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Randomised Clinical Trial
Dental Implants

Polyglactin 910 suture compared with polyglactin 910 coated with triclosan in dental implant surgery: randomized clinical trial

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Abstract. Antibacterial coating of surgical sutures is a suggested approach to prevent surgical site infections. The aim of this study was to compare the incidence of surgical site infection following the use of polyglactin 910 (Vicryl) and polyglactin 910 coated with triclosan (Vicryl Plus) sutures in dental implant surgery. This single-blind, randomized clinical trial evaluated patients who received three implants in the posterior mandible. Patients were randomly divided into two groups to receive either Vicryl Plus sutures (group 1) or Vicryl sutures (group 2). A total of 320 patients were included in the study ($n = 160$ in each group). Twelve patients (7.5%) in group 1 and 11 patients (6.9%) in group 2 had a surgical site infection. Analysis of the data did not demonstrate any significant difference in the incidence of surgical site infection between the two groups ($P = 0.5$). The incidence of surgical site infection in fresh socket implant placement was higher than that in delayed implant placement, irrespective of the type of suture used ($P = 0.001$). Triclosan-coated Vicryl sutures did not decrease the incidence of surgical site infection in dental implant surgery.

Key words: polyglactin 910; surgical wound infection; dental implants; infection control.

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Postoperative infection is an uncommon complication that usually occurs within a few days to 1 month after dental implant placement. The prevalence of postoperative infection varies across reports, with estimates reaching up to 11.5%[1]. Postoperative infection is a major risk factor for impaired osseointegration[2,3] and increases the risk of early implant failure by almost 80-fold[1].

The use of antibacterial-coated sutures has been suggested to decrease the risk of surgical site infection[4]. Triclosan (2,2,4′-trichloro-2′-hydroxyphenyl ether) is a synthetic broad-spectrum antimicrobial agent

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that has been used for more than 40 years[5]. The braided polyglactin 910 suture coated with triclosan is an absorbable suture marketed under the brand name Vicryl Plus (Ethicon Inc., Johnson & Johnson Company, Somerville, NJ, USA).

Preclinical in vitro studies have demonstrated that Vicryl Plus effectively inhibits the growth of *Staphylococcus aureus*, *Staphylococcus epidermidis*, methicillin-resistant *Staphylococcus epidermidis*, and methicillin-resistant *Staphylococcus aureus*, which are the main microorganisms typically involved in surgical site infections[6]. Previous studies have demonstrated that Vicryl Plus sutures decrease the rate of postoperative infection in various surgical procedures[7,8]. However, other studies have reported contradictory results and found no change in the infection rate with the use of Vicryl Plus sutures[9,10]. In dental implant surgery, several local methods have been recommended to reduce postoperative infection, such as chlorhexidine mouth wash, local antibiotics[11], and antibiotic-coated implants[12]. A search of the literature yielded no study on the efficacy of Vicryl Plus for the prevention of surgical wound infection in dental implant surgery.

The purpose of this study was, therefore, to address the following question: Can Vicryl Plus decrease the prevalence of postoperative infection in patients undergoing dental implant surgery? It was hypothesized that Vicryl Plus would decrease the rate of postoperative infection in dental implant surgery. Therefore, the aim of this study was to compare the incidence of surgical site infection following the use of Vicryl and Vicryl Plus sutures in dental implant surgeries.

Materials and methods

A single-blind, randomized clinical trial was designed. The study sample was derived from the population of patients presenting to the Oral and Maxillofacial Surgery Department of Shahid Beheshti University of Medical Sciences and Khanevadeh Clinic between September 1, 2016 and July 30, 2018. The study was approved by the committee of the medical ethics group of Shahid Beheshti University of Medical Sciences and was registered at ClinicalTrials.gov (NCT03659344). Subjects eligible for study inclusion were scheduled to undergo dental implant surgery and receive three dental implants in the posterior mandible. The patients signed an informed consent agreement prior to surgery and participation in the study. Subjects were excluded from study enrolment if they were diabetic or smokers, or had poor oral hygiene. Patients who needed hard and soft tissue augmentation were also excluded. If the patient required bone augmentation due to exposed threads during insertion, they were excluded from the study.

The patients were randomly divided into two groups using a computer-generated randomization list: patients in group 1 received 4–0 Vicryl Plus sutures (Ethicon Inc., Johnson & Johnson Company, Somerville, NJ, USA) for surgical wound closure, while patients in group 2 received 4–0 Vicryl sutures (Ethicon Inc., Johnson & Johnson Company, Somerville, NJ, USA).

All dental implants were placed by elevating a sub-periosteal flap through a crestal incision with two short releasing incisions (2–3 mm). A dental implant brand was used (SGS Dental, Budapest, Hungary). Dental implants with diameters of 4.2 mm and 4.5 mm were used in both groups.

All patients received prophylactic antibiotics (2 g amoxicillin) 1 hour before surgery. Antibiotics were not administered postoperatively. Patients rinsed with 0.2% chlorhexidine mouthwash before dental implant surgery and were instructed to continue using it for 7 days postoperatively.

Cases of fresh socket dental implant placement were documented in each group. All implants were placed by an oral and maxillofacial surgeon (R.T.). Patients were visited and followed up by two examiners on days 7, 14, 21, and 28 postoperative. The time to diagnosis of an infection was documented. Delayed placement of dental implants was defined as the placement of dental implants 2 months or later after tooth extraction. All implants were placed at bone level (two-stage).

Postoperative infection was defined as local erythematous changes in the mucosa around the dental implant with a purulent discharge, or localized abscess formation at the surgical site, and/or increasing pain and swelling in the operated area. Wound dehiscence was defined as a wound rupture along the surgical incision. The occurrence of wound dehiscence was also documented. In patients with a peri-implant infection, the surgical sites were irrigated locally with normal saline and chlorhexidine 0.2%. Systemic antibiotic therapy was prescribed (clindamycin 300 mg every 8 hours for 7 days). Early dental implant failure resulting in the removal of fixtures (before prosthetic loading) was documented.

Patients were blinded to the type of suture used. The age and sex of the patients and fresh socket or delayed placement of the dental implants were the variables investigated in this study. The incidence of surgical site infection and dehiscence were the outcome measures, and the use of Vicryl Plus or Vicryl sutures were the predictive factors.

Sample size estimation

A minimum sample size of 74 patients in each group was calculated, according to a previous study[1], assuming a 5% level of significance, type II error of 20% or smaller, power of 90%, and prevalence of infection of 5% and 15%.

Statistical analysis

The statistical analysis was performed using IBM SPSS Statistics version 21.0 (IBM Corp., Armonk, NY, USA). The χ^2 test was used to compare the numbers of patients with infection and dehiscence in the two groups. The independent *t*-test was applied to compare the mean age of the patients in the two groups.

Results

A total of 320 patients were included in the study ($n = 160$ in each group; Table 1). The mean age of the patients in group 1 was 44.73 ± 12.82 years and in group 2 was 44.64 ± 12.24 years; the two groups did not differ significantly with regard to the mean age of the patients ($P = 0.95$). Group 1 included 83 male patients and 77 female patients and group 2 included 88 male patients and 72 female patients; the two groups were not significantly different regarding the sex of the patients ($P = 0.65$).

Overall, 34 patients (21.2%) in group 1 and 24 patients (15%) in group 2 underwent fresh socket implant placement. There was no statistically significant difference between groups 1 and 2 in the number of patients who underwent fresh socket implant placement ($P = 0.19$; Table 2). Delayed implants were placed 80.53 ± 21.40 days after tooth removal in group 1 and 79.60 ± 19.93 days after tooth removal in group 2. There was no difference between the groups regarding the delay to implant placement after tooth removal ($P = 0.72$).

Twelve patients (7.5%) in group 1 and 11 patients (6.9%) in group 2 developed a surgical site infection. Analysis of the data did not demonstrate any significant difference in the number of patients who had a surgical site infection between the two groups ($P = 0.5$; Table 3).

The mean time to diagnosis of the infection was 13.42 ± 4.68 days after surgery for group 1 patients and 15.9 ± 4.63 days after surgery for group

Table 1. Characteristics of the study population[a].

Variables	Descriptive findings
Age (years)	44.68 ± 12.51
Sex	
Male	171 (53.4%)
Female	149 (46.6%)
Implant placement	
Delayed	262 (81.9%)
Fresh socket	58 (18.1%)
Surgical site infection	
Absent	297 (92.8%)
Present	23 (7.2%)
Dehiscence	
Absent	290 (90.6%)
Present	30 (9.4%)
Time to infection diagnosis (days)	14.60 ± 4.68
Number of early implant failures	9 (2.8%)
Time to delayed implant placement after tooth removal (days)	80.5 ± 20.62

[a] Results are presented as the number and percentage (*n* (%)), or as the mean ± standard deviation values.

Table 2. Comparison of variables between the study groups: Vicryl Plus and Vicryl[a].

Variables	Group 1 Vicryl Plus	Group 2 Vicryl	*P*-value
Age (years)	44.73 ± 12.82	44.64 ± 12.24	0.95[b]
Sex			0.65[c]
Male	83 (51.9%)	88 (55%)	
Female	77 (48.1%)	72 (45%)	
Implant placement			0.19[c]
Delayed	126 (78.8%)	136 (85%)	
Fresh socket	34 (21.2%)	24 (15%)	
Time to delayed implant placement after tooth removal (days)	80.53 ± 21.40	79.60 ± 19.93	0.72

[a] Results are presented as the number and percentage (*n* (%)), or as the mean ± standard deviation values.
[b] Independent *t*-test.
[c] χ^2 test.

Table 3. Comparison of the frequency of surgical site infection and dehiscence between the study groups: Vicryl Plus and Vicryl[a].

Outcomes	Group 1 Vicryl Plus	Group 2 Vicryl	*P*-value[b]
Surgical site infection			0.5
Absent	148 (92.5%)	149 (93.1%)	
Present	12 (7.5%)	11 (6.9%)	
Surgical site dehiscence			0.18
Absent	141 (88.1%)	149 (93.1%)	
Present	19 (11.9%)	11 (6.9%)	
Time to infection diagnosis (days)	13.42 ± 4.68	15.9 ± 4.63	0.21
Early implant failure			0.90
Failure	5 (3.1%)	4 (2.5%)	
No failure	155 (96.9%)	156 (97.5%)	

[a] Results are presented as the number and percentage (*n* (%)), or as the mean ± standard deviation values.
[b] χ^2 test.

2 patients. There was no significant difference in the time to diagnosis of the infection between the two groups ($P = 0.21$).

In group 1, there were five early dental implant failures (3.1%); there were four early dental implant failures (2.5%) in group 2. Analysis of the data did not demonstrate any difference in early dental implant failure between the two groups ($P = 0.90$). Overall, 13 of the 22 infected dental implants (59.1%) survived.

Nineteen (11.9%) of the 160 patients in group 1 and 11 (6.9%) of the 160 patients in group 2 experienced dehiscence. There was no significant difference in the number of patients with dehiscence between the two groups ($P = 0.18$; Table 3).

Furthermore, nine of the 262 patients who underwent delayed placement of implants had a surgical site infection. In contrast, 14 out of 58 patients who received fresh socket implants had a surgical site infection. There was a significant difference between fresh socket and delayed placement implants in terms of surgical site infection ($P = 0.001$; Table 4).

Discussion

Despite the low prevalence of surgical site infection in dental implant surgery, it is an important complication responsible for dental implant failure[13,14]. Surgical site infection following dental implant placement can compromise the survival rate of implants[3]. Since the introduction of triclosan-coated suture material, many clinical studies have evaluated its efficacy for the prevention of infection in various medical fields. However, the results have been mainly controversial regarding the efficacy of antibacterial-coated sutures for the prevention of surgical site infection[4]. In this study, it was hypothesized that the use of Vicryl Plus sutures would decrease the rate of surgical site infection in dental implant surgery. The results showed that the use of Vicryl or Vicryl Plus sutures made no difference and did not affect the incidence rate of surgical site infection.

Generally, postoperative infections are more common in mandibular tooth extractions[1]. Thus the posterior mandible was used as the study site in this investigation. In cases of delayed implant placement, the fixtures were placed a minimum of 2 months after tooth removal in order to provide sufficient soft tissue coverage. The placement of several implants in the same patient requires a larger mucoperiosteal flap and is associated with a longer operating time and higher risk of contamination of the surgical wound, which can increase the risk of postoperative complications. Figueiredo et al. showed that patients who received more than four fixtures were at higher risk of surgical wound infection, by approximately three-fold, than those who received fewer than four fixtures[1].

To control variables, the time delay to implant placement after tooth removal, time to diagnosis of the infection, and number of failed dental implants that were removed after infection were compared between the study and control groups. All of these parameters were analyzed and no differences were found between the study and control groups. The incidence of infection did not differ signifi-

Table 4. Comparison of the frequency of surgical site infection between fresh socket and delayed placement of dental implants.

Outcome	Delayed placement *n* (%)	Fresh socket placement *n* (%)	*P*-value (χ^2 test)
Surgical site infection			0.001
Present	9 (3.4%)	14 (24.1%)	
Absent	253 (96.6%)	44 (75.9%)	

cantly between the test and control groups. The survival of dental implants after treatment of the infection was 59.1%, which shows the importance of prevention in dental implant treatment.

The incidence of surgical site infection was significantly higher in those undergoing fresh socket implant placement than in those undergoing delayed placement of implants, irrespective of the type of suture used. As the numbers of subjects with delayed implant placement (262 cases) and fresh socket placement (58 cases) differed, the comparison of the incidence of infection may be associated with bias.

The use of mouthwash (chlorhexidine) in order to reduce the incidence of surgical site infection has been recommended[15]. Many other approaches have also been tested to decrease the prevalence of surgical site infection, such as the use of triclosan-coated sutures[16]. The efficacy of antiseptic-coated sutures to prevent bacterial colonization of suture material in surgical wounds and decrease the incidence of wound infection has been the topic of many studies over the past years. The antibacterial efficacy of triclosan-coated sutures has also been tested in animal models[16]. Moreover, bacterial adherence to triclosan-coated material has been studied in vitro, and a significant reduction of bacterial adhesion to triclosan-coated material has been documented[16].

Triclosan was introduced for use in the healthcare industry in 1972 and was first used in surgical scrubs[17]. It was later used in medical products such as skin antiseptics, impregnated/coated catheters, ointments, and sutures[4]. Recently, there has been controversy regarding the toxicity, carcinogenicity, and efficacy of triclosan mainly in healthcare and personal products. Moreover, eminent societies and regulatory authorities in many developed countries have been reviewing the efficacy and safety of triclosan in medical devices and healthcare products[4]. Daoud et al. performed a meta-analysis and concluded that the use of triclosan antimicrobial sutures decreases the incidence of surgical site infection after clean, clean-contaminated, and contaminated surgery[18]. However, Deliaert et al. reported that the incidence of dehiscence increased with the use of triclosan-coated sutures[19]. The results of the present study showed a slightly higher prevalence of dehiscence in the Vicryl Plus group. Chen et al. reported that triclosan-coated Vicryl sutures did not decrease the incidence of infection in cervical wounds after head and neck cancer surgery[10].

Although the patients were provided with instructions for home care after their surgery, the degree of local care was not evaluated in this study, which could be considered a limitation. Furthermore, the diagnosis of infection was based on clinical evaluation. Laboratory tests showing an increase in white blood cell count and C-reactive protein level, along with microbiological culture, may be useful for the confirmation of infection.

In conclusion, triclosan-coated Vicryl sutures did not decrease the incidence of surgical site infection following dental implant surgery. The incidence of dehiscence was slightly higher in the Vicryl Plus group, which calls for further caution when using Vicryl Plus sutures.

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Competing interests

The authors declare no conflict of interest.

The manuscript did not meet any conflict of interest

Ethical approval

This study was approved by the Medical Ethics Committee of Shahid Beheshti University of Medical Sciences (IR.SBMU.RIDS.REC.1395.336).

Patient consent

All subjects signed a consent agreement for participation in the study.

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