

■ ARTHROPLASTY

The effect of triclosan-coated sutures on the rate of surgical site infection after hip and knee arthroplasty: a double-blind randomized controlled trial of 2546 patients

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Aims

Surgical site infection (SSI) is a common complication of surgery with an incidence of about 1% in the United Kingdom. Sutures can lead to the development of a SSI, as micro-organisms can colonize the suture as it is implanted. Triclosan-coated sutures, being antimicrobial, were developed to reduce the rate of SSI. Our aim was to assess whether triclosan-coated sutures cause a reduction in SSIs following arthroplasty of the hip and knee.

Patients and Methods

This two-arm, parallel, double-blinded study involved 2546 patients undergoing elective total hip (THA) and total knee arthroplasty (TKA) at three hospitals. A total of 1323 were quasi-randomized to a standard suture group, and 1223 being quasi-randomized to the triclosan-coated suture group. The primary endpoint was the rate of SSI at 30 days postoperatively.

Results

The baseline characteristics of age, gender and comorbidities were well matched in the two groups. The rates of superficial SSI were 0.8% in the control group and 0.7% in the intervention group ($p = 0.651$), and when deep and superficial SSIs were combined the rates were 2.5% and 1.8 ($p = 0.266$). The length of stay in hospital and the rates of medical complications did not differ significantly between the groups ($p = 1.000$).

Conclusion

This trial provided no evidence that the use of triclosan-coated sutures in THA and TKA leads to a reduction in the rate of SSI.

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More than 180 000 arthroplasties of the hip and knee were performed in 2015 in England and Wales.¹ The number of procedures undertaken is rising due to increased availability of healthcare resources, patient demand and the awareness of the benefits related to surgery being undertaken earlier. A study based in the United States has estimated a growth of 174% in total hip (THA) and 673% in total knee arthroplasty (TKA), by 2030.²

Arthroplasties of the hip and knee are generally safe, with low rates of complications.¹ One of the most serious complications is surgical site infection (SSI),³ the incidence of which is about 1% in the United Kingdom. This may be an underestimation as higher rates (2.2%) have been reported from centres undertaking active surveillance.^{4–6} Many factors affect the rate of SSIs and much effort has been concen-

trated on this challenging area in an endeavour to reduce it.^{7,8} SSIs are defined as affecting the superficial or deeper tissues handled during THA or TKA,⁹ according to the Health Protection Agency (HPA). The costs associated with a SSI are escalating annually in the United Kingdom; in 2012, approximate costs were £61 million.¹⁰ Frequently, additional societal costs, such as time off work and quality of life are not addressed, which increases the financial burden further. SSI is also seen as a surrogate measure of the quality of health care, with implications for hospitals and providers at a local and national level.¹¹ These factors have reinvigorated enthusiasm at many levels to focus on ways of reducing the rate of SSI.

One such focus is on wound closure, aimed at promoting rapid healing by the apposition of skin edges, preventing the entry of bacteria

Table I. Health Protection Agency definition of superficial and deep surgical site infection

Incisional infection
<p>Superficial incisional infection*</p> <p>SSI that occurs within 30 days of surgery, involves only the skin or subcutaneous tissue of the incision, and meets at least one of the following criteria:</p> <ol style="list-style-type: none"> 1. Purulent drainage from superficial incision 2. Culture of organisms and pus cells present in fluid/tissue from superficial incision wound swab from superficial incision 3. At least two symptoms of inflammation: a) pain, b) tenderness, c) localized swelling, d) redness, e) heat, and either: f) incision deliberately opened to manage infection, or g) clinician's diagnosis of superficial SSI
<p>Deep incisional infection</p> <p>SSI involving the deep tissues (i.e. fascial and muscle layers), within 30 days of surgery (or one year if an implant is in place), and the infection appears to be related to the surgical procedure and meets at least one of the following criteria:</p> <ol style="list-style-type: none"> 1. Purulent drainage from deep incision (not organ space) 2. Organisms from culture and pus cells present in fluid/tissue from deep incision or wound swab from deep incision 3. Deep incision dehisces or deliberately opened and patient has at least one symptom of fever or localized pain/tenderness 4. Abscess or other evidence of infection in deep incision: reoperation, histopathology, or radiology 5. Clinician's diagnosis of deep incisional SSI

*Stitch abscesses (minimal inflammation/discharge at suture point) do not classify as deep surgical site infection (SSI)

and leaving a cosmetically acceptable scar.¹² During the past century, the material used to close the wound has evolved from natural to synthetic sutures, such as absorbable synthetic fibres. Vicryl (Ethicon-Johnson & Johnson Medical Limited, Kirkton Campus, West Lothian, United Kingdom) is a braided version of this type of suture, which is used ubiquitously across surgical specialities. It elicits little tissue reaction and was one of the first synthetic absorbable sutures to be developed. It is absorbed and retains 65% of its strength 14 days after implantation, 40% of its strength at 21 days and absorption is complete by 70 days.¹³

An important factor for the development of SSI is colonization of suture material, particularly in knots, which may form a nidus for infection.¹⁴ Micro-organisms colonize the suture as it is implanted, potentially developing a biofilm,¹⁵ which may subsequently establish immunity to both systemic and local antimicrobial treatment. This has led to an industry aimed at decreasing the risk of colonization of suture material. Previous authors have shown a greater effectiveness of combined systemic and local antibacterial administration.¹⁶ Any broad-spectrum local antibacterial agent may be used. However, it must have an established safety profile that does not interfere with the suture material. Triclosan is an established agent that has been effectively used in consumer products for more than 40 years.¹⁷ *In vitro* studies have shown that triclosan-coated sutures create an 'active zone' around the suture, inhibiting *Staphylococcus aureus*, *Staphylococcus epidermidis* and methicillin-resistant strains of *Staphylococcus* (MRSA and MRSE), the leading bacteria at the site of surgery, from colonizing on the suture for a minimum of 48 hours.^{13,18,19}

The World Health Organization supports the use of triclosan-coated sutures for the purpose of reducing the risk of SSI.²⁰ The Society for Healthcare Epidemiology of America and Infectious Diseases Society of America practice recommendation is against its routine use, due to unclear evidence.²¹ The National Institute for Health and Care

Excellence report that triclosan may reduce the risk of SSI compared with uncoated sutures²² and will reassess the guidance this year. The interest in triclosan-coated sutures has increased during the last decade with several randomized controlled trials (RCT) assessing its effectiveness. Two meta-analyses have reported contradictory results.^{23,24}

The aim of this study was to determine if using a triclosan-coated suture can significantly reduce the rate of SSI after primary THA or TKA. The 30-day follow-up was the primary outcome measure. We collected data for secondary outcome measures at baseline and at defined timepoints: a) deep incisional infection is defined as a SSI involving the deep tissues (fascial and muscle layers) that occurs within 30 days of surgery if no implant is in place, or within a year if an implant is in place, if the infection appears to be related to the operation, and if the infection meets at least one of the criteria in Table I; b) 30-day and 90-day mortality; c) length of stay (days); d) *Clostridium difficile* infections; e) complications recorded during the course of the trial; f) critical care admission.

Patient and Methods

This study was a three-centre, two-arm, parallel-group, patient-and-assessor-blinded, quasi-randomized controlled trial with block treatment allocation conducted in the United Kingdom. The full details have been described previously,²⁵ and a summary of the methodology follows below. In this pragmatic trial, patients were eligible if they were aged > 18 years, medically fit for an operation and suitable for primary THA or TKA. The surgical approach was determined by the preference of the surgeon.

Patients were recruited between May 2008 and November 2013 from all elective admissions at teaching acute hospital and elective centres. Potential patients were screened and, if eligible, recruited under Good Clinical Practice protocol Inclusion criteria were that the patient was suitable for a THA or TKA, and willing to provide informed consent. Exclusion criteria included revision arthroplasty and patients who were unable to consent. The patients were

treated on a standardized enhanced recovery pathway for the whole period of the trial.²⁶ The allocation of treatment was undertaken using opaque envelopes randomized according to the date of surgery. This was based on random monthly assignment into one of the two interventions, each centre providing one form of treatment for a calendar month. It was impossible, for practical reasons, to randomly allocate individuals to treatment groups and the best option was to randomize based on monthly blocks of time.²⁵ Envelopes were opened at the start of a month, so allocation was not known at the time of putting the patient on the waiting list, which was a mean of three months prior to surgery. The participating surgeons were not blinded to the allocation. However, the patients, research team, statistician, clinical staff and associates involved in assessment of outcomes, were all blinded.

The study treatments were standard vicryl suture (control) or triclosan-coated vicryl plus suture (intervention arm). Both sutures used are commercial products, manufactured by the same company (Ethicon, Sommerville, New Jersey). The layer closed with the vicryl was dependent on the preference of the surgeon, ranging from deep fascia to the subcutaneous layer. All vicryl used during the operation was the suture which was allocated. Dressings were standardized in October 2009 to Aquacel Surgical (Convatec, Reading, United Kingdom). Prior to this, it was decided by the preference of the surgeon. All patients entered the same pathway, involving preoperative education, enhanced perioperative management and accelerated discharge.²⁶ Patients had the allocated surgery and all had the same exercises postoperatively in an enhanced recovery program. Unless the operating surgeon specifically advised otherwise, all patients were fully weight-bearing immediately. We did not stipulate the methods of analgesia, anaesthesia or postoperative care. The only deviation from this was a change in prophylactic antibiotics. At the start of trial, the regimen was gentamicin (4.5 mg/kg) and this was changed to gentamicin (3 mg/kg) and teicoplanin (400 mg) on 1 February 2009, in line with our trust guidelines for prophylaxis when undertaking primary arthroplasty.

The primary outcome measure was superficial SSI based on definitions published by the HPA as part of the Surgical Site Infection Surveillance Scheme, which originate from the Centres for Disease Control and Prevention 1992 definition.²⁷ Superficial SSI is defined as an infection that occurs within 30 days of surgery and involves only the skin or subcutaneous tissue of the incision, and meets at least one of the criteria in Table I. We collected data for this outcome up to the 30-day endpoint with telephone follow-up, and patients were monitored for readmission. In order to ensure complete data on SSI that developed after discharge, patients were asked to report problems with the healing of their wound 30 days after the operation using the HPA-designated questionnaire.²⁸ Trained surveillance nurses telephoned patients on or soon after their 30th postoperative day.

A total of 2546 patients awaiting primary THA or TKA were recruited and randomized to the standard care or intervention arms. At the initiation of the study, the combined hospitals' 12-month audited rate of SSI was 2.5% for THA and TKA. This is in line with other centres in England performing high-quality surveillance using HPA methodology.²⁸ This sample size was calculated based on 80% power to detect a reduction of SSI from 2.5% to 1%, for an uncorrected chi-squared test, at the 5% level, indicating that 1200 patients were needed in each group and 2400 in total. This difference represents a significant reduction, which would have an important clinical impact.

Statistical analysis. Baseline demographic and comorbidity data were summarized to check comparability between treatment arms. Additional comorbidities were also recorded that have been shown to increase SSI, such as diabetes²⁹ and rheumatoid arthritis.³⁰ In order to alleviate any possible bias regarding the method of randomization, we undertook formal statistical testing of differences in baseline characteristics between treatment arms to assess whether there was evidence of systematic imbalance introduced by the randomization procedure; independent-samples *t*-tests and Fisher's exact test or chi-squared tests were used, with significance set at $p < 0.05$.

The main analysis assessed differences in the primary endpoint, superficial SSI, on an intention-to-treat basis, between groups using logistic regression analysis of complete case data, adjusting for both the age and gender of the patients. Regression coefficients were significant if $p < 0.05$. Differences between intervention arms in other secondary outcomes (mortality and critical care stay) and postoperative complications were assessed using chi-squared test or Fisher's exact test as appropriate. Length of hospital stay was compared between groups using a Mann-Whitney U test. All analyses were undertaken using the statistical software R (R foundation for statistical computing, Vienna, Austria).³¹

Results

A total of 2762 patients were eligible for inclusion; 216 were excluded. Of these, 146 were not approached or had irregular consent processes, 49 declined to participate and 21 were excluded due to being enrolled in other trials. Thus, 2546 patients consented to take part in the trial. The Consolidated Standards of Reporting Trials diagram shows the flow of these patients through the trial (Fig. 1). All those in the control and intervention arms received the allocated treatment. A total of 1323 were randomized to the standard suture and 1223 to the intervention suture. No patient withdrew consent after being randomized. At the primary endpoint of 30 days, loss to follow-up was $< 0.5\%$ in both groups as 2437 patients (95.7%) provided SSI data at this time (Fig. 1). Table II summarizes the demographic characteristics of the patients at baseline. The two groups were well matched and were representative of patients undergoing THA and TKA in the United Kingdom during this

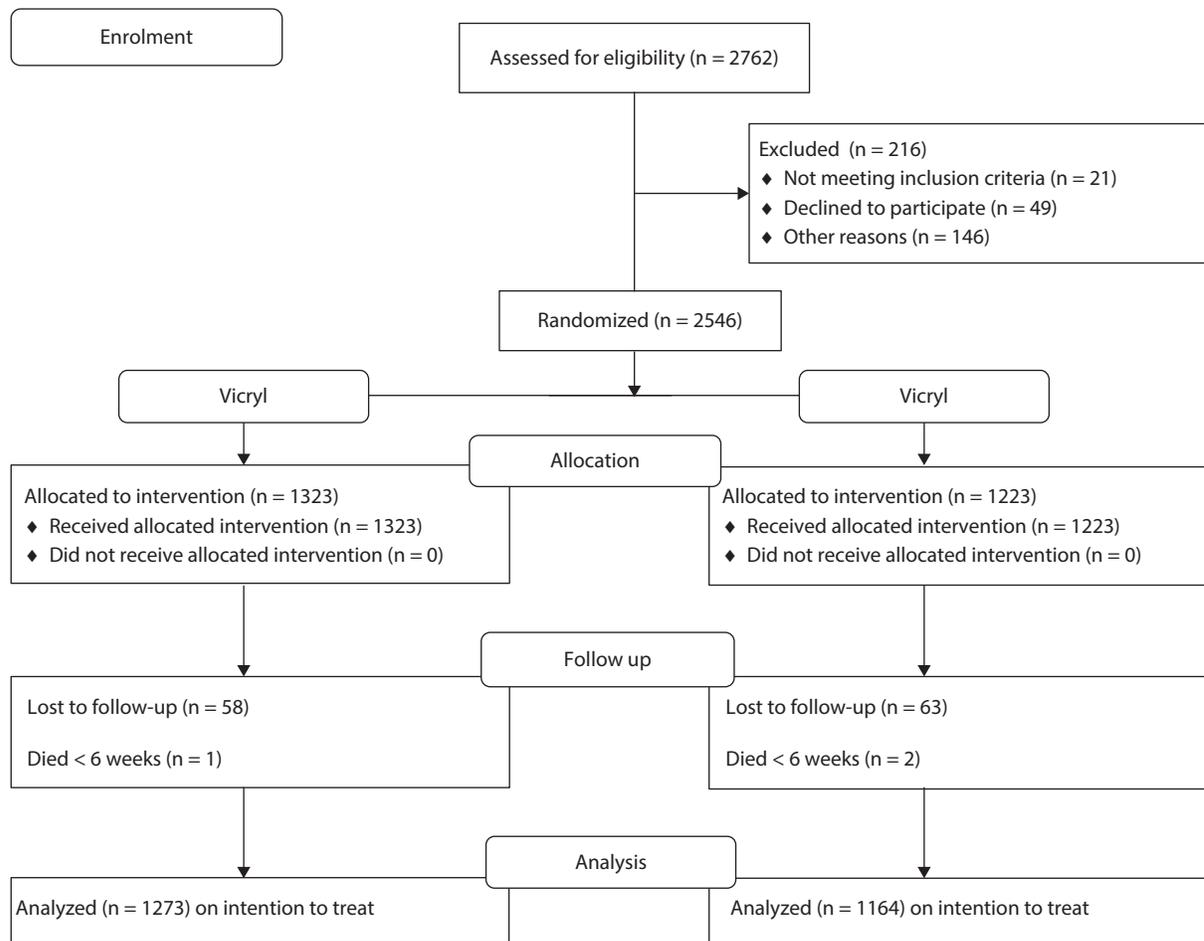


Fig. 1

Consolidated Standards of Reporting Trials flowchart of patients through the study in the Vicryl (standard suture) and Vicryl plus (triclosan-coated) suture groups.

period.³² There was no difference in gender distribution ($p = 0.879$), age ($p = 0.564$) or any comorbidity between the groups (Table II).

The rate of superficial SSI (Table III) did not differ between the control (0.8%) and intervention (0.7%) groups, based on an intention-to-treat basis. The unadjusted odds ratio was 0.78 (95% confidence interval (CI) 0.27 to 2.15); adjustment for site, operation, age and gender made little difference to the conclusions, with the odds ratio from the logistic regression analysis estimated as 0.78 (95% CI 0.30 to 1.93).

The rate of deep SSI showed no statistical difference, being 1.6% in the control group and 1.1% in the intervention group ($p = 0.300$) (Table III). When superficial and deep SSI data were combined the rate of infection was 2.5% and 1.8% respectively ($p = 0.266$) (Table III). Further analyses to compare superficial and deep SSI combined between age groups (2.1% ($n = 32$) for those aged < 70 years and 2.1% ($n = 21$) for those aged > 70 years) showed no statistically significant difference. The rate of mortality was not significantly different, being 0.3% in both groups ($p = 1.000$) (Supplementary table i).

The median length of stay in hospital was not significantly different, being 4.1 days in the control group and 3.9 days in the intervention group ($p = 0.386$) and there was no difference in the rate of complications between the groups (Table IV).

Discussion

We found that using a triclosan-coated suture material did not reduce the rate of superficial or overall SSI in primary THA and TKA, in this randomized clinical trial. The groups were equally matched and had statistically similar rates of complications including critical care episodes and comorbidities. All patients received their allocated intervention. No contamination occurred in the crossover phase of the trial, due to the robust method of block randomization.

Some recent meta-analyses have compared the effect of triclosan-coated sutures with standard sutures. In 2012, a comparison of seven RCTs involving 836 patients undergoing a variety of operations concluded that triclosan-coated sutures do not reduce the rates of SSIs or wound breakdown.²³ Two further meta-analyses were performed in

Table II. The demographics and comorbidities in the vicryl (standard suture) and the vicryl plus (triclosan-coated) suture groups

Characteristic	Vicryl (n = 1323)	Vicryl+(n = 1223)	p-value*
Mean age, yrs (SD)	67.2 (9.7)	67.5 (10)	0.564
Gender, female:male (% female)	719:604 (54.4)	660:563 (54)	0.879
Operation, n (%)			0.782
Hip	590 (46.3)	532 (45.7)	
Knee	683 (53.7)	632 (54.3)	
Site, n (%)			< 0.001
Hexham Hospital	495 (38.9)	493 (40.3)	
NTG Hospital	150 (11.8)	200 (16.4)	
Wansbeck General Hospital	628 (49.3)	530 (43.3)	
Medical history available, n (%)	1273	1164	
Hypertension	595 (46.74)	586 (50.34)	0.082
Atrial fibrillation	61 (4.79)	57 (4.9)	0.979
Ischemic Heart Disease	93 (7.31)	81 (6.96)	0.800
Hypothyroid	99 (7.78)	74 (6.36)	0.199
Type 1 Diabetes	7 (0.55)	8 (0.69)	0.797
Type 2 Diabetes	135 (10.6)	109 (9.36)	0.341
Peripheral Vas Disease	54 (4.24)	66 (5.67)	0.125
COPD	42 (3.3)	43 (3.69)	0.674
Dementia	1 (0.08)	1 (0.09)	1.000
Alzheimers	2 (0.16)	3 (0.26)	0.675
Pressure sores	2 (0.16)	0 (0)	0.501
Psoriatic arthritis	8 (0.63)	3 (0.26)	0.231
Rheumatoid arthritis	34 (2.67)	21 (1.8)	0.193
Hypercholesterlaemia	70 (5.5)	75 (6.44)	0.369

Independent sample *t*-test

NTG, North Tyneside General; COPD, chronic obstructive pulmonary disease

Table III. The rate of surgical site infection in the two groups, defined according to the Health Protection Agency criteria

Outcome	Vicryl	Vicryl+	Total	p-value*
Superficial SSI, n (%)	11/1273 (0.8)	8/1164 (0.7)	19/2437 (0.7)	0.651
Deep SSI, n (%)	21/1273 (1.6)	13/1164 (1.1)	34/2437 (1.3)	0.300
Deep and superficial SSI, n (%)	32/1273 (2.5)	21/1164 (1.8)	53/2437 (2.1)	0.266

*Fisher's exact test

†SSI, surgical site infection

2013.^{33,34} Wang et al³³ included 17 RCTs comparing vicryl with vicryl plus in 2160 patients and concluded that triclosan-coated suture had a beneficial effect in the prevention of SSI after surgery. However, this was not specific for orthopaedics. They also recorded that there was not enough information to allow meta-analysis based on detailed individual data.

Recently, Diener et al³⁴ reported the results of a large multicentre, randomized controlled group-sequential superiority trial involving 24 German hospitals and 1224 patients. They concluded that triclosan-coated polydioxanone with triclosan (PDS Plus) did not reduce the rate of SSI after elective midline laparotomy. This represents the largest multicentre RCT in this area and has similar findings to ours, which if combined for a new meta-analysis may change the overall conclusions.

The latest meta-analysis of 21 RCTs by de Jonge et al²⁴ included 6462 patients and was published in 2017. They found that the use of triclosan-coated sutures was associated with a decrease in the rate of SSI. Pooled effects showed a risk ratio of 0.72 (95% CI 0.60 to 0.86; $p < 0.001$). We recruited 2546 patients into a randomized controlled trial comparing standard vicryl with a triclosan-coated vicryl, which represents a significant proportion of all previous trials. The results of our study and the available literature have not brought about a change in practice at our sites.

This trial has strengths, including its pragmatic design. Although we recruited patients from only three hospitals, the large number of surgeons at various grades involved realistically reflects the wider surgical practice.³⁵ Other strengths included the use of a nationally recognized

Table IV. The postoperative complications in the two groups; p-values are calculated using Fisher's exact test unless indicated otherwise

Complication	Vicryl (n = 1273)	Vicryl+ (n = 1164)	p-value [†]
Deep vein thrombosis, 60 days, n (%)	4 (0.31)	7 (0.6)	0.370
Pulmonary embolism, 60 days, n (%)	13 (1.02)	10 (0.86)	0.834
Stroke, 30 days	1 (0.08)	2 (0.17)	0.609
Transient ischaemic attack, 30 days, n (%)	0 (0.00)	0 (0.00)	N/A
Gastrointestinal bleed, 30 days, n (%)	5 (0.39)	2 (0.17)	0.456
Renal failure, 30 days, n (%)	7 (0.55)	4 (0.34)	0.552
Urinary retention, 30 days, n (%)	21 (1.65)	24 (2.06)	0.456
Urinary tract infection, 30 days, n (%)	17 (1.34)	9 (0.77)	0.236
Myocardial infarction, 30 days, n (%)	2 (0.16)	4 (0.34)	0.434
Pneumonia, 30 days, n (%)	9 (0.71)	6 (0.52)	0.612
Thrombocytopenia, 30 days, n (%)	1 (0.08)	1 (0.09)	1.000
Ileus, 30 days, n (%)	0 (0)	0 (0)	N/A
<i>Clostridium difficile</i> , n (%)	0 (0)	1 (0.09)	N/A
Readmission <i>Clostridium difficile</i> , n (%)	0 (0)	2 (0.17)	N/A
Blood transfusion, n (%)	2 (0.16)	2 (0.17)	1.000
Readmission, n (%)	92 (7.23)	79 (6.79)	0.730*
Aspiration pneumonia, n (%)	1 (0.08)	1 (0.09)	1.000
Low sodium, n (%)	13 (1.02)	8 (0.69)	0.391
Return to theatre (same), n (%)	3 (0.24)	2 (0.17)	1.000
Return to theatre (other), n (%)	9 (0.71)	6 (0.52)	0.612
One or more complications, n (%)	158 (12.42)	144 (12.37)	1.000*

*chi-squared test

definition of SSI, which was assessed by HPA-trained nurses, and the high level of follow-up data (95%) at the primary endpoint. The patients, assessors and statistician were blinded to the type of suture which was used. The 100% rate of allocation, which was a further strength, is based on the simplicity of the allocation of treatment, as the sutures for that month were only made available once the randomization had taken place.

The key weakness of the trial was the selected quasi-randomization method, which is widely recognized as being less rigorous than conventional randomization. Differences in the target population, local environment and procedures at each site had the potential to confound the effects of the intervention, so block randomization was used and interventions were randomly assigned using a concealed system on a monthly basis to ensure, as far as possible, that the characteristics of the patients and unknown systematic effects across treatments were balanced. The demographics and important expected comorbidities in the two groups were comparable.

Another limitation was that we did not take into the account the differences in surgical approach between surgeons, nor the grade of the surgeon. The approach could affect closure and the grade of surgeon could affect certain outcomes. In addition to this, the layer at which the vicryl was used was dependent on the preference of the surgeon, and could be any layer from deep layer to subcuticular fascia. However, we believe this variation reflects the pragmatic design of the study and represents the wider surgical practice.

In conclusion, this trial has provided no evidence that triclosan-coated sutures in THA and TKA leads to a reduction in the rate of SSI. Surgeons will be able to use this new

information when deciding which type of suture to use when undertaking THA and TKA.



Take home message:

- Triclosan coated sutures do not significantly reduce surgical site infections in elective hip and knee replacement surgery
- This is the first randomised controlled trial assessing the clinical effectiveness of triclosan coated sutures in orthopaedic surgery

Supplementary material

 A table showing mortality rates and critical care admission between Vicryl (standard suture) and the Vicryl plus (triclosan coated) suture groups is available alongside the online version of this article at www.bjj.boneandjoint.org.uk

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I. Ahmed: Revising the manuscript, Presenting and interpreting the data, Reviewing the literature, Responding to post-submission queries.

C. Jensen: Registering and managing the trial, Leading recruitment, Steering committee, Preparing the manuscript.

P. Partington: Conception of the study, Ethics, Developing the protocol, Preparing the manuscript.

K. Emmerson: Contract negotiation with funder, Institutional clearance, Preparing the manuscript.

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