"COMPARISON OF EFFICACY OF CHLORHEXIDINE-DIACETATE COATED SILK SUTURES VERSUS PLAIN BLACK BRAIDED SILK SUTURES IN POST OPERATIVE HEALING AFTER IMPACTED MANDIBULAR THIRD MOLAR SURGERY-A RANDOMIZED CLINICAL TRIAL"

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LIST OF ABBREVIATIONS

SR. NO.	ABBREVATIONS	FULL FORM
1	IMTM	Impacted mandibular third molars
2	POD	Post-operative Day
3	M	Male
4	F	Female
5	PRE-OP	Pre operative
6	POST-OP	Post operative
7	Hb	Hemoglobin
8	BT	Bleeding time
9	CT	Clotting time
10	RBS	Random Blood Sugar
11	IOPA	Intra-oral peri-apical radiograph
12	OPG	Orthopantomogram
13	BBS	Black braided silk suture
14	CHX	Chlorhexidine-diacetate coated suture
15	RCT	Randomized controlled trial
16	PI	Pederson's Index
17	SG	Study group
18	CG	Control group
19	SSI	Surgical site infection

ABSTRACT

INTRODUCTION

In oral and maxillofacial surgery, surgical removal of an impacted molar is regarded as a clean-contaminated technique. Hence, debate is going on regarding the prescription of antibiotics after such minor surgical procedures due to higher percentage of cases of antibiotic resistance. Chlorhexidine-diacetate coated black braided silk suture is an alternative method to decrease local erythema and infection of surgical site after surgical removal of impacted third molars by reducing local antimicrobial load and decrease the usage of systemic antibiotics.

MATERIALS AND METHODS

Two groups of twenty-three patients each were formed out of the 46 patients in total. Patients in the study group were subjected to Chlorhexidine diacetate coated black braided silk suture and in the control group with plain black braided silk suture. Post-operative erythema and infection were assessed on post-operative day 2 and day 7.

RESULT

The mean erythema score was 1.39 ± 0.8 and 0.65 ± 0.6 in the BBS group and CHS group on post operative day 2 also 0.87 ± 0.9 and 0.21 ± 0.42 in the BBS group and CHS group on POD 7 which shows statistically significant results ($p < 0.05$).

The mean infection score was 0.739 ± 0.68 and 0.261 ± 0.49 in the BBS group and CHS group on post operative day 2 also 0.435 ± 0.78 and 0.087 ± 0.28 in the BBS group and CHS group on POD 7 which shows statistically significant results ($p < 0.05$).

CONCLUSION

Chlorhexidine-diacetate coated black braided silk suture is shown to be effective in decreasing post-surgical local erythema and infection of surgical site after the surgical removal of the impacted mandibular third molar.

KEYWORDS:

Post-operative antibiotic prophylaxis, Chlorhexidine diacetate coated suture, Antibiotic Side effect assessment of antibiotics, surgical extraction, 3rd molar

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INTRODUCTION

The cornerstone of chairside treatments for clean-contaminated oral and maxillofacial surgeries is the surgical extraction of impacted third molars [1]. Various studies are showing that the incidence of infection is 1% to 5.8% after surgical extraction of 3rd molar. As the incidence of infection is very less, the use of routine antibiotics after the procedure is not advisable [2]. Some authors consider after surgical extraction; complications are mainly due to the procedure rather than an infectious event thus use of antibiotics will not be beneficial; and they suggest using anti-inflammatory drugs.

The use of systemic antibiotics has the potential to cause antibiotic resistance, a major global problem at the moment. Six to seven percent of people who are prescribed antibiotics experience some sort of negative reaction. Thus, the recent advances keep an eye towards giving an antibiotic locally as compared to systematically.

The oral surgeon will stitch up the wound from the extraction of an impacted mandibular wisdom tooth in order to speed up the healing process.. Due to their near proximity to the wound surface, these sutures rapidly coat in fibrinogen and fibronectin, creating an ideal environment for the development of microorganisms that can cause surgical site infections. Using the Chlorhexidine-Diacetate coated Black Braided Silk Suture (CDC-BBS) which has a local antimicrobial effect can help to prevent the growth of bacteria and reduce the risk of Surgical site infections. Gram positive and gram-negative microorganisms are both defeated by the broad-spectrum antiseptic chlorhexidine. The potential positive impact of local drug delivery may lead to enhanced patient outcomes and decreased need for additional medical supplements.

AIM AND OBJECTIVES OF THE STUDY

AIM: To assess the efficacy of chlorhexidine-diacetate coated silk suture versus black braided silk suture on post-surgical healing after impacted 3rd molar surgery.

OBJECTIVES:

- To assess and compare the local erythema and postoperative infection following the surgical extraction of the mandibular third molar that is impacted using a Chlorhexidine-diacetate coated black braided silk suture.

- To assess and compare the local erythema and postoperative infection following the surgical extraction of the mandibular third molar that is impacted using a black braided silk suture.

REVIEW OF LITERATURE

1. In a 2019 study, **Mohan S et al.** discovered that, when accounting for the inflammatory effects of localized erythema, discomfort, and trismus after the procedure, chlorhexidine diacetate-impregnated sutures performed better than postsurgical antibiotic prophylaxis with plain polyglactin sutures. [2]

2. After removing an impacted mandibular third molar, **Sneha Krishnan et al.** published a paper in 2020 comparing the effectiveness of triclosan- and chlorhexidine-coated sutures in preventing surgical site infections. They came to the conclusion that polyglactin sutures impregnated with triclosan and chlorhexidine have a significant potential to prevent surgical site infections. [3]

3. In 2019, Raphael Cavalcante **COSTA et al.** released a paper. Chlorhexidine and cinnamon aldehyde-modified sutures: anti-Candida efficacy, bioavailability, and mechanical qualities concludes that there was no anti-Candida effect even when sutures containing cinnamon aldehyde and chlorhexidine were released for 48 hours, increasing their bioavailability. [4]

4. In 2021, **Raees Khan** and colleagues released a piece. Triclosan-containing sutures: research indicates that TCS has hepatogenic, neurotoxic, and carcinogenic effects and that safety and resistance concerns must be resolved before widespread use.. [5]

5. In a 2014 paper by **Andreas Obermeier et al**. draw conclusions about the suture's tolerable cytotoxicity as assessed by ISO and its strong antimicrobial efficacy.. [6]

6. In 2006, **Hanife Atao'glu et al.** released an essay. Regular antibiotic prophylaxis is not required during third-molar extraction procedures, according to research that shows this to be true for healthy individuals undergoing routine third-molar extraction procedures. [1]

7. In 2023, an article was published by **S. Chaganti et al.** A randomized controlled trial comparing bacterial colonization on absorbable non-coated sutures with sutures coated with either chlorhexidine or triclosan found that the antibacterial-coated sutures are more effective at reducing bacterial accumulation than the non-coated sutures. Thus, using these sutures can be quite beneficial for periodontal flap surgery. [7]

8. A 2016 study by **Kunal Sunder Sethi et al.** compared the ability to suppress oral biofilm formation and the antibacterial efficacy of sutures coated with triclosan and chlorhexidine against periodontal infections. [8]

9. In 2022, **Soya Alfred Xavier et al.** released a paper. double-blind clinical trial finds virtually little difference in postoperative pain between the two types of suture materials. However, there were no indications that the polyglycolic acid sutures were irritating.[9]

10. In a 2018 paper by **Onseti et al.** reviewed the literature and found that the antimicrobial suture was effective in reducing the risk of surgical site infections after surgery for a range of surgical patients. [10]

11. **Shivangi Gaur et al.** found that there was no discernible drop in the quantity of pathogens adherent to suture material coated with chlorhexidine in their study in 2021.

12. A review by **Chua et al.** in 2022 indicates that using antimicrobial sutures can effectively reduce the incidence of surgical site infections while also battling antibiotic resistance. [12]

13. In 2004, a paper was published by **Poeschl P et al.** concludes that because oral antibiotics do not encourage mouth opening, reduce discomfort, speed up wound healing, or prevent inflammatory issues, they are not recommended for usage on a regular basis following a lower third molar extraction. [13]

14. In 2013, **Scaffaro et al.** released a paper, it was found that the threads impregnated with the chemical showed no negative effects that could have compromised the survival of human fibroblast cells in vitro.[14]

15. In 2013, **Cruz F. et al.** released a paper. Antiseptic pomade-coated sutures that stop bacteria from colonizing: According to the results of a randomized clinical experiment, the antiseptic pomade effectively reduced bacterial colonization on silk braided sutures during oral surgery. [15]

16. In 2017, an article was released by **Leader D et al**. Strong anti-microbial effect of coated sutures makes them suitable for frequent surgical wound infections, according to research on the importance of antimicrobial sutures in preventing SSI. [16]

17. In 2017, **Wu et al.** conducted a Meta-analysis concluded that there might be a chance to lower the frequency of surgical site infections by applying antimicrobial coatings to sutures.[17]

MATERIALS AND METHODS

The study was conducted on 46 patients reporting to the outpatient Department of Oral and Maxillofacial Surgery, KLE VK Institute of Dental Sciences, K.A.H.E.R, Belagavi, , who gave consent to participate with their free will and Chlorhexidine-diacetate coated silk sutures or black braided silk suture will be placed after impacted mandibular 3rd molar surgery.

STUDY DESIGN: Randomized controlled trial

DURATION OF THE STUDY: May 2022- July 2023

STATISTICAL ANALYSIS: The statistical analysis used were

- Descriptive statistical analysis was done for demographic details.
- Mann Whitney / unpaired 't' test will be done.
- Post-hoc test was used for intra group comparison.

SAMPLE SIZE ESTIMATION: The sample size was calculated using the formula

Sample size at 95% power and 95% confidence interval

$$N = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 * (p^1 1q1 + p2q2)}{(p1 - p2)^2}^{1}$$

where,

$p_1 = 52.2\ \%$ $p_2 = 94.2\ \%$

$q_1 = 47.8\ \%$ $q_2 = 5.8\ \%$

$z_{1-\frac{\alpha}{2}} = 1.96$ $z_{1-\beta} = 1.64$

n= 22.34 ≈ 23 (per group) **TOTAL** 23*2 =46

Therefore, the sample size is **46**

All the participants had to meet the following criteria.

INCLUSION CRITERIA: Patients fulfilling the following criteria were included:

- Patients belonging to the age category of 18-40 years.
- Patients who have not used any antibiotic/antimicrobial or anti-inflammatory drugs 1 week before surgery.
- Patients with moderate surgical difficulty score on Pederson's index (4-6).
- Patients with ASA status I and having normal bleeding & clotting times.
- Patients who are non-smokers.

EXCLUSION CRITERIA: Patients with the following criteria were excluded:

- Patients who were not willing to participate in the study.
- Patients using medications such as aspirin, NSAIDs, steroids, and cytotoxic agents that could potentially change the study's trajectory and impact the surgical site's ability to recover.
- Those who had taken penicillin or cephalosporin for upper respiratory tract infections or head and neck infections two to three weeks earlier.
- Patients having poor oral hygiene.
- Patients with prior infection.

METHODOLOGY

- There were total 46 patients with impacted mandibular 3rd molar diagnosed by established clinical and radiographic parameters and who meet the inclusion criteria will be allotted into two groups of 23 each by computer generated random allocation

Study participants were categorized into two groups:

Group I: Patients subjected to chlorhexidine-diacetate coated silk suture after surgery. (n=23)

Group II: Patients subjected to plain black braided silk suture after surgery (n=23).

- The position of impacted tooth was assessed using Pederson's Difficulty Index and tooth with a score of 5 to 6 were included in the study.
- All the patients were screened for inclusion and exclusion criteria.

PRE-OPERATIVE ASSESSMENT:

- Hemoglobin
- Bleeding time
- Clotting time
- Random Blood Sugar
- Orthopantomogram/ Intra-Oral Periapical radiograph

ARMAMENTARIUM AND MATERIALS: (as shown in Figure-1)

- Surgical gloves
- Mouth mirror
- Dental explorer
- 2ml Disposable Syringe
- Gauze piece
- Surgical scalpel blade no. 15
- Straight elevator
- Artery forceps
- Curette
- Bone file
- Needle holder
- Adson's tissue forceps
- Scissors
- Surgical handpiece and bur
- Kidney tray
- Irrigation syringe 20ml
- Surgical drape
- Towel clip
- Suction tip
- Tweezer
- Langenbeck retractor
- Sponge holder
- Periosteal elevator

Figure 1 - Armamentarium

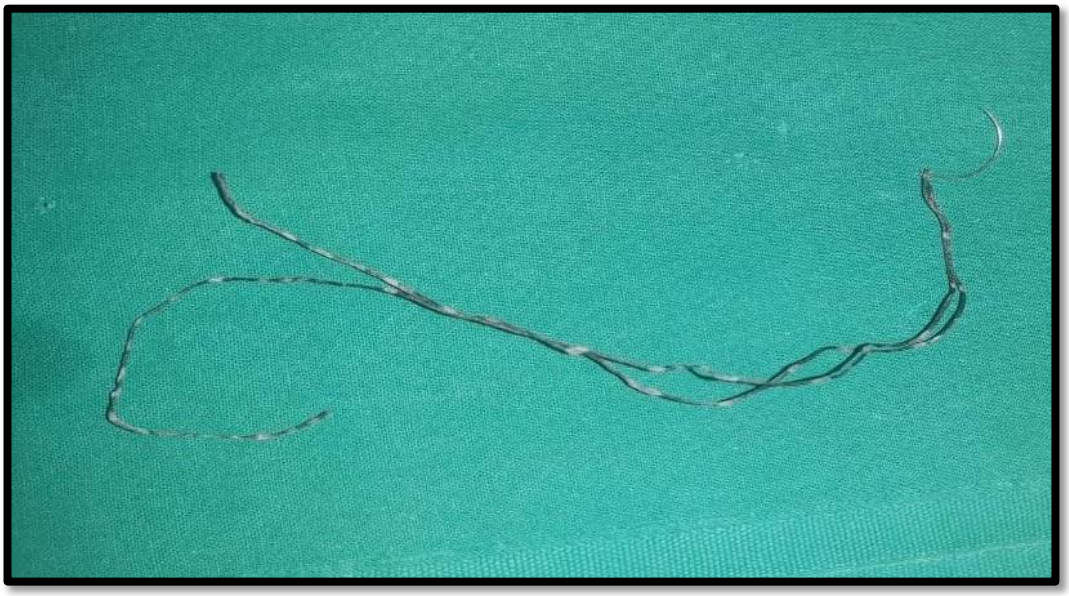


Figure 2 CHX -diacetate coated suture

Follow up: was done on the 2nd and 7th day of surgical extraction of third molar.

SURGICAL PROTOCOL FOLLOWED DURING THE RESEARCH

- The allocated patients were split into two groups using a randomly generated computerized allocation.
- Patients underwent surgical procedure in the department by the same experienced surgeon.
- Regional anesthesia was given by blocking the inferior alveolar nerve using 2% lignocaine plus adrenaline 1:80,000.
- After raising a full thickness mucoperiosteal flap, osteotomy and odontotomy were carried out under copious saline irrigation, utilizing a straight handpiece and bur.
- After the completion of the surgical extraction, a thorough curettage with bone filing of the socket was done.

In group 1- After being relocated, the flap will be sutured with chlorhexidine-diacetate coated silk suture

In group 2- After being relocated, the flap will be sutured with plain 3-0 black braided silk sutures.

- A pressure pack will be placed on the extraction site. All patients will receive post-extraction instructions.
- Patients in both the groups received tablet PARACETAMOL 650MG TID (for 3 days).
- On 2nd and 7th postoperative day patients were recalled for follow up to check post-operative healing.
- Suture removal was done on post operative day 7.

EVALUATION CRITERIA

Acc to Sana Mohan et al and B.S Jayanth et al [2]

ERYTHEMA

0 = absence of any signs of erythema.

1 = presence of redness and hyperemia around the surgical site.

2 = bleeding from the surgical site.

3 = ulceration of the surgical site.

INFECTION

0 = No signs of infection.

1 = purulent discharge, either swollen or painful, in the extraction socket.

2 = localized abscess is present.

FOLLOW UP

On the post-surgical 2nd day and 7th day of surgical extraction of the third molars.

PATIENTS IN STUDY GROUP (CHX)

Figure 3 (Post-op day 2)

Figure 4 (Post-op day 7)

PATIENTS IN CONTROLL GROUP (BBS)

Figure 5 (Post-op day 2)

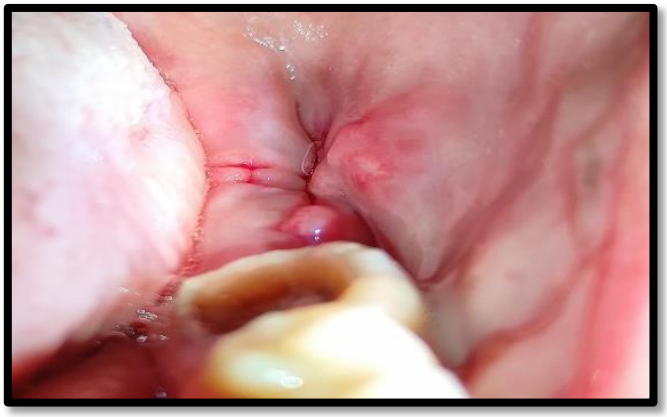


Figure 6 (Post-op day 7)

RESULTS

SEX DISTRIBUTION

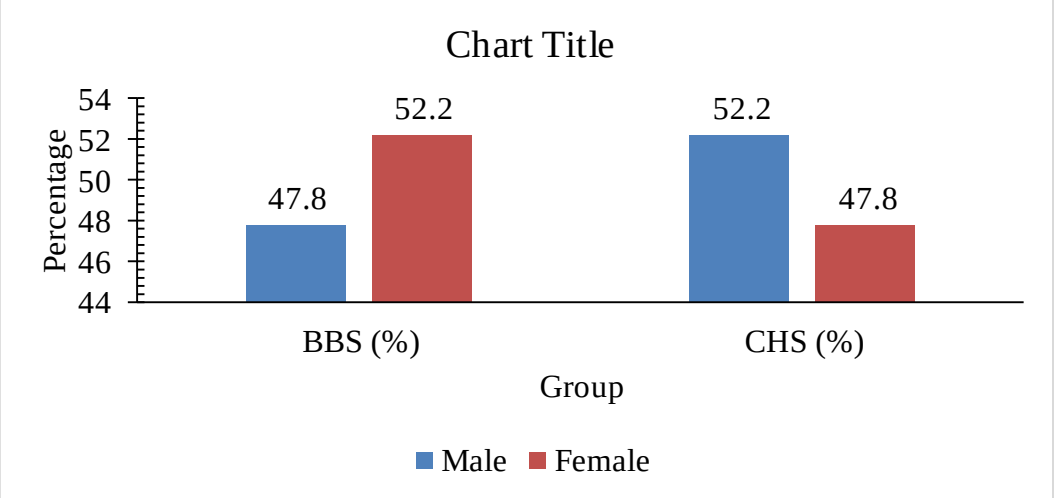
TABLE 1: DISTRIBUTION OF MALE AND FEMALE IN THE STUDY GROUP (CHX) AND CONTROL GROUP (BBS)

Table 1

	BBS Group		CHS Group	
Sex	n	%	n	%
Male	11	47.8	12	52.2
Female	12	52.2	11	47.8

The distribution of male patients in the two groups was 11 and 12 respectively, whereas the distribution of female patients in the two group was 12 and 11 respectively. Percentage of female patients was high in control study as well as low in study group."

Graph 1



AGE DISTRIBUTION

TABLE 2: AGE DISTRIBUTION AMONG THE STUDY GROUP AND CONTROL GROUP

Table 2

Group	N	Mean	SD	SE	H Value	P Value
BBS	23	28.4348	4.75611	0.99172	2.95	0.086
CHS	23	25.9565	4.90341	1.02243		

The average age in the BBS group was found to be 28.4348 and the average age in the CHS group was found to be 25. 9565.The comparison between them were not found to be statistically significant (p=0.086) which denotes no baseline difference between the two groups.

PEDERSON'S INDEX

TABLE 3: COMPARISON OF STUDY GROUP AND CONTROL GROUP WITH MEAN PEDERSON'S INDEX

Table 3

Group	N	Mean	SD	SE	H Value	P Value
BBS	23	5.5217	0.51075	0.1065	0.085	0.771
CHS	23	5.4783	0.51075	0.1065		

Graph 2

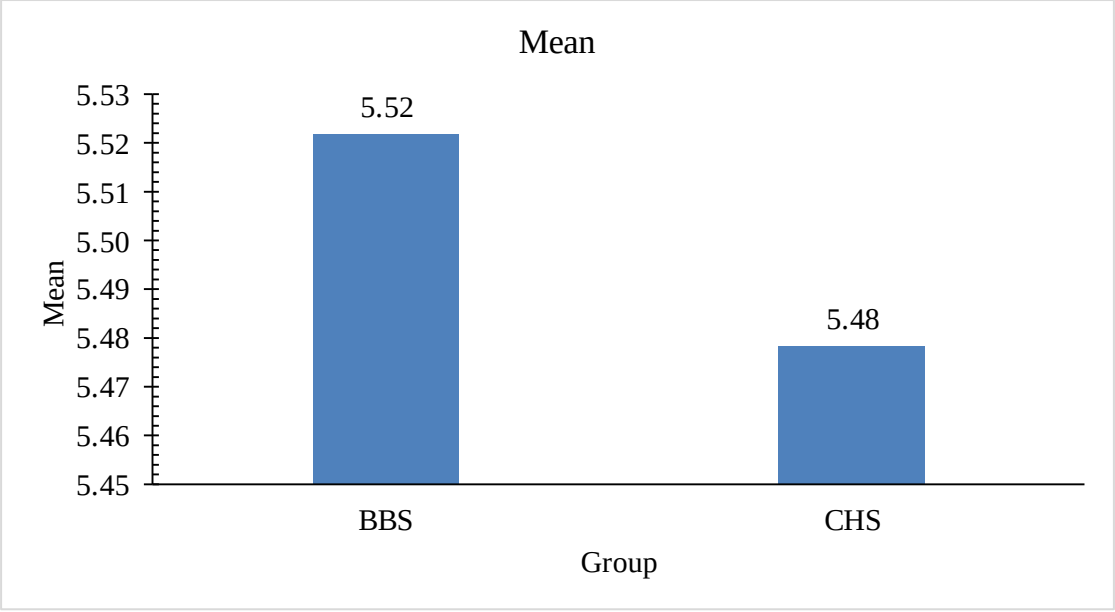


TABLE 4: COMPARISON OF STUDY GROUP AND CONTROL GROUP WITH MEAN PEDERSON'S DIFFICULTY INDEX

Table 4

	BBS Group		**CHS Group**	
Pederson Index	n	%	n	%
5	11	47.8	12	52.2
6	12	52.2	11	47.8

OBSERVATION:

The Pederson's index was 5 for 47.8 % of the participants in the BBS group and 52.2 % of the participants in the CHS group. The Pederson's index was 6 for 52.2% of participants in the BBS group and 47.8% of participants in the CHS group.

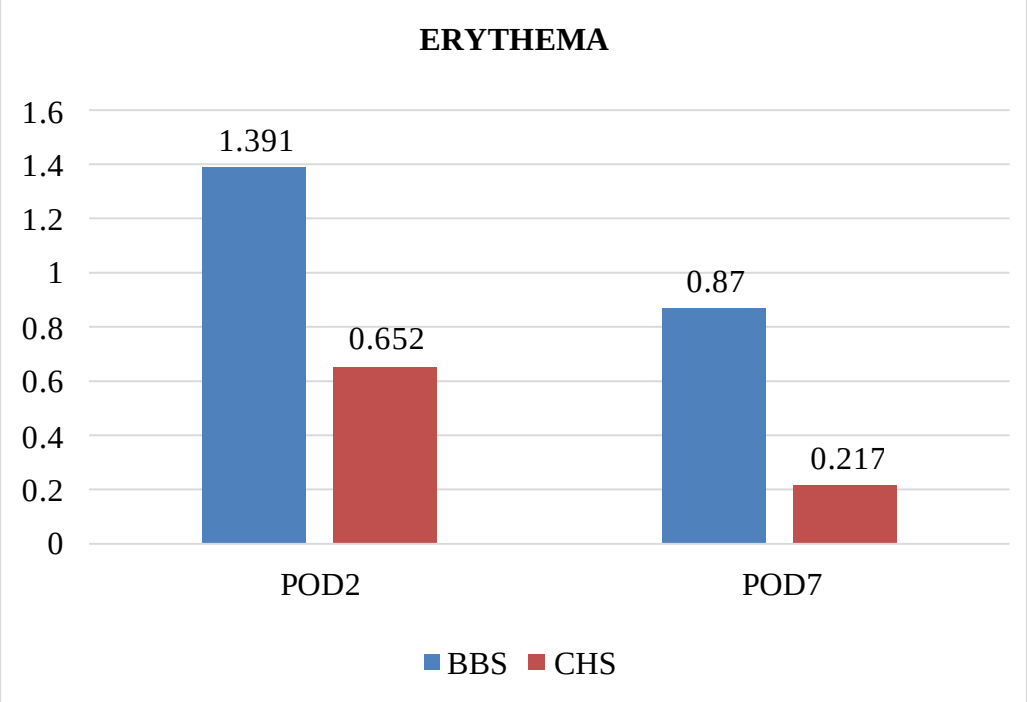
ASSESSMENT OF ERYTHEMA:

TABLE 5: COMPARISON OF ERYTHEMA BETWEEN TWO GROUPS AT POST-OP DAY 2 AND POST-OP DAY 7

Table 5

	Group	N	Mean	SD	SE	Z value	P value
Post-op Day 2 (Erythema)	BBS	23	1.391	0.839	0.175	-2.27	0.023
	CHS	23	0.652	0.647	0.135		
Post-op Day 7 (Erythema)	BBS	23	0.87	0.968	0.202		
	CHS	23	0.217	0.422	0.088		

Graph 3



OBSERVATION:

The mean score was 1.39 ± 0.8 and 0.65 ± 0.6 in the BBS group and CHS group on post operative day 2, 0.87 ± 0.9 and 0.21 ± 0.42 in the BBS group and CHS group on POD 7. The comparison between two group on post operative Day 2 and Day 7 was calculated using Mann Whitney U test and Standard t test was found statistically significant (p=0.023).

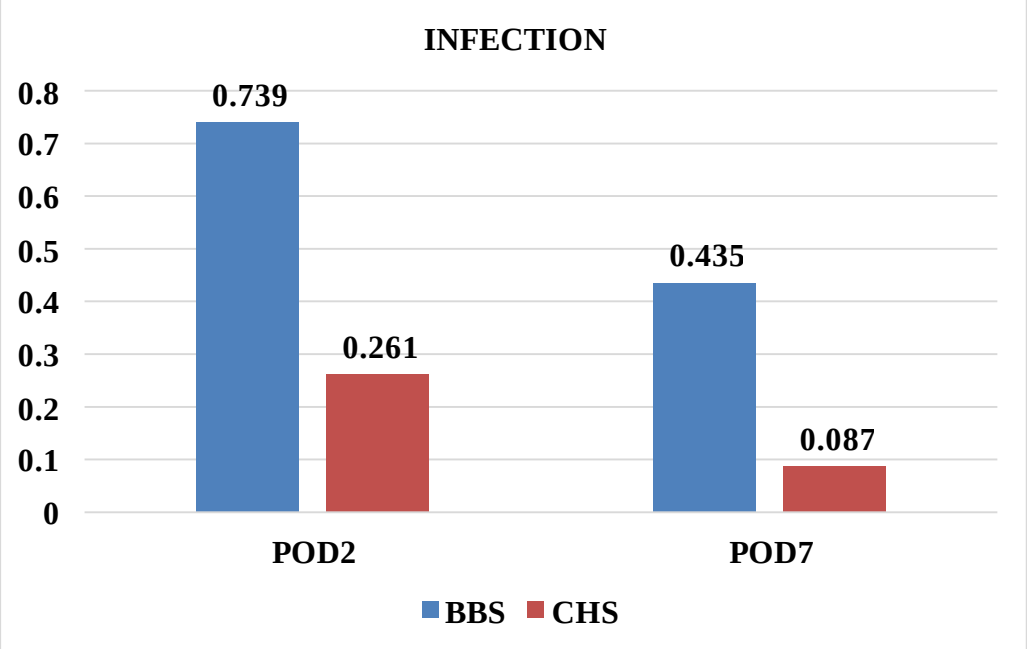
ASSESSMENT OF INFECTION:

TABLE 6: COMPARISON OF INFECTION BETWEEN TWO GROUPS AT POST-OPE DAY 2 AND POST-OP DAY 7

Table 6

	Group	N	Mean	SD	SE	Z value	P value
Post-op Day 2 (Infection)	BBS	23	0.739	0.689	0.144	-1.858	0.046
	CHS	23	0.261	0.449	0.094		
Post-op Day 7 (Infection)	BBS	23	0.435	0.788	0.164		
	CHS	23	0.087	0.288	0.060		

Graph 4



OBSERVATION:

The mean score was 0.739 ± 0.68 and 0.261 ± 0.49 in the BBS group and CHS group on post operative day 2, 0.435 ± 0.78 and 0.087 ± 0.28 in the BBS group and the CHS group on POD 7. . The comparison between two group on post operative Day 2 and Day 7 was calculated using Mann Whitney U test and Standard t test was found statistically significant (p=0.046).

DISCUSSION

A frequent surgical treatment that has a number of intra- and post-operative risks is the surgical extraction of the impacted mandibular third molar. The extraction of impacted third molars inevitably leads to some level of erythema, infection surrounding the surgical area, and also swelling, pain, wound dehiscence and trismus.[18] To overcome these antibiotics are prescribed, among which the most commonly used is penicillin which is a broad-spectrum antibiotic. However, many recent studies have proved that antibiotics are not required after surgical extraction of the third molar.

Hence the local drug delivery is the only way where there are fewer complications seen and also the load of systematic use of antibiotics is decreased thus decreasing antibiotic sensitivity. For decades the discussion has been going on the role of suture material in causing surgical site infection [9.] Suture coated with an anti-microbial agent i.e., Chlorhexidine- Diacetate helps to reduce the local microbial load and also decreases systematic use of antibiotics. Chlorhexidine is broad range, dual-action biguanide that works against gram-positive and gram-negative microorganisms. The mechanism of action of Chlorhexidine is shown in the chart. [19]

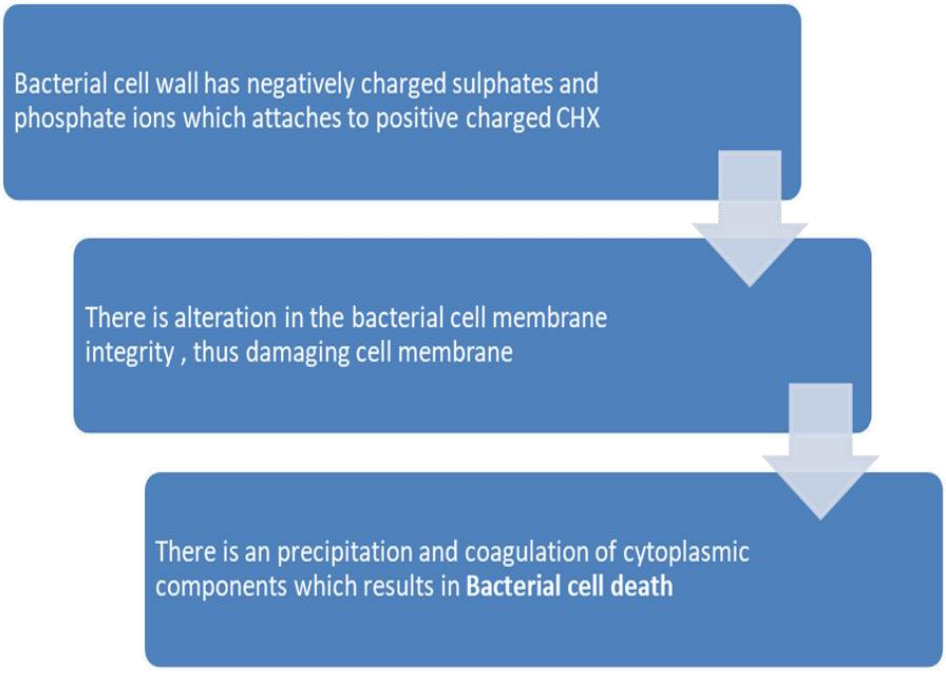


Figure 7 Mechanism of action of CHX

In our recent study ,46 patients in all were split into two equal groups with 23 individuals in each group. showed that there was less post-operative erythema and infection in the CHX group. The study did not show any single patient with an allergic reaction to the coated suture material. Our results were following the study conducted by Mohan et al in 2019 that antimicrobial coated suture reduces the erythema, pain and decreased mouth opening in healthy patients undergoing surgical extraction of impacted mandibular third molar [2]. In a study by Soya Xavier et al states that there is only a marginal difference in post-operative pain, however no signs of inflammation by using chlorhexidine coated suture [9].

The mean score of infection post-op day 2 in the BBS group is 0.739 and the CHX group is 0.261 which highly challenges the benefit of Chlorhexidine diacetate coated black braided silk suture in third molar surgery patients who are healthy. A distinct difference in erythema between the two groups suggested that the coated suture material was preventing the formation of biofilms [2]. In a study by Obermeier

et al who tested the effectiveness of chlorhexidine laurate suture on Staphylococcus Aureus, exhibited rapid anti-bacterial action and increased drug release during the first 48 hours [6]. In study conducted by Mohan et al shows that 17.65% of patients complained of adverse effects who took antibiotics. One major factor leading to the development of antibiotic resistance is the misuse of medicine. According to Petersons antibiotics are prescribed in case if the procedure is for more than 3 hours or a foreign body insertion, none of these was done in this procedure. Therefore, routine antibiotic usage without a risk of infection cannot be justified in normally healthy individuals [20].

CONCLUSION

This study concludes that Chlorhexidine-diacetate impregnated black braided silk suture showed a superior outcome when compared to plain black braided silk suture in account for local erythema and infection after surgical removal of impacted mandibular third molar.

LIMITATION

- Due to small sample size, it was difficult to generalize the results, hence further studies are needed to evaluate the efficacy of Chlorhexidine-diacetate coated black braided silk suture in decreasing the local erythema and infection after the surgical removal of impacted mandibular third molar.

- As it is not the split mouth study, the healing mechanism differs in the individuals will be a reason for the study's bias.

RECOMMENDATION

Chlorhexidine-diacetate coated suture can be used routinely after surgical extraction of impacted third molar, as it is a cheap and easy alternative to decrease the surgical site infection and also reduce usage of systemic antibiotic, thus decreasing antibiotic resistance.

SUMMARY

The present study was a clinical randomized controlled trial of total 46 participants were categorized into two groups: Group I (Chlorhexidine-diacetate coated black braided silk suture), Group II (plain black braided silk suture). Follow up period was on 2nd day and 7th day postoperatively to evaluate local erythema and infection. There was a significant decrease in the post-op surgical site erythema and infection on 2nd day and 7th day post operatively in case of Group 1 (chlorhexidine diacetate coated black braided silk suture). This indicated that using a Chlorhexidine-diacetate coated black braided silk suture after surgical removal of impacted teeth is found to be an effective and economical alternative in reducing surgical site infection and erythema.

BIBLIOGRPHY

1. Ataoğlu H, Öz GY, Çandirli C, Kiziloğlu D. Routine antibiotic prophylaxis is not necessary during operations to remove third molars. British Journal of Oral and Maxillofacial Surgery. 2008 Mar;46(2):133–5.

2. Mohan S, Jayanth BS, Saralaya S, Sunil SM, Sageer ASM, Harikrishnan R. Comparative Study on the Efficacy of Postsurgical Oral Prophylactic Antibiotic Versus Antimicrobial Suture Placement Alone in Preventing Surgical Site Infection After Removal of Impacted Mandibular Third Molar. J Maxillofac Oral Surg. 2020 Dec 1;19(4):546–51.

3. Krishnan S, Periasamy S, Murugaiyan A. Comparing the Efficacy of Triclosan Coated Sutures versus Chlorhexidine Coated Sutures in Preventing Surgical Site Infection after Removal of Impacted Mandibular Third Molar. J Pharm Res Int. 2020 Aug 26;138–48.

4. COSTA RC, CAVALCANTI YW, VALENÇA AMG, ALMEIDA L de FD de. Sutures modified by incorporation of chlorhexidine and cinnamaldehyde: anti-Candida effect, bioavailability and mechanical properties. Rev Odontol UNESP. 2019;48.

5. Khan R, Yee AL, Gilbert JA, Haider A, Jamal SB, Muhammad F. Triclosan-containing sutures: safety and resistance issues need to be addressed prior to generalized use. Vol. 12, Applied Nanoscience (Switzerland). Springer Science and Business Media Deutschland GmbH; 2022. p. 3061–70.

6. Obermeier A, Schneider J, Wehner S, Matl FD, Schieker M, Von Eisenhart-Rothe R, et al. Novel high efficient coatings for anti-microbial surgical sutures

using chlorhexidine in fatty acid slow-release carrier systems. PLoS One. 2014 Jul 1;9(7).

7. Comparison of bacterial colonization on absorbable non-coated suture with Triclosan- or Chlorhexidine-coated sutures: a randomized controlled study - Google Search [Internet]. [cited 2024 Feb 20]. Available from: https://www.google.com/search?q=Comparison+of+bacterial+colonization+on+absorbable+non-coated+suture+with+Triclosan-+or+Chlorhexidine-coated+sutures%3A+a+randomized+controlled+study&oq=Comparison+of+bacterial+colonization+on+absorbable+non-coated+suture+with+Triclosan-+or+Chlorhexidine-coated+sutures%3A+a+randomized+controlled+study&gs_lcrp=EgZjaHJvbWUyBggAEEUYOTIGCAEQRRg90gEJMzkzN2owajE1qAIAsAIA&sourceid=chrome&ie=UTF-8

8. Comparative evaluation of sutures coated with triclosan and chlorhexidine for oral biofilm inhibition potential and antimicrobial activity against periodontal pathogens: An in vitro study - Google Search [Internet]. [cited 2024 Feb 20]. Available from: https://www.google.com/search?q=Comparative+evaluation+of+sutures+coated+with+triclosan+and+chlorhexidine+for+oral+biofilm+inhibition+potential+and+antimicrobial+activity+against+periodontal+pathogens%3A+An+in+vitro+study&oq=Comparative+evaluation+of+sutures+coated+with+triclosan+and+chlorhexidine+for+oral+biofilm+inhibition+potential+and+antimicrobial+activity+against+periodontal+pathogens%3A+An+in+vitro+study&gs_lcrp=EgZjaHJvbWUyBggAEEUYOTIGCAEQRRg90gEJMTYxM2owajE1qAIAsAIA&sourceid=chrome&ie=UTF-8

9. Xavier SA, Wahab A. Comparison of chlorhexidine coated polyglycolic acid sutures with silk sutures during third molar surgery. Int J Health Sci (Qassim). 2022 Jun 30;3609–16.

10. Carella S. Effectiveness of antimicrobial-coated sutures for the prevention of surgical site infection: A review of the literature. 2018; Available from: https://www.researchgate.net/publication/327777421

11. Shivangi Gaur, Subhashini R, Madhulaxmi M, Abdul Wahab P U. Chlorhexidine Coated Polyglactin Sutures In Prevention Of Surgical Site Infection. International Journal of Research in Pharmaceutical Sciences. 2020 Dec 21;11(SPL4):2254–8.

12. Surgical site infection and development of antimicrobial sutures: a review.

13. Poeschl PW, Eckel D, Poeschl E. Postoperative Prophylactic Antibiotic Treatment in Third Molar Surgery - A Necessity? Journal of Oral and Maxillofacial Surgery. 2004;62(1):3–8.

14. Scaffaro R, Botta L, Sanfilippo M, Gallo G, Palazzolo G, Puglia AM. Combining in the melt physical and biological properties of poly(caprolactone) and chlorhexidine to obtain antimicrobial surgical monofilaments. Appl Microbiol Biotechnol. 2013 Jan;97(1):99–109.

15. Cruz F, Leite F, Cruz G, Cruz S, Reis J, Pierce M, et al. Sutures coated with antiseptic pomade to prevent bacterial colonization: A randomized clinical trial. Vol. 116, Oral Surgery, Oral Medicine, Oral Pathology and Oral Radiology. Mosby Inc.; 2013.

16. Leaper D, Wilson P, Assadian O, Edmiston C, Kiernan M, Miller A, et al. The role of antimicrobial sutures in preventing surgical site infection. Vol. 99, Annals of the Royal College of Surgeons of England. Royal College of Surgeons of England; 2017. p. 439–43.

17. Wu X, Kubilay NZ, Ren J, Allegranzi B, Bischoff P, Zayed B, et al. Antimicrobial-coated sutures to decrease surgical site infections: a systematic review and meta-analysis. European Journal of Clinical Microbiology and Infectious Diseases. 2017 Jan 1;36(1):19–32.

18. Kasapoğlu Ç, Brkić A, Gürkan-Köseoğlu B, Hülya Koçak-Berberoğlu, Kasapoğlu Ç, Brkić A, et al. Complications Following Surgery of Impacted Teeth and Their Management. A Textbook of Advanced Oral and Maxillofacial Surgery [Internet]. 2013 Jun 26 [cited 2024 Feb 21]; Available from: https://www.intechopen.com/chapters/44949

19. Chlorhexidine in Dentistry: Pharmacology, Uses, and Adverse Effects - Google Search [Internet]. [cited 2024 Mar 3]. Available from: https://www.google.com/search?q=Chlorhexidine+in+Dentistry%3A+Pharmacology%2C+Uses%2C+and+Adverse+Effects&oq=Chlorhexidine+in+Dentistry%3A+Pharmacology%2C+Uses%2C+and+Adverse+Effects&gs_lcrp=EgZjaHJvbWUyBggAEEUYOTIGCAEQRRg90gEJMjMyMGowajE1qAIAsAIA&sourceid=chrome&ie=UTF-8

20. Peterson LJ. Antibiotic prophylaxis against wound infections in oral and maxillofacial surgery. Journal of Oral and Maxillofacial Surgery. 1990;48(6):617–20.

ANNEXURES – I –

ETHICAL CLEARANCE

Research and Ethics Committee
KLE VK INSTITUTE OF DENTAL SCIENCES
A Constituent Unit of KLE Academy of Higher Education & Research
Accredited 'A' Grade by NAAC | Placed in Category 'A' by MHRD (GoI)
Nehru Nagar, Belagavi - 590 010, Karnataka State
☎: 0831-2470362 | Web: http://www.kledental-bgm.edu.in
FAX: 0831-2470640 | E-mail:principal@kledental-bgm.edu.in

Sl. No. : 1583

CERTIFICATE

EC/NEW/INST/2021/2435
Research & Ethics Committee

This is to Certify that the synopsis titled

Comparison of Efficacy of Chlorhexidine-diacetate Coated Silk Sutures Versus Plain Black Braided Silk Sutures in Post Operative Healing After Impacted Mandibular Third Molar Surgery - A Randomized Clinical Trial *Submitted by*

Dr. _____ *P. G. Student /*

Staff, Guided by _____ *from Department of*

Oral and Maxillofacial Surgery *has been critically evaluated by committee members and granted ethical clearance to conduct the above mentioned study*

Date : 3/4/24

Member Secretary
Research and Ethical Committee
KLEVK Institute of Dental Sciences,
Belagavi

MEMBER SECRETARY
Research & Ethical Committee
KLEVK Institute of Dental Sciences
BELAGAVI

Chairman
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

Chairman
Research and Ethical Committee
KLEVK Institute of Dental Sciences

ANNEXURES – II –

BIOSTATISTICS CLEARANCE CERTIFICATE

KLE V.K. Institute of Dental Sciences
(A Constituent unit of KLE Academy of Higher Education & Research
Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Nehru Nagar, Belagavi-590 010 INDIA
Accredited 'A+' grade by NAAC (3rd Cycle) & Placed in Category 'A' by MHRD (GoI)
☎: 0831-2470362
FAX: 0831-2470640
Web: http://www.kledental-bgm.edu.in
E-mail: principal@kledental-bgm.edu.in

Biostatistics Clearance Certificate

This is to certify that the Biostatistics aspect of this dissertation/ Thesis work of post-graduate student, under the guidance of Professor, Department of **Oral and Maxillofacial Surgery**, entitled **"Comparison of efficacy of Chlorhexidine-diacetate coated silk sutures versus Plain black braided silk sutures in post operative healing after impacted mandibular third molar surgery- A Randomzied clinical trial"** has been done under my guidance and completed satisfactorily.

Place: Belagavi

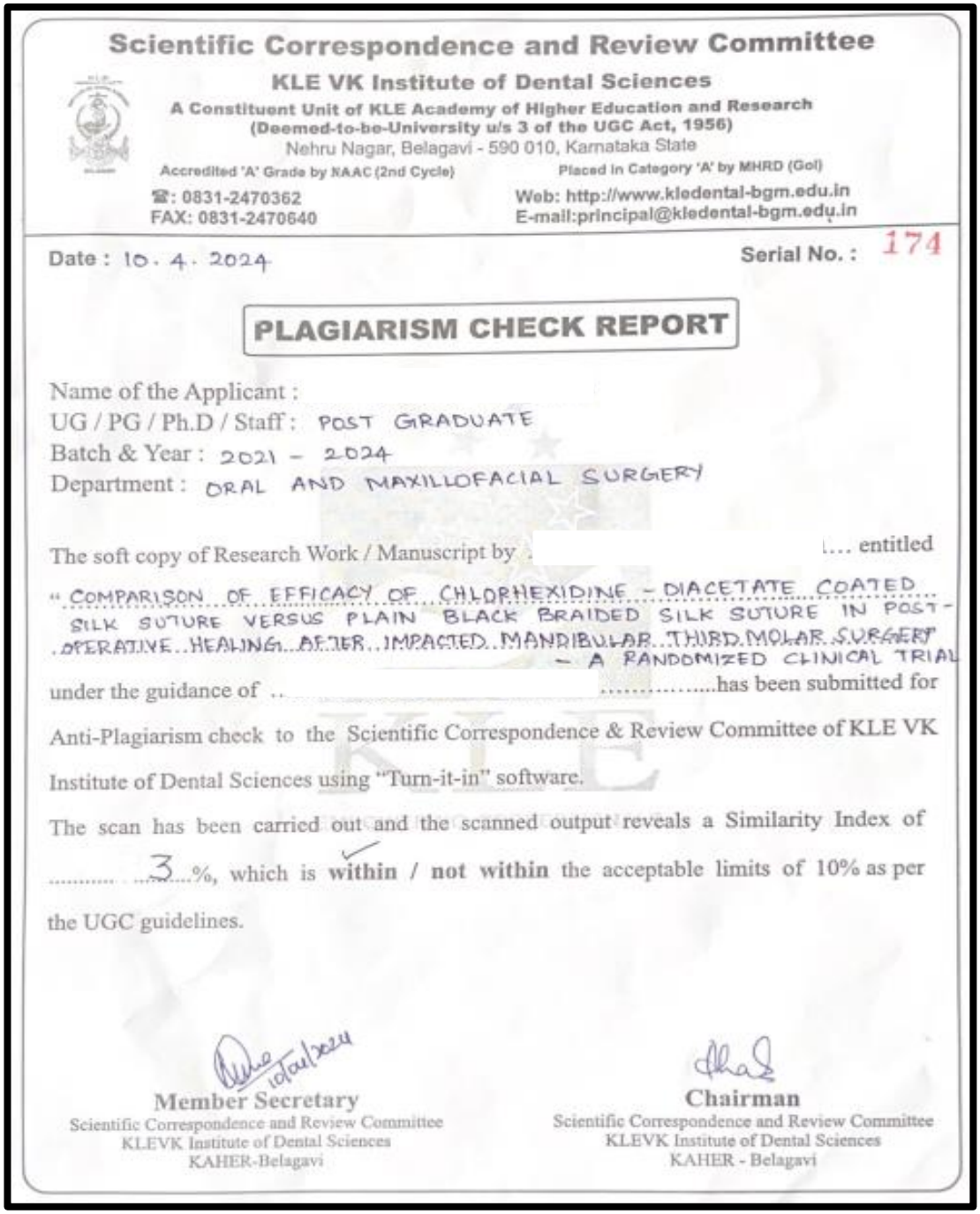
Date: 8/04/24

Name & Signature of Biostatistician
Dr Nagaraj Patil

DEPARTMENT OF EPIDEMIOLOGY & BIOSTATISTICS • KAHERS
BELAGAVI

ANNEXURES – III –

PLAGIARISM CHECK REPORT



Scientific Correspondence and Review Committee

KLE VK Institute of Dental Sciences

A Constituent Unit of KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Nehru Nagar, Belagavi - 590 010, Karnataka State

Accredited 'A' Grade by NAAC (2nd Cycle) | Placed in Category 'A' by MHRD (GoI)

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E-mail:principal@kledental-bgm.edu.in

Date : 10. 4. 2024 Serial No. : 174

PLAGIARISM CHECK REPORT

Name of the Applicant :
UG / PG / Ph.D / Staff : POST GRADUATE
Batch & Year : 2021 – 2024
Department : ORAL AND MAXILLOFACIAL SURGERY

The soft copy of Research Work / Manuscript by .... entitled

"COMPARISON OF EFFICACY OF CHLORHEXIDINE – DIACETATE COATED SILK SUTURE VERSUS PLAIN BLACK BRAIDED SILK SUTURE IN POST-OPERATIVE HEALING AFTER IMPACTED MANDIBULAR THIRD MOLAR SURGERY – A RANDOMIZED CLINICAL TRIAL

under the guidance of .....has been submitted for Anti-Plagiarism check to the Scientific Correspondence & Review Committee of KLE VK Institute of Dental Sciences using "Turn-it-in" software.

The scan has been carried out and the scanned output reveals a Similarity Index of ..... 3 %, which is **within** / **not within** the acceptable limits of 10% as per the UGC guidelines.

10/4/2024

Member Secretary
Scientific Correspondence and Review Committee
KLEVK Institute of Dental Sciences
KAHER-Belagavi

Chairman
Scientific Correspondence and Review Committee
KLEVK Institute of Dental Sciences
KAHER - Belagavi

ANNEXURE-IV

KAHER's KLE VK Institute of Dental Sciences

Department of Oral and Maxillofacial Surgery Belagavi

"COMPARISON OF EFFICACY OF CHLORHEXIDINE-DIACETATE COATED SILK SUTURES VERSUS PLAIN BLACK BRAIDED SILK SUTURES IN POST OPERATIVE HEALING AFTER IMPACTED MANDIBULAR THIRD MOLAR SURGERY-A RANDOMIZED CLINICAL TRIAL"

K.L.E.'s V.K. Institute of Dental Sciences Department of Oral and Maxillofacial Surgery, Belgaum

CONSENT TO SURGERY & ANAESTHETICS

Date: Time: a.m./ p.m.

1. I authorize the performance upon self or Mr./Miss./Mrs._____ the following operation (Nature and extent) to be performed under the direction of Dr. _____and by Dr._____in my own vernacular language.
2. I agree to give my personal details like name, age, sex, address, history of treatment taken and any other details required for the study to the best of my knowledge.
3. I will cooperate with the surgeon for examination and also for various investigations.
4. I consent to the administration of anesthetics as may be considered necessary or advisable by the doctor responsible for this service.
5. I consent to the administration of drugs as may be considered necessary or advisable by the doctor responsible for this service.

6. I permit the surgeon to utilize the information given by me and the results obtained from this study for presentation and publication.
7. I permit the surgeon to take my photographs to utilize it for the study and presentation purpose.
8. I am participating in this study with my own wish and will and the surgeon has explained the nature and the effect of procedure including surgical extraction of tooth followed by closure with Chlorhexidine-diacetate coated BBS suture instead of plain BBS suture and its effect on the postoperative local erythema and infection in my vernacular language.
9. The nature and purpose of the operation and the materials being used, possible alternative methods of treatment, the risk involved and the possibility of complications have been fully explained to me in my vernacular tongue. No guarantee or assurance has been given by anyone as to the results that may be obtained.
10. I have read and understood the above information given by surgeon about the study and willingly agree to participate in the study and willingly agree to come for follow up on the 2nd and 7th day.

Name: Date:

Signature: Mob. No:

Name of the Doctor:

Dr. Doctor's contact:

Hospital contact:

ANNEXURE V

KLE Vishwanath Katti Institute of Dental Sciences, Belagavi

Department of Oral and Maxillofacial Surgery

Patient Information Sheet

Comparison of Efficacy of Chlorhexidine-diacetate Coated Silk Sutures Versus Plain Black Braided Silk Sutures in Post Operative Healing After Impacted Mandibular Third Molar Surgery-A Randomized Clinical Trial

Dear Patient,

You are invited to take part in a research study related to the use of anti-microbial suture during the extraction of your impacted mandibular third molar to evaluate the postoperative responses. I wouldlike to interview you to ask you about the symptoms of the condition and also perform the surgical procedure on you. This research is a part of a MDS, main dissertation at KLE Academy of Higher Education and Research.

Before you decide whether to take part in the study it is important that you understand what the researchis for and what you will be asked to do. Please take time to read the following information and discussit with others if you wish. It is up to you to decide whether or not to take part in this study. If you decide to take part you will be given this information sheet to keep. You will be also asked to sign a consent form. You can change your mind at any time and withdraw from the study without giving any reason. The standard of care you receive will not change whether or not you decide to participate in this study. You are welcome to contact me if you would like any further information. The purpose of this research study is to

evaluate and compare the efficacy of chlorhexidine diacetate coated silk suture after surgical removal of impacted mandibular third molars.

You have been chosen because you have been diagnosed with impacted mandibular third molar needing surgical extraction. The study will involve 46 participants who will be examinedand surgical extraction will be performed on them. During this procedure, in group 1-chlorhexidine diacetate coated silk suture material and in group-2 3-0 black braided silk sutures are used. Irrespective of any method is used after the procedure, I assure you that it will not affect the steps of the procedure, duration and outcome of the planned treatment. Multiple photographs will be recorded during the pre-operative and post-operative stage to compare the changes in the post-operative responses like infection, erythema. You will be asked to report for a review and follow-up visit on 2nd and 7th day after the procedure.

The information gained from this research will be used to publish in scientific platforms/ journals without revealing your identity to make recommendations for the best practice and the results of the study may also lead onto further studies into the management of surgical extraction of impacted mandibular third molar.

I,_____,age years, have been explained the details of the study undertaken. I am fully satisfied with the procedure and instructions given by Dr._____and hereby give my permission to participate inthis study.

Place:

Date:

Signature of participant:

Contact no

ANNEXURE VI - PROFORMA FOR CASE HISTORY

NAME: **AGE:**

SEX:

OCCUPATION: **O.P.NO.:**

ADDRESS: **DATE:**

CONTACT NO:

CHIEF COMPLAINT:

HISTORY OF PRESENTING ILLNESS:

PAST DENTAL HISTORY:

PAST MEDICAL HISTORY:

DRUG ALLERGY: PERSONAL HISTORY:

Smoking/ Alcohol/ Tobacco chewing

GENERAL PHYSICAL EXAMINATION: EXTRA-ORAL EXAMINATION:

Facial Symmetry: TMJ:

Lymph Node:

Mouth Opening:

INTRA-ORAL EXAMINATION:

- Soft Tissue Surrounding the Impacted Tooth: Normal/ Inflamed
- Ulcer: Present/ Absent
- Fibrosed: Yes/ No
- Pericoronitis:
- Swelling:
- Discharge:
- Pain/ Difficulty in Chewing:

PROVISIONAL DIAGNOSIS: INVESTIGATIONS:

IOPA:

OPG:

Routine Blood Investigation**:**

RADIOGRAPH AND CLINICAL CORRELATION: DIAGNOSIS:

PEDERSONS INDEX:

CLASSIFICATION	**VALUE**
Spatial relationship	
Mesioangular	1
Horizontal/Transverse	2
Vertical	3
Distoangular	4

Depth

Level A: High occlusal level	1
Level B: Medium occlusal level	2
Level C: Low occlusal level	3

Ramus Relationship/Space available

Class I: Sufficient space	1
Class II: reduced space	2
Class III: no space	3

Difficulty index

Very difficult	7-10
Moderately difficult	5-7
Slightly difficult	3-4

TOTAL SCORE: TREATMENT PLANNING: DETAILS OF SURGERY:

DATE:

START TIME (INCISION): END TIME (CLOSURE):

SURGICAL PROCEDURE:

Local Anesthesia: Incision:

Flap:

Method of Extraction:

Closure of Site:

MEDICATION FOLLOW-UP:

COMPLICATIONS:

- ALVEOLAR OSTEITIS
- PARASTHESIA
- DELAYED WOUND HEALING
- INFECTION
- ANY OTHER