Int. J. Oral Maxillofac. Surg. 2015; 44: 871–875
http://dx.doi.org/10.1016/j.ijom.2015.02.001, available online at http://www.sciencedirect.com

International Journal of
Oral & Maxillofacial Surgery

Clinical Paper
Oral Surgery

Evaluation of fibrin sealant as a wound closure agent in mandibular third molar surgery—a prospective, randomized controlled clinical trial

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M. Gogulanathan, P. Elavenil, A. Gnanam, V.B. Krishnakumar Raja: Evaluation of fibrin sealant as a wound closure agent in mandibular third molar surgery—a prospective, randomized controlled clinical trial. Int. J. Oral Maxillofac. Surg. 2015; 44: 871–875.

Abstract. The aim of this randomized controlled trial was to assess the effectiveness of fibrin sealants in achieving haemostasis and wound closure following mandibular third molar extraction, in comparison with conventional suturing. Thirty patients with bilateral mandibular third molar impactions were recruited for the study. Using a split-mouth study design, wound closure following extraction was done using fibrin sealant on the study side and suturing on the control side. Sample allocation was done by simple randomization. The primary outcome measures were (1) the time taken to achieve wound closure and haemostasis and (2) postoperative mouth opening, pain, and swelling. Data analysis involved descriptive statistics and paired *t*-tests ($P < 0.05$). IBM SPSS software (v.20.0) was used for the data analysis. The study group demonstrated a statistically significant reduction in duration to achieve haemostasis (1.2 vs. 251.9 s; $P < 0.001$) and wound closure (152.8 vs. 328.8 s; $P < 0.001$) in comparison with the control group. The study group also exhibited significantly reduced pain scores (2.0 vs. 3.5; $P < 0.001$) and increased post-surgical mouth opening ($P < 0.001$). No adverse effects of fibrin sealant were observed. In conclusion, fibrin sealant is a superior intraoral wound closure and haemostatic agent and a worthy alternative to suturing.

Key words: fibrin sealant; third molar impaction; haemostasis; wound closure.

Accepted for publication 2 February 2015
Available online 23 February 2015

0901-5027/070871 + 05

The achievement of haemostasis and good mechanical closure of the wound are of immense importance in the field of surgery. Sutures have remained the mainstay for wound and haemorrhage management for centuries, despite their relative demerits.[1] Novel materials including staples, tapes, and tissue adhesives have been utilized as potential substitutes for sutures to achieve optimal surgical outcomes. Of these resources, tissue adhesives developed in the twentieth century, such as fibrin sealants, cyanoacrylates, bovine collagen and thrombin, polyethylene glycol polymer, and gluteraldehyde, have a unique place in the management of wounds.[2,3]

Amongst all the other tissue adhesives, fibrin sealants, which mimic natural fibrin mesh, have garnered much attention. They have been in use since the early 1900s. The first reported use as a haemostatic agent was by Bergel in 1909.[2,4] Since then, there have been many publications describing the role of fibrin glue as a haemostatic agent, tissue adhesive, and anastomotic agent for nerve and skin grafting.[2,4]

Fibrin sealants have diverse clinical applications. They have been specifically indicated for haemostasis in cardiac, liver, and splenic procedures and for sealing colonic anastomoses. They are used widely in thoracic procedures for the management of bronchopleural fistulae. Fibrin sealants have also shown significant utility in the fields of microsurgery, burns, and ophthalmic and gynaecological surgery as a haemostatic agent, adhesive, and tissue approximating agent.[1,2]

Mention of fibrin sealants in the oral and maxillofacial literature is limited, with only a few reports of its application as an 'adjunct' in vestibuloplasty,[5] aesthetic facial surgery,[6–11] head and neck reconstruction,[4] and periodontal procedures.[12–14] The role of fibrin sealants in routine dentoalveolar and intraoral surgical procedures needs to be explored and assessed, for better clinical application. These sealants may also be a valuable tool where there are special indications, such as for haemophiliacs and patients on anticoagulants, for whom a greater degree of haemorrhage control is required.

This clinical trial was designed to study the efficacy of fibrin sealant as an intraoral wound closure material and to compare it with conventional suturing, and at the same time, to evaluate patient response parameters.

Patients and methods

Study design

The study was designed as a randomized controlled clinical trial comparing fibrin sealant with conventional suturing using 3–0 black silk, for a sample of 30 patients undergoing bilateral extraction of mandibular third molars. The necessary approval for the study was obtained from the institutional review board and the study was performed in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement. The study was done using the 'split-mouth method', where one side was assigned for fibrin sealant (study group) and the contralateral side for conventional suturing (control group) (Fig. 1). Thus each patient was his/her own control, to negate inter-patient bias. The second side surgery was performed 3 weeks after the first side. This ensured complete healing of the surgical wound and eliminated an overlap of symptoms as well as a distortion of the results while calculating pain, swelling, and mouth opening. The patient pool was sequentially numbered 1–30. Lots were drawn, one for each patient, from sealed envelopes that contained combinations of the agent (fibrin sealant/suturing) and the side to be operated (right/left).

Patient selection

Thirty consecutive patients requiring surgical removal of bilateral mandibular third molars, with similar grades of difficulty, were recruited for this clinical trial. Patients were provided with an explanation of the study and gave consent for the procedure and clinical study.

The following inclusion criteria were applied: (1) ASA 1 (American Society of Anesthesiology) patient with no systemic diseases or conditions; (2) patient requiring surgical removal of bilaterally impacted mandibular third molars; (3) bilateral impactions with a relatively similar classification and degree of difficulty, based on the Pell and Gregory system (Fig. 2); (4) patient agreement to the surgical procedure and clinical trial, providing informed consent.

The following exclusion criteria were applied: (1) presence of systemic diseases; (2) presence of bleeding disorders; (3) patients on anti-platelet or anticoagulant therapy; (4) pregnant or nursing mothers; (5) patients with a known history of allergy to lignocaine; (6) patient not consenting to the procedure or study.

Surgical procedure

All patients underwent surgical removal of the impacted teeth under local anaesthesia.

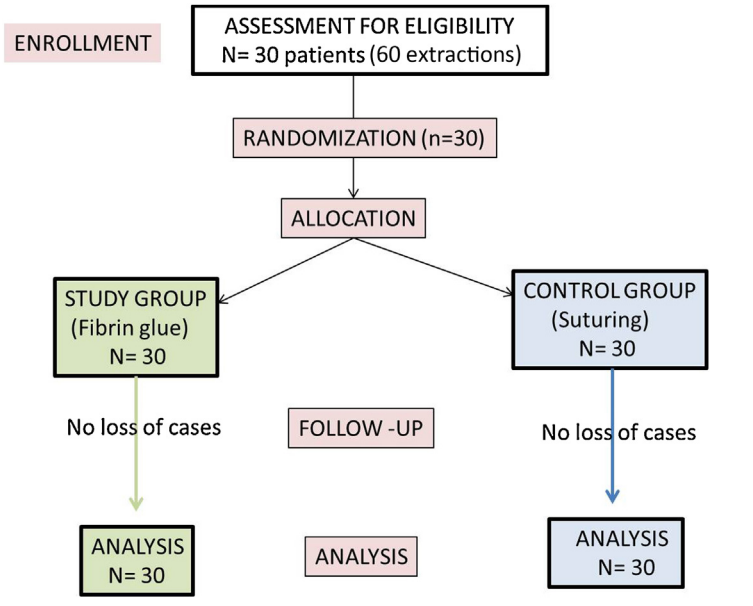

Fig. 1. CONSORT study flow chart.

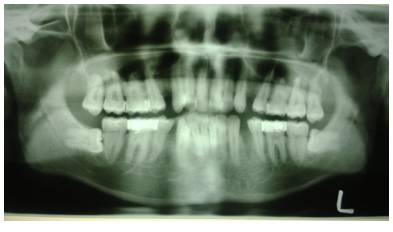

Fig. 2. Orthopantomogram of a sample subject demonstrating bilateral mandibular third molar impactions with similar clinical features.