CLINICALLY COMPARE THE EFFICACY OF N-BUTYL 2- CYANOACRYLATE AND VICRYL SUTURE IN INTRA ORAL WOUND CLOSURE: An In Vivo Study

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CERTIFICATE

This is to certify that the dissertation entitled **"CLINICALLY COMPARE THE EFFICACY OF N-BUTYL 2- CYANOACRYLATE AND VICRYL SUTURE IN INTRA ORAL WOUND CLOSURE: AN INVIVO STUDY"** is a bonafide research work done by Dr. K. MURUGAN, Post graduate student during the period of 2013 - 2016 under my guidance and supervision. This dissertation is submitted to the Tamil Nadu Dr. M.G.R. Medical University, Chennai in partial fulfillment of the requirements for the award of Master of dental surgery, Branch III (Oral and Maxillofacial surgery). It has not been submitted (partially or fully) for the award of any other degree or diploma.

Guide
Dr. Dhineksh kumar MDS
Professor
Department of Oral and
Maxillofacial surgery
Sree Mookambika Institute of
Dental Sciences
Kulasekharam -629 161

Dr. N. DHINEKSH KUMAR, M.D.S
Professor
Dept. of Oral and Maxillofacial Sugery
Sree Mookambika Institute of Dental Sciences
Kulasekharam-629 161

Co – Guide
Dr. Mathew jose. MDS
Professor & Head
Department of Oral and
Maxillofacial surgery
Sree Mookambika Institute of
Dental Sciences
Kulasekharam -629 161

Dr. Mathew Jose
Professor & HOD
Dept. of Oral & Maxillofacial Surgery
Sree Mookambika Institute of Dental Sciences
Kulasekharam - 629 161

SREE MOOKAMBIKA INSTITUTE OF DENTAL SCIENCES

KULASEKHARAM

ENDORSEMENT BY THE PRINCIPAL / HEAD OF THE INSTITUTION

This is to certify that the dissertation entitled "Clinically compare the efficacy of N Butyl 2 cyanoacrylate and vicryl sutures in intra oral wound closure: An In Vivo study" is a bonafide research work done by Dr. K.Murugan under the guidance of Dr. Dhineksh kumar MDS, professor Department of Oral and Maxillofacial surgery, Sree Mookambika Institute of Dental Sciences, Kulasekharam.

SREE MOOKAMBIKA INSTITUTE OF DENTAL SCIENCES

Dr. Elizabeth Koshi MDS
Principal
Sree Mookambika Institute of Dental Sciences
VPM Hospital Complex
Padamthalavilai, Kulasekharam-629 161
K.K Dist., Tamil Nadu

Dr. Elizabeth Koshi MDS
Principal
Sree Mookambika Institute of Dental Sciences,
VPM Hospital Complex,
Kulasekharam,
K.K. Dist., Tamil Nadu - 629 161

Date:

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LIST OF ABBREVIATIONS

AIDS	-	Acquired Immune Deficiency Syndrome
APTT	-	Activated Partial Thromboplastin Time
OCA	-	Octyl Cyanoacrylate
NBCA	-	N Butyl 2 Cyanoacrylate
BUN	-	Blood Urea Nitrogen
CRE	-	Creatinine
ALT	-	Alanine Amino Transferace
AST	-	Aspartate Amino Transferace
TBI	-	Total Bilirubin
TP	-	Total Protein
ALB	-	Albumin
AML	-	Amylase
CO_2	-	Carbon di Oxide
SPSS	-	Statistical Package for Social Sciences

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Wound closure is assisted by usage of appropriate suturing technique and suture material in intra oral and general surgical procedures and aimed at maintaining form, function and aesthetics of surgical site.[1]

Suturing the wound reduced the inflammatory cells accumulation around the suture material and it leads to faster healing.[2] In Diabetic and immunocompromised patient tissue response produced for the suture material gains importance.[3]

Healing by primary intension requires proper approximation of wound edges, complications of healing after surgery may result because of any of the following reasons or a combination of them,

1. Improper preoperative assessment

2. traumatic surgery

3. poor post operative care

Generally infection or reinfection in the wound hinders the healing process. This is the most important aspects in healing of intra oral wounds. Increased chance of intra oral wound infection is due to presence of plaque and food debris in the oral cavity, so intra oral surgical procedures are more prone to infections. To minimize the post operative infection in the intra oral wound need a aseptic environment and proper handling of the soft tissue and hard tissue structures.

Properly assessed and planned surgery need immobilization of healing tissue and this can be performed by using appropriate suturing technique and suture material or tissue adhesive. Surgical Wounds are closed with the sutures from the time of

immemorial. Though advanced suturing techniques and suture materials are present, fistulations, rail road track scars and suture granulomas remain as disadvantages for sutures. It also has disadvantages of pricking the normal parenchymal tissue and inflammatory tissues while suturing of wound. Because of capillary action of suture materials, there is increased chance of infection or reinfection. Suturing technique increases the time of surgical procedure and anesthesia. The surgeon should exert control force during suturing otherwise the excess forces may lead to the tension in the suture and result in tearing or necrosis at wound margin. Loose suturing causes gaping between the wound edges, so it may lead to increase the chance of infection and delay the healing process. While suturing accidental needle prick causes increased chance of transmission of disease like AIDS and Hepatitis to the surgeon. Because of the iatrogenic complication of suturing, alternative technique like tissue adhesive emerged to close the wound margins. Tissue adhesive materials completely eliminate the needle prick injury and tearing of the wound margin while closing the wound margins. So tissue adhesives are becoming popular. Because of the increased necessity of tissue adhesive, the effectiveness, advantages and disadvantages of the tissue adhesive was compared over traditional method of wound closure of suture.

Property of ideal tissue adhesive for intra oral wound closure:

Stability,

It should undergo complete polymerization in presence of moisture, (saliva, blood and water)

It should have adequate working time to apply,

It should cover the optimum area,

During polymerization it should not exert more heat to the tissue,

It should be biodegradable,

It should be easy to use,

It should not be carcinogenic,

Complete Wettability.

Among the materials in tissue adhesive, N Butyl 2 cyanoacrylate fulfills most of the ideal properties of tissue adhesives.

Adhesive property of cyanoacrylate was discovered in 1959. Initial tissue adhesives were in alkyl form and ethyl form. These tissue adhesive were discontinued because of their toxic effects on the tissue. But long molecular chain of N Butyl 2 cyanoacrylate is not toxic and it has the advantages achieving haemostasis, bacteriostatic properties and exhibit adhesive property with hard and soft tissue structures. So, it can be used for repair of organs, mucosa, skin, nerves, vessels and closure of wounds.[6,7,8]

Clinical use of N Butyl 2 cyanoacrylate was approved at the beginning of 1996. It is becoming a popular method for closure of wound under less tension. It provides good cosmetic closure than suturing. Moreover it has minimal time to apply and is a pain free method of closure than the suturing. It has advantages of better tensile strength and readily polymerize even in contact with moisture. We can increase the flexibility of the material by adding the plasticizer to the N Butyl 2 cyanoacrylate. It can also be used for the management of arteriovenous malformations, gastric and oesophageal varices and for embolizations. Nowadays it is most commonly used for management of intracranial arteriovenous malformations.[10]

Absorbable suture material is commonly used in various surgical procedures like general surgery, gynecological surgery, ophthalmic surgery, neurosurgery and dermatology. Vicryl is an absorbable, safe and non toxic product. It is available in the form of coated as well as non coated form.

Vicryl is a synthetic, monofilament/multifilament absorbable suture material. It is a copolymer of lactide and glycolide coated with polygalactin 370 and calcium stearate. Tissue reaction of viryl suture is mild. Vicryl 910 or vicryl plus is coated with triclosan material.[11] Triclosan is a broad spectrum antibacterial agent and effective against the most common pathogens associated with surgical site infections. In vicryl rapide, it is treated with gamma irradiation and become low molecular weight than coated vicryl. It loses all its strength between10 to12th days and gets totally absorbed within 42 days.

To achieve proper wound healing, the incision should be accurate, tissue handling should be delicate, precise wound reapproximation, closure material should have ideal working property and aseptic. Various other factors also contributing for ideal wound healing are systemic health, nutritional status, immune responses of individual and presence or absence of infection in the wound.

The purpose of present study is clinically comparing the efficacy of N Butyl 2 Cyanoacrylate and vicryl suture in intra oral mucosal incision.

AIM:

The aim of the study is to clinically compare the efficacy of n-butyl-2-cyanoacrylate with vicryl suture in the closure of intra oral mucosal incisions.

OBJECTIVES:

Postoperatively evaluate the

- Pain
- Wound dehiscence.

Bhaskar SN et al in 1966[25] conducted a study to evaluate the material of N - butyl cyanoacrylate (a chemical adhesive) for the clinical use of dressing in periodontal surgery and other common surgical procedures in human. The study was conducted in 105 patients out of 276 applicators, and result showed N - Butyl cyanoacrylate had better periodontal dressing property than other dressing agents. Mode of application to tissue was easy, it was a better hemostatic agent, it was not bulky so it won't interfere with wearing of prosthesis. Even application was possible after single tooth extraction, postoperative pain was less, single application was satisfactory and not induced any granulation and it promote the healing process. It produced immediate hemostasis on fresh extraction socket. In case of recurrent apthous and leukemia, large ulcer present on the intra oral mucosa, application of cyanoacrylate over the ulcer causes reduction of pain and discomfort for the patient.

Bhaskar SN et al in 1967[28] conducted a study to determine the effectiveness of N Butyl cyanoacrylate on the healing process in extraction wounds. In 48 adult rat extractions of 96 mxillary first molars were performed. Spray of butyl cyanoacrylate was used to cover the half of the extracted socket while the other half were left uncovered. When animals were killed from 1 to 21 days postoperatively, it was found that the cyanoacrylate spray covered wound consistently showed less inflammatory cell infiltration than the control wounds. Moreover, cyanoacrylate covered wound showed epithelialization and collagenation better than the control groups. So, he concluded that N Butyl 2 cyanoarylate was able to prevent the formation of dry socket after the extraction.

Schmeissner et al in 1971[48] studied on the histotoxicity of cyanoacrylates. He concluded that cyanoacrylate had bactericidal effect against 10 test bacilli.

Bessermann M in 1977[27] evaluated the effect of n-Butyl-cyanoacrylate as an hemostatic agent. It can produce maximum effect, when it was applied as thin and elastic film by local application with spray. Spray for the oral cavity was available in the form of plastic ampule. This cyanoacrylate spray was used for 27 patients to achieve hemostasis in prolonged bleeding state. Among 27 patients, 18 patients have different hemorrhagic diatheses and to achieve hemostasis of these patient general hemostatic procedures has been performed. Among 27 patients, 9 patients were in without hemorrhagic diathesis, the cyanoacrylate glue spraying replaced more complicated procedures. Among 27 patients, 24 patients treated successfully with N Butyl 2 cyanoacrylate as a hemostatic agent. He concluded that N Butyl 2 cyanoacrylate had a better hemostatic property.

Tse et al in 1984[7] conducted a study to evaluate the adhesive property of cyanoacrylate. He used cyanoacrylate in orbital surgery to stop cerebrospinal fluid leaks. His study results showed n butyl 2 cyanoacrylate had bacteriostatic effect mainly against the gram positive organism.

Javelet et al in 1985[26] conducted a study to compare the closure of mucosal incisions in monkey with isobutyl cyanoacrylate and sutures, then evaluated clinically and histologically. Eight young green vervet monkeys were selected for the study. In this study he did the bilateral vertical incisions in the maxillary and mandibular labial mucosa. He did the closure of mucosal incision with the 4-0 black silk on one side; on other side he used the isobutyl cyanoacrylate for closure of the wound. On histological examination, the scoring for degree of inflammation was obtained on 1st, 3rd, 10th, and 20th weeks for the mucosa containing the incision. The results showed that the inflammatory responses for cyanoacrylates and sutures were not similar. Cyanoacrylate showed a lesser inflammatory reaction than suture.

Dalvi et al in 1986[33] conducted a comparative study between N Butyl 2 cyanoacrylate and catgut in closure of skin on 30 patients. He concluded that skin closure done by N Butyl 2 cyanoacrylate resulted in low incidence of infection and procedure was time saving when compared with catgut suture.

Mehta et al in 1987[50] conducted a study to evaluate N Butyl cyanoacrylate for the use of osteosynthesis in mandibular fractures. He concluded that the use of N Butyl 2 cyanoacrylate adhesives was nontoxic, non mutagenic and non carcinogenic. The surgical treatment of fractures seems satisfactory.

Toriumi DM et al in 1990[44] conducted a study to evaluate histotoxicity and bone graft-binding property between the ethyl-2-cyanoacrylate and butyl-2-cyanoacrylate. In this study bone grafts from the anterior wall of the maxillary sinus were placed in a subcutaneous pocket glued to auricular cartilage in the rabbit. Ethyl-2-cyanoacrylate was used in one side and butyl-2-cyanoacrylate was used in opposite ears. At 1, 2, 4, 12, 24, and 48 weeks, examination of specimens was done. Results showed Ethyl-2-cyanoacrylate demonstrated severe histotoxicity, butyl-2-cyanoacrylate had minimal histotoxic effect and good bone graft-cartilage binding ability.

Leahey AB et al in 1993[30] conducted a study to investigate the occular use of N-butyl cyanoacrylate tissue adhesive. He proposed the indications, result outcome and complications of the N Butyl 2 cyanoacrylate in ocular use. Author had used N-butyl cyanoacrylate on 44 patients over a period of 2 years. Author suggested the possible use of N butyl-2-cyanoacrylate in corneal perforation (19 eyes), descemetoceles (9 eyes), leaking filtering blebs (6 eyes), stromal thinning (5 eyes), wound leaks (4 eyes), and exposure keratopathy (1 eye). A bandage contact lens was used over the dried tissue adhesive in 38 of the 44 eyes. Length of glue adherence ranged from 1 to 660

days (mean, 72 days). Outcome was penetrating keratoplasty (19 eyes), no further intervention (14 eyes), enucleation (4 eyes), surgical revision of a filter (2 eyes), scleral patch graft (1 eye), conjunctival transplant (1 eye), failed tarsorrhaphy (1 eye), suturing of wound (1 eye), and a lamellar graft (1 eye). Vision improved in 52% (23/44) of eyes. The authors stated that it was an effective method of temporary or permanent closure of an impending or frank perforation.

Howell et al in 1995[17] conducted a study on 11 male albino guinea pigs weighing between 650 and 800 g each to compare the effectiveness of suture and cyanoacrylate tissue adhesive on contaminated lacerations wound with bacteria. 3 cm long four dorsal lacerations were made parallel to the spine to deep fascia. He used sterile gauze to achieve hemostasis. Each laceration inoculated with 0.1ml of bacterial inoculums with a sterile pipette system. The lacerations were inoculated with Staphylococcus aureus adjusted to a spectrophotometric absorbance of 0.138 to 0.139. Inoculate were quantified at approximately 108 CFU/ml by standard microbiological methods. In selected lacerations, the wound edges were reapproximated manually then thin layer of adhesive was applied along the wound margin with a plastic applicator. Also in selected wounds, one intradermal stitch of 4-0 braided polyglactin 910 sutures was placed. He concluded that contaminated wounds closed with cyanoacrylate alone had significantly lower staphylococcal counts than lacerations containing suture material.

Giray et al in 1997[19] performed a study in 15 patients. All the patients underwent root resections of the upper incisors bilaterally. Silk suture was used to close the incision on one side of the frenum and on the other side n-butyl-2-cyanoacrylate was used. Clinically comparison of silk suture and N Butyl 2 cyanoacrylate was made on the 1st, 2nd, 3rd, 7th, 14th and 21st postoperative days. On the seventh postoperative day small punch biopsy was taken from N-Butyl-2-cyanoacrylate treated side and sutured

sides after the removal of sutures and N Butyl 2 cyanoacrylate. Then the biopsy specimens were examined with transmission electron microscope. Clinically third and seventh postoperative days showed epithelialization was better on the sides treated with n-butyl-2-cyanoacrylate. On the 21st postoperative day, local inflammation was significant during healing process and scar formation was significant in sutured site. The tissue specimens were observed under electron microscope which revealed normal ultrastructural morphology.

Mayraperez et al in 2000[9] conducted a study on N Butyl-2-cyanoacrylate and evaluated tissue adhesive nature of it clinically and biologically. Intra oral wound closure was done with the cyanoacrylate as a non suture method. He did the wound closure with tissue adhesive for 130 patients, for 30 patients wound closure done with suture. Apicoectomy, extraction of molars, and mucogingival grafting procedures were performed. N Butyl 2 cyanoacrylate permitted immediate hemostasis and normal healing of incisions. Pain relief was observed when Tissuacryl was used to cover the donor sites and mucosal ulceration.

Kutcher MJ in 2001[34] evaluated the bioadhesive device for aphthous ulcers management. He tested the device in two blinded and sham controlled studies. He selected 200 patients with a complaint of single, painful aphthous ulcers. In the first trial, tissue adhesive were applied by the investigators to the ulcers. The subjects themselves were made to apply the tissue adhesive to their ulcer in the second trial. Reduction in pain and healing times were evaluated. The authors concluded that 2OCA tissue adhesives were safe and pain reduction was satistically significant when applied by either the investigators or the subjects.

Montanaro L in 2001[18] conducted a study to evaluate the two cyanoacrylate glues for surgical use. He evaluated Cytotoxicity, blood compatibility and antimicrobial activity of two cyanoacrylate glues (Glubran and Glubran 2). Two cyanoacrylate surgical glues were tested for cytotoxicity, blood compatibility and the evaluation of antimicrobial activity also performed. The polymerized glues were used to test the cytotoxicity and biocompatability. The extracts from Glubran and Glubran 2 after polymerization, it was found that non-toxic to L929 cells in the neutral red uptake test, and this test was performed with diluted 1:10 with culture medium. A significant decrease of activated partial thromboplastin time (APTT) was induced by glubran and glubran 2. Thus it was favorable for achieving desired haemostasis and results in good adhesion of glue. Otherwise, no significant variation of prothrombin activity, fibrinogen, platelet number, total and differential leukocyte count was induced by the glues, which, in addition, did not show haemolytic effect. Glubran and Glubran 2 had no difference in their haemocompatibility. Bacillus subtilis was used for testing the glues antimicrobial activity for a time period of 3 weeks: the author concluded that cytotoxicity was severe with the undiluted glues, but was acceptable when glues were diluted. Blood compatibility was acceptable for the use of the glues. After polymerization no difference was found between the gluberan and glubran2.

Cantasdemir M et al in 2003[31] evaluated the effectiveness of N-butyl cyanoacrylate (NBCA) for selective endovascular embolisation in the treatment of traumatic intrarenal arterial pseudoaneurysms. He selected five patients (four males and one female) with massive haematuria problem. Angiographically, five pseudoaneurysms were detected. Penetrating trauma was the etiology of all the cases. Size of the pseudoaneurysm ranged between 7 and 30 mm (mean: 13.8 mm). Embolization was performed using NBCA and Lipiodolmixture were performed after

superselective catheterization with a microcatheter-microguide wire system. All the pseudoaneurysms were successfully embolized. They were excluded from the circulation without any other major intrarenal arterial branch occlusion. There were no major or minor complications related to the embolization procedures. Haematuria stopped in 1–3 days after the embolization. During the follow-up period no occurrence of re-bleeding and deterioration of renal function were seen. The endovascular management for the renal artery branch pseudoaneurysms was performed by embolization with NBCA. He concluded that it was an effective therapeutic technique for intrarenal arterial psuedoaneurysm.

Koranyi et al in 2004[15] performed a comparitive study between the 7/0 vicryl suture and fibrin glue. They assessed the duration of surgery and patient complaints, post operatively. The authors concluded after assessing postoperatively that the fibrin glue group had less discomfort and time taken for the procedure was less.

Chai et al in 2006[35] evaluated the efficacy of cyanoacrylate in its role in the healing process of the large perforation of maxillary sinus membrane during sinus lifting procedures. He conducted a study in six rabbits. cyanoacrylate adhesive was used to repair of sinus membrane on one side of the maxillary sinus, an identical laceration on the other side was not repaired. After 2 weeks histologic evaluation was done. There was newly formed sinus epithelium on the cyanoacrylate applied side. Sinusitis was present on the other side of the maxillary sinus.

Jehangirnezhad in 2006[43] conducted a study for treatment of gingival recession with coronally repositioned flap using tissue adhesive. He did the same procedure on without adhesive also. The authors concluded that coronally repositioned semilunar

flap alone or with epiglu was an effective method of root coverage in anterior and premolar teeth. In shallow defects epiglu improves root coverage.

Sametinal et al in 2006[12] conducted a study on 10 male wistar rats with the weight of 220 to 270 g. On buccal mucosa straight incisions were made. Wounds were closed primarily with N-Butyl cyanoacrylate(indermil). Before the surgical procedure blood samples were taken from the vena cava after 2, 14 21 and 65 days. The control group was blood sample taken before the procedure and study group blood specimens were taken on 2, 14, 21, and 65 days after the application of cyanoacrylate. The stored plasma samples were analyzed for blood urea nitrogen (BUN), creatinine (CRE), alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin (TBI), total protein (TP), albumin (ALB), and amylase (AML). In addition to biochemical parameters, histopathological examination was also performed. Blood parameter values of the control and study groups were statistically compared with the Duncan test. There were no significant differences in the values of blood urea nitrogen, creatinine, alanine aminotransferase, aspartate aminotransferase, total bilirubin, total protein, albumin and amylase between the contro group and study group on 2, 14, 21, and 65th days. This study concluded that N-Butyl-2-Cyanoacrylate was a suitable adhesive oral surgical procedures.

Alonso FC et al in 2007[21] evaluated the wound healing after the incisions in the upper aerodigestivetract. He conducted a study of prospective and blind study in 186 adult rats. He divided these rats into six groups to create the incisions in the tongue. With a steel scalpel, wound was made in the first three groups. In the first group no substance was applied over the wound, but in the second group N-butyl-2-cyanoacrylate was applied, and trichloroacetic acid at 50 percent concentration was applied in the third group. In the fourth, fifth, and sixth groups, the wounds created

with the cryosurgery, electrocautery, and CO2 laser. In this study parameters were hemostasis, wound healing and postoperative oral intake were measured. Second group showed no hemorrhaging in the wound region, faster reepithelialization and resolution of the inflammatory response in the wound region. He concluded that N-Butyl-2-cyanoacrylate had a property of hemostasis and reduction of inflammatory response.

Knott et al in 2007[42] performed a study with the use of Octyl-2-Cyanoacrylate. He appreciated the advantage of watertight closure of the Octyl-2-cyanoacrylate tissue adhesive as it reduced the exposure to nasal secretion which had high bacterial count.

Kulkarni S et al in 2007[32] conducted a study to evaluate the healing of the periodontal flaps. After the surgery, wound closure performed by conventional silk sutures and tissue adhesive of N-butyl cyanoacrylate. He conducted a study on 24 patients who needed flap surgical procedure for elimination of periodontal pocket. He founded that healing with the cyanoacrylate was associated with less amount of inflammation during the first week when compared with silk. However, over a period between 21 days to 6 weeks, there was no significant difference in healing process between both groups. He concluded that cyanoacrylate promote the initial healing.

Morettineto et al in 2008[16] conducted a study to evaluate the biocompatibility property of three different cyanoacrylate based tissue adhesives. He selected Thirty-six wistar rats for study. He divided thirty-six wistar rats into four groups of 9 animals each: A (control group) – distilled water, B group – incision closed with cyanoacrylate ester (Super Bonder), group C – incision closed with N-Butyl-cyanoacrylate (Histoacryl) and group D – incision closed with alpha-cyanoacrylate (Three Bond). These materials were carried in sponge of polyvinyl chloride. After the

animals were incised, the sponges were inserted into the subcutaneous tissue and sutured. Then each group was sub-divided into the time of sacrifice of the animals: 7^{th}, 21^{st} and 45^{th} days. Histologic analysis showed all groups had some degree of irritability. Alpha cyanoacrylate showed an inflammatory reaction similar to control group, so alpha cyanoacrylate showed good biocompatibility than the other cyanoacrylate. Cyanoacrylate ester and N Butyl 2 cyanoacrylate showed more inflammatory reaction than the control group. He concluded that alpha cyanoacrylate was the most biocompatible material when compared to the other cyanoacrylate materials.

Ghoreishian et al in 2009[39] conducted a controlled clinical trial study to compare the cyanoacrylate and 3-0 silk suture. He selected sixteen patients with similar type of bone impaction bilaterally. After the surgical removal of impacted tooth, one side incision was closed with cyanoarylate on other side incision was closed with 3-0 silk suture. Based on his study he concluded that cyanoacrylate can achieve hemostasis better than the silk suture.

Hasan et al in 2009[40] conducted a study on pediatric population with the cyanoacrylate material. He concluded that Cyanoacrylate had a advantage of easy application and time consuming was less. Moreover, it didn't need removal of stitch and less nursing care in the follow up period.

Khalil et al in 2009[46] conducted a study to compare the efficacy of closure of intra oral surgical incision with the 3-0 silk suture and tissue adhesive of N-butyl-2-cyanoacrylate. He selected 20 patients and divided them into two equal groups. N-butyl-2-cyanoacrylate exhibited better initial healing with no gaps compared than the silk suture. He concluded that N-butyl-2-cyanoacrylate can reduce the patient

discomfort and irritation and it was an easy and effective method of intra oral wound closure.

Sybelesaska et al in 2009[45] conducted a study to evaluate the compatibility of the adhesives of Ethyl cyanoacrylate (Super Bonder) and Butyl-cyanoacrylate (Histoacryl). He analyzed the healing of incisions in the dorsum of rats with respective adhesives and suture. Author concluded that Butyl-cyanoacrylate and Ethylcyanoacrylate promoted healing of incised tissues and without promoting the inflammatory reaction. Moreover, adhesives reduced the surgical time for closure of wound than incision closed with suture. These adhesives allowed low inflammatory reaction in the subcutaneous layer of rats, so prevented the tissue necrosis. He concluded that cyanoacrylate adhesives can be used for lacerated wound and cutaneous incision wound.

Shahlakakoei et al in 2010[1] conducted study to compare histopathological reaction in closure of wound with four materials. Materials are Silk, Polyglycolic acid, Catgut and Polyvinylidene fluoride. He conducted a study in albino rabbits. Based on this study polyvinylidene fluoride suture exhibited less inflammatory reaction than other materials.[1]

Taira et al in 2010[20] conduted a study to compare the wound bursting strength of three materials, namely N Butyl 2 cyanoacrylate, Octyl cyanoacrylate (Dermabond) and adhesive tape in the form of steri-strips. For this study he selected 15 Sprague-Dawley rats. With the use of No 15 surgical blade, he made bilateral standardized full-thickness incision, then the incision with 1 of the 3 materials being studied. Failure of wound closure was due to either breakdown of the wound closure material or loss of adhesion to the surface of the skin. Wound closure done with the octyl or

butyl cyanoacrylate showed adhesive, cohesive or mixed failure breakdowns. Octyl cyanoacrylate showed statistically significant greater strength than the N Butyl 2 cyanoacrylate. Failure of skin adhesive property was more common in N Butyl 2 cyanoacrylate than the Octyl cyanoacrylate. N Butyl 2 cyanoacrylte showed better cohesive property than the Octyl cyanoacrylate. He concluded that Octyl cyanoacrylate showed better wound bursting strength than the N Butyl 2 cyanoacylate, but both performed better than the steri-strips in wound closure.

Cotton et al in 2011[29] conducted a study to evaluate the usefulness of preoperative percutaneous injections in the treatment of vertebral hemangioma. Four patients selected with the complicated vertebral hemangioma. Among the four cases three cases were spinal cord compression, one case was intermittent spinal claudication. Initially arterial embolization done in three cases, then percutaneous injection of methyl methacrylate done on one day later to strengthen it. On surgery N Butyl 2 cyanoacrylate was injected into the posterior arch to optimize hemostasis. Finally one day after percutaneous injection, epidural hemangioma excision and decompressive laminectomy done (if present). The laminectomy procedure was performed with minimal blood loss. The epidural component in three cases was excised without any difficulty. Patient reviewed for 20 months, there was no evidence of vertebral collapse. He concluded that in vertebral hemangioma surgery, injection of methyl methacrylate and N Butyl 2 cyanoacrylate prior to surgery was useful.

Joshi a et al in 2011[14] conducted a study to compare the efficacy of wound closure with the cyanoacrylate adhesive with conventional suture after the surgical removal of mandibular impacted third molar. He selected thirty patients with bilaterally impacted third molar. Then he performed a controlled clinical trial. On one side incision was closed with the conventional suture after the surgical removal of

impacted third molar. On other side incision was closed with the cyanoacrylate adhesive after removal of third molar. On first and second post operative day bleeding was significantly less in cyanoacrylate han with the suture site. There was statistically no significant difference in severity of pain between the incision closed with the suture and incision closed with the cyanoacrylate. He concluded that efficacy of wound closure with the cyanoacrylate and conventional suture similar property in the severity of pain but cyanacrylate showed better hemostasis than conventional suture.

Abhisheksoni et al in 2013[36] conducted a study to compare the incision in the maxillofacial region was closed with the octyl 2 cyanoacrylate issue adhesive with the subcuticular suture to evaluate the duration of closure , wound morbidity and patient satisfaction between the both groups. This study was a prospective randomized clinical trial. He conducted a study in 29 patients. Mean difference between the wound complication and patient satisfaction was good in octyl 2 cyanoacrylate group.

Ankitavastani et al in 2013[22] conducted a study to compare healing of intraoral wounds closed with 3-0 silk suture and incision closed with the isoamy 2-cyanoacrylate glue, clinically as well as histologically. They selected 30 patient for this study. All the patients underwent alveoloplasty procedure in the anterior edentulous mandibular region. Length of the incision was same from the midline in all the cases. Incision was closed with 3-0 silk material on one side, on other side incision was closed with the isoamyl 2-cyanoacrylate. The surgical sites were evaluated clinically on first, seventh, fourteenth, and twenty-first postoperative days for tenderness and erythema on both side. On seventh post operative day, incisional biopsy was performed on both sutured site and tissue adhesive site for 15 cases. On fourteenth postoperative day incisional biopsy was performed on both sutured site and cyanoacrylate site for other 15 cases. All the specimens were examined with the

microscope to detect the inflammatory cell infiltration, vascularity and fibroblastic activity. On the sutured site erythema and tenderness was more in first, seventh and fourteenth postoperative days than the incision closed with the cyanoacrylate. But on twenty-first postoperative day erythema and tenderness was same on both side. On the seventh postoperative day, the inflammatory cell infiltration and vascularity were higher on the sutured side than the cyanoacrylate side. But in fourteenth postoperative day, vascularity was higher on the sutured site than the cyanoacrylate site. Thus he concluded that isoamyl 2-cyanoacrylate promote initial wound healing than the suture.

Gumus et al in 2014[23] conducted a study to evaluate the amount of shrinkage after the free gingival graft technique with three different method of stabilization. He conducted a study on 45 patients, for them after free gingival graft, stabilization of graft achieved with conventional technique, microsurgery and cyanoacrylate adhesive. For conventional group he used standard 5-0 sutures to stabilize the graft. For microsurgery group, he used 7-0 sutures and loupe for stabilize the graft. For third group he used cyanoacrylate to stabilize the free gingival graft. Width of the keratinized tissue, gingival recession and surface area of the graft were calculated on 1^{st}, 3^{rd} and 6^{th} month by using the specific software on the standard photograph. Duration of surgery for each group also recorded. Pain was recorded by using visual analogue scale on first week after the surgery in both recipient site as well as donor site. Based on the findings, shrinkage of free gingival graft was comparatively less in cyanoacrylate group than the others. Pain and duration of surgery was also less in cyanoacrylate group than the conventional group and microsurgery group. He concluded that cyanoacrylate can be used as a stabilization agent after free gingival graft alternative to conventional suturing technique.

Howard B et al in 2014[13] conducted a study for evaluate the efficacy of Octyl – cyanoacrylate skin adhesive in posterior spinal injury wound closure without increased risk of wound complication. He conducted a study in three hundred eighty two patients. All the patients underwent posterior spinal surgery for reason of degenerative disease, oncologic problem and traumatic injury. He analyzed site specific complication of cerebrospinal fluid leak, wound infection and wound dehiscence. Results showed incisions for posterior spinal injury wound closed successfully with subcuticular monocryl and cyanoacrylate skin adhesive. The complication of cerebrospinal fluid leak, wound dehiscence and wound infection were not increased. However incidence of complication was not significant when compared with the posterior spinal injury incision closed with the conventional wound closure technique of suture in the established literature. So, he concluded that cyanoacrylate skin adhesive can be used for posterior spinal injury wound closure without increased possibility of wound complication even patient undergoing intradural procedure.

Snehasetrya et al in 2015[37] conducted a study to evaluate the efficacy of cyanoacrylates, then advantages and disadvantages of cyanoacrylate for suture less method of wound closure after surgical removal of impacted mandibular third molar. In this controlled clinical trial, he selected fifty patients. These patients had bilaterally symmetrical impacted third molar. After surgical removal of impacted third molar, he did the conventional suture on the controlled side for wound closure and cyanoacrylate glue on study side for wound closure. On 1st, 2nd and 7th day after the surgery, patient experienced comparatively less pain on cyanoacrylate glue site than conventional suture site. On 1st postoperative day, postoperative swelling and bleeding were less significant on cyanoacrylate glue site than with the conventional sutured site.

Study design:

This is a comparative interventional study for comparing the efficacy of N Butyl 2 cyanoacrylate and vicryl suture in intra oral wound closure.

Study setting:

Patients who reported to the Department of Oral and Maxillofacial surgery, Sree Mookambika Institute of Dental science, Kulasekharam, K.K district, Tamilnadu were included in the study. Thirty patients who fulfilled the inclusion criteria formed the study sample.

Number of group:

Two group.

Description of group:

Thirty patients reporting for intra oral mucosal incision for extraction procedure were included in this study.

Group I: Incision closed with vicryl suture material.

Group II: Incision closed with N Butyl 2 cyanoacrylate material.

Sample size of each group:

30 patients

Total sample size of the study

60(30 patients)

Scientific basis of sample size used in study

Sample size is formula used here is $\left[\frac{2pq(z\alpha + z\beta)2}{(P_1 - P_2)2}\right]$

Where $p = \frac{p_1+p_2}{2.}$

Q = 1-p

P_1 = proportion of 1 group

P_2 = proportion of 2 group

$Z\alpha$ = 1.96

$Z\beta$ = 0.84

Sampling technique

Convenient sampling technique.

SELECTION CRITERIA:

Inclusion criteria;

- Patient in the age group of 18-55 years will be selected irrespective of sex, caste, religion and socio-economic status.
- Bilaterally symmetrical mucoperiosteal flap with the same length and design for removal of teeth and alveoloplasty procedures were included.
- Only clean incisions which can be approximated without tension using cyanoacrylate were included.
- Length of incision should be 1 to 3 centimeter.
- Patients who agreed to follow the study protocol.

Exclusion criteria:

- Immunodeficiency disease.
- Uncontrolled systemic diseases.
- Patient with anti-coagulant therapy.
- smoker.
- Uncooperative patients; mentally retarded patients.
- Patients, who are likely not to maintain their oral hygiene.
- Flap, which cannot be approximated passively.
- Patients not willing to commit to an appropriate post procedure follow-up.

This study protocol was reviewed then approved by our departmental review board, research committee, ethical committee and all the patients in this study were informed of the benefits and possible risks of this procedure.

Parameters to be studied:

Pain-observed based on visual analogue scale.

Wound dehiscence/gaping- observed clinically by visual examination only.

Armamentarium:

- Mouth mirror(sirag surgical)
- Straight probes(sirag surgical)
- Tweezers(sirag surgical)
- Towel clips(sirag surgical)
- Suction cannula(sirag surgical)
- Disposable syringe(2 ml) with needles(24 gauge)(Dispovan).

- Lignox 2%.(Lignocaine2% with adrenaline 1:80,000-Warren indoco)
- Surgical scalpel No:3(sirag surgical)
- Bard Parker blade no. 15(from Paramount surgimed Ltd)
- Periosteal elevators No -9(sirag surgical)
- Straight elevators(sirag surgical)
- Winters Cryer's elevator(sirag surgical)
- Bone file(sirag surgical)
- Bone rongeur(sirag surgical)
- Needle holder(sirag surgical)
- Adsons tissue forceps(sirag surgical)
- Scissors(sirag surgical)
- Straight mosquito forceps(sirag surgical)
- 3-0 vicryl(Ethicon)
- Pre-sterilized N-Butyl 2- cyanoacrylate ampule(Reevax life sciences)

Procedure in detail:

After proper case recording and selecting the patients, the surgical procedure and also the use of n-butyl cyanoacrylate tissue adhesive for closure of surgical wounds as an alternative to sutures was explained thoroughly to the patients. Under aseptic precautions, patient was anaesthetized with 2% lignocaine with adrenaline 1:80000(LIGNOX-2% manufactured by Warren indoco) and prepared for surgery. The length of incision varied from 1-3 cm depending on the surgical access required for the procedure. The extraction procedure performed, if required alveolopasty procedures will be performed. After performing the surgical procedure and achieving adequate hemostasis, closures was performed on one side with n-butyl cyanoacrylate tissue adhesive and on the other side with 3-0 vicryl and these sides were randomly

chosen. The side of the incision where n-butyl cyanoacrylate tissue adhesive was to be applied, isolated with dry gauze. The incised edges were accurately approximated, trying not to leave any gap between them. N butyl 2-cyanoacrylate was applied at the approximated wound margins in the form of drops for closure of the mucoperiosteal flaps. Same surgical procedure performed on other side also, incision was closed with 3-0 vicryl suture. The post-operative sites pressure pack was given at the sutured sites. Post-operative instructions regarding diet, avoid disrupting the wound at glue site, oral hygiene maintenance and warm saline gargles were given to the patients.

Following medications with their standard dosages were given:-

1. Tab. Fenacplus(Diclofenac sodium 50mg+Paracetamol 500mg) twice a day for three days

2. Cap. Amox 500mg(Amoxycillin) thrice a day for five days

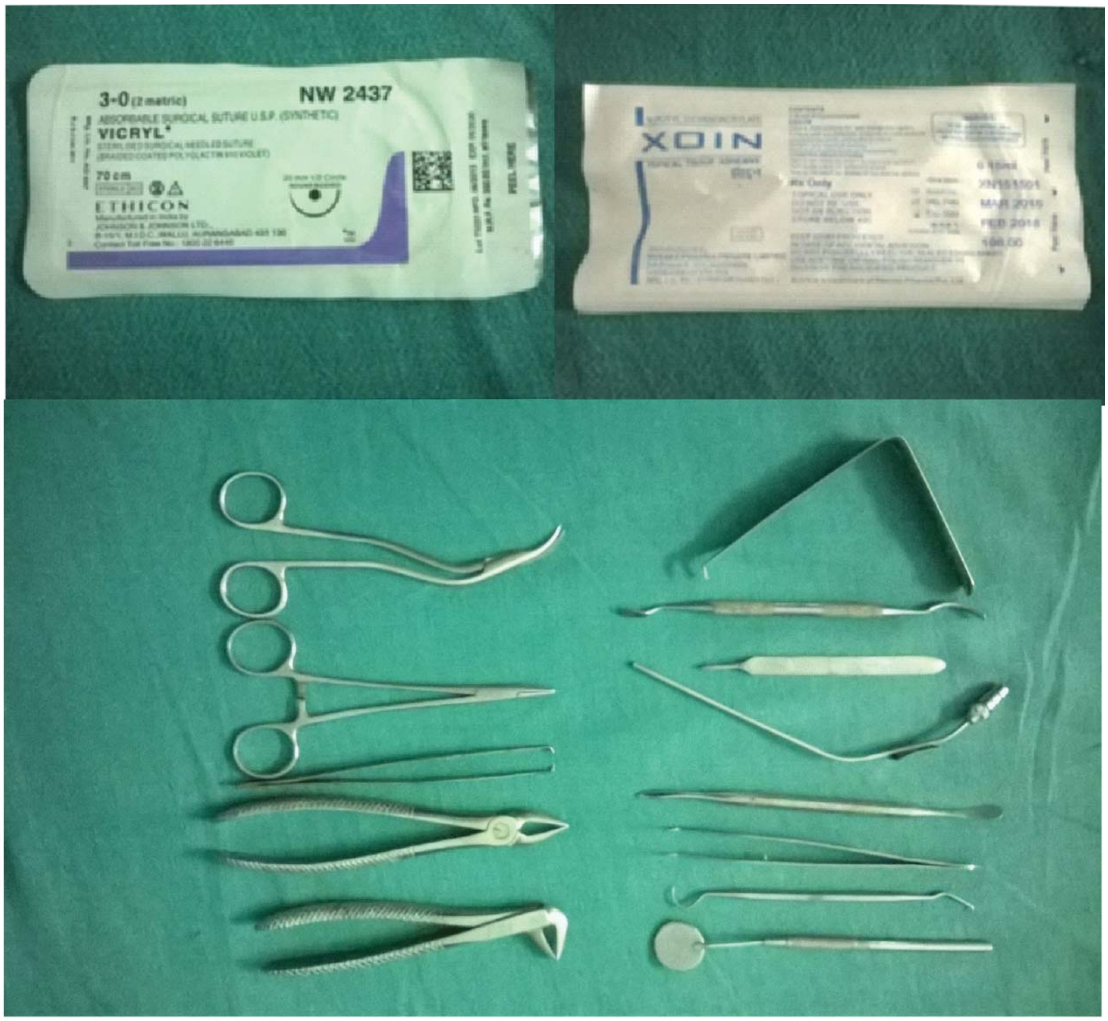
Follow-up was made at third, fifth and seventh post-operative days. During each follow up visit, pain was recorded on a visual analogue scale. The pain scale was 4 cm long subdivided into 4 equal parts, one end corresponding to no pain, the other to extremely severe pain. It will be recorded at1st day, 3rd day, 5th, and 7th day.

Visual analog scale to evaluate pain: reference values were given to patients

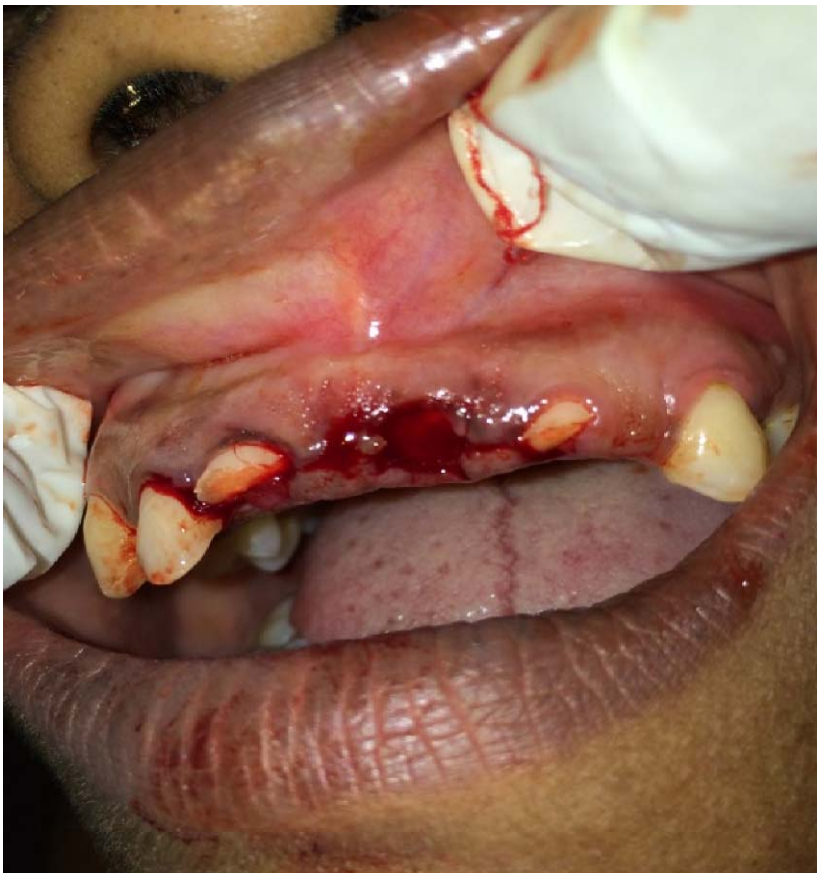
0	No pain	patient feels well
1	Mild pain	patient is distracted he or she does not feel the pain
2	Severe pain	patient is very disturbed but nevertheless can continue with normal activities
3	Very severe pain	patient is forced to abandon normal activities

Wound dehiscence was observed clinically on 1stday, 3rd day, 5th and 7th post operative days based on visual examination.

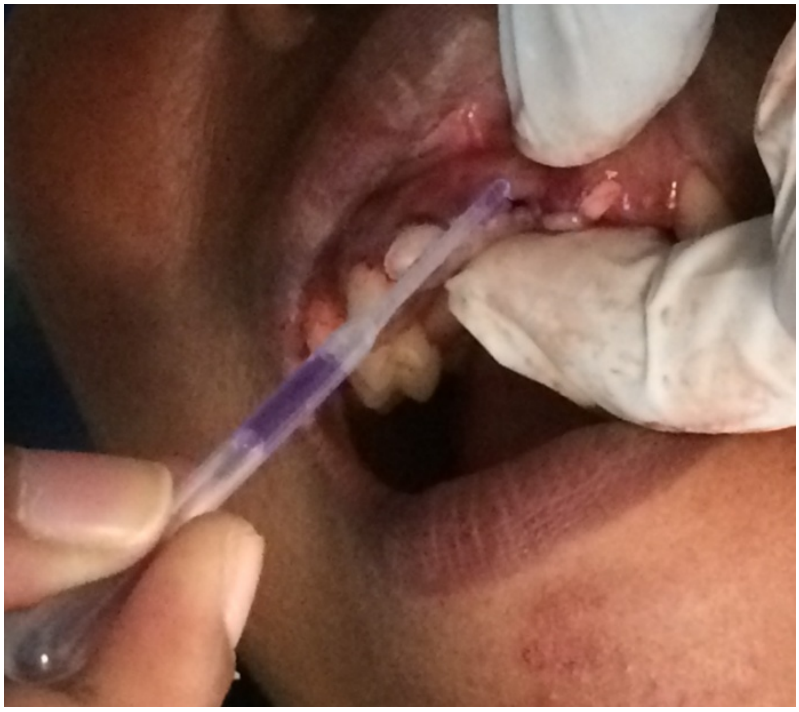
Statistical analysis of the information obtained was performed. The differences with a $P < 0.05$ were found to be statistically significant.



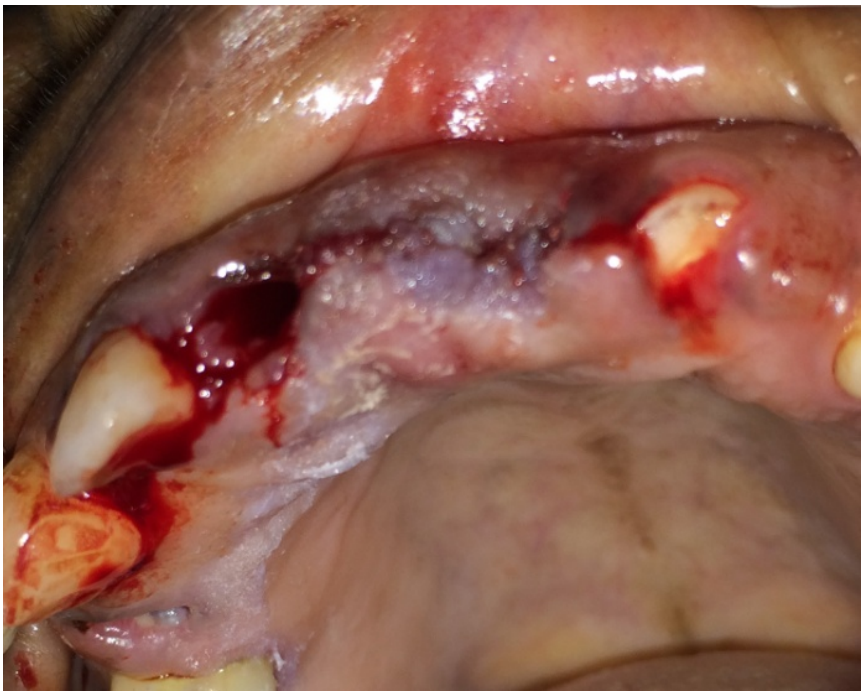
ARMAMENTARIUM



IMMEDIATE POST EXTRACTION OF 21



APPLICATION OF N BUTYL 2 CYANOACRYLATE



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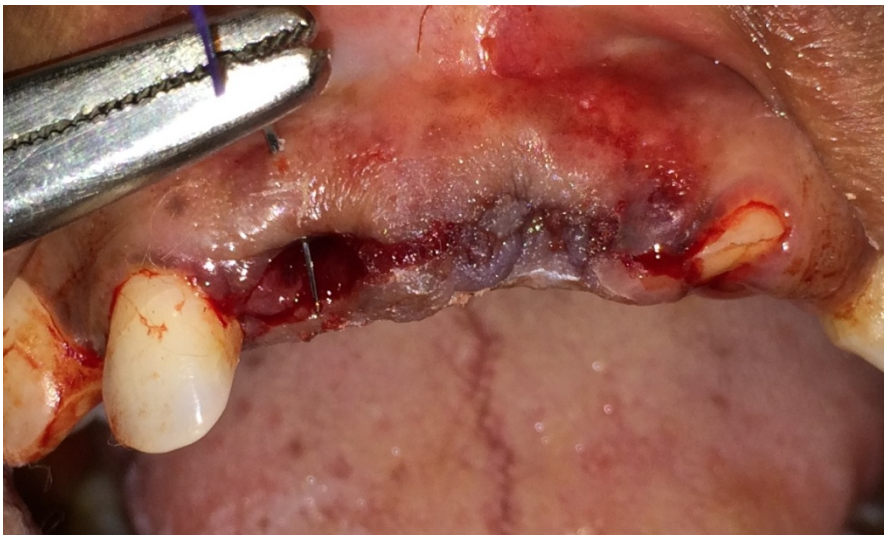
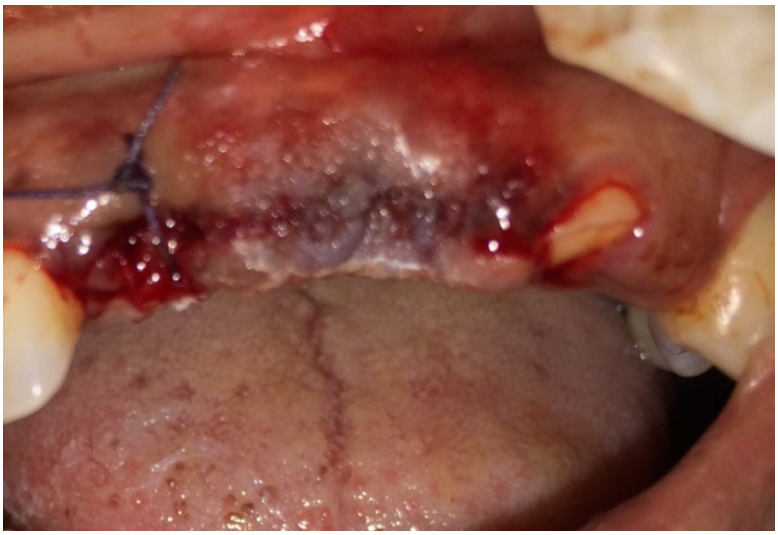
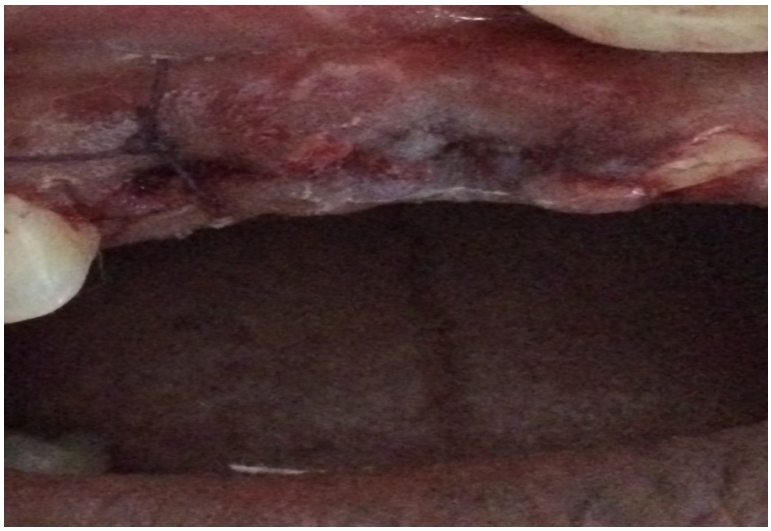


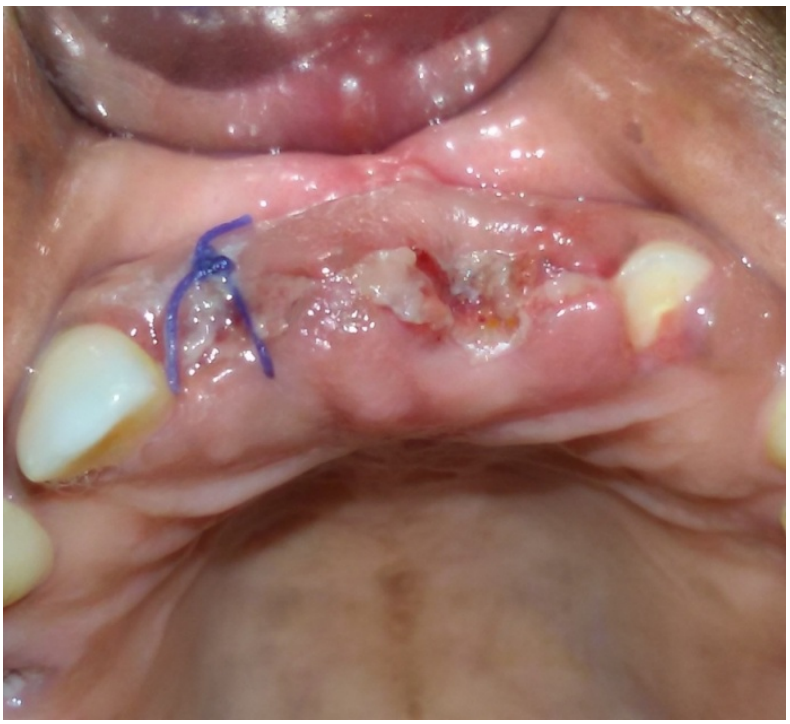
SUTURING WOUND WITH VICRYL



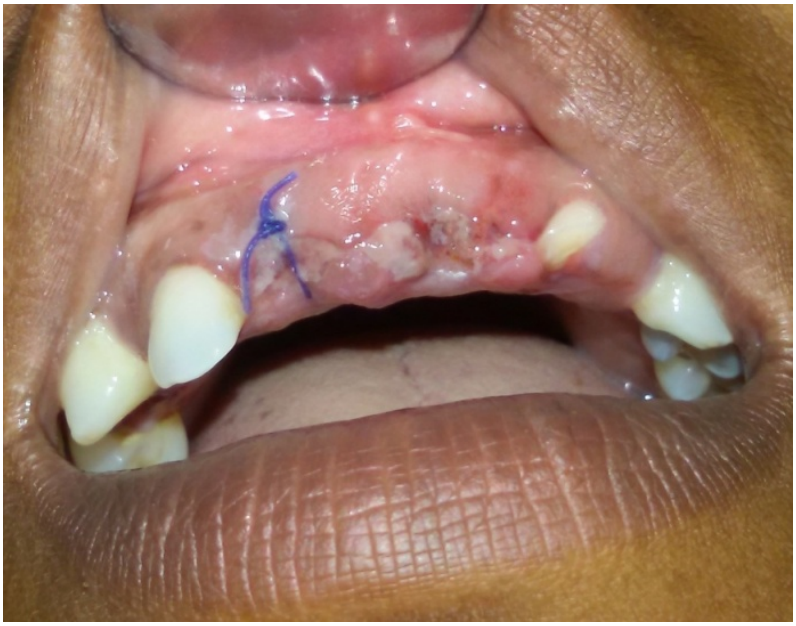
On DAY -1



On DAY -3



On DAY -5



On DAY -7

Statistical analysis:

The study was analyzed by Statistical Analysis for Social Sciences (SPSS 16.0) version. Chi square test applied to find the significant between the groups. P value less than 0.05 ($p<0.05$) considered statistically significant at 95% confidence interval.

Table-1: Demographic data

Demographic data	Age (MEAN±SD)	Gender			
		Male		Number	
		Number	Percentage (%)	Number	Percentage (%)
Groups	38.47±4.56	15	50.00	15	50.00

Graph-1: Distribution of patients according to gender

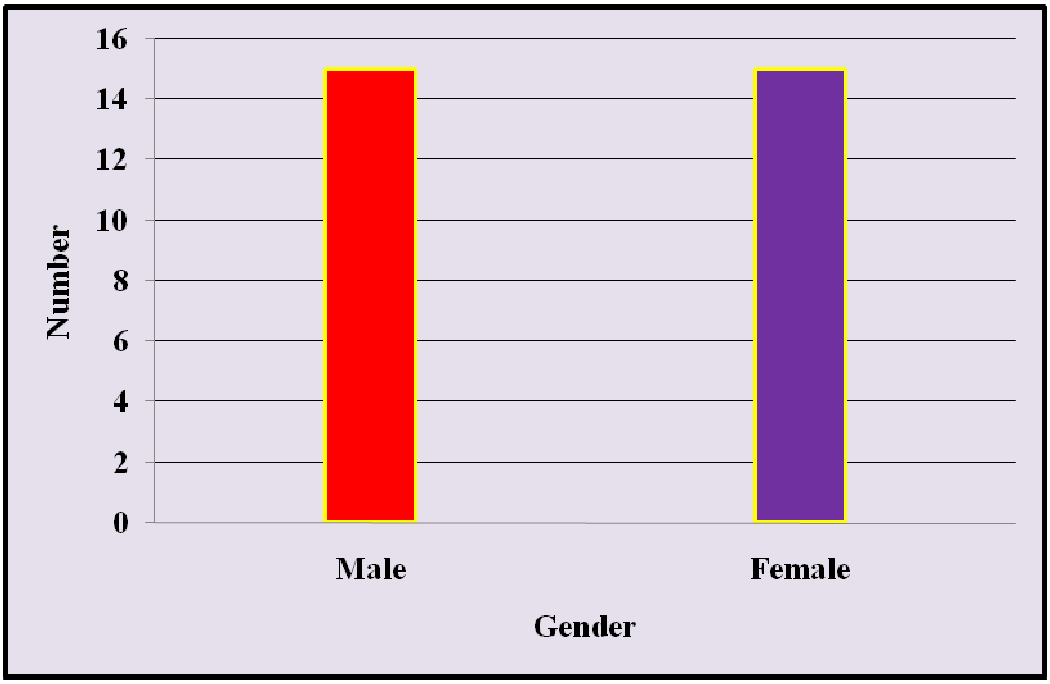


Table-2: Number and percentage of patients based on presence of wound dehiscence at different time periods

Groups	Day 1		Day 3		Day 5		Day 7	
	Number	%	Number	%	Number	%	Number	%
Group-I	2	6.67	9	30.00	16	53.33	18	60.00
Group-II	6	20.00	14	46.67	17	56.67	19	63.33

Table-3: Number and percentage of patients based on absence of wound dehiscence at different time periods

Groups	Day 1		Day 3		Day 5		Day 7	
	Number	%	Number	%	Number	%	Number	%
Group-I	28	93.33	21	70.00	4	46.67	12	40.00
Group-II	24	80.00	16	53.33	13	43.33	11	36.67

\

Table-4: Comparison of wound dehiscence between the groups at day 1

Groups	Day 1				p value
	Presence		Absence		
	Number	Percentage (%)	Number	Percentage (%)	
Group-I	2	6.67	28$^{\#}$	93.33	0.03
Group-II	6*	20.00	24$^{\#}$	80.00	
p value	0.04		0.87		

(*$p<0.05$ significant compared between the groups, $^{\#}p<0.05$ significant compared within the groups)

Table-5: Comparison of wound dehiscence between the groups at day 3

Groups	Day 3				p value
	Presence		Absence		
	Number	Percentage (%)	Number	Percentage (%)	
Group-I	9	30.00	21[#]	70.00	0.03
Group-II	14*	46.67	16*	53.33	
p value	0.02		0.45		

(*p<0.05 significant compared between the groups, [#]p<0.05 significant compared within the groups)

Table-6: Comparison of wound dehiscence between the groups at day 5

Groups	Day 5				p value
	Presence		Absence		
	Number	Percentage (%)	Number	Percentage (%)	
Group-I	16	53.33	14[#]	46.67	0.04
Group-II	17	56.67	13[#]	43.33	
p value	0.78		0.67		

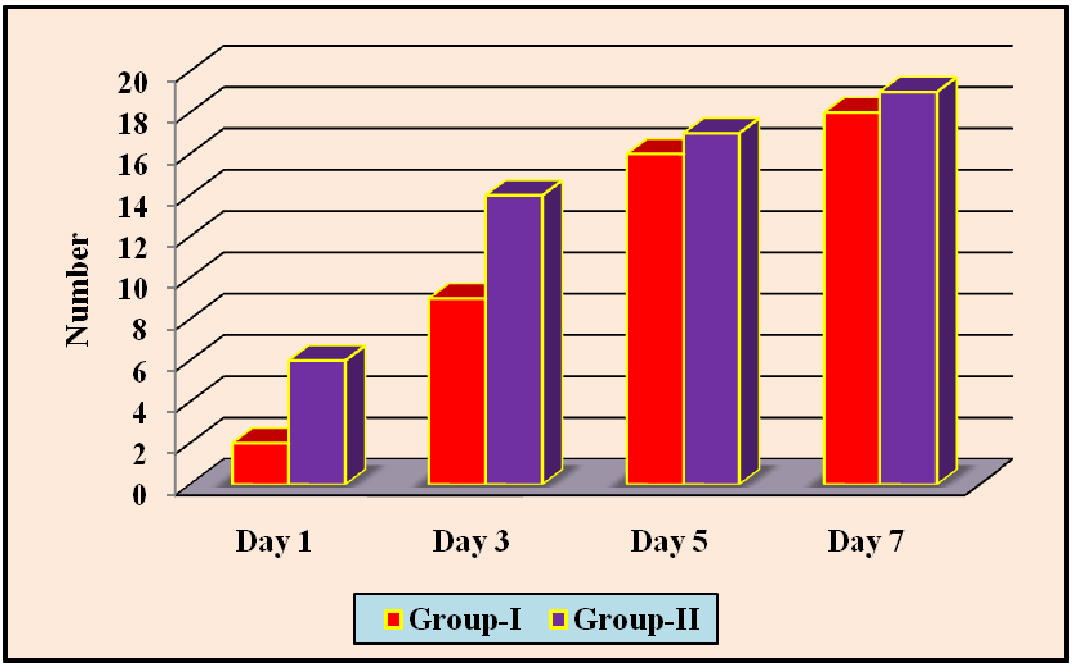
(p>0.05 no significant compared between the groups, [#]p<0.05 significant compared within the groups)

Table-7: Comparison of wound dehiscence between the groups at day 7

Groups	Day 7				p value
	Presence		Absence		
	Number	Percentage (%)	Number	Percentage (%)	
Group-I	18	60.00	12[#]	40.00	0.02
Group-II	19	63.33	11[#]	36.67	
p value	0.45		0.19		

($p>0.05$ no significant compared between the groups, [#]$p<0.05$ significant compared within the groups)

Graph-2: Number and percentage of patients based on presence of wound dehiscence at different time periods



Graph-3: Number and percentage of patients based on absence of wound dehiscence at different time periods

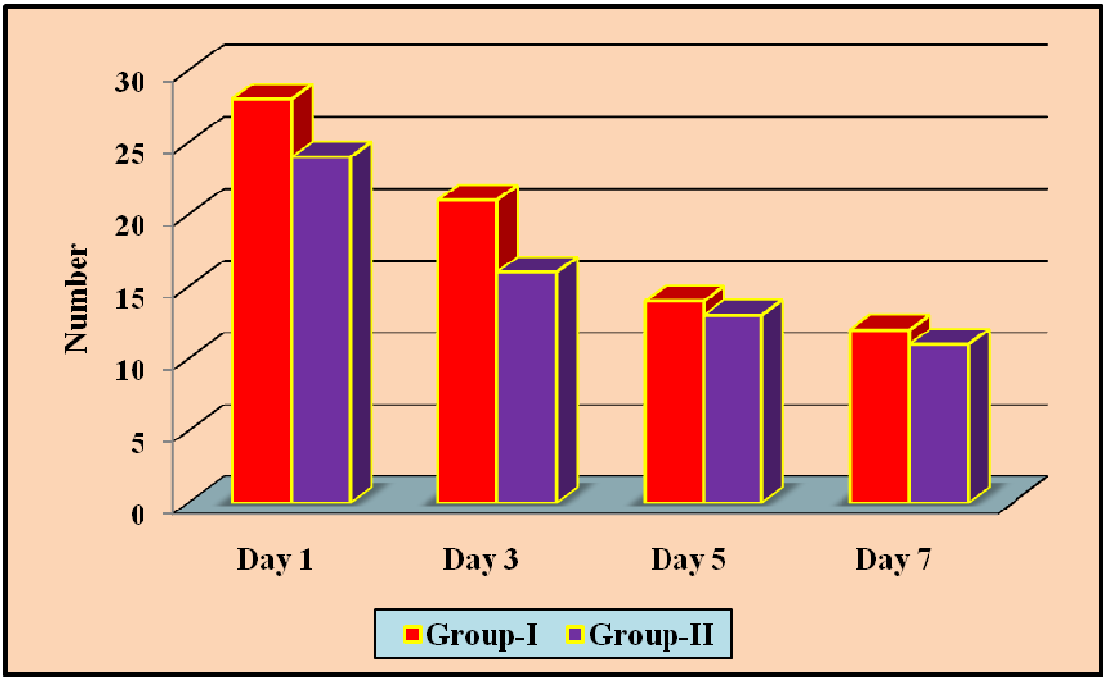


Table-8: Comparison of number and percentage of patients based on the pain score on day 1

Pain Score	Group-I		Group-II	
	Number	**Percentage (%)**	**Number**	**Percentage (%)**
Score 0	0	0.00	1	3.33
Score 1	9*	30.00	11*	36.67
Score 2	18*,#	60.00	17*,#	56.67
Score 3	3*,#,$	10.00	1#,$	3.33

(*p<0.05 significant compared score 0 with other scores within the groups,

#p<0.05 significant compared score 1 with other scores within the groups,

$p<0.05 significant compared score 2 with other scores within the groups)

Table-9: Comparison of number and percentage of patients based on the pain score on day 3

Pain Score	Group-I		Group-II	
	Number	**Percentage (%)**	**Number**	**Percentage (%)**
Score 0	7	23.33	10	33.33
Score 1	15*	50.00	15*	50.00
Score 2	8#	26.67	5*,#	16.67
Score 3	0*,#,$	0.00	0*,#,$	0.00

(*p<0.05 significant compared score 0 with other scores within the groups,

#p<0.05 significant compared score 1 with other scores within the groups,

$p<0.05 significant compared score 2 with other scores within the group

Table-10: Comparison of number and percentage of patients based on the pain score on day 5

Pain Score	Group-I		Group-II	
	Number	Percentage (%)	Number	Percentage (%)
Score 0	19	63.33	20	66.67
Score 1	11*	36.67	10*	33.33
Score 2	0*,#	0.00	0*,#	0.00
Score 3	0*,#	0.00	0*,#	0.00

(*p<0.05 significant compared score 0 with other scores within the groups,

#p<0.05 significant compared score 1 with other scores within the groups,

$p<0.05 significant compared score 2 with other scores within the groups)

Table-11: Comparison of number and percentage of patients based on the pain score on day 7

Pain Score	Group-I		Group-II	
	Number	Percentage (%)	Number	Percentage (%)
Score 0	26	86.67	27	90.00
Score 1	4*	13.33	3*	10.00
Score 2	0*,#	0.00	0*,#	0.00
Score 3	0*,#	0.00	0*,#	0.00

(*p<0.05 significant compared score 0 with other scores within the groups,

#p<0.05 significant compared score 1 with other scores within the groups,

$p<0.05 significant compared score 2 with other scores within the groups)

Table-12: Comparison of number of patients based on the pain score between the groups at different pain scores on day 1

Groups	Score 0	Score 1	Score 2	Score 3
Group-I	0	9	18	3
Group-II	1	11*	17	1
p value	**0.23**	**0.04**	**0.45**	**0.83**

(*p<0.05 significant compared score 1 between the groups)

Table-13: Comparison of number of patients based on the pain score between the groups at different pain scores on day 3

Groups	Score 0	Score 1	Score 2	Score 3
Group-I	7	15	8	0
Group-II	10	15	5	0
p value	**0.45**	**0.67**	**0.29**	

(p>0.05 no significant compared between the groups)

Table-14: Comparison of number of patients based on the pain score between the groups at different pain scores on day 5

Groups	Score 0	Score 1	Score 2	Score 3
Group-I	19	11	0	0
Group-II	20	10	0	0
p value	**0.67**	**0.19**		

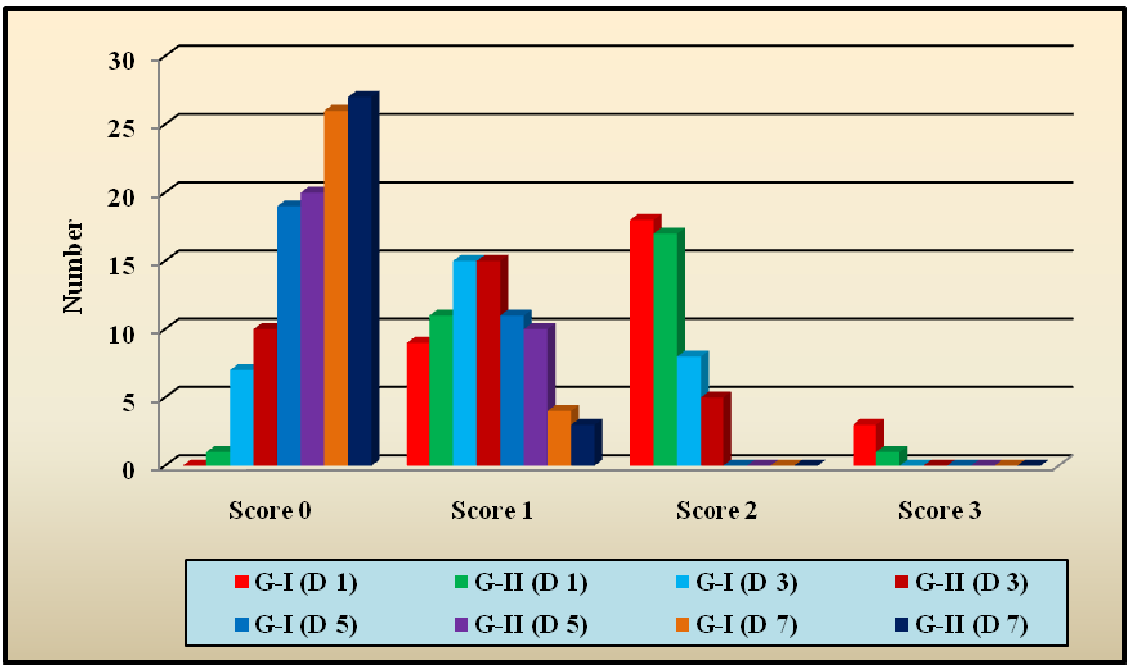
(p>0.05 no significant compared between the groups)

Table-15: Comparison of number of patients based on the pain score between the groups at different pain scores on day 7

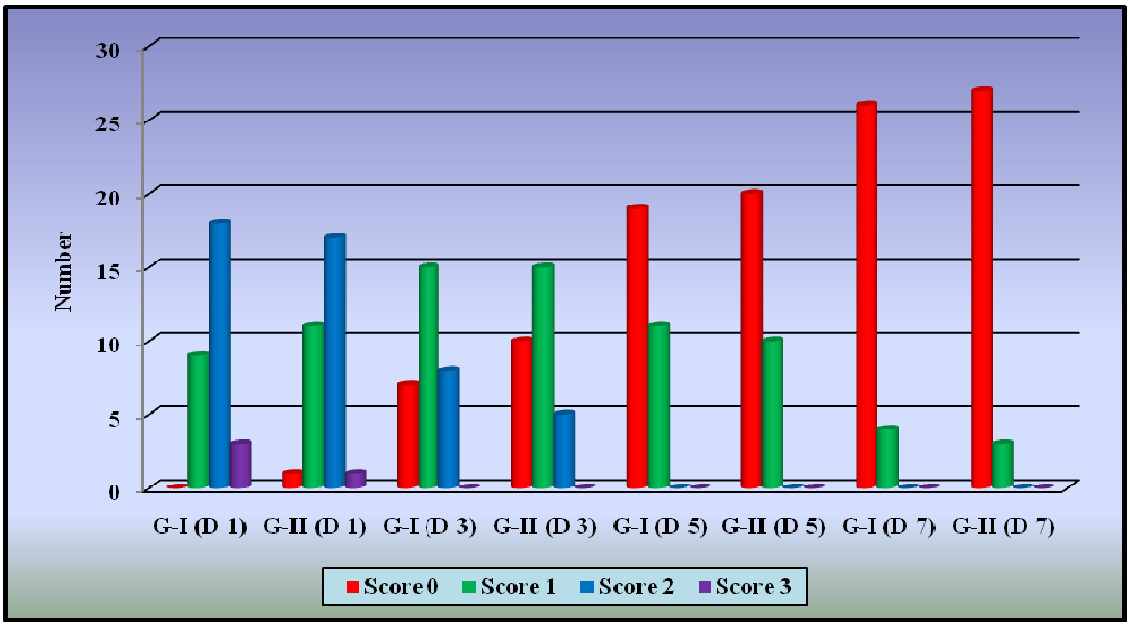
Groups	Score 0	Score 1	Score 2	Score 3
Group-I	26	4	0	0
Group-II	27	3	0	0
p value	**0.28**	**0.56**		

(p>0.05 no significant compared between the groups)

Graph-4: Comparison of pain score bwtween th groups



Graph-5: Comparison of pain score within the groups



Group I- Incision closed with vicryl suture..

Group II- Incision closed with N Butyl 2 cyanoacrylate

Table 1: Comparison of gender involving this study and the mean age of the patient.

Table 2: Comparison of presence of wound dehiscence at different time periods. In group I, 6.67% of wound dehiscence was observed on first day, 30% of wound dehiscence was observed 3rd day, 53.33% of wound dehiscence was observed on 5th day, 60% of wound dehiscence was observed on 7th day. In group II, 20% of wound dehiscence was observed on 1st day, 46.67% of wound dehiscence was observed on 3rd day, 56.67% of wound dehiscence was observed on 5th day, 63.33% of wound dehiscence was observed on 7th day.

Table 3: Comparison of absence of wound dehiscence at different time periods. In group I, wound dehiscence was not observed in 93.33% on 1st day, wound dehiscence was not observed in 70% on 3rd day, wound dehiscence was not observed in 46.67% on 5th day, wound dehiscence was not observed in 40% on 7th day. In group II, wound dehiscence was not observed in 80% on 1st day, wound dehiscence was not observed in 53.33% on 3rd day, wound dehiscence was not observed in 43.33% on 5th day, wound dehiscence was not observed in 36.67% on 7th day.

Table 4: Comparison of wound dehiscence between group I and group II on day 1. In group I wound dehiscence was observed in 6.67% on 1st day, in group II wound dehiscence was observed 20% on 1st day. In group I, wound dehiscence was not observed in 93.3% on 1st day, in group II wound dehiscence was not observed in 80% on 1st day. There was statistically significant difference between group I and group II in comparing presence of wound dehiscence.

Table 5: Comparison of wound dehiscence between group I and group II on day 3. In group I wound dehiscence was observed in 30% on 3rd day, in group II

wound dehiscence was observed 46.67% on 3rd day. In group I, wound dehiscence was not observed in 70% on 3rd day, in group II wound dehiscence was not observed in 53.33% on 3rd day. There was statistically significant difference between group I and group II in comparing presence of wound dehiscence.

Table 6: Comparison of wound dehiscence between group I and group II on day 5. In group I wound dehiscence was observed in 53.33% on 5th day, in group II wound dehiscence was observed 56.67% on 5th day. In group I, wound dehiscence was not observed in 46.67% on 5th day, in group II wound dehiscence was not observed in 43.33% on 5th day. There was statistically no significant difference between group I and group II

Table 7: Comparison of wound dehiscence between group I and group II on day 7. In group I wound dehiscence was observed in 60% on 7th day, in group II wound dehiscence was observed 63.33% on 7th day. In group I, wound dehiscence was not observed in 40% on 7th day, in group II wound dehiscence was not observed in 36.67% on 7th day. There was statistically no significant difference between group I and group II.

Table 8: Comparison of number and percentage of patients based on the pain score on 1st day. Group I, all patient experienced pain, 30% experienced mild pain (score 1), 60% experienced severe pain (score2), 10% experienced very severe pain. Group II, 3.33% patient not experienced pain (score0), 36.67% experienced mild pain (score 1), 56.67% experienced severe pain(score2), 3.33% experienced very severe pain. There was statistically no significant difference between group I and group II.

Table 9: Comparison of number and percentage of patients based on the pain score on 3rd day. Group I, 23.33% experienced no pain(score0), 50% experienced

mild pain(score 1), 26.67% experienced severe pain(score2), 0% experienced very severe pain(score 3).Group II, 33.33% patient not experienced pain(score0), 50% experienced mild pain(score 1), 16.67% experienced severe pain(score2), 0% experienced very severe pain(score 3). There was statistically no significant difference between group I and group II.

Table 10: Comparison of number and percentage of patients based on the pain score on 5^{th} day. Group I, 63.33% experienced no pain(score0), 36.67% experienced mild pain(score 1), 0% experienced severe pain(score2), 0% experienced very severe pain(score 3).Group II, 66.67% patient not experienced pain(score0), 33.33% experienced mild pain(score 1), 0% experienced severe pain(score2), 0% experienced very severe pain(score 3). There was statistically no significant difference between group I and group II.

Table 11: Comparison of number and percentage of patients based on the pain score on 7^{th} day. Group I, 86.67% experienced no pain(score0), 13.33% experienced mild pain(score 1), 0% experienced severe pain(score2), 0% experienced very severe pain(score 3).Group II, 90% patient not experienced pain(score0), 10% experienced mild pain(score 1), 0% experienced severe pain(score2), 0% experienced very severe pain(score 3). There was statistically no significant difference between group I and group II.

Table 12: Comparison between groups based on the pain score on 1^{st} day. Group I- all experienced pain (score 0), 9 experienced mild pain (score 1), 18 experienced severe pain (score 2), 3 experienced very severe pain (score 3).Group II- 1 experienced no pain (score 0), 11 experienced mild pain (score 1), 17 experienced

severe pain (score 2), 1 experienced very severe pain (score 3). $p<0.05$ There was statistically significant difference between group I and Group II on score 1.

Table 13: Comparison between the groups based on the pain score on 3rd day. Group I- 7 experienced no pain (score 0), 15 experienced mild pain (score 1), 8 experienced severe pain (score 2), 0 experienced very severe pain (score 3). Group II- 10 experienced no pain (score 0), 15 experienced mild pain (score 1), 5 experienced severe pain (score 2), 0 experienced very severe pain (score 3). $p>0$. There was statistically no significant difference between group I and group II.

Table 14: Comparison between the groups based on the pain score on 5th day. Group I- 19 experienced no pain (score 0), 11 experienced mild pain (score 1), 0 experienced severe pain (score 2), 0 experienced very severe pain (score 3). Group II- 20 experienced no pain (score 0), 10 experienced mild pain (score 1), 0 experienced severe pain (score 2), 0 experienced very severe pain (score 3). $p>0.05$ There was statistically no significant difference between group I and group II.

Table 15: Comparison of both groups based on the pain score on 7th day. Group I- 26 experienced no pain (score 0), 4 experienced mild pain (score 1), 0 experienced severe pain (score 2), 0 experienced very severe pain (score 3). Group II- 27 experienced no pain (score 0), 3 experienced mild pain (score 1), 0 experienced severe pain (score 2), 0 experienced very severe pain (score 3). $p>0.05$ There was statistically no significant difference between group I and group II.

Graph 1: In comparison of distribution of patient according to gender, both male and female were in equal proportion.

Graph 2: comparison of presence of wound dehiscence at different time periods. On day 1, wound dehiscence was present in 2 patients in group I, 6 patients in group II. On day 3, wound dehiscence was present in 9 patients in group I, 14 patients in group II. On day 5, wound dehiscence was present in 16 patients in group I, 17 patients in group II. On day 7, wound dehiscence was present in 18 patients in group I, 19 patients in group II.

Graph 3: comparison of absence of wound dehiscence at different time periods. On day 1, wound dehiscence was absent in 28 patient in group I, 24 patient in group II. On day 3, wound dehiscence was absent in 21 patient in group I, 16 patient in group II. On day 5, wound dehiscence was absent in 14 patient in group I, 13 patient in group II. On day 7, wound dehiscence was absent in 12 patient in group I, 11 patient in group II.

Graph 4: comparison of pain score between group I and group II at different time periods. There was statistically no significant difference between two groups.

Graph 5: Comparison of pain score within the group. Statistically significant difference present within the group at different time period for both groups.

Wound healing is a reparative process of tissue after injury. Wound healing process is divided into four phases. Haemostasis is the first phase, Inflammation is the second phase, proliferation is the third face and maturation is the fourth phase. Immediately after injury, platelets adhered to the injured site. Then adhered platelets change its shape and release chemical mediators for clotting. Finally activates fibrin to form a clot. In inflammatory phase, inflammatory cells are released into wound and engulf the pathogen and dead cells. In proliferation phase growth of newly formed cells will occur. Angiogenesis, new collagen formation, epithelial tissue formation, granulation tissue formation and wound contraction will occur. During maturation period type III collagen is replaced by type I collagen. Wound healing is affected by local and systemic factors.

Wound closure can be done by primary intention, secondary intention and tertiary intention. In primary intention wound edges are re-approximated with sutures, staples and tissue adhesive like N Butyl 2 cyanoacrylate. Advantage of primary intention is to minimize scarring, faster healing when compared to secondary intention. Usually done in well repaired laceration, properly reduced bone fractures and healing after flap surgery. In secondary intention wound is allowed to granulate. Usually healing is slow and more scar tissue. In tertiary intention, wound is cleaned and debrided for 4 to 5 days before wound closure.

Attainment of ideal wound closure is the important factor for healing at surgical site. The wound closure material should re-approximate the wound edges properly for sufficient period for healing to occur. Ideal property of wound closure material is easy to apply, rapid application, biocompatibility, better tissue tolerance, enough tensile strength to retain the re-approximated wound edges, free from toxic substances and free from allergic reaction.

Usually intra oral incision is closed with suture material like vicryl and silk suture materials. Suture material is commonly used for wound closure than staples and tissue

adhesives. Because of the property like better tensile strength, low dehiscence rate, proper wound closure. But it has disadvantage like crosshatched marks, needle penetration of normal tissue on either side of the wound, tissue reactivity, anxiety, and it is a time consuming procedure. Because of theses disadvantages alternative procedure become developed like tissue adhesive.

In 1949 Ardis discovered cyanoacrylates. In 1959 cover et al suggested its adhesive property. Initially it was rejected because of not biocompatibility to the tissue and more inflammatory reaction. Later in 1964 Tennese Eastman lab developed longer molecular cyanoacrylate, which one better biocompatibility and produces less inflammatory reaction.

Advantage of N Butyl 2 cyanoacryate over suture material is easy to handle, shorter duration of application, comfortable for anxiety and fear of patient, better bacteriostatic property, eliminate the risk of needle prick injury, decreased healing time, haemostatic property and better esthetic property.

In this comparative interventional study, N Butyl 2 cyanoacrylate and vicryl suture were compared in intraoral wound closure. Parameters for evaluation in this study was pain and wound dehiscence.

Pain:

Patient experienced more pain on day1, progressively pain get reduced on day 3, day 5 and day 7 for both groups. On day 1, only one patient experienced no pain in group II, 9 patient experienced mild pain in group I, 11 patient experienced mild pain in group II, 18 patient experienced severe pain in group I, 17 patient experienced severe pain in group II, 3 patient experienced very severe pain group I, 1 patient experienced very severe pain in group II. Experience of pain between both groups on day 1, score 1 is statistically significant.

On day 3- 7 patient experienced no pain in group I, 10 patient experienced no pain in group II, 15 patient experienced mild pain in group I, 15 patient experienced mild pain in group II, 8 patient experienced severe pain in group I, 5 patient experienced severe pain in group II, 0 patient experienced very severe pain group I, 0 patient experienced very severe pain in group II.

On day 5- 19 patient experienced no pain in group I, 20 patient experienced no pain in group II, 11 patient experienced mild pain in group I, 10 patient experienced mild pain in group II, 0 patient experienced severe pain in group I, 0 patient experienced severe pain in group II, 0 patient experienced very severe pain group I, 0 patient experienced very severe pain in group II.

On day 7- 26 patient experienced no pain in group I, 27 patient experienced no pain in group II, 4 patient experienced mild pain in group I, 3 patient experienced mild pain in group II, 0 patient experienced severe pain in group I, 0 patient experienced severe pain in group II, 0 patient experienced very severe pain group I, 0 patient experienced very severe pain in group II.

Difference in experience of pain between both groups on day1, day3, day5 and day 7 was statistically not significant ($p>0.05$) except on experience of mild pain between both groups on day 1 was statistically significant different.

Wound dehiscence:

On 1st day and 3rd day percentage of wound dehiscence was more in group II than group I. On 5th day and 7th day percentage of wound dehiscence was more or less equal in group I and group II. In day one, percentage of wound dehiscence in group I was 6.67, for group II was 20. In day 3, percentage of wound dehiscence in group I was 30, for group II

was 46.67. In day 5, percentage of wound dehiscence in group I was 53.33, for group II was 56.67. In day 7, percentage of wound dehiscence in group I was 60, for group II was 63.33.

Difference in percentage of wound dehiscence between both groups in day 1 was statistically significant ($p<0.05$). Percentage of wound dehiscence was increased on day 3 on both group. Difference in percentage of wound dehiscence between both groups on day 3 was statistically significant ($p<0.05$). Percentage of wound dehiscence was increased on day 5 on both groups. Difference in percentage of wound dehiscence between both groups on day 5 was statistically not significant ($p>0.05$). Percentage of wound dehiscence was increased on day 5 on both group. Difference in percentage of wound dehiscence between both groups on day 7 was statistically not significant ($p>0.05$).

N butyl 2 cyanoacrylate has the advantage of bacteriostatic and haemostatic property. Time consumed for application of N Butyl 2 cyanoacrylate was very low when compared to vicryl suture. Patient satisfaction was high on N Butyl 2 cyanoacrylate than vicryl suture. Effects of N Butyl 2 cyanoacrylate and vicryl suture in intra oral wound closure have not been evaluated on previous studies in cross over basis. In previous studies N Butyl 2 cyanoacrylate compared mainly with silk suture in intra oral wound closure.

Ajit D. Joshi et al clinically compare the efficacy of cyanoacrylate (tissue glue) and conventional suture after surgical removal of impacted mandibular third molars. He conducted a study on thirty patients. Based on his study, efficacy of wound closure with cyanoacrylate and conventional suturing were similar in the severity of pain, but use of cyanoacrylate showed better haemostasis. The present study showed severity of pain in both group was statistically no significant at the end of fifth day.

Mohammad Elshall et al conducted study for closure of intra oral incision with tissue adhesive of N Butyl 2 cyanoacrylate and silk suture. He conducted a study on 20 patients. He

concluded that difference in pain score between N Butyl 2 cyanoacrylate and silk suture was not statistically significant. But patient anxiety and psychological stress was reduced with N Butyl 2 cyanoacrylate. The present study also showed severity of pain in both group was statistically no significant at the end of third, fifth and seventh day.

Wound closure can be done by suture materials, staples and tissue adhesives. Purpose of this study is, clinically compare the efficacy of N Butyl 2 cyanoacrylate with vicryl suture, an in vivo study.

Intra oral mucosal incision was performed in all the patients for the purpose of tooth extraction due to dental caries and periodontal problems in the same jaw bilaterally or one in upper jaw and another one in lower arch.

Group I was intra oral mucosal incision was closed with vicryl suture material, main criteria was flap should be re-approximated passively, before suture. Pain was recorded by visual analogue scale. Wound dehiscence was recorded by direct visual examination. Pain and wound dehiscence recorded on 1^{st} day, 3^{rd} day, 5^{th} day and 7^{th} day.

Group II was intra oral mucosal incision was closed with N Butyl 2 cyanoacrylate, before apply this material after the extraction, the flap was re-approximated passively. Parameters of pain and wound dehiscence was recorded on 1^{st} day, 3^{rd} day, 5^{th} day and 7^{th} day. Pain was recorded by visual analogue scale. Wound dehiscence was recorded by direct visual examination.

In this study, statistically significant more score on mild pain present on 1^{st} day in incision closed with vicryl suture material over incision closed with N Butyl 2 cyanoacrylate. There was statistically no significant on experience of pain between both groups on 3^{rd} day, 5^{th} day and 7^{th} day.

The measurement of pain and wound dehiscence measured on 1^{st}, 3^{nd}, 5^{th}, 7^{th} day for all the patients and statistical analysis performed between both groups to find out the benefit. Based on this analysis, statistically significant score was obtained on

comparing the mild pain between both groups on day one only. In all other score for pain on day 1, day 3, day, day 5 and day 7 showed statistically no significance between the both groups. There was statistically significant score was obtained on presence of wound dehiscence between both groups on day 1and day 3, where presence of wound dehiscence was more in incision closed with N Butyl 2 cyanoacrylate than incision closed with vicryl suture. But, on 5^{th}, 7^{th} day there was statistically no significant difference in presence of wound dehiscence between groups.

N Butyl 2 cyanoacrylate has a minimal role in closure of intra oral mucosal incision. Further studies are needed to evaluate the tensile strength of material and long term effects of N Butyl 2 cyanoacrylate.

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Sree Mookambika Institute of Medical Sciences
Kulasekharam (K.K District, TN) 629161

Phone No: 04651-280866, Fax No. 04651-280740

Institutional Human Ethics Committee

Registered under CDSCO with Reg No. ECR/446/Inst/TN/2013

Ref. No. SMIMS/IHEC/2015/A/13 **Date: 10th April 2015**

Certificate

This is to certify that the Research Protocol Ref. No. **SMIMS/IHEC/2015/A/13**, entitled "Clinically Compare The Efficacy of N-Butyl 2-Cyanoacrylate and Vicryl Suture in Itraoral Wound Closure: An *In Vivo* Study" submitted by Dr. K. Murugan, Postgraduate of Department of Oral and Maxillofacial Surgery, SMIDS has been approved by the Institutional Human Ethics Committee at its meeting held on 13th of March 2015.

[This Institutional Human Ethics Committee is organized and operates according to the requirements of ICH-GCP/GLP guidelines and requirements of the Amended Schedule-Y of Drugs and Cosmetics Act, 1940 and Rules 1945 of Government of India.]

SRI MOOKAMBIKA INSTITUTE OF MEDICAL SCIENCES
IHEC
Date 10/4/15

Dr. Rema Menon. N
Member Secretary
Institutional Human Ethics Committee
Professor of Pharmacology and HOD
SMIMS, Kulasekharam [K.K District]
Tamil Nadu -629161

SREE MOOKAMBIKA INSTITUTE OF DENTAL SCIENCES

KULASEKHARAM, KANYAKUMARI DIST., TAMIL NADU, INDIA.

INSTITUTIONAL RESEARCH COMMITTEE

Certificate

This is to certify that the research project protocol, ***Ref no. 11/08/2014*** titled, ***"Clinically compare the efficacy of N-Butyl 2-cyanoacrylate and Vicryl sutures in intra oral wound closure – an in vivo study"*** submitted by ***Dr. K. Murugan, II Year MDS, Department of Oral and Maxillofacial Surgery*** has been approved by the Institutional Research Committee at its meeting held on 14th ***August 2014.***

Convener
Dr. T. Sreelal

Secretary
Dr. Anuroopa A.

CONSENT FORM

PART 1 OF 2 INFORMATION FOR PARTICIPANTS OF THE STUDY

Dear Volunteers,

We welcome you and thank you for your keen interest in participation in this research project. Before you participate in this study, it is important for you to understand why this research is being carried out. This form will provide you all the relevant details of this research. It will explain the nature, the purpose, the benefits, the risks, the discomforts, the precautions and the information about how this project will be carried out. It is important that you read and understand the contents of the form carefully. This form may contain certain scientific terms and hence, if you

1. **Name of the Principal Investigator:**

Dr.K.MURUGAN,
Post Graduate student,
Department of Oral and Maxillofacial surgery,
Sree Mookambika Institute of Dental Sciences,
Kulasekharam, Kanyakumari District-629161

2. **Name of the Guide:**

Dr.N.Dhineksh Kumar,
Professor,
Department Of Oral and Maxillofacial Surgery.
Sree Mookambika Institute of Dental Sciences,
Kulasekharam, Kanyakumari District-629161

3. Name of the Co-Guide:

Dr. Mathew Jose,
Head of the department,
Department Of Oral and Maxillofacial Surgery,
Sree Mookambika Institute of Dental Sciences,
Kulasekharam, Kanyakumari District-629161

4. Institute:

Sree Mookambika Institute of Dental Sciences,
V.P.M Hospital complex, Padanilam, Kulasekharam,
Kanyakumari – 629161
Tamil Nadu.

5. Title of the study :

"CLINICALLY COMPARE THE EFFICACY OF N-BUTYL 2-CYANOACRYLATE AND VICRYL SUTURES IN INTRA ORAL WOUND CLOSURE" - AN IN VIVO STUDY

6. Background information:

Conventionally ideal wound closure is achieved by suture material but because of namely prolonged duration of surgery and anaesthesia, tissue reactivity,risk of needle stick, undesirable trauma to the intact tissue on either side of wound,permanent suture tracts, early removal which results in dehiscence, anxiety and pain during removal and inadequate esthetics effect causes alternate procedures arrived for wound closure ,that is tissue adhesive.The best tissue adhesive material is N-Butyl 2-cyanoacrylate.Which is easy to apply,reduce the anxiety of the patient.It also acts as a haemostatic agent and antimicrobial agent.

7. Aim and objectives:

The aim of the study is to compare clinically the efficacy of n-butyl-2-cyanoacrylate with vicryl suture in the closure of oral mucosal incisions.

To evaluate

- Pain
- Wound dehiscence.

8. Scientific justification of the study:

Incision is a basic step for surgical procedures,Suitable closure and optimal maintenance of the surgical area are the most important factors that affect proper wound healing and surgical success.The conventional method of wound closure causes trauma and many other undesirable effects .The use of tissue adhesives as an alternative to, or replacement for, sutures in wound closure has long been an area of interest. A group of these tissue adhesives are - Cyanoacrylates. They have a wide range of applications in surgery and are supposed to offer some advantages.Previous study showsn-butyl-2-cyanoacrylate can be used for intra oral wound closure effectively. The procedure is relatively painless and quick.

9. Procedure for the study:

- Under aseptic precautions, patient was anaesthetized with 2% lignocaine with adrenaline 1:80000 and prepared for surgery.
- In extraction procedures or Alveoloplasties, bilaterally symmetrical crestal incision was made on the arch.
- After performing the surgical procedure and achieving adequate haemostasis, closures was performed on one side with n-butyl cyanoacrylate tissue adhesive and on the other side with 3-0 vicryl suture and these sides were randomly chosen.

- The incised edges were accurately approximated, trying not to leave any gap between them. After loading the glue in a syringe, it was applied at the approximated wound margins through the needle in the form of drops for closure of the mucoperiosteal flaps.
- Under same aseptic precautions, anaesthesia, and surgical procedure on the other side, suturing was done with interrupted braided black 3-0 vicryl suture.The post-operative sites pressure pack was given at the sutured sites. Post-operative instructions regarding diet, avoid disrupting the wound at glue site, oral hygiene maintenance and warm saline gargles were given to the patients.
- Following medications with their standard dosages were given:-
  1. Tab. Fenac plus twice a day for three days
  2. Cap. Amox500mg thrice a day for five days
- Follow-up was made at third,fifth & seventh postoperative days. During each follow up visit, pain and wound dehiscence were recorded on a visual analogue scale.

10. Expected risks for the participants:

- When flap closure done under tension ,wound dehiscence may happened.

11. Expected benefits of research for the participants:

- You will not be required to pay for this procedure.
- You can enquire about the outcome of the procedures and your details.
- You will get a better treatment at the end of the procedure.

12. Maintenance of confidentiality:

- You have the right to confidentiality regarding the privacy of your medical information(Personal details, results of physical examinations, investigations, and your medical history).
- By signing this document, you will be allowing the research team investigators, other study Personnel, sponsors, institutional ethics committee and any person or agency required by law to view your data, if required.
- The results of clinical tests and therapy performed as part of this research may be included in your medical record.

- The information from this study, if published in scientific journals or presented at scientific meetings, will not reveal your identity.

13. Why have I been chosen to be in this study?

a. Chosen because of grouping under the inclusion and exclusion criteria
b. Need of good sampling size
c. Patient phsycologically fear with suturing,while removal they have pain,risk of needle prick injury and prolonged duration of surgery and anaesthesia to overcome this problem tissue adhesive is a better in shorter duration,easy to use better patient compliance.
d. To improve the aesthetic appearance.

14. How many people will be in the study? **30**individuals

15. Agreement of compensation to the participants (In case of a study related injury):

Patient will be taken care in case of complication and medical treatment will be provided in the institution at the expense of the principle investigator.

16. Anticipated prorated payment, if any, to the participant(s) of the study:

For your cooperation to the study, the expenses for the routine blood investigations for which you originally visited the clinic will be settled by the principal investigator.

17. Can I withdraw from the study at any time during the study period?

The participation in this research is purely voluntary and you have the right to withdraw from this study at any time during the course of the study without giving any reasons.

18. If there is any new findings/information, would I be informed? Yes

19. Expected duration of the participant's participation in the study: 1 week

20. Any other pertinent information : No other information

21.Whom do I contact for further information?

For any study related queries, you are free to contact:

Dr.K.Murugan
Post Graduate student.
Department of Oral & Maxillofacial Surgery,
Sree Mookambika Institute of Dental Sciences,
Kulasekharam, Kanyakumari District-629161.
Mobile No: 9894269313
Dr.murugankj@gmail.com

Place: **Signature of Principal Investigator**

Date:

Signature of the participant

CONSENT FORM

PART 2 OF 2

PARTICIPANTS CONSENT FORM

The details of the study have been explained to me in writing and the details have been fully explained to me. I am aware that the results of the study may not be directly beneficial to me but will help in the advancement or medical sciences. I confirm that I have understood the study and had the opportunity to ask questions. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I have been given an information sheet giving details of the study. I fully consent to participate in the study titled

"CLINICALLY COMPARE THE EFFICACY OF N-BUTYL 2-CYANOACRYLATE AND VICRYL SUTURE IN INTRA ORAL WOUND CLOSURE"

Serial no / Reference no :

Name of the participant :

Address of the participant :

Contact number of the participant :

Signature / thumb impression of the participant / Legal guardian

Witnesses:

1.

2.

Date:
Place:

ஒப்புதல் படிவம்

பகுதி1-2

ஆய்வில் பங்கேற்பவருக்கான படிவம்

மதிப்பிற்குரிய தன்னார்வலரே

தாங்கள் இந்த ஆய்வில் பங்கேற்க வந்தமைக்கு நன்றி. இந்த ஆய்வில் பங்கேற்பதற்கு முன் இந்த ஆய்வின் முழுவிபரங்களையும் உங்களுக்கு தெரிவிக்கும் ஆய்வில் பங்கேற்பதற்கு முன் இந்தபடிவத்தை முழுவதும் படித்து புரிந்து கொண்ட பின் பங்கேற்க வேண்டும். இந்த படிவத்தில் சில மருத்துவ மற்றும் அறிவியல் சொற்கள் உள்ளன. ஆதலால் ஏதேனும் சந்தேகங்கள் ஏற்பட்டால். இந்த படிவத்தின் இறுதியில் குறிப்பிட்டுள்ள நபரிடம் ஆய்வில் பங்கேற்பதற்கு முன் தெளிவு பெற வேண்டும்.

ஆய்வாளர்

மரு.கு. முருகன்

முதுகலை பட்டதாரி

வாய் மற்றும் முகசீரமைப்பு பிரிவு

ஸ்ரீ மூகாம்பிகை பல் மருத்துவமனை கல்லூரி

குலசேகரம்

கன்னியாகுமரி மாவட்டம்

வழிகாட்டி

மரு.தினேஷ்க் குமார்

துணை பேராசிரியர்

வாய் மற்றும் முகசீரமைப்பு பிரிவு

ஸ்ரீ மூகாம்பிகள பல் மருத்துவமனை கல்லூரி

குலசேகரம்

கன்னியாகுமரி மாவட்டம

துணைவழிகாட்டி

மரு.மேத்யு ஜோஸ்

பேராசிரியர் தலைமையாளர்

வாய் மற்றும் முகசீரமைப்பு பிரிவு

ஸ்ரீ மூகாம்பிகள பல் மருத்துவமனை கல்லூரி

குலசேகரம்

கன்னியாகுமரி மாவட்டம்

ஆய்வு நிலையம்

ஸ்ரீ மூகாம்பிகள பல் மருத்துவமனை கல்லூரி

குலசேகரம்

கன்னியாகுமரி மாவட்டம்

1. **தலைப்பு**

வாயினுள் ஏற்படும் காயங்களை சையனோ அக்கிரிலேட் மூலமும் வைக்ரில் தையல் மூலமும் சரி செய்வதை ஒப்பிடுதல்.

2. **ஆய்வின் பின்பலம்**

வாயினுள் ஏற்படும் காயங்களை சரிசெய்ய தையல் போடப்படும். ஆனால் இந்நிகழ்வு நோயாளிகளுக்கு பயத்தையும் ஏற்படுத்தும். சையனோ அக்ரிலேட் என்ற வேதியல் பொருளை வைத்து காயத்தை சரி செய்வதின் மூலம் பயத்தையும் காலதாமதத்தையும் தவிர்க்கலாம்.

3. **குறிக்கோள்**

வாயினுள் ஏற்படும் காயங்களை வைக்ரில் மூலம் சரி செய்தல் மற்றும் வாயினுள் ஏற்படும் காயங்களை சையனோ அக்ரிலேட் என்று வேதியல் பொருள் மூலம் சரிசெய்தல்.

இரண்டிற்கும் இடையேயான வித்தியாசத்தை ஒப்பிட்டு தீர்வைக் கண்டுபிடித்தல்.

4. **அறிவியல் பின்பலம்**

சில காலங்களாக நடத்தப்பட்ட ஆய்வுகளின் மூலம் சையனோ அக்ரிலேட் என்ற வேதியல் பொருளும் வைக்ரில் தையலும் சம அளவு தன்னை உடையது.

5. **செயல்முறை**

- தாங்கள் இந்த ஆய்வில் பங்கு பெற்ற பின் தனி இலக்க எண் கொடுக்கப்படும்.

- சிக்ட்சையின் போது சதையில் ஏற்பட்ட காயத்தை சரிசெய்ய ஒரு பகுதி வைக்ரில் தையல் மூலம் சரிசெய்யப்படுகிறது. மறுபகுதியில் சையனோ அக்ரிலேட் என்ற வேதியல் பொருள் மூலம் சரிசெய்யப் படுகிறது.

6. **எதிர்மறை விளைவுகள்**:இல்லை

7. **ஏற்படும் நன்மைகள்**

- ஆய்விற்காக பணம் எதும் தர தேவையில்லை

- ஆய்வின் முடிவுகளை நீங்கள் அறிந்து கொள்ளலாம்

8. **தகவலின் பாதுகாப்பு**

- உங்களுடைய தகவல்கள் அனைத்தும் பாதுகாக்கப்படும் எந்த நிலையிலும் வெளியிடப்படாது.

- நீங்கள் இந்த ஆய்வில் பங்கேற்றப்பின் எங்களது ஆய்வாளர் உங்களுடைய தகவல்களை தெரிந்து கொள்ள முடியும். மேலும் தேவை ஏற்பட்டால் எத்திக்கல் கமிட்டியிடமும் காண்பிக்கப்படும்.

- ஆய்வின் முடிவின் உங்களுடைய மருத்துவ தகவல் படிவத்தில் (கோப்பில்) பதிவு செய்யப்படும்.

- இந்த ஆய்வு முடிவு வெளியிடப்படும் பொழுது உங்களது தகவல்கள் வெளியிடப்படாது.

9. **இந்த ஆய்வில் நீங்கள் சேர்வதற்கான காரணம்?**

- நீங்கள் இந்த ஆய்வின் சேர்ப்பு மற்றும் விடுப்பு வகுப்புகளின் உள் அமைப்படுவதால்.

10. **ஆய்வின் மாதிரி எண்ணிக்கை:**60(30 நபர்)

11. **நஷ்டயீடு**

ஆய்வில் ஏற்படும் மாற்றங்களுக்கான சிகிட்சை ஆய்வு நிலையத்தில் வழங்கப்படும்.

12. **நஷ்டயீடு பணம்:** பணம் எதுவும் வழங்கபடாது.

13. **ஆய்வில் இருந்து எந்த நேரத்திலும் எந்த காரணமும் இன்றி விலகலாம்**

14. **ஆய்வின் முன்னேற்றத்தில் ஏற்படும் மாற்றங்கள் தெரிவிக்கப்பட வேண்டும்.**

15. **ஆய்வின் கால அவகாசம்: ஒரு ஆண்டு**

16. **வேறு எந்த தகவல்களும் தேவை இல்லை.**

17. **தொடர்வு கொள்ள வேண்டிய நபர்**

மரு. கு. முருகன்

முதுகலை பட்டதாரி

வாய் மற்றும் முகசீரமைப்பு பிரிவு

ஸ்ரீ மூகாம்பிகள பல் மருத்துவமனை கல்லூரி

குலசேகரம், கன்னியாகுமரி மாவட்டம்

தொலைபேசி எண்:9894269313

மின் அஞ்சல்:dr.murugankj@gmail.com

இடம்:குலசேகரம் ஆய்வாளர் கையொப்பம்

தேதி:

பங்குபெறுபவர் கையொப்பம்

ஒப்புதல் படிவம்

பகுதி-2

பங்குபெறுபவரின் ஒப்புதல் படிவம்

இந்த ஆய்வின் முழு விபரங்களும் எழுத்து மூலமாகவும் விரிவாகவும் என்னிடம் கூறப்பட்டது. எனக்கு இந்த ஆய்வின் விளைவுகள் எந்த பயனும் தரவில்லை என்றாலும் மருத்துவ அறிவியலின் மேம்பாட்டிற்காக பயன்படுத்தப்படும் என்று அறிவேன். நான் இந்த ஆய்வில் எந்த நிர்பந்தமும் இல்லாமல் பங்கு பெறுகிறேன். மேலும் இந்த ஆய்வின் எல்லா விதிகள் மற்றும் விதிமுறைகளையும் அறிவேன். எந்த சந்தோகத்திற்கும் கேள்வி கேட்கவோ அல்லது ஆய்வில் இருந்து விலகவோ எல்லா உரிமைகளும் எனக்கு உண்டு என்று அறிவேன். இந்த ஆய்வின் விளைவுகள் எந்த அறிவியல் பயன்பாட்டிற்கும் பயன்படுத்த எனக்கு தடையில்லை. எனக்கு இதற்கு முன்பாக ஆய்வின் தகவல் படிவம் கொடுக்கப்பட்டது. எனக்கு இந்த ஆய்வில் பங்குபெற முழு சம்மதம்.

ஆய்வின் பெயர்

வாயினுள் ஏற்படும் காயங்களை சையனோ அக்கிரிலேட் மூலமும் வைக்ரில் தையல் மூலமும் சரி செய்வதை ஒப்பிடுதல்.

குறிப்பு எண்:

பெயர்:

முகவரி:

தொலைபேசி எண்:

சாட்சி 1: கையொப்பம்

2.

இடம்:குலசேகரம்

தேதி:

സമ്മത പത്രം – ഭാഗം – 1

പഠനവുമായി സഹകരിക്കുന്ന വ്യക്തികളുടെ അറിവിലേയ്ക്ക്

പ്രിയപ്പെട്ട സന്നദ്ധ സേവകൻ / സേവക,

ഞങ്ങൾ നിങ്ങളെ സ്വാഗതം ചെയ്യുന്നു. അതോടൊപ്പം ഈ പഠനവുമായി സഹകരിക്കാനുള്ള സന്നദ്ധതയോട് നന്ദി രേഖപ്പെടുത്തുന്നു. നിങ്ങൾ ഈ പഠനത്തിൽ പങ്കെടുക്കുന്നതിനു മുൻപ് ഈ പഠനം എന്തിനാണ് നടത്തപ്പെടുന്നത് എന്ന് അിറയേ തു ്. അതിനാൽ ഈ ഫോറത്തിൽ ഗവേഷണ പഠനത്തിന്റെ വിവരങ്ങളും മറ്റും വിശദമായി രേഖപ്പെടുത്തിയിരിക്കുന്നു. ഈ പഠനത്തിന്റെ രീതി, ഉദ്ദേശം, പ്രയോജനം, അപകടസാദ്ധ്യത, ക്ലേശം, മുൻകരുതൽ, എങ്ങനെ ഈ പഠനം മുൻപോട്ടു കൊ ുപോകുന്നു എന്നിങ്ങനെ എല്ലാ വിവരങ്ങളും ഫോറത്തിൽ രേഖപ്പെടുത്തിയിരിക്കുന്നു. സദയം ഈ വിവരങ്ങൾ വായിച്ചു മനസ്സിലാക്കുവാൻ അഭ്യർത്ഥിക്കുന്നു. ഈ വിവരങ്ങളിൽ ശാസ്ത്രപരമായ പദങ്ങൾ ഉള്ളതിനാൽ സംശയനിവാരണത്തിനു പ്രധാന പഠനകർത്താവിനോടോ താഴെ രേഖപ്പെടുത്തി യിരിക്കുന്ന വ്യക്തികളോടോ ഫോറം ഒപ്പിടുന്നതിനു മുൻപോ അല്ലെങ്കിൽ ഈ പഠനത്തിന്റെ കാലാവധി തീരുന്നതുവരേയോ സമീപിക്കാവുന്നതാണ്.

മുഖ്യ ഗവേഷകൻ : **ഡോ. കെ. മുരുകൻ**
പോസ്റ്റുഗ്രാജുവേറ്റ്
ഡിപ്പാർട്ട്മെന്റ് ഓഫ് മാക്സിലോഫേഷ്യൽ സർജറി
ശ്രീ മൂകാംബിക ഇൻസ്റ്റിറ്റ്യൂട്ട് ഓഫ് ഡെന്റൽ സയൻസ്,
കുലശേഖരം - 629 161.
കന്യാകുമാരി ജില്ല.

പ്രധാന മാർഗ്ഗദർശി : **ഡോ. ദിനേഷ്ക് കുമാർ**
റീഡർ (അസി.പ്രൊഫസർ)
ഡിപ്പാർട്ട്മെന്റ് ഓഫ് മാക്സിലോഫേഷ്യൽ സർജറി
ശ്രീ മൂകാംബിക ഇൻസ്റ്റിറ്റ്യൂട്ട് ഓഫ് ഡെന്റൽ സെന്റർ,
കുലശേഖരം

സഹ മാർഗ്ഗ ദർശി : **ഡോ. മാത്യൂ ജോസ്**
ഹെഡ് ഓഫ് ദി ഡിപ്പാർട്ട്മെന്റ്,
പ്രൊഫസർ,
ഡിപ്പാർട്ട്മെന്റ് ഓഫ് മാക്സിലോഫേഷ്യൽ സർജറി
ശ്രീ മൂകാംബിക ഇൻസ്റ്റിറ്റ്യൂട്ട് ഓഫ് ഡെന്റൽ സയൻസസ്,
കുലശേഖരം.

ഇൻസ്റ്റിറ്റ്യൂട്ട് : **ശ്രീ. മൂകാംബിക ഇൻസ്റ്റിറ്റ്യൂട്ട് ഓഫ് ഡെന്റൽ സയൻസസ്**
പടനിലം, കുലശേഖരം,
കന്യാകുമാരി - 629 161.
തമിഴ്നാട്.

1. **പഠനത്തിന്റെ ശീർഷകം** : വായിൽ ഏർപ്പെടുന്ന മുറിവുകളെ സൈനോ അക്രിലേറ്റ് മുഖേനയും വൈക്രയിൽ തയ്യൽ മുഖേനയും ശരിചെയ്യുന്നതിന്റെ താരതമ്യം.

2. പശ്ചാത്തല വിവരം ?

വായിൽ ഏർപ്പെടുന്ന മുറിവുകളെ ശരിയാക്കാൻ തയ്യൽ ഇടുന്നതാണ്. എന്നാൽ ഈമുറ രോഗികൾക്ക് ഭയത്തെയും കാലതാമസത്തെയും ഏർപ്പെടുത്തും. സൈനോ അക്രിലേറ്റ് എന്ന ശാസ്ത്രീയ സാധനത്തെ വച്ച് മുറിവിനെ ശരിയാക്കുന്നതു മുഖേന ഭയത്തെയും, കാലതാമസത്തെയും ഒഴിവാക്കാം.

3. ലക്ഷ്യങ്ങളും ഉദ്ദേശങ്ങളും

വായ്ക്കകത്ത് ഏർപ്പെടുന്ന മുറിവുകളെ വൈക്രയിൽ മൂലം ശരിയാക്കുക മറ്റും

വായ്ക്കകത്ത് ഏർപ്പെടുന്ന മുറിവുകളെ സൈനോ അക്രിലേറ്റ് എന്ന ശാസ്ത്രീയ സാധനം മുഖേന ശരിയാക്കൽ.

ര ിനും ഇടയിലുള്ള വ്യത്യാസത്തെ താരതമ്യപ്പെടുത്തി ക ുപിടിക്കൽ

4. ഗവേഷണം നടത്താനുള്ള ന്യായീകരണം

കുറെ കാലങ്ങളായി നടത്തപ്പെട്ട ഗവേഷണങ്ങൾ മുഖേന സൈനോ അക്രലേറ്റും, വൈക്രയിലും ശാസ്ത്രീയമായ രീതിയിൽ ശരിയാക്കുന്നത് വളരെ നല്ലതാണെന്ന് തെളിയിച്ചിട്ടു ്.

5. പഠന രീതി

പഠനത്തിന്റെ ഭാഗമായി വ്യക്തിക്ക് ഒരു നമ്പർ നൽകുന്നതാണ്.
ഈ ചികിത്സയുടെ ഭാഗമായി ചതയിൽ ഏർപ്പെട്ട മുറിവിനെ ശരിയാക്കാൻ ഒരുഭാഗത്ത് സിൽക്ക് തയ്യൽ മുഖേന ശരിയാക്കുന്നു. മറുഭാഗത്ത് സൈനോ അക്രലേറ്റ് എന്ന ശാസ്ത്രീയ സാധനം മുഖേന ശരിയാക്കുന്നു.

6. **പ്രതീക്ഷിക്കുന്ന അപകട സാദ്ധ്യതകൾ** – ഇല്ല

7. **ഈ പഠനത്തിൽ പങ്കെടുക്കുന്നതുകൊ ്എനിക്ക് എന്തെങ്കിലും പ്രയോജനമു ോ ?**

- O ഗവേഷണത്തിന് പണം ഒന്നും തരേ ആവശ്യമില്ല
- O ഗവേഷണത്തിന്റെ ക ുപിടിത്തംനിങ്ങൾക്ക് അറിയാവുന്നതാണ്.

12. **ഞാൻ ഈ പഠനത്തിൽ പങ്കെടുക്കുന്ന വിവരം രഹസ്യമായി വയ്ക്കുമോ ?**

- ➢ നിങ്ങളുടെ ഗവേഷണത്തിന്റെ ക ുപിടിത്തം ഭദ്രമായി സൂക്ഷിക്കുന്നതാണ് ഏതൊരു കാരണവശാലും വെളിപ്പെടുത്തുന്നതല്ല.
- ➢ നിങ്ങൾ ഈ ഗവേഷണത്തിൽ പങ്കെടുത്തതിനു ശേഷം ഞങ്ങളുടെ ഗവേഷകൻ നിങ്ങളുടെ കെ ത്തലുകൾ അറിയാൻ സാധിക്കാവുന്നതാണ്. മേലും ആവശ്യപ്പെട്ടാൽ എത്തിക്കൽ കമ്മറ്റിയെ അറിയിക്കുന്നതാണ്.

- ഗവേഷണത്തിന്റെ അവസാനം നിങ്ങളുടെ പേരു വിവരങ്ങൾ ആശുപത്രി റെക്കാർഡിൽ റെക്കോട് ചെയ്യുന്നതാണ്.
- ഈ ഗവേഷണത്തിന്റെ കെ ത്തലുകൾ വെളിപ്പെടുത്തുമ്പോൾ നിങ്ങളെ കുറിച്ചുള്ള രേഖകൾ പുറത്തു അിറയിക്കുന്നതല്ല.

9. എന്നെ എന്തുകൊ ് ഈ പഠനത്തിൽ ഉൾപ്പെടുത്തി ?

- പഠനത്തിന് നല്ല ശതമാനം ആളുകൾ ആവശ്യമാണ്
- ചില കൂട്ടിക്കുറച്ചിലുകൾക്കൊടുവിൽ നിങ്ങൾ ഉൾപ്പെടുന്ന വിഭാഗത്തെ തെരഞ്ഞെടുക്കപ്പെട്ടു.
- നിങ്ങളുടെ സഹകരണം മൂലം സമൂഹത്തിന് സഹായവും നന്മയും ഉ ാകുന്നു.

10. എത്ര ആളുകൾ ഈ പഠനത്തിൽ ഉൾപ്പെടുന്നു. 30

11. നഷ്ടപരിഹാര ഉടമ്പടി

പഠനവിദേയമായി ഏതെങ്കിലും തരത്തിൽ രോഗം സങ്കീർണ്ണമായാൽ രോഗിയെ ഈ സ്ഥാപനത്തിൽ വിദഗ്ദചികിത്സയ്ക്ക് വിധേയനാക്കുന്നതാണ്.

12. ഏതെങ്കിലും വിധത്തിൽ വേതനം ലഭിക്കുമോ – ഇല്ല

13. എപ്പോൾ വേണമെങ്കിലും നിങ്ങൾക്ക് ഈ പഠനത്തിൽ നിന്ന് പിൻമാറാവുന്നതാണ്.

14. ഈ ഗവേഷണത്തിന്റെ ഫലമായി പുതിയ എന്തെങ്കിലും കെ ത്തലുകളു ങ്കിൽ അത് നിങ്ങളെ അിറയിക്കേ താണ്.

15. ഈ പഠനത്തിന്റെ സമയ ദൈർഘ്യം ഒരു വർഷം.

16. വേറെ ഒരു അറിയിപ്പുകളും ആവശ്യമില്ല.

17. ബന്ധപ്പെടേ വ്യക്തി.

ഡോ. കെ. മുരുകൻ
പോസ്റ്റുഗ്രാജുവേറ്റ്
ഡിപ്പാർട്ട്മെന്റ് ഓഫ് മാക്സിലോഫേഷ്യൽ സർജറി
ശ്രീ മൂകാംബിക ഇൻസ്റ്റിറ്റ്യൂട്ട് ഓഫ് ഡെന്റൽ സയൻസ്,
കുലശേഖരം - 629 161.കന്യാകുമാരി ജില്ല.
Ph: 9894269313
E-mail: murugankj@gmail.com

സ്ഥലം:
തീയതി :

സമ്മതപത്രം

ഭാഗം – 2

ഈ പഠനത്തെ പറ്റിയുള്ള എല്ലാ കാര്യങ്ങളും എനിക്ക് പറഞ്ഞ് മനസ്സിലാക്കി തരികയും അതിന്റെ ഒരു പകർപ്പ് എനിക്കു നൽകുകയും ചെയ്തിട്ടു ്. ഈ പഠനം ഗവേഷണത്തിനായി ഉള്ളതാണെന്നും എനിക്ക് ഇതിൽ നിന്ന് നേരിട്ട് ഒരു ഫലവും ഉ ാകില്ലെന്നും ഞാൻ മനസ്സിലാക്കുന്നു. ഈ പഠനത്തിന്റെ രീതിയും ഉദ്ദേശവും എനിക്ക് മനസ്സിലാക്കി തന്നിട്ടു ്. അതു പോലെ എനിക്ക് സംശയങ്ങൾ ചോദിക്കാൻ അവസരങ്ങൾ ലഭിച്ചിട്ടുമു ്. ഇതിൽ പങ്കെടുക്കാനും പങ്കെടുക്കാതിരിക്കാനും ഉള്ള അവകാശം എനിക്കു െന്നും അതുപോലെ പഠനത്തിന്റെ ഏതു ഘട്ടത്തിലും ഇതിൽ നിന്ന് പിൻവങ്ങാനുള്ള സ്വാതന്ത്ര്യവും എനിക്കു െന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. ഈ പഠനത്തിൽ പങ്കെടുക്കുന്നതുകൊ ോ, പങ്കെടുക്കാത്തതുകൊ ോ എന്റെ മറ്റു ചികിത്സകളെ ബാധിക്കുന്നതല്ലെന്ന് ഞാൻ അിറയുന്നു.

"വായിൽ ഏർപ്പെടുന്ന മുറിവുകളെ സൈനോ അക്രിലേറ്റ് മുഖേനയും വൈക്രയിൽ തയ്യൽ മുഖേനയും ശരിചെയ്യുന്നതിന്റെ താരതമ്യം" എന്ന ഗവേഷണത്തിൽ പങ്കെടുക്കുന്നതിനും ഇതിന്റെ ഫലങ്ങൾ ശാസ്ത്രലേഖനത്തിൽ പ്രസിദ്ധീകരിക്കുന്നതിനും എനിക്ക് സമ്മതമാണെന്ന് ഞാൻ ഇതിനാൽ അിറയിച്ചുകൊള്ളുന്നു.

സീരിയൽ നമ്പർ / റഫറൻസ് നമ്പർ :

പങ്കെടുക്കുന്ന ആളിന്റെ പേര് :

മേൽവിലാസം :

ഫോൺ നമ്പർ :

ഒപ്പ് / വിരലടയാളം

സാക്ഷി :

സ്ഥലം :

തീയതി

SREE MOOKAMBIKA INSTITUTE OF DENTAL SCIENCES

DEPARTMENT OF ORAL AND MAXILLOFACIAL SURGERY

CLINICALLY COMPARE THE EFFICIENCY OF N-BUTYL 2-CYANOACRYLATE AND VICRYL SUTURE IN INTRA ORAL WOUND CLOSURE: AN INVIVO STUDY

DATA RECORD SHEET

Patient name : **Date:**

Age : **Op.No:**

Sex :

Height :

Weight :

Parameter	Particulars	1st day		3rd day		5th day		7th day	
		Group 1	Group2	Group1	Group2	Group 1	Group2	Group1	Group2
Pain	Refernce value based on VAS								
Wound dehiscence	Presence								
	Absence								

Group1- Vicryl suture. Group2- N-Butyl 2-cyanoacrylate. VAS- visual analogue scale.

0- No pain, 1- Mild pain, 2- severe pain, 3- very severe pain.

Participant's Signature **Investigator's Signature,**

Date: