Evidence

The search identified 68 titles. We excluded 2 duplicate studies. From the remaining 66 studies, after reading the title and abstract, we excluded 60 studies. After reading the full text of these 6 eligible studies we excluded all studied for different reasons (See Figure 4).

References of the studies retrieved for full text analysis but subsequently excluded, along with the reason of exclusion, are listed in the Appendix 8.

Figure 4: Flow-chart of Economic evidence



We found no studies reporting economic evidence fulfilling our inclusion criteria.

## 6. Conclusion and discussion

Eight randomized controlled trials, comparing sutures with antibacterial (PGLA/Triclosan) to standard sutures (PGLA), were identified and included in this systematic review.

We identified primary and secondary outcomes, respectively wound infection and cosmetic outcomes assessable by mean outcome measures. However, a rigid distinction between efficacy and safety outcomes is very difficult as the two perspectives are complementary. If a wound opens up again post intervention, this failure could be due to infection, poor surgical technique or poor conditions of the patients. These can be interpreted as harms but all impact on the outcome "suture failure" which is an effectiveness outcome. Instead of trying to artificially classify such mixed outcomes in categories we reported them separately.

Seven out of 8 studies included reported information on the efficacy results of primary outcome.

The total number of patients enrolled in the studies ranged from 730 in the Active group to 682 in the Control group.

In particular, two studies (*Galal et al. 2011, Rasic et al. 2011*) concluded that the incidence of surgical wound infection is statistically significant lower in patients treated with PGLA/Triclosan sutures compared to PGLA sutures standard. The same result was reported in other two studies (*Rozzelle et al. 2008, Williams et al. 2011*), but in one of them the result is associated with a reduced risk of postoperative infection and in the other one the use of PGLA/Triclosan sutures was part of a surgical site infection prevention bundle (*Williams et al. 2011*). In addition both studies highlighted the need for a larger randomized controlled trial to confirm these results. Three studies reported PGLA/Triclosan sutures as non-effective (*Chen et al. 2011, Ford et al. 2005, Mingmalairak et al. 2009*). The incidence rate of surgical wound infections is not significantly lower compared to PGLA standard sutures. Besides, it is important to note that, excepting to two studies (*Galal et al. 2011, Williams et al. 2011*), the other included studies resulted at "Unclear risk of bias" and at "High risk of bias" concerning to the "Blinding of outcome assessment". No studies reported information on cosmetic wound outcomes.

Many studies reported other results about different parameters to measure the efficacy of PGLA/Triclosan sutures. In particular, three studies analysed the wound healing (*Chen et al. 2011, Dealiaert et al. 2007, Rasic et al. 2011*); one of them considered this factor as independent risk factor for wound infection while the other two studies considered the dehiscence as indicator of wound healing, not detecting significant differences between two

groups. Other parameter was the Mean Operation Time or Time to closure, investigated as risk factor in three studies (*Mingmalairak et al. 2009, Rasic et al. 2011, Rozzelle et al. 2008*) reporting no statistically significant differences between groups treated with PGLA/Triclosan suture compared to PGLA standard suture. Last parameter investigated was the Incisional Hernia incidence, analysed in one study (*Rasic et al. 2011*) that showed no statistically difference between two groups.

Regarding the safety of the technology, included studies did not report significant adverse events, concluding that the PGLA/Triclosan suture seems to be safe to date. Harms from the added use of Triclosan should also be observed and reported in a standardized manner.

In the studies included, different outcomes and age groups and heterogeneous follow up time coupled with unclear reporting led to a considerable loss of data.

We recommend that a large multicenter study should be carried out to test the equipoise currently visible in the data presented in this review. Given their higher cost, compared to standard sutures, such a trial is essential to have a clear evidence for decision making. Until such time a clear evidence of dominance of Triclosan coated sutures is not available.



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## **8. Competing interests declaration**

The authors declare that they will not receive either benefits or harms from the publication of this systematic review. None of the authors have or have held shares, consultancies or personal relationships with any of the producers of the devices assessed in this document.





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## Appendix 1

### Search Strategy - Efficacy and Safety

➤ **MEDLINE** (Pubmed)

DATE: 9 February 2012

LIMITS: Humans; language: English and Italian; Publication Date from 2000/01/01 to 2012/02/9

#### Key words and search strategy

- #1 "Polyglactin 910"[Mesh]
- #2 PGLA[Text Word] OR Polygalactin[Text Word]
- #3 Polylactic[Text Word] AND acid[Text Word] AND Polyglycolic[Text Word] AND acid[Text Word]
- #4 poly[Text Word] AND lactic-co-glycolic[Text Word] AND acid[Text Word]
- #5 Polylactic[Text Word] AND glycolic[Text Word] AND acid[Text Word]
- #6 glycolide[Text Word] AND lactide[Text Word]
- #7 (#1 OR #2 OR #3 OR #4 OR #5 OR #6)
- #8 "Sutures"[Mesh]
- #9 (#7 AND #8)
- #10 antibacterial[Text Word]
- #11 antiseptic[Text Word]
- #12 antimicrobial[Text Word]
- #13 antibiotic[Text Word]
- #14 "Anti-Infective Agents"[Mesh]
- #15 "Anti-Bacterial Agents"[Mesh]
- #16 triclosan[Text Word]
- #17 irgacare[Text Word]
- #18 (#10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17)
- #19 (#9 AND #18)
- #20 "Vicryl Plus"
- #21 (#19 OR #20)
- #22 infection\*[Text Word]
- #23 pathogen\*[Text Word]
- #24 (#22 OR #23)
- #25 surgical[Text Word] AND site[Text Word] OR surgical-site[Text Word]
- #26 surgical[Text Word] OR surger\*[Text Word]
- #27 "Surgical wound" [Text Word] OR "Surgical incision" [Text Word]
- #28 (#25 OR #26 OR #27)
- #29 (#24 AND #28)
- #30 "Surgical Wound Infection"[Mesh]
- #31 healing[Text Word] OR closure[Text Word]
- #32 (#27 AND #31)
- #33 (#29 OR #30 OR #32)
- #34 (#21 AND #33)
- #35 side[Text Word] AND effect[Text Word] OR complication\*[Text Word]
- #36 adverse[Text Word] AND (event OR reaction OR effect\*)

#37 Wound[Text Word] AND bleeding[Text Word]  
 #38 "Surgical Wound Dehiscence"[Mesh]  
 #39 "Hematoma"[Mesh]  
 #40 "Granuloma"[Mesh]  
 #41 "incisional hernia"[Text Word]  
 #42 (#35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41)  
 #43 (#21 AND #42)  
 #44 (#34 OR #43)  
 #45 (#44 OR #58 Limits: Humans, English, Italian, Publication Date from 2000/01/01 to 2012/02/09)

## Results: 15

### ➤ **EMBASE** (Embase.com)

DATE: 27 February 2012

LIMITS: Humans; language: English and Italian; Publication Date from 2000 to 2012

### Key words and search strategy

- #1. 'polyglactin'/exp
- #2. pgl OR polygalactin
- #3. 'polylactic acid'/exp OR 'polylactic acid' AND ('polyglycolic acid'/exp OR 'polyglycolic acid')
- #4. poly AND lactic+co+glycolic AND ('acid'/exp OR acid)
- #5. 'polylactic glycolic acid'
- #6. glycolide AND lactide
- #7. 'polyglactin'/exp OR pgl OR polygalactin OR ('polylactic acid'/exp OR 'polylactic acid' AND ('polyglycolic acid'/exp OR 'polyglycolic acid')) OR (poly AND lactic+co+glycolic AND ('acid'/exp OR acid)) OR 'polylactic glycolic acid' OR (glycolide AND lactide)
- #8. 'suture'/exp
- #9. 'polyglactin'/exp OR pgl OR polygalactin OR ('polylactic acid'/exp OR 'polylactic acid' AND ('polyglycolic acid'/exp OR 'polyglycolic acid')) OR (poly AND lactic+co+glycolic AND ('acid'/exp OR acid)) OR 'polylactic glycolic acid' OR (glycolide AND lactide) AND 'suture'/exp
- #10. 'antibacterial'/exp OR antibacterial
- #11. 'antiseptic'/exp OR antiseptic
- #12. 'antimicrobial'/exp OR antimicrobial
- #13. 'antibiotic'/exp OR antibiotic
- #14. 'antiinfective agent'/exp
- #15. 'triclosan'/exp OR triclosan
- #16. irgacare
- #17. 'antibacterial'/exp OR antibacterial OR 'antiseptic'/exp OR antiseptic OR 'antimicrobial'/exp OR antimicrobial OR 'antibiotic'/exp OR antibiotic OR 'antiinfective agent'/exp OR 'triclosan'/exp OR triclosan OR irgacare
- #18. 'polyglactin'/exp OR pgl OR polygalactin OR ('polylactic acid'/exp OR 'polylactic acid' AND ('polyglycolic acid'/exp OR 'polyglycolic acid')) OR (poly AND lactic+co+glycolic AND ('acid'/exp OR acid)) OR 'polylactic glycolic acid' OR (glycolide AND lactide) AND 'suture'/exp AND ('antibacterial'/exp OR antibacterial OR 'antiseptic'/exp OR antiseptic OR 'antimicrobial'/exp OR antimicrobial OR 'antibiotic'/exp OR antibiotic OR 'antiinfective agent'/exp OR 'triclosan'/exp OR triclosan OR irgacare)
- #19. 'vicryl Plus'

#20. 'polyglactin'/exp OR pglactin OR polygalactin OR ('polylactic acid'/exp OR 'polylactic acid' AND ('polyglycolic acid'/exp OR 'polyglycolic acid')) OR (poly AND lactic+co+glycolic AND ('acid'/exp OR acid)) OR 'polylactic glycolic acid' OR (glycolide AND lactide) AND 'suture'/exp AND ('antibacterial'/exp OR antibacterial OR 'antiseptic'/exp OR antiseptic OR 'antimicrobial'/exp OR antimicrobial OR 'antibiotic'/exp OR antibiotic OR 'antiinfective agent'/exp OR 'triclosan'/exp OR triclosan OR irgacare) OR 'vicryl Plus'

#21. infection\*

#22. pathogen\*

#23 infection\* OR pathogen\*

#24 surgical NEXT/3 site OR surgical+site

#25 surgical OR surger\*

#26 'surgical wound'/exp OR 'surgical wound' OR 'surgical incision'

#27 surgical NEXT/3 site OR surgical+site OR surgical OR surger\* OR 'surgical wound'/exp OR 'surgical wound' OR 'surgical incision'

#28 infection\* OR pathogen\* AND (surgical NEXT/3 site OR surgical+site OR surgical OR surger\* OR 'surgical wound'/exp OR 'surgical wound' OR 'surgical incision')

#29 'surgical infection'/exp

#30 'healing'/exp OR healing OR closure

#31 'surgical wound'/exp OR 'surgical wound' OR 'surgical incision' AND ('healing'/exp OR healing OR closure)

#32 infection\* OR pathogen\* AND (surgical NEXT/3 site OR surgical+site OR surgical OR surger\* OR 'surgical wound'/exp OR 'surgical wound' OR 'surgical incision') OR 'surgical infection'/exp OR ('surgical wound'/exp OR 'surgical wound' OR 'surgical incision' AND ('healing'/exp OR healing OR closure))

#33 'polyglactin'/exp OR pglactin OR polygalactin OR ('polylactic acid'/exp OR 'polylactic acid' AND ('polyglycolic acid'/exp OR 'polyglycolic acid')) OR (poly AND lactic+co+glycolic AND ('acid'/exp OR acid)) OR 'polylactic glycolic acid' OR (glycolide AND lactide) AND 'suture'/exp AND ('antibacterial'/exp OR antibacterial OR 'antiseptic'/exp OR antiseptic OR 'antimicrobial'/exp OR antimicrobial OR 'antibiotic'/exp OR antibiotic OR 'antiinfective agent'/exp OR 'triclosan'/exp OR triclosan OR irgacare) OR 'vicryl Plus' AND (infection\* OR pathogen\* AND (surgical NEXT/3 site OR surgical+site OR surgical OR surger\* OR 'surgical wound'/exp OR 'surgical wound' OR 'surgical incision') OR 'surgical infection'/exp OR ('surgical wound'/exp OR 'surgical wound' OR 'surgical incision' AND ('healing'/exp OR healing OR closure)))

#34 side NEXT/3 effect\* OR complication\*

#35 adverse AND (event OR reaction OR effect\*)

#36 wound NEAR/3 bleeding

#37 'wound dehiscence'/exp

#38 'hematoma'/exp

#39 'granuloma'/exp

#40 'incisional hernia'/exp OR 'incisional hernia'

#41 side NEXT/3 effect\* OR complication\* OR (adverse AND (event OR reaction OR effect\*)) OR wound NEAR/3 bleeding OR 'wound dehiscence'/exp OR 'hematoma'/exp OR 'granuloma'/exp OR 'incisional hernia'/exp OR 'incisional hernia'

#42 'polyglactin'/exp OR pglactin OR polygalactin OR ('polylactic acid'/exp OR 'polylactic acid' AND ('polyglycolic acid'/exp OR 'polyglycolic acid')) OR (poly AND lactic+co+glycolic AND ('acid'/exp OR acid)) OR 'polylactic glycolic acid' OR (glycolide AND lactide) AND 'suture'/exp AND ('antibacterial'/exp OR antibacterial OR 'antiseptic'/exp OR antiseptic OR 'antimicrobial'/exp OR antimicrobial OR

'antibiotic'/exp OR antibiotic OR 'antiinfective agent'/exp OR 'triclosan'/exp OR triclosan OR irgacare) OR 'vicryl Plus' AND (side NEXT/3 effect\* OR complication\* OR (adverse AND (event OR reaction OR effect\*))) OR wound NEAR/3 bleeding OR 'wound dehiscence'/exp OR 'hematoma'/exp OR 'granuloma'/exp OR 'incisional hernia'/exp OR 'incisional hernia')

#43 'polyglactin'/exp OR pglactin OR polygalactin OR ('polylactic acid'/exp OR 'polylactic acid' AND ('polyglycolic acid'/exp OR 'polyglycolic acid')) OR (poly AND lactic+co+glycolic AND ('acid'/exp OR acid)) OR 'polylactic glycolic acid' OR (glycolide AND lactide) AND 'suture'/exp AND ('antibacterial'/exp OR antibacterial OR 'antiseptic'/exp OR antiseptic OR 'antimicrobial'/exp OR antimicrobial OR 'antibiotic'/exp OR antibiotic OR 'antiinfective agent'/exp OR 'triclosan'/exp OR triclosan OR irgacare) OR 'vicryl Plus' AND (infection\* OR pathogen\* AND (surgical NEXT/3 site OR surgical+site OR surgical OR surgeon\* OR 'surgical wound'/exp OR 'surgical wound' OR 'surgical incision')) OR 'surgical infection'/exp OR ('surgical wound'/exp OR 'surgical wound' OR 'surgical incision' AND ('healing'/exp OR healing OR closure))) OR ('polyglactin'/exp OR pglactin OR polygalactin OR ('polylactic acid'/exp OR 'polylactic acid' AND ('polyglycolic acid'/exp OR 'polyglycolic acid')) OR (poly AND lactic+co+glycolic AND ('acid'/exp OR acid)) OR 'polylactic glycolic acid' OR (glycolide AND lactide) AND 'suture'/exp AND ('antibacterial'/exp OR antibacterial OR 'antiseptic'/exp OR antiseptic OR 'antimicrobial'/exp OR antimicrobial OR 'antibiotic'/exp OR antibiotic OR 'antiinfective agent'/exp OR triclosan'/exp OR triclosan OR irgacare) OR 'vicryl Plus' AND (side NEXT/3 effect\* OR complication\* OR (adverse AND (event OR reaction OR effect\*))) OR wound NEAR/3 bleeding OR 'wound dehiscence'/exp OR 'hematoma'/exp OR 'granuloma'/exp OR 'incisional hernia'/exp OR 'incisional hernia'))

#44 'polyglactin'/exp OR pglactin OR polygalactin OR ('polylactic acid'/exp OR 'polylactic acid' AND ('polyglycolic acid'/exp OR 'polyglycolic acid')) OR (poly AND lactic+co+glycolic AND ('acid'/exp OR acid)) OR 'polylactic glycolic acid' OR (glycolide AND lactide) AND 'suture'/exp AND ('antibacterial'/exp OR antibacterial OR 'antiseptic'/exp OR antiseptic OR 'antimicrobial'/exp OR antimicrobial OR 'antibiotic'/exp OR antibiotic OR 'antiinfective agent'/exp OR 'triclosan'/exp OR triclosan OR irgacare) OR 'vicryl Plus' AND (infection\* OR pathogen\* AND (surgical NEXT/3 site OR surgical+site OR surgical OR surgeon\* OR 'surgical wound'/exp OR 'surgical wound' OR 'surgical incision')) OR 'surgical infection'/exp OR ('surgical wound'/exp OR 'surgical wound' OR 'surgical incision' AND ('healing'/exp OR healing OR closure))) OR ('polyglactin'/exp OR pglactin OR polygalactin OR ('polylactic acid'/exp OR 'polylactic acid' AND ('polyglycolic acid'/exp OR 'polyglycolic acid')) OR (poly AND lactic+co+glycolic AND ('acid'/exp OR acid)) OR 'polylactic glycolic acid' OR (glycolide AND lactide) AND 'suture'/exp AND ('antibacterial'/exp OR antibacterial OR 'antiseptic'/exp OR antiseptic OR 'antimicrobial'/exp OR antimicrobial OR 'antibiotic'/exp OR antibiotic OR 'antiinfective agent'/exp OR triclosan'/exp OR triclosan OR irgacare) OR 'vicryl Plus' AND (side NEXT/3 effect\* OR complication\* OR (adverse AND (event OR reaction OR effect\*))) OR wound NEAR/3 bleeding OR 'wound dehiscence'/exp OR 'hematoma'/exp OR 'granuloma'/exp OR 'incisional hernia'/exp OR 'incisional hernia')) AND ([english]/lim OR [italian]/lim) AND [humans]/lim AND [2000-2012]/py

**Results: 644**

➤ **Cochrane Library** (Bibliosan.it)

DATE: 14 February 2012

LIMITS: Publication Date from 2000 to 2012

**Key words and search strategy**

- #1 MeSH descriptor Polyglactin 910 explode all trees
- #2 (PGLA) or (Polygalactin)
- #3 "Polylactic acid" and "Polyglycolic acid"
- #4 (Poly ) and "lactic co glycolic" AND acid
- #5 "Polylactic glycolic acid"
- #6 (Polylactic NEXT glycolic NEXT acid)
- #7 (glycolide ) and (lactide)
- #8 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7)
- #9 MeSH descriptor Sutures explode all trees
- #10 (#8 AND #9)
- #11 (antibacterial)
- #12 (antiseptic)
- #13 (antimicrobial)
- #14 (antibiotic)
- #15 MeSH descriptor Anti-Infective Agents explode all trees
- #16 MeSH descriptor Anti-Bacterial Agents explode all trees
- #17 (triclosan)
- #18 (irgacare)
- #19 (#11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18)
- #20 (#10 AND #19)
- #21 "Vicryl Plus"
- #22 (#20 OR #21)
- #23 (infection\*) or (pathogen\*)
- #24 (surgical NEXT site OR "surgical site") or (surgical OR surger\*)
- #25 "Surgical wound" or "Surgical incision"
- #26 (#24 OR #25)
- #27 (#23 AND #26)
- #28 MeSH descriptor Surgical Wound Infection explode all trees
- #29 (healing) or (closure)
- #30 (#25 AND #29)
- #31 (#27 OR #28 OR #30)
- #32 (#22 AND #31)
- #33 (side effect) or (complication\*)
- #34 (adverse) and (event OR reaction OR effect\*)
- #35 (wound bleeding)
- #36 MeSH descriptor Surgical Wound Dehiscence explode all trees
- #37 MeSH descriptor Hematoma explode all trees
- #38 MeSH descriptor Granuloma explode all trees
- #39 "incisional hernia"
- #40 (#33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39)

- #41 (#22 AND #40)
- #42 (#32 OR #41)
- #43 (#42), from 2000 to 2012

**Results: 6**

### ➤ **Web of Science**

DATE: 1 March 2012

LIMITS: language: English and Italian; date from January 2000 to February 2012

#### **Key words and search strategy**

- #1 (Polyglactin 910)
- #2 (PGLA) OR (Polygalactin)
- #3 (Polylactic) AND (acid) AND (Polyglycolic)
- #4 (poly) AND (lactic-co-glycolic) AND (acid)
- #5 (Polylactic) AND (glycolic) AND (acid)
- #6 (glycolide) AND (lactide)
- #7 (irgacare)
- #8 (triclosan)
- #9 (vicryl Plus)
- #10 (#9 OR #8 OR #7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1)
- #11 (suture\*)
- #12 #11 AND #10
- #13 ("Anti-Bacterial Agents") OR ("Anti-Infective Agents") OR (antibiotic) OR (antimicrobial) OR (antiseptic) OR (antibacterial)
- #14 (#13 AND #12 )
- #15 (surgical site OR surgical-site) OR (surgical OR surgeon\*) OR ("Surgical wound" OR "Surgical incision") OR (healing OR closure) OR ("side effect\*" OR complication\*) OR ("adverse event\*" OR "adverse reaction" OR "adverse effect\*") OR ("Wound bleeding") OR ("Surgical Wound Dehiscence") OR (Hematoma) OR (Granuloma) OR ("incisional hernia")
- #16 (#15 AND #14 )
- #17 (#15 AND #14) AND Language=(English)
- #18 (#15 AND #14) AND Language=(Italian)
- #19 (#18 OR #17), Timespan=2000-2012

**Results: 30**



➤ **CIHNAL** (EBSCOhost)

DATE: 1 March 2012

LIMITS: Humans; language: English and Italian; date from January 2000 to February 2012

**Key words and search strategy**

S1 "Polyglactin 910"

S2 PGLA OR Polygalactin

S3 Polylactic AND acid AND Polyglycolic

S4 poly AND lactic-co- glycolic AND acid

S5 Polylactic AND glycolic AND acid

S6 glycolide AND lactide

S7 TX irgacare

S8 triclosan

S9 vicryl Plus

S10 (S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9)

S11 suture\*

S12 (MH "Sutures")

S13 (S11 or S12)

S14 (S10 AND S13)

S15 "Anti-Bacterial Agents" OR "Anti-Infective Agents" OR antibiotic OR antimicrobial OR antiseptic OR antibacterial

S16 (MH "Antiinfective Agents+")

S17 (S15 or S16)

S18 (S14 and S17)

S19 ("surgical site" OR surgical-site OR surgical OR surger\* OR "Surgical wound "OR " Surgical incision OR healing OR closure ) OR ( "side effect\*" OR complication\* OR "adverse event\*" OR "adverse reaction" OR "adverse effect\*" OR "Wound bleeding" OR "Surgical Wound Dehiscence" OR Hematoma OR Granuloma OR "incisional hernia")

S20 (S18 AND S19) Limiters - Published Date from: 20000101- 20120231; English Language; Human; Language: Italian Search modes - SmartText Searching

**Results: 0**



# Appendix 2

## Data Extraction Form

GENERAL-Data Extraction Sheet

date

**"Poly(lactic-glycolic acid) absorbable synthetic suture (p(g)la) plus antibacterial: a systematic review."**

### Characteristics of the included study (RCT/CCT)

#### Section A. Background information

Screener Identification*	
Study reference	
Study ID (first Author)**	
Published (Yes/No)	
Year	
Period study conducted	
Country(ies) of study	
Setting***	
Objective(s)	

\*e.g., Chiara Rivoiro = RC

\*\*e.g., John Smith = Smith J

\*\*\*e.g., Surgery, Orthopaedics, ENT...

1

GENERAL-Data Extraction Sheet

date

**"Poly(lactic-glycolic acid) absorbable synthetic suture (p(g)la) plus antibacterial: a systematic review."**

#### Section B. Inclusion criteria

Trial registration number: \_\_\_\_\_

<b>1. Study design</b> A) <input type="checkbox"/> Randomized Clinical Trial (RCT) <input type="checkbox"/> Controlled Clinical Trial (CCT) B) <input type="checkbox"/> Two arms <input type="checkbox"/> Multiple arms C) <input type="checkbox"/> Superiority <input type="checkbox"/> Non-inferiority <input type="checkbox"/> Equivalence D) <input type="checkbox"/> Early stopped trial		
<b>2. Participants</b> (a) Number of participants (b) Age** (c) Type of disease (d) Type of surgical procedure	<b>Intervention group*</b>	<b>Comparison group*</b>
<b>3. Comparison</b>	<b>Intervention:</b> <input type="checkbox"/> <b>Type of suture:</b> <input type="checkbox"/> <input type="checkbox"/> Other _____	<b>Comparator:</b> <input type="checkbox"/> <b>Type of suture:</b> <input type="checkbox"/> <input type="checkbox"/> _____

\*If Multiple arms list as A), B), C), ...

\*\*Please record data as reported in the study (e.g. Mean, mean and [Range], mean ± Standard deviation (SD), etc.).

2

**“Polylactic-glycolic acid absorbable synthetic suture (pgla) plus antibacterial: a systematic review.”**



<b>4. Primary outcome:</b>	Outcome measure*: n/tot	Intervention group=	Control group=
<b>5. Secondary outcome:</b> (a) _____	<b>Outcome measure:</b> _____		
(b) _____	Outcome measure: _____		
(c) _____	Outcome measure: _____		
(d) _____	Outcome measure: _____		
<b>6. Follow up (in months)</b>			
<b>7. Funding</b>	Funding Entity <input type="checkbox"/> For profit agency <input type="checkbox"/> Private not for profit <input type="checkbox"/> Governmental <input type="checkbox"/> Not funded <input type="checkbox"/> Not reported		Sponsor involved in study design or conduct <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> not reported

e.g. Mean difference, Relative Risk, Odds Ratio... with point estimates and confidence interval

**“Polylactic-glycolic acid absorbable synthetic suture (pgla) plus antibacterial: a systematic review.”**

<b>8. Conflict of interest:</b>	<input type="checkbox"/> Author(s) declare no competing interest <input type="checkbox"/> Financial ties disclosed <input type="checkbox"/> Other financial ties <input type="checkbox"/> Conflicts of interest not reported		
<b>Notes:</b>	_____ _____ _____		

**“Polylactic-glycolic acid absorbable synthetic suture (ppla) plus antibacterial: a systematic review.”**

**Section C. Reporting (adapted from CONSORT-Statement.org)**

<b>Flow-chart</b>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>Sample size</b>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>Post-randomisation exclusion</b> (pts enrolled but not included in the outcome data analysis)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>Lost-to-follow up</b>	<input type="checkbox"/> Yes	<input type="checkbox"/> No

5

**“Polylactic-glycolic acid absorbable synthetic suture (ppla) plus antibacterial: a systematic review.”**

**Section D. Methodological Quality (Risk of Bias) [adapted from Cochrane-Handbook.org]**

<b>Adequate Sequence generation (randomization)*?</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear	
<b>Adequate Allocation concealment*?</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear	
<b>Blinding of patients?</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear	
<b>Blinding of investigators (clinical staff)?</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear	

\*In CCT the answer is obviously NO

\*\*paste as reported in the study, if available

6

**“Poly(lactic-glycolic acid) absorbable synthetic suture (p(g)la) plus antibacterial: a systematic review.”**

<b>Blinding of outcome assessors?</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear	
<b>Blinding of data analysts?</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear	
<b>Intention to treat analysis-ITT?</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear	
<b>Outcome reporting bias?</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear	
<b>Other bias?</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear	

I

7

**“Poly(lactic-glycolic acid) absorbable synthetic suture (p(g)la) plus antibacterial: a systematic review.”**

**Section E. Notes**



**Author's conclusions:**

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**Reviewer Conclusions:**

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**Other screener's comments**

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8

## Appendix 3

### Search Strategy – Economic literature

➤ **MEDLINE** (Pubmed)

DATE: 5 March 2012

LIMITS: Humans; language: English and Italian; Publication Date from 2000/01/01 to 2012/03/5

#### Key words and search strategy

#1 "Polyglactin 910"[Mesh]

#2 PGLA[Text Word] OR Polygalactin[Text Word]

#3 Polylactic AND acid[Text Word] AND Polyglycolic AND acid[Text Word]

#4 poly[Text Word] AND lactic-co-glycolic[Text Word] AND acid[Text Word]

#5 Polylactic[Text Word] AND glycolic[Text Word] AND acid[Text Word]

#6 glycolide[Text Word] AND lactide[Text Word]

#7 (#1 OR #2 OR #3 OR #4 OR #5 OR #6)

#8 "Sutures"[Mesh]

#9 (#7 AND #8)

#10 antibacterial[Text Word]

#11 antiseptic[Text Word]

#12 antimicrobial[Text Word]

#13 antibiotic[Text Word]

#14 "Anti-Infective Agents"[Mesh]

#15 "Anti-Bacterial Agents"[Mesh]

#16 triclosan[Text Word]

#17 irgacare[Text Word]

#18 (#10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17)

#19 (#9 AND #18)

#20 "Vicryl Plus"

#21 (#19 OR #20)

#22 (cost[Text Word]) AND analysis[Text Word]

#23 ("cost minimization"[Text Word]) OR CMA[Text Word]

#24 ("cost effectiveness"[Text Word]) OR CEA[Text Word]

#25 ("cost utility"[Text Word]) OR CUA[Text Word]

#26 (economic) AND (evaluation OR analysis OR aspects OR assessment OR comparison)

#27 ("health care") AND cost\*

#28 (#22 OR #23 OR #24 OR #25 OR #26 OR #27)

#29 (#21 AND #28)

#30 (#21 AND #28) Limits: Humans, English, Italian, Publication Date from 2000/01/01 to 2012/03/05

**Results: 1**

➤ **EMBASE** (Embase.com)

DATE: 1 March 2012

LIMITS: Humans; language: English and Italian; Publication Date from 2000 to 2012

**Key words and search strategy**

- #1. 'polyglactin'/exp
- #2. pglA OR polygalactin
- #3. 'polylactic acid'/exp OR 'polylactic acid' AND ('polyglycolic acid'/exp OR 'polyglycolic acid')
- #4. poly AND lactic+co+glycolic AND ('acid'/exp OR acid)
- #5. 'polylactic glycolic acid'
- #6. glycolide AND lactide
- #7. 'polyglactin'/exp OR pglA OR polygalactin OR ('polylactic acid'/exp OR 'polylactic acid' AND ('polyglycolic acid'/exp OR 'polyglycolic acid')) OR (poly AND lactic+co+glycolic AND ('acid'/exp OR acid)) OR 'polylactic glycolic acid' OR (glycolide AND lactide)
- #8. 'suture'/exp
- #9. 'polyglactin'/exp OR pglA OR polygalactin OR ('polylactic acid'/exp OR 'polylactic acid' AND ('polyglycolic acid'/exp OR 'polyglycolic acid')) OR (poly AND lactic+co+glycolic AND ('acid'/exp OR acid)) OR 'polylactic glycolic acid' OR (glycolide AND lactide) AND 'suture'/exp
- #10. 'antibacterial'/exp OR antibacterial
- #11. 'antiseptic'/exp OR antiseptic
- #12. 'antimicrobial'/exp OR antimicrobial
- #13. 'antibiotic'/exp OR antibiotic
- #14. 'antiinfective agent'/exp
- #15. 'triclosan'/exp OR triclosan
- #16. irgacare
- #17. 'antibacterial'/exp OR antibacterial OR 'antiseptic'/exp OR antiseptic OR 'antimicrobial'/exp OR antimicrobial OR 'antibiotic'/exp OR antibiotic OR 'antiinfective agent'/exp OR 'triclosan'/exp OR triclosan OR irgacare
- #18. 'polyglactin'/exp OR pglA OR polygalactin OR ('polylactic acid'/exp OR 'polylactic acid' AND ('polyglycolic acid'/exp OR 'polyglycolic acid')) OR (poly AND lactic+co+glycolic AND ('acid'/exp OR acid)) OR 'polylactic glycolic acid' OR (glycolide AND lactide) AND 'suture'/exp AND ('antibacterial'/exp OR antibacterial OR 'antiseptic'/exp OR antiseptic OR 'antimicrobial'/exp OR antimicrobial OR 'antibiotic'/exp OR antibiotic OR 'antiinfective agent'/exp OR 'triclosan'/exp OR triclosan OR irgacare)
- #19. 'vicryl Plus'
- #20. 'polyglactin'/exp OR pglA OR polygalactin OR ('polylactic acid'/exp OR 'polylactic acid' AND ('polyglycolic acid'/exp OR 'polyglycolic acid')) OR (poly AND lactic+co+glycolic AND ('acid'/exp OR acid)) OR 'polylactic glycolic acid' OR (glycolide AND lactide) AND 'suture'/exp AND ('antibacterial'/exp OR antibacterial OR 'antiseptic'/exp OR antiseptic OR 'antimicrobial'/exp OR antimicrobial OR



'antibiotic'/exp OR antibiotic OR 'antiinfective agent'/exp OR 'triclosan'/exp OR triclosan OR irgacare) OR 'vicryl Plus'

#21. 'cost'/exp OR cost AND ('analysis'/exp OR analysis)

#22 'cost minimization'/exp OR 'cost minimization' OR cma

#23. 'cost effectiveness'/exp OR 'cost effectiveness' OR 'cea'/exp OR cea

#24. 'cost utility'/exp OR 'cost utility' OR cua

#25. economic

#26. 'evaluation'/exp OR evaluation OR 'analysis'/exp OR analysis OR aspects OR assessment OR 'comparison'/exp OR comparison

#27. economic AND ('evaluation'/exp OR evaluation OR 'analysis'/exp OR analysis OR aspects OR assessment OR 'comparison'/exp OR comparison)

#28. 'health care'/exp OR 'health care' AND cost\*

#29. 'cost'/exp OR cost AND ('analysis'/exp OR analysis) OR 'cost minimization'/exp OR 'cost minimization' OR cma OR 'cost effectiveness'/exp OR 'cost effectiveness' OR 'cea'/exp OR cea OR 'cost utility'/exp OR 'cost utility' OR cua OR (economic AND ('evaluation'/exp OR evaluation OR 'analysis'/exp OR analysis OR aspects OR assessment OR 'comparison'/exp OR comparison)) OR ('health care'/exp OR 'health care' AND cost\*)

#30. 'polyglactin'/exp OR pglactin OR polygalactin OR ('polylactic acid'/exp OR 'polylactic acid' AND ('polyglycolic acid'/exp OR 'polyglycolic acid')) OR (poly AND lactic+co+glycolic AND ('acid'/exp OR acid)) OR 'polylactic glycolic acid' OR (glycolide AND lactide) AND 'suture'/exp AND ('antibacterial'/exp OR antibacterial OR 'antiseptic'/exp OR antiseptic OR 'antimicrobial'/exp OR antimicrobial OR 'antibiotic'/exp OR antibiotic OR 'antiinfective agent'/exp OR 'triclosan'/exp OR triclosan OR irgacare) OR 'vicryl Plus' AND ('cost'/exp OR cost AND ('analysis'/exp OR analysis) OR 'cost minimization'/exp OR 'cost minimization' OR cma OR 'cost effectiveness'/exp OR 'cost effectiveness' OR 'cea'/exp OR cea OR 'cost utility'/exp OR 'cost utility' OR cua OR (economic AND ('evaluation'/exp OR evaluation OR 'analysis'/exp OR analysis OR aspects OR assessment OR 'comparison'/exp OR comparison)) OR ('health care'/exp OR 'health care' AND cost\*))

#31. 'polyglactin'/exp OR pglactin OR polygalactin OR ('polylactic acid'/exp OR 'polylactic acid' AND ('polyglycolic acid'/exp OR 'polyglycolic acid')) OR (poly AND lactic+co+glycolic AND ('acid'/exp OR acid)) OR 'polylactic glycolic acid' OR (glycolide AND lactide) AND 'suture'/exp AND ('antibacterial'/exp OR antibacterial OR 'antiseptic'/exp OR antiseptic OR 'antimicrobial'/exp OR antimicrobial OR 'antibiotic'/exp OR antibiotic OR 'antiinfective agent'/exp OR 'triclosan'/exp OR triclosan OR irgacare) OR 'vicryl Plus' AND ('cost'/exp OR cost AND ('analysis'/exp OR analysis) OR 'cost minimization'/exp OR 'cost minimization' OR cma OR 'cost effectiveness'/exp OR 'cost effectiveness' OR 'cea'/exp OR cea OR 'cost utility'/exp OR 'cost utility' OR cua OR (economic AND ('evaluation'/exp OR evaluation OR 'analysis'/exp OR analysis OR aspects OR assessment OR 'comparison'/exp OR comparison)) OR ('health care'/exp OR 'health care' AND cost\*)) AND ([english]/lim OR [italian]/lim) AND [humans]/lim AND [2000-2012]/py

**Results: 65**

➤ **Cochrane Library** (Bibliosan.it)

DATE: 14 February 2012

LIMITS: Publication Date from 2000 to 2012

**Key words and search strategy**

- #1 MeSH descriptor Polyglactin 910 explode all trees
- #2 (PGLA) or (Polygalactin)
- #3 "Polylactic acid" and "Polyglycolic acid"
- #4 (Poly ) and "lactic co glycolic" AND acid
- #5 "Polylactic glycolic acid"
- #6 (Polylactic NEXT glycolic NEXT acid)
- #7 (glycolide ) and (lactide)
- #8 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7)
- #9 MeSH descriptor Sutures explode all trees
- #10 (#8 AND #9)
- #11 (antibacterial)
- #12 (antiseptic)
- #13 (antimicrobial)
- #14 (antibiotic)
- #15 MeSH descriptor Anti-Infective Agents explode all trees
- #16 MeSH descriptor Anti-Bacterial Agents explode all trees
- #17 (triclosan)
- #18 (irgacare)
- #19 (#11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18)
- #20 (#10 AND #19)
- #21 "Vicryl Plus"
- #22 (#20 OR #21)
- #23 (Cost analysis)
- #24 "cost minimization analysis" or (CMA)
- #25 "cost effectiveness" or (CEA)
- #26 "cost utility" or (CUA)
- #27 (economic) and (evaluation OR analysis OR aspects OR assessment OR comparison)
- #28 "health care" and cost\*
- #29 (#23 OR #24 OR #25 OR #26 OR #27 OR #28)
- #30 (#22 AND #29)
- #31 (#30), from 2000 to 2012

**Results: 2**

➤ **EconLit**

DATE: 1 March 2012

LIMITS: date from January 2000 to February 2012; language: English and Italian

**Key words and search strategy**

- 1 Polyglactin 910 {No Related Terms}
- 2 PGLA OR Polygalactin {No Related Terms}
- 3 Polylactic AND acid AND Polyglycolic {No Related Terms}
- 4 poly AND lactic-co-glycolic AND acid {No Related Terms}
- 5 Polylactic AND glycolic AND acid {No Related Terms}

- 6 glycolide AND lactide {No Related Terms}
- 7 irlgacare {No Related Terms}
- 8 triclosan {No Related Terms}
- 9 vicryl Plus {No Related Terms}
- 10 (1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9)
- 11 suture\* {No Related Terms}
- 12 (11 and 10)
- 13 "Anti-Bacterial Agents" OR "Anti-Infective Agents" OR antibiotic OR antimicrobial OR antiseptic OR antibacterial {No Related Terms}
- 14 (13 and 12)
- 15 "surgical site" OR surgical-site OR surgical OR surger\* OR "Surgical wound" OR "Surgical incision" OR healing OR closure OR "side effect\*" OR complication\* OR "adverse event\*" OR "adverse reaction" OR "adverse effect\*" OR "Wound bleeding" OR "Surgical Wound Dehiscence" OR Hematoma OR Granuloma OR "incisional hernia" {No Related Terms}
- 16 (15 and 14)
- 17 limit 16 to (yr="2012" and italian and english)

**Results: 0**



## Appendix 4

### Data Extraction Form Economic studies



## SYSTEMATIC REVIEW

### *Polylactic-Glycolic Acid Absorbable Synthetic Suture (PGLA) Plus Antibacterial*

<b><i>General information</i></b>	
Reviewer name:	Date of extraction:
Author/Year:	
Title:	
Journal:	
Source of funding:	
<b><i>Study Characteristics</i></b>	
Objective of study:	
Study population:	
Intervention:	
Comparator:	
<i>Economic Study Type</i>	<i>Perspective</i>
Cost-effectiveness Analysis <input type="checkbox"/>	
Cost-utility Analysis <input type="checkbox"/>	NHS <input type="checkbox"/>
Cost-benefit Analysis <input type="checkbox"/>	Societal <input type="checkbox"/>

Cost-Consequence Analysis <input type="checkbox"/>	Hospital <input type="checkbox"/>
Cost-Study <input type="checkbox"/>	Not Stated <input type="checkbox"/>
Other (specify) <input type="checkbox"/>	Other (please specify) <input type="checkbox"/>
Not reported <input type="checkbox"/>	
<i>Modelling</i>	
Was a model used?	
Yes <input type="checkbox"/>	
No <input type="checkbox"/>	
If yes, state purpose and type:	
<b><i>Source of Data</i></b>	
<i>Source of effectiveness data</i>	<i>Source of Cost Data</i>
Single study <input type="checkbox"/>	Actual source (survey, direct contact, etc.) <input type="checkbox"/>
Synthesis of Previous Publication <input type="checkbox"/>	Literature source <input type="checkbox"/>

**Source of effectiveness data**

**Effectiveness data from a single study**

**Study design**

- RCT
- Non-RCT with concurrent controls
- Cohort study
- Historical control
- Before and after study
- Case series
- Other (specify)
- Not reported

**Study population**

Number of patients in intervention group

Number subject in control group

Number excluded from study

**Methods of sample selection:**

**Follow-up**

Duration of follow-up

Loss to follow-up

**Number of centres:**

**Any blinding for assessment of outcomes:**

**Analysis of clinical studies:**

Treatment completers

Intention to treat

**Effectiveness results**



**Effectiveness data from a synthesis of previous publications (model)**

<b>Study inclusion criteria:</b>	<b>Study designs included:</b>	<b>Number of primary studies included:</b>
<b>Study exclusion criteria reported:</b>	<input type="checkbox"/> RCT <input type="checkbox"/> Non-RCT with concurrent controls <input type="checkbox"/> Cohort study <input type="checkbox"/> Historical control <input type="checkbox"/> Before and after study <input type="checkbox"/> Case series <input type="checkbox"/> Other (specify) <input type="checkbox"/> Not reported	<b>Method of combination of primary study:</b>
<b>Sources searched reported:</b>		<input type="checkbox"/> Meta-analysis <input type="checkbox"/> Narrative methods <input type="checkbox"/> Other (specify)
<b>Criteria used to judge validity:</b>		
<input type="checkbox"/> Concealment of randomisation <input type="checkbox"/> Blind assessment <input type="checkbox"/> Low drop-out rates <input type="checkbox"/> Other (specify) <input type="checkbox"/> Not reported		

**Results of the review (Effectiveness results):**

**Economic evaluation**

Measures of Benefits used in the Economic Analysis      yes       no

If yes, specify:

Side effect considered

yes

no

**Direct costs: Health service**

Estimation based on:

- A guess
- Actual data
- Derived using Modelling
- Other
- Not reported

**Direct costs: Patients**

Estimation based on:

- A guess
- Actual data
- Derived using Modelling
- Other
- Not reported

**Source of Direct costs Data:**

**Price Year:**

**Currency:**

**Conversion rates used:**

**Discounting Undertaken?**

Yes

No

**Discount rate**

**Indirect Costs**

Estimation based on:

- A guess
- Actual data
- Derived using Modelling
- Other
- Not reported

**Source of indirect Cost Data:**

Price Year

**Discounting Undertaken?**

Yes

No

Discount rate

**Currency:****Conversion rates used:*****Statistical/sensitivity analyses***

Statistical tests carried out?

Yes No 

Types of tests used in analysis of costs:

**Type of sensitivity analysis**

- One-way analysis
- Two-way analysis
- Multi-way analysis
- Threshold analysis

- Analysis of Extremes
- Probabilistic analysis
- Other
- Not reported
- Not carried out

**Areas of uncertainty tested:**

***Results of study***

**Clinical Outcome/benefit:**

Duration of Benefits:

**Costs results:**

**Cost of adverse events considered** Yes  No  Not relevant

**How were the estimates of costs and benefits combined?**

- Cost/Life saved
- Cost/life Gained
- Cost/QALY
- Not benefit
- Incremental net benefit

<input type="checkbox"/> Other
<input type="checkbox"/> Not Combined
<b>Results of Synthesis of costs and benefits:</b>
<b>Author's conclusion:</b>
<b>Reviewer's conclusion:</b>
<b>Overall assessment of study quality:</b>

Adapted from Bamford J, *et al.* Current practice, accuracy, effectiveness and cost-effectiveness of the school entry hearing screen. *Health Technol Assess* 2007; 11.



## Appendix 5

### List of included effectiveness and safety studies

1. Chen, S. Y.; Chen, T. M.; Dai, N. T.; Fu, J. P.; Chang, S. C.; Deng, S. C., and Chen, S. G. Do antibacterial-coated sutures reduce wound infection in head and neck cancer reconstruction? *Eur. J. Surg. Oncol.* 2011; 37(4):300-304; ISSN: 0748-7983. 1532-2157.
2. Deliaert, A. E.; Van den Kerckhove, E.; Tuinder, S.; Fieuws, S.; Sawor, J. H.; Meesters-Caberg, M. A., and van der Hulst, R. R. The effect of triclosan-coated sutures in wound healing. A double blind randomised prospective pilot study. *J. Plast. Reconstr. Aesthetic Surg.* 2009; 62(6):771-773; ISSN: 1748-6815.
3. Ford H. R., Jones P., Gaines B., Reblock K., and Simpkins D.L. Intraoperative handling and wound healing: Controlled clinical trial comparing coated Vicryl(registered trademark) plus antibacterial suture (coated polyglactin 910 suture with triclosan) with coated Vicryl(registered trademark) suture (coated polyglactin 910 suture). *Surg. Infect.* 2005; 6(3):313-321; ISSN: 1096-2964.
4. Galal I. and El-Hindawy K. Impact of using triclosan-antibacterial sutures on incidence of surgical site infection. *Am. J. Surg.* 2011; 202(2):133-138; ISSN: 0002-9610. 1879-1883.
5. Mingmalairak C., Ungbhakorn P., and Paocharoen, V. Efficacy of antimicrobial coating suture coated polyglactin 910 with triclosan (Vicryl Plus) compared with polyglactin 910 (Vicryl) in reduced surgical site infection of appendicitis, double blind randomized control trial, preliminary safety report. *J. Med. Assoc. Thailand.* 2009; 92(6):770-775; ISSN: 0125-2208. 0125-2208.
6. Rasic, Z.; Schwarz, D.; Adam, V. N.; Sever, M.; Lojo, N.; Rasic, D.; Matejić, and, T. Efficacy of antimicrobial triclosan-coated polyglactin 910 (Vicryl\* Plus) suture for closure of the abdominal wall after colorectal surgery. CN-00798789. *Collegium Antropologicum.* 2011; 35(2):439-43. Notes: Publication Type: Clinical Trial; Journal Article; Randomized Controlled Trial
7. Rozzelle, C. J.; Leonardo, J., and Li, V. Antimicrobial suture wound closure for cerebrospinal fluid shunt surgery: A prospective, double-blinded, randomized controlled trial. *J. Neurosurg. Pediatr.* 2008; 2(2):111-117; ISSN: 1933-0707. 1933-0715.
8. Williams, N.; Sweetland, H.; Goyal, S.; Ivins, N., and Leaper, D. J. Randomized trial of antimicrobial-coated sutures to prevent surgical site infection after breast cancer surgery. *Surg. Infect.* 2011; 12(6):469-474; ISSN: 1096-2964. 1557-8674.





## Appendix 6

### List of excluded effectiveness and safety studies with reasons of exclusion

#### No meet the comparator and study design criteria

1. Zhang, Z. T.; Zhang, H. W.; Fang, X. D.; Wang, L. M.; Li, X. X.; Li, Y. F.; Sun, X. W.; Carver, J.; Simpkins, D.; Shen, J., and Weisberg, M. Cosmetic outcome and surgical site infection rates of antibacterial absorbable (Polyglactin 910) suture compared to Chinese silk suture in breast cancer surgery: a randomized pilot research. *Chin Med J (Engl)*. 2011 Mar; 124(5):719-24.
2. Justinger, C.; Moussavian, M. R.; Schlueter, C.; Kopp, B.; Kollmar, O., and Schilling, M. K. Antibiotic coating of abdominal closure sutures and wound infection. *Surgery (USA)*. 2009; 145(3):330-334; ISSN: 0039-6060.
3. Justinger, C.; Schuld, J.; Sperling, J.; Kollmar, O.; Richter, S., and Schilling, M. K. Triclosan-coated sutures reduce wound infections after hepatobiliary surgery-a prospective non-randomized clinical pathway driven study. *Langenbeck's Arch. Surg*. 2011; 396(6):845-850; ISSN: 1435-2443. 1435-2451.
4. Justinger C., Slotta J. E., and Schilling, M. K. Incisional hernia after abdominal closure with slowly absorbable versus fast absorbable, antibacterial-coated sutures. *Surgery (USA)*. 2012; 151(3):398-403; ISSN: 0039-6060. 1532-7361.



## Appendix 7 – Clinicaltrials.gov

Official title (trial number)	Purpose	Primary outcomes [Time frame]	Type	Phase	Arms		Enrolment	Date (Start – Completion)	Country	Sponsor
					Intervention	Comparator				
<b>RECRUITING</b>										
Antimicrobial Coated Sutures in Paediatric Surgery (NCT01220700)	To determine if suture material coated by antimicrobial agent triclosan would decrease the incidence of surgical site infections (SSI) in paediatric surgery compared to ordinary sutures.	Occurrence of surgical site infection [30 days]	Interventional	n.r.	Vicryl	Vicryl Plus	1500	Start: October 2010 Completion: December 2011	Finland	University of Oulu
Triclosan-coated Sutures in Cardiac Surgery: Effects on Leg Wound Infections and Costs (NCT01212315)	To assess if triclosan-coated /sutures reduces wound infections after saphenous vein harvesting in CABG patients. Secondary objectives are the effect triclosan-coated sutures on sterna wound infections and a cost analysis.	Proportion of subjects with leg wound infection [60 days]	Interventional	4	No intervention	Triclosan coated sutures	360	n.r.	Sweden	Sahlgrenska University Hospital, Sweden
Do Antibacterial nSkin Sutures Reduce Surgical Site Infections After Open Abdominal Surgery? (NCT01540279)	Hypothesis: the use of antibacterial skin sutures with triclosan poliglecaprone 25 reduces the rate of SSI after open abdominal surgery.	n. r.	Observational	n.r.	Cohort 2: abdominal wall closure with Monocryl Plus	Cohort 1: abdominal wall closure with Monocryl	300	Start: July 2011	Switzerland	University Hospital, Basel
<b>NOT YET RECRUITING</b>										
Effectiveness of Triclosan Coated VICRYL/MONOCRYL sutures in preventing leg wound infection compared to POLYSORB/BIOSYN sutures in patients after coronary bypass surgery – Randomized Controlled Trial (NCT01457859)	The purpose of this study is to assess whether triclosan-coated sutures reduces wound infections compared to regular non-coated sutures, after saphenous vein harvesting in CABG patients.	Leg wound infection [up to 45 days postsurgery]	Interventional	4	Triclosan – coated sutures	Regular non-coated sutures	n.r.	n.r.	Israel	Rambam Health Care Campus

<b>COMPLETED</b>										
The Impact of Using Triclosan-antibacterial Sutures on the Incidence of Surgical Site Infection (NCT01019447)	To compare conventional polyglactin 910 sutures with triclosan-coated polyglactin 910 antimicrobial sutures for the reduction of surgical site infections and any associated health and economic benefits.	Signs of Surgical Site Infections (SSI) according to Centers for Disease Control (CDC) criteria [30 days (or 1 year in case of prosthesis)]	Interventional	4	Vicryl Plus	Vicryl	701	Start: November 2009 Completion: March 2011	Egypt	Cairo University
Do Triclosan Coated Sutures Reduce Wound Infection After Hepatobiliary Surgery? A Prospective Non Randomized Clinical Pathway Driven Study. (NCT00932503)	To ascertain if the use of Vicryl Plus® reduced the number of wound infections after transverse laparotomy comparing to polydioxanon suture.	The primary outcome was the number of wound infections [10 days after demission of patient from hospital]	Interventional	n.r.	Vicryl Plus		839	Start: October 2003 Completion: October 2007	Germany	University Hospital, Saarland
Oral Bacteria on Suture Materials – Clinical Comparison of an Antibacterial-coated and a Non-coated Suture Material (VICRYL PLUS® vs. VICRYL®, Ethicon) in Intraoral Dentoalveolar Surgery (NCT00946049)	Antibacterial Triclosan-coated suture material (VICRYL PLUS®, Ethicon) and non-coated (VICRYL®) was compared for bacterial colonization after third molar extraction. Sutures were removed postoperatively and adhered bacteria were investigated.	n.r.	Interventional	n.r.	Vicryl Plus	Vicryl	n.r.	Start: March 2005 Completion: February 2008	Germany	University Hospital Freiburg
Pilot Evaluation of Cosmetic Outcome and Surgical Site Infection Rates of Coated VICRYL * Plus Antibacterial (Polyglactin 910) Suture Compared to Chinese Silk in Scheduled Breast Cancer Surgery (NCT00768222)	This is a 90-day study to evaluate cosmetic outcome and Surgical Site Infection in approximately 100 patients from 6 centers in China undergoing scheduled modified radical mastectomy for breast cancer.	Mean Score on Cosmetic Outcome Visual Analog Scale (VAS) [30days (+/- 5) post-operative]	Interventional	4	Experimental: Vicryl Plus	Chinese Silk Suture	101	Start: October 2008 Completion: May 2009	China	Ethicon, Inc.

Triclosan Coated Suture Wound Closure for Peripheral Vascular Surgery: a Prospective Multicenter Study. (NCT01101789)	This is a prospective randomized multicenter study which purpose is to determine whether triclosan-coated sutures for wound closure after lower limb vascular surgery would reduce the incidence of surgical wound infections.	Surgical wound infection [one month after surgical procedure]	Interventional	n.r.	Triclosan coated suture for surgical wound closure	-	276	Start: April 2010 Completion: January 2011	Finland	North Carelia Central Hospital
<b>ENROLLING BY INVITATION</b>										
Pilot Study of Vicryl Plus and Monocryl Plus in Breast Surgery (NCT00830271)	This is a randomized pilot study comparing conventional sutures (Vicryl and Monocryl) with antiseptic coated equivalents (Vicryl Plus and Monocryl Plus) in elective breast surgery.	Reduction of surgical site infection [6-7 months]	Interventional	4	Experimental: Vicryl Plus and Monocryl Plus	Placebo comparator: Vicryl and Monocryl	150	Start: December 2008 Completion: September 2009	United Kingdom	Cardiff and Vale university Health Board
<b>UNKNOWN RECRUITMENT STATUS</b>										
Abdomen Closure Using Triclosan Coated Absorbable Suture vs Uncoated Sutures of the Same Base Material (NCT01123616)	The goal of the investigators randomized, prospective, multicentric, internet-based study is to compare rate of SSI after surgery of colon and rectum by using triclosan-coated suture for abdominal wall closure. 180-180 cases in seven centres are involved in this study. Two arms are separated by computer randomization at abdominal wall closure: application of triclosan-coated and non-coated PDS suture (PDS vs. PDS-Plus). Triclosan is an antiseptic material which the investigators hope will provide better local infection control at the site with reducing the risk of bacterial colonization.	Quality and quantity of wound discharge [30 days]	Interventional	2	PDS plus	PDS	Estimated: 1	Start: November 2009 Completion: June 2010	Hungary	University of Pecs

**RECRUITMENT STATUS** indicates the current stage of a trial, whether it is planned, ongoing, or completed. Possible values include:

- Not yet recruiting: participants are not yet being recruited or enrolled
- Recruiting: participants are currently being recruited and enrolled
- Enrolling by invitation: participants are being (or will be) selected from a predetermined population
- Completed: the study has concluded normally; participants are no longer being examined or treated (i.e., last patient's last visit has occurred)

## Appendix 8

### List of excluded economic studies with reasons for exclusion

#### Not meet the study design criterion

1. Aasen AO, Barie PS, Faist E, Ford HR, Fry DE, Hau T. Panel discussion: Current issues in the prevention and management of surgical site infection - Part 2. *Surg. Infect.* 2002; 3(SUPPL. 1):S, 99-S-102.
2. Chen SY, Chen TM, Dai NT *et al.* Do antibacterial-coated sutures reduce wound infection in head and neck cancer reconstruction? *European Journal of Surgical Oncology : the Journal of the European Society of Surgical Oncology and the British Association of Surgical Oncology* 2011; 37(4):300-4. Notes: Publication Type: Controlled Clinical Trial; Journal Article; Research Support, Non-U.S. Gov't
3. Galal I, El-Hindawy K. Impact of using triclosan-antibacterial sutures on incidence of surgical site infection. *Am J Surg* 2011; 202(2):133-8. Notes: Publication Type: Journal Article; Randomized Controlled Trial
4. Huddleston PM, Clyburn TA, Evans RP *et al.* Surgical site infection prevention and control: An emerging paradigm. *J. Bone Jt. Surg. Ser. A* 2009; 91(SUPPL. 6):2-9.
5. Neligan PC. Bioactive sutures. *Plast. Reconstr. Surg.* 2006; 118(7):1645-7.
6. Zhang Z-T, Zhang H-W, Fang X-D *et al.* Cosmetic outcome and surgical site infection rates of antibacterial absorbable (Polyglactin 910) suture compared to Chinese silk suture in breast cancer surgery: A randomized pilot research. *Chin. Med. J.* 2011; 124(5):719-24.

## Glossary

### **Case-control study**

Observational study in which groups from the same population with (cases) and without (controls) a specific outcome of interest, are compared to evaluate the association between exposure to an intervention and the outcome.

### **CINAHL**

The Cumulative Index to Nursing and Allied Health Literature, is the most comprehensive resource for nursing and allied health literature. While starting out as a single bibliographic database, CINAHL has expanded to offer four databases including two full-text versions. CINAHL is owned and operated by EBSCO Publishing, with the Cinahl editorial team continuing to work out of the offices in Glendale, California. The CINAHL databases are available on EBSCOhost®, one of the most-used research platforms available.

### **Cochrane Library (CLIB)**

The Cochrane Library is a collection of databases, published on disk, CD-ROM and internet by the Cochrane Collaboration. It is published quarterly and includes: regularly updated reviews of the efficacy of health assistance; structured evaluations and abstracts of systematic reviews published in the principal journals; bibliographic information about over 446,000 controlled clinical studies; a manual, a glossary and other references on the methodology of systematic reviews; information about Collaborative Review Groups and other Cochrane Collaboration bodies; references to Internet for further information about the efficacy of health interventions.

### **Cohort study**

Observational study in which a defined group of participants is followed over time and comparison is made between those who did and did not receive an intervention.

### **CRD York**

This is a department at the University of York which handles the management of the following databases: DARE (Database of Abstracts of Reviews of Effects) which contains the abstracts of systematic reviews further to the works and protocols of Cochrane reviews and protocols; NHS EED (NHS Economic Evaluation Database) which contains the abstracts of economic assessment studies; and the Health Technology Assessment (HTA) Database



which contains the details of all the HTA assessments completed or in course at the international level.

## **EMBASE**

The bibliographic database specialised in medical literature with particular attention to the pharmacology and toxicology sector. It is produced by Elsevier Science and contains more European literature with respect to Medline.

## **Guidelines**

Clinical guidelines are recommendations on the appropriate treatment and care of people with specific diseases and conditions based on the best available evidence. Guidelines help healthcare professionals in their work, but they do not replace their knowledge and skills.

## **MedLine**

The electronic database produced by the National Library of Medicine (USA). It covers the international biomedical literature from 1966 to date in the medicine, nursing, dentistry, veterinary medicine, health organisation sectors. Since June 1997 MEDLINE can be consulted free on the Web via the PubMed service, with daily updates of the data.

## **Randomized Controlled trial (RCT)**

Clinical trial which randomizes eligible participants to two or more groups, treats according to assignment, and compares the groups with respect to outcomes of interest. Participants are allocated to groups using both randomisation (allocation involves the play of chance) and concealment (ensures that the intervention that will be allocated cannot be known in advance).

## **Web of science**

Web of Science is an electronic bibliographic database, searching over 12,000 journals and 120,000 conference proceedings across the sciences, social sciences, and arts and humanities to find the high quality research most relevant to your area of interest.



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