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7 **Comparison of Tissue Adhesive Glue with Subcuticular Absorbable Suture**  
8 **for Skin Closure Following Thyroid Surgery**

9 *A single blinded randomized controlled trial*

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19

20 **Abstract**

21 **Objectives:** The objective of this study was to compare the skin closure time, postoperative  
22 pain and the scar outcome between tissue adhesive and sub-cuticular sutures in thyroid  
23 surgery. **Methods:** This was a prospective, single-blinded, randomized controlled trial. A  
24 sample size of 64 in each group was calculated. Adult patients undergoing thyroid surgery  
25 were included while those with previous neck surgery, history of keloids/hypertrophic scars  
26 and those undergoing concomitant neck dissections were excluded. Following platysma  
27 closure, they were randomised into two groups - tissue adhesive or subcuticular sutures, using  
28 Serially Numbered Opaque Sealed Envelopes technique. The primary outcome was the skin  
29 closure time. The secondary outcomes were postoperative pain at 24 hours and scar scoring at  
30 1st and 3<sup>rd</sup> post-operative month. Statistical analysis was done using SPSS software version  
31 19.0 for Windows. **Results:** The median skin closure time and postoperative pain was  
32 significantly lower in the tissue adhesive group as compared to the suture group (p<0.01).  
33 However, there was no statistically significant difference in scar outcome at 1st month

34 (p=0.088) and in 3rd month (p=0.137) between the two groups. There were no wound-related  
35 complications in either group. It was seen on a subgroup analysis that there was no difference  
36 in the scar outcome or wound-related complications in patients with comorbidities. There  
37 were no instances of allergic contact dermatitis to the tissue adhesive. **Conclusion:** The use  
38 of tissue adhesive leads to lower operative time and less post-operative pain in thyroid  
39 surgeries. The scar outcome is comparable between tissue adhesives and subcuticular sutures.  
40 **Keywords:** Thyroidectomy; scar; tissue glue; subcuticular sutures

41

#### 42 **Advances in Knowledge**

- 43 • There is a decrease in operating time when tissue adhesive is used for skin closure as  
44 compared to sutures
- 45 • There is lower immediate postoperative pain when tissue adhesive is used, as  
46 compared to sutures.
- 47 • There is no difference in scar outcome or wound complications between tissue  
48 adhesive and sutures, irrespective of patients' comorbidities
- 49 • There is an increase in cost when tissue adhesives are used.

50

#### 51 **Applications to Patient Care**

- 52 • During thyroidectomy, tissue adhesive can be an attractive option to use, instead of  
53 sutures, in order to decrease operative time and post-operative pain.
- 54 • The patient must be counselled that the scar outcome is not likely to improve by using  
55 tissue adhesive as compared to sutures.
- 56 • The patient must be made aware of the increase in cost, if tissue adhesives are used.

57

#### 58 **Introduction**

59 Thyroid diseases are more common in women and in younger age groups, which makes them  
60 the main population group to undergo thyroid surgeries.<sup>1</sup> Conventional thyroid surgeries are  
61 done via a collar-neck incision, which is in the anterior aspect. Such incisions have the  
62 potential to leave a conspicuous scar, if skin closure is not optimal. Advances such as  
63 minimally invasive thyroidectomies were designed in order to achieve a better cosmesis.<sup>2</sup>  
64 However, these surgeries require sophisticated surgical equipment and expertise.<sup>3,4</sup> Hence,  
65 conventional thyroid surgery is still the standard procedure in most patients.

66

67 The ideal method of skin closure is a rapid, easy-to-apply technique with a good cosmetic  
68 outcome. Initially, simple sutures were used, but was found to have a poor scar outcome due  
69 to railroad tracking.<sup>6</sup> Subsequently, subcuticular sutures were used, which showed a better  
70 scar outcome with less post-procedure pain.<sup>6</sup> However, it needs meticulous work, time to gain  
71 expertise<sup>7,8</sup> and has the risk of needlestick injuries<sup>9</sup>.

72  
73 Tissue adhesive glue was introduced as an ideal system of wound closure.<sup>10</sup> It is composed of  
74 monomeric cyanoacrylate which polymerizes on contact with moisture to form an adhesive  
75 layer over the skin.<sup>10</sup> It is an attractive choice for thyroidectomies as it is easy to apply<sup>8</sup> and  
76 takes less time. Its main disadvantage is contact dermatitis<sup>11</sup>, which has been purported to  
77 vary with the climate.<sup>12</sup> This is because the antigen presenting cells identify the monomeric  
78 form of cyanoacrylate. In arid climates, it takes time for polymerization thus increasing the  
79 chance of reaction.<sup>12</sup>

80  
81 Studies have been performed, comparing subcuticular sutures to tissue adhesives in thyroid  
82 surgeries but differences in postoperative pain, wound dehiscence rates and operative time  
83 has not been clearly elucidated. In our study, we aim to study the effects of both methods of  
84 repair on post-thyroidectomy patients in a South Asian country, with equatorial climate as  
85 well as a wide variation in the skin type of its population.

## 86 **Methodology**

### 87 ***Study design***

88 The study was designed as a prospective, single-blinded, randomized controlled trial. It was  
89 conducted from March 2017 to December 2019 in the Department of General Surgery in a  
90 tertiary care hospital after obtaining approval from Institute Ethics Committee  
91 (JIP/IEC/2017/0213) and registration in CTRI (CTRI/2018/02/011698).

### 92 ***Sample size and patient enrolment***

93  
94 The sample size was calculated based on a similar study conducted by Consorti et al.<sup>13</sup> Using  
95 Open Epi software, a sample size of 64 in each group was calculated, taking the difference in  
96 time required for skin closure as the primary criterion, with level of significance as 5% and  
97 the power of study set to 90% expecting a dropout rate of 10%. All patients between 18 to 80  
98 years of age undergoing thyroid surgery during the study period were included. Patients with  
99 previous neck surgery, history of keloids or hypertrophic scars and those undergoing  
100

101 concomitant neck dissections were excluded. Written informed consent was obtained from  
102 the participants.

103

104 All patients received an intravenous dose of prophylactic antibiotic (Inj. Cloxacillin 500mg)  
105 within 30 minutes from the time of skin incision, as per the departmental policy at our centre.  
106 The surgery was done as per the standard operating procedure. Once the resection was done,  
107 a 14 F closed-suction drain was placed in all patients, which is part of the operative policy at  
108 our centre. The strap muscles and platysma were approximated using 2-0 and 3-0 round-  
109 bodied vicryl simple sutures respectively. Following platysma closure, the patients were  
110 randomised into the two groups. Tissue adhesive (Octyl 2-cyanoacrylate)- DERMABOND®  
111 from ETHICON Inc, Johnson and Johnson (San Lorenzo, Puerto Rico) was used in the study  
112 while 3-0 sized monocryl suture, from Lotus Surgicals Pvt Limited (Uttarakhand, India) was  
113 used for subcuticular suturing. For each patient, one unit was used, according to the group  
114 allotted.

115

116 Postoperative analgesia was standardized in both groups, with all patients receiving  
117 intravenous tramadol and ketorolac alternately every 4th hourly for first 24 hours in the  
118 postoperative period. Scar assessment was done at the first and third postoperative month.

119

#### 120 ***Randomisation details***

121 Randomisation was done using computer generated random numbers and allocation was done  
122 using Serially Numbered Opaque Sealed Envelopes (SNOSE) technique, which were opened  
123 after platysma closure.

124

#### 125 ***Outcome assessment***

126 The primary outcome measured was the skin closure time (minutes). In the tissue adhesive  
127 group (Group A), after closing the platysma, the skin closure start time was noted once the  
128 skin edges were dry. The tissue adhesive was applied slowly in 2 layers, using a brushing  
129 motion. A gap of 15 seconds was given between the applications and the adhesive was  
130 allowed to set for 60 seconds, at which point the skin closure end time was noted. Dressing  
131 was not applied.

132

133 In the subcuticular suture group (group B), after closing the platysma, the skin closure start  
134 time was noted. The skin was closed by subcuticular absorbable suture and a dressing was  
135 applied. Once done, the skin closure end time was noted.

136

137 The secondary outcomes measured were postoperative pain at 24 hours and scar scoring at  
138 1st and 3<sup>rd</sup> post-operative month. Post-operative pain was assessed using a 10-point Visual  
139 Analog Scale.<sup>14</sup> The scar cosmesis was assessed by a person who was blinded regarding the  
140 method of skin closure, using the Manchester Scar Scale.<sup>15</sup> The cost per unit used was also  
141 compared between the two groups.

142

### 143 *Statistical analysis*

144 Statistical analysis was done using SPSS software version 19.0. Continuous variables were  
145 expressed as mean or median based on the distribution. Ordinal variables were expressed as  
146 median. Categorical variables were expressed as proportions, frequencies or percentages.  
147 Continuous variables were compared using unpaired t-test. Ordinal variables were tested  
148 using Pearson Chi-Square test. The difference of medians of skin closure time, pain, scar  
149 scores at 1st and 3rd postoperative months between both the groups were tested using Mann-  
150 Whitney U test.

151

### 152 **Results**

153 Among the 143 patients who underwent thyroid surgery during this study period, 124 patients  
154 were included in the study based on the inclusion criteria. The schematic representation of the  
155 study as per the CONSORT 2010 (Consolidated Standards of Reporting Trials) flow diagram  
156 is shown in Figure 1. As shown in table 1, the baseline characteristics were comparable  
157 between the two groups. The mean age of patients in the suture group was  $42.62 \pm 12.28$   
158 years and of tissue adhesive group was  $42.03 \pm 11.8$ . The majority of the study participants  
159 were female, both in the suture group and in the tissue adhesive group (72.13% and 82.53%  
160 respectively). The preoperative diagnosis distribution and type of surgery done in both the  
161 groups were similar.

162

163 The median skin closure time in suture group and the adhesive group was 390 and 250  
164 seconds respectively and the difference was found to be statistically significant ( $p < 0.01$ ) by  
165 Mann-Whitney test, as shown in Table 2. The median pain score between the two groups also  
166 showed significant difference ( $p < 0.01$ ), as shown in Table 3. However, there was no

167 statistically significant difference in scar outcome at 1st month ( $p=0.088$ ) and in 3rd month  
168 ( $p=0.137$ ) between both the groups, as shown in Table 4 and Table 5. There were no wound-  
169 related complications in either group. The cost of one unit of tissue adhesive was found to  
170 2000 INR and one unit of suture was 899 INR.

171

## 172 **Discussion**

173 The use of tissue adhesives has gained significance in recent days owing to the concept of no-  
174 suture cosmetic surgery. Previously, subcuticular suturing was a standard technique used for  
175 skin closure especially in areas of cosmetic interest. Studies comparing subcuticular suturing  
176 and tissue adhesive are few in number with contradicting results. Therefore, we conducted  
177 this study to add to the body of existing knowledge.

178

179 The present study showed that there was a significant difference in skin closure time between  
180 the tissue adhesive group and suture group. Tissue adhesive reduced skin closure time by  
181 36% to that of subcuticular suture. Saving theatre time is essential to avoid wastage of  
182 hospital resources and to avoid dissatisfaction of staff, which would affect the quality of  
183 work.<sup>16</sup> Bozkurt<sup>17</sup> and Consorti<sup>13</sup> also came to the same conclusion as this study.

184

185 Postoperative pain between the two groups has been analysed in our study, which showed a  
186 significant difference on the first postoperative day between the suture and tissue adhesive  
187 group, which is a novel finding. In the available literature, there is no clear evidence that  
188 postoperative pain is affected by using tissue adhesive, as compared to sutures. In a  
189 randomized cohort study by Chamariya et al in 2016, it was found that using a tissue  
190 adhesive causes less pain after closure of the episiotomy wound as compared to suturing.<sup>18</sup>  
191 However, the skin closure technique was mattress suturing and the area of interest was the  
192 perineum. With respect to thyroid surgeries, Pronio et al<sup>20</sup> mentioned that 26.3% of  
193 patients in the control group and 9.3% of the study group, which was a significant difference;  
194 however, they compared between staples and tissue adhesives. Amin et al<sup>21</sup> compared pain  
195 at first and tenth postoperative day using the visual analogue scale and concluded that there  
196 is no difference between both the groups ( $p=0.829$  and  $p=0.931$ ). Our findings can be  
197 explained by the fact that there was a lower amount of tissue handling and dissection, no  
198 needle pricks and no suture lying within the skin postoperatively in the tissue adhesive  
199 group.

200

201 Scar outcome is one another important factor for assessing a skin closure technique.  
202 Consorti<sup>13</sup> have assessed scar outcome at 6 weeks using Patient and Observer Scar  
203 Assessment Scale (POSAS) score. Based on observer assessment, subcuticular suture was  
204 favoured above tissue adhesive, but there was no difference on the patients' assessment. This  
205 study was, however, criticized for assessing scars at 6 weeks as it may be too early to assess  
206 scar outcome with most surgical scars taking an optimal time of 3 months to mature. Ciufelli  
207 et al concluded that there was better scar in tissue adhesive group than suture group at tenth  
208 day, but at three months, there was no difference.<sup>19</sup> Pronio<sup>20</sup>, Amin<sup>21</sup> and Yang<sup>22</sup> also showed  
209 that there was no significant difference in the scar outcome at the 3rd month between both the  
210 groups. We found concordant results in our study with there being no difference in the scar  
211 outcome both at 1<sup>st</sup> month and at 3rd month between the groups.

212

213 In the Cochrane review published by Dumville, it was stated that sutures were significantly  
214 better than tissue adhesives for minimising dehiscence, but the available evidence was of a  
215 low quality. A need to study a subset of the population that have comorbidities that influence  
216 the rates of wound breakdown was also noted.<sup>9</sup> In our present study, we have tried to bridge  
217 this gap in knowledge by taking comorbidities into account with 16.39% patients in suture  
218 group and 15.87% patients in the tissue adhesive group having comorbidities. It was seen on  
219 a subgroup analysis that there was no difference in the scar outcome or wound-related  
220 complications in these patients. However, the validity of this statement was questionable due  
221 to the small subgroup size (15-16%) and this statement requires larger studies to reinforce  
222 this conclusion.

223

224 Regarding the time for closure of the skin incision, it would depend on the skin incision  
225 length which depends on the extent of surgery. Pronio<sup>20</sup> and Ciufelli<sup>19</sup> did not differentiate  
226 between the different types of thyroid surgeries. Consorti<sup>13</sup> had only taken patients  
227 undergoing total thyroidectomy patients, whereas Bozkurt<sup>17</sup> had taken all head and neck  
228 surgeries into account. In our study, we have taken patients undergoing different extents of  
229 thyroid surgeries and randomized them into both groups, and as table 1 demonstrates, were  
230 equally distributed into either arm. Our study shows that hemithyroidectomy took  
231 significantly less time in both groups, which may be attributed to the incision length. As all  
232 types of thyroid surgeries were included in our study, this was prevented from being a  
233 confounding factor.

234

235 In the present study, each patient required one package of 3-0 monocryl suture which costs  
236 899 INR or one vial of tissue adhesive which costs 2000 INR. This showed that the tissue  
237 adhesive was twice as expensive as a suture. However, there was no need of dressing or  
238 follow-up visits for suture removal in tissue adhesive. Hence, the overall cost involved in  
239 both groups was difficult to estimate and compare. Bozkurt and Saydam<sup>17</sup> also had similar  
240 results in their study done in 2008.

241  
242 The disadvantages of cyanoacrylate were mainly technical, and care should be taken to  
243 prevent them. In literature, it was seen that the adhesive can seep into the wound edges,  
244 impairing the wound healing and affecting the scar cosmesis by causing a foreign body  
245 reaction.<sup>23</sup> Asai et al reported that 9/577 patients had developed allergic contact dermatitis  
246 after the first application of cyanoacrylate tissue adhesive.<sup>11</sup> Bitterman et al<sup>12</sup> reported a  
247 papulovesicular rash at the application site, 2 weeks postoperatively, which on close  
248 examination, showed residual glue found at the incision site, which improved once the glue  
249 was washed off. None of these effects were noted in any of our patients.

250  
251 Another advantage of tissue adhesive is the antimicrobial nature. Cyanoacrylate, in the  
252 unused form, is manufactured in the monomeric state. When it encounters moisture, it  
253 polymerizes forming a layer of waterproof material, which forms a physical barrier to the  
254 entry of microbes, obviating the need for dressing. It can also inhibit microbial growth in  
255 vitro. This is thought to be due to high electronegative charge on the cyanoacrylate monomer  
256 which reacts with the positively charged polysaccharide capsule of organisms.<sup>24</sup>

257  
258 The present study was not without limitations of its own. It was a single institutional study.  
259 The skin closure was not done by a single surgeon in all patients. Thus, the experience of the  
260 surgeon with the technique may have affected our results especially skin closure time and  
261 scar outcome. The length of the skin incision was not measured which can affect the skin  
262 closure time. Scar outcome was assessed by a blinded observer using Manchester scar score  
263 which is a subjective score. Patient satisfaction and their assessment of the scar were not  
264 evaluated which can tell us the patient's preference which may affect the choice of skin  
265 closure.

266

267 **Conclusion**



268 Tissue adhesive is faster to apply than subcuticular sutures in all types of thyroid surgeries.  
269 They also result in less immediate postoperative pain and the two groups have a comparable  
270 scar cosmesis. There was no difference seen in the wound-related complications between the  
271 two groups, even among patients with comorbidities. However, the cost involved in tissue  
272 adhesives is significantly higher as compared to sutures. Hence, we propose that the use of  
273 tissue adhesives can replace subcuticular sutures in thyroid skin closure, if the patient is able  
274 to afford it.

275

### 276 **Conflict of Interest**

277 The authors declare no conflicts of interest.

278

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280 No funding was received for this study.

281

### 282 **Authors' Contribution**

283 AM was involved in the formulation of the protocol and of its execution. EMKS was  
284 involved in the data collection and the writing of the final manuscript. AKS was involved in  
285 protocol creation and the editing of the manuscript. ETP and MAS were involved in the  
286 overall process of supervising the study and editing the manuscript.

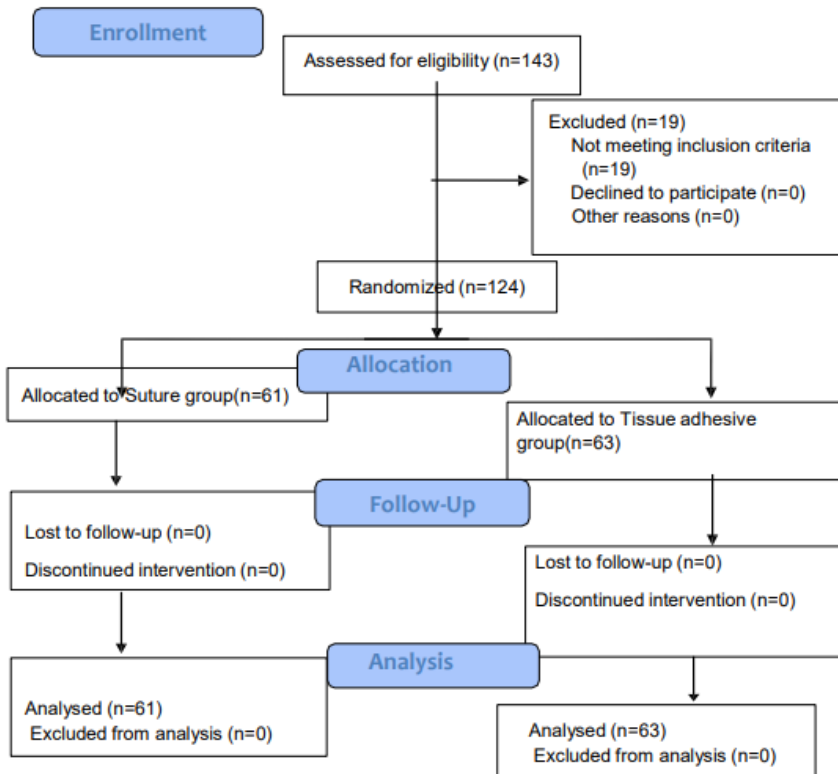
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- 364



365  
366 **Figure 1:** CONSORT 2010 Flow Diagram

367  
368 **Table 1:** Demographic and clinical parameters comparison between the two groups

<b>Parameters</b>		<b>Subcuticular suture</b>	<b>Tissue adhesive</b>	<b>P value</b>
<b>Mean Age</b>		42.62 ± 12.28	42.03 ± 11.8	0.785
<b>Gender</b>	<b>Male [n(%)]</b>	17(27.87)	11(17.46)	0.166
	<b>Female [n(%)]</b>	44(72.13)	52(82.54)	
<b>Preoperative diagnosis</b>	<b>Benign [n(%)]</b>	44(72.13)	46(73.02)	0.912
	<b>Malignant [n(%)]</b>	17(27.86)	17(26.98)	
<b>Type of surgery</b>	<b>Hemithyroidectomy [n(%)]</b>	29(47.54)	30(47.62)	0.993
	<b>Subtotal and Total thyroidectomy [n(%)]</b>	32(52.46)	33(52.38)	

369  
370 **Table 2:** Comparison of Skin closure time in each group

<b>Group</b>	<b>Median (in seconds)</b>	<b>Minimum (in seconds)</b>	<b>Maximum (in seconds)</b>	<b>p-value<sup>#</sup></b>
Suture	390	130	750	<0.01*
Tissue adhesive	250	90	720	

371 #Mann-Whitney U test

372 \*statistically significant with 1% level of significance

373

374 **Table 3:** Comparison of post-operative pain score in each group

Group	Median	Minimum	Maximum	p-value <sup>#</sup>
Suture	6	1	9	<0.01*
Tissue adhesive	5	1	9	

375 #Mann-Whitney U test

376 \*statistically significant with 1% level of significance

377

378 **Table 4:** Comparison of scar score in the 1<sup>st</sup> postoperative month

Group	Median	Minimum	Maximum	p-value <sup>#</sup>
Suture	10	6	15	0.088
Tissue adhesive	9	5	15	

379 #Mann-Whitney U test

380

381 **Table 5:** Comparison of scar score in the 3<sup>rd</sup> postoperative month in each group

Group	Median	Minimum	Maximum	p-value <sup>#</sup>
Suture	8	6	13	0.137
Tissue adhesive	8	5	13	

382 #Mann-Whitney U test