



Barbed Sutures in TKA: Are they really useful? A Randomized Controlled Trial

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Abstract:	<p>Purpose and Hypothesis Bidirectional Barbed sutures (BBS) have recently been investigated in TKA. The contrasting results from the scarce literature suggest that BBS are safe, save time and money and give results comparable to traditional sutures. The purpose of the study is to test the real effect of BBS on closure time in TKA and assess the functional results as well as the complications related to them.</p> <p>Methods It was a randomized controlled trial (RCT). Eighty-five patients undergoing primary TKA were assigned to receive traditional closure with Vycril (V-Group) or with BBS (Q-group). The exclusion criteria were significant coronal deformity, flexion contracture or the need for stem and/or augmentation. The closure time for the capsule and subcutaneous layer were registered separately. Intraoperative incidences were recorded. The follow-up was up to 1-month, during which range of motion, superficial or deep infection and wound dehiscence were assessed.</p> <p>Results There was a significant reduction in the capsule layer (27 sec, $p=0,02$) and global time closure (51 sec, $p=0,01$) in the Q-group. No differences were found in the subcutaneous layer (24sec, $P=0,055$). There were more intraoperative suture breakages in the Q-group, mainly in the subcutaneous layer ($p < 0,001$). No differences in terms of dehiscence, infection and ROM were observed at the 1-month follow up.</p> <p>Conclusions BBS sutures allow for slightly faster wound closure than Vicryl during a TKA. However the differences observed have minimal clinical repercussions. Moreover, no differences in the infection rate (deep or superficial), dehiscence or ROM were found.</p>

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3 ABSTRACT

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6 results from the scarce literature suggest that BBS are safe, save time and money and give
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14 and/or augmentation. The closure time for the capsule and subcutaneous layer were
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22 $P=0,055$). There were more intraoperative suture breakages in the Q-group, mainly in the
23 subcutaneous layer ($p< 0,001$). No differences in terms of dehiscence, infection and ROM were
24 observed at the 1-month follow up.

25 **Conclusions**

26 BBS sutures allow for slightly faster wound closure than Vicryl during a TKA. However the
27 differences observed have minimal clinical repercussions. Moreover, no differences in the
28 infection rate (deep or superficial), dehiscence or ROM were found.

29

30 **Keywords:**

31 Barbed suture, Total Knee Arthroplasty, Closure time TKA

32

33 **1. INTRODUCTION**

34 Surgical time and effective wound closure are both important elements in preventing
35 complications in Total Knee arthroplasty (TKA) ¹. Barbed sutures have recently been
36 investigated for their capacity to reduce closure time and thus the cost of surgery in TKA ²⁻³⁻⁴⁻
37 ⁵⁻⁶. They make it possible for the surgeon to perform a knotless running suture with the same
38 mechanical properties as conventional sutures ⁷. Few reports describe bi-directional barbed
39 sutures (BBS) as an effective tool to perform a rapid and effective wound closure with similar
40 results to conventional sutures in terms of functional and complication outcomes ⁸⁻⁹⁻¹⁰⁻¹¹. The
41 safety of this new kind of suture has recently been questioned due to reports of an elevated
42 infection rate with respect to the conventional suture ¹²⁻¹³.

43 Published literature provides little evidence to support using this new tool when performing
44 TKA.

45 **1.1 Purpose**

46 The aim of the study was to test the effectiveness of BBS in reducing closure time. The
47 secondary objectives were to assess the infection rate, wound dehiscence, functional
48 outcomes and incidences occurring during surgery. The initial hypothesis was that the closure
49 time was not influenced by the type of suture used.

50

51 **2. MATERIAL AND METHODS**

52 **2.1 Study population**

53 A randomized controlled blind trial (RCT) was carried out between January and July 2016 in
54 one single institution. Approval was given by institution's ethics committee (2015/6529).
55 Patients programmed to receive primary TKA were enrolled after signing informed consent.
56 Patients with a previous knee surgery or necessitating a tibial or femoral stem were excluded.
57 Other exclusion criteria were a coronal deformity over 15 degrees or a flexion contracture
58 superior to 20 degrees.

59

60 **2.2 Surgical technique**

61 A cemented TKA was implanted in a standard way with the patient lying supine and a thigh
62 tourniquet was applied. A medial parapatellar approach was used in all cases. The patella was
63 always substituted in this work. After closure, the wound was finally sealed with metallic
64 staples in all cases. The knee was immobilized in extension with a removable splint. Articular
65 aspirating drainage was left in place for 24 hours.

66 All surgeries were performed by 4 different knee surgeons. Three different TKA models were
67 implanted during the study period: Triathlon® – Stryker (Mahwah, New Jersey, United
68 States), Genutech® – Surgival (Valencia, España), U2®– United Orthopedic Corporation
69 (Taiwan).

70 Patients from both groups followed the same rehabilitation protocol. It included continuous
71 passive motion beginning the day after surgery that lasted until hospital discharge at around
72 the fourth postoperative day. All of them had a minimum of 10 physiotherapy sessions in the
73 outpatient clinic.

74

75 **2.3 Randomization**

76 Patients were randomly assigned to receive a standard wound closure (V-group) or with
77 barbed sutures (Q-Group). The randomization process was carried out with the closed
78 envelope system just before starting the closure process. Closure was then performed
79 simultaneously by the chief surgeon and the first assistant starting from the centre of the
80 wound and running to opposite ends. Previous to the study, all the participants went through
81 a training period with BBS with at least 10 cases. In the V-group, polyglactin 910 (Vycril-
82 Ethicon, Somerville, New Jersey, United States) was used with interrupted sutures while BBS
83 (Quill- Angiotech, Vancouver, Canada) was used in a continuous running fashion in the Q-
84 group. Size 2 sutures were used for the capsular layer and size 2-0 for the subcutaneous layer
85 in both groups. The capsule and subcutaneous layer closure times were registered separately
86 and together (global time). The incidence of suture rupture was also collected.
87 Range of motion (ROM) at 1-month was measured. Additionally, any superficial or deep
88 infection as well as dehiscence of the wound was documented. The diagnosis of superficial
89 wound infection was established using the CDC criteria for superficial incisional SSI ¹⁴⁻¹⁵,
90 revised in January 2016 ¹⁶. Follow-up was up to 1-month.

91

92 **2.4 Statistical analysis**

93 The statistical analysis was performed using the SPSS v22 software package. The Student's t-
94 Test and Chi-Square test were used to analyse the data and $P < 0.05$ was considered to be
95 significant. A power analysis was previously done anticipating a 10% loss to follow up. The
96 sample size was calculated based on the results of previous studies ³⁻⁹⁻¹⁰⁻¹⁷. A minimum of 33
97 patients in each group was considered sufficient to arrive at consistent findings.

98

99 **3. RESULTS**

100 Eighty-five patients were enrolled and randomized into two groups. They were the V-group
101 with 44 patients and the Q-group with 41. The demographic characteristics of the sample are
102 summarized in Table 1. Both groups were comparable relative to the basal characteristics.
103 There were no patients lost to follow-up.
104 The closure of the capsular layer was superior in the V-group than the Q-group ($p=0.02$).
105 However, this difference was not observed in the subcutaneous layer (n.s.). The global
106 surgical wound closure time (capsular plus sub-cutaneous) was also shorter in the Q-group
107 than in the V-group ($p=0.01$). All these results are summarized in the Table 2. This table also
108 shows the different complications observed in both groups.

109

110

111 4. DISCUSSION

112 The main finding of this study is that BBS significantly reduce closure time following a TKA
113 when is compared to Vicryl sutures. In that sense, our initial hypothesis was not confirmed. A
114 second finding of this study was that the complications observed do not depend on the type of
115 suture used.

116 Different publications have reported on the effectiveness of BBS in shortening closure time
117 after a TKA³⁻⁴⁻⁵⁻⁹. Chan et al², with a sample similar to our study group, found an average
118 reduction time of about 4 minutes while Gilliland et al. reported a reduction of 4.6 minutes in
119 the overall closure time². Smith et al. even observed a difference up to 9 minutes in both
120 groups¹⁷. On the other hand, a meta-analysis conducted by Meena et al did not find differences
121 in total procedure time using BBS in comparison to conventional sutures⁹. The authors
122 suggested that these results were due to the different levels of training of the surgeons and
123 because additional factors may affect the entire duration of the procedure⁹⁻¹⁷.

124 Wound closure in the BBS group was 51 seconds faster than in the Vicryl group. It is a smaller
125 reduction than described in other studies, which may be due to the shorter global closure
126 time ³⁻¹⁷⁻¹⁸. The presence of 2 surgeons closing the wound simultaneously may justify this
127 finding. However, Gilliland et al. and Sah used a similar protocol but longer closure times ³⁻¹⁸.
128 On the other hand, it is controversial as to whether the difference observed (51 sec) is
129 clinically significant. The authors do not feel that such a reduction in the time needed to
130 perform a TKA has any repercussion on the result of this procedure.

131 The results in terms of ROM at 1-month showed no differences between traditional sutures
132 and BBS. The same findings were reported by Chan et al ². Slightly better results would be
133 expected from BBS because running sutures are supposed to share out mechanical forces
134 better, but again many aspects are coming together to condition better or worse ROM.

135 It has been suggested that barbed monofilament sutures decrease bacterial adhesion in
136 comparison to traditional sutures. Theoretically, this fact could protect against infection ¹⁹. In
137 the present study, wound related complications and the infection rate were similar in both
138 groups. Neither were any differences reported in 2 meta-analyses and other published RCT ²⁻
139 ³⁻⁸⁻⁹. However, Campbell et al. described a higher incidence of wound problems (19,5%) that
140 included superficial and deep infections and dehiscence using the barbed suture for skin
141 closure ¹². Chawla et al. also reported an odds ratio of wound infection of about 22 with uni-
142 compartmental knee arthroplasty while describing 8 complications out of 333 patients in
143 which BBS were used ¹³. Both studies are of a retrospective nature but are characterized by a
144 large sample size ¹²⁻¹³.

145 Evident differences were found in intraoperative incidence using the barbed suture. Most of
146 them were suture breakage in the subcutaneous layer (16 in subcutaneous – 1 capsule
147 $p<0.000$). The rate of suture rupture was higher in the Q-group than the V-group. In fact, no
148 problems were reported in this cohort with traditional sutures. Suture rupture is an aspect

149 highlighted in a meta-analysis by Borzio et al. and in an RCT published by Gilliland et al in
150 which 6% of the sutures ruptured intraoperatively³⁻⁸. The rate of suture breakage observed
151 (41%) is superior in our study. This fact could be due to less familiarity with this suture
152 although each surgeon had used it for at least 10 cases before initiating this trial. The authors
153 saw that BBS had a good strong sealing capacity in harder connective tissue like the capsule
154 layer where barbs can also provide more effective anchorage. This is not as true as in the
155 subcutaneous layer in which connective tissue is softer and efficient closure, in case of suture
156 breakage, cannot be assured.

157

158 **5.1 Limitations**

159 This study is not free of limitations. One is that the number of sutures used for each patient
160 was not recorded and neither was the price for the sutures used in each case. Regardless, cost
161 analysis was not our goal. Although not only two different types of sutures but also two
162 different techniques were used, the real goal of this research was to confirm if BBS could offer
163 some advantages over traditional closure technique used in our institution. Another limitation
164 is that the patients were followed for a limited time but it was enough time to observe the
165 results related to the sutures or any complications. Moreover, the presence of more than four
166 surgeons might have introduced a bias although it may have improved external validity.

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168

169 **5. CONCLUSION**

170 Barbed sutures allow for a slightly shorter wound closure time in comparison to conventional
171 interrupted sutures. No differences were found in the deep or superficial infection rate,
172 wound dehiscence and ROM between BBS and Vycril sutures. Finally, an elevated number of
173 intra-operative suture breakages is to be expected when used in the subcutaneous layer.

174 The results obtained here lead the authors not to recommend the use of barbed sutures in the
175 subcutaneous layer although it may be useful in the capsular layer.

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Table 1

	V-Group	Q-group	p
Age (years)	73.8 ± 7.5	74.2 ± 8.2	n.s.
Gender (%)	31.7% M / 68.3% W	38.6% M / 61.4% W	n.s.
Weight (kg)	80.2 ± 13.4	75.9 ± 15	n.s.
BMI (kg/m ²)	30.6 ± 4.6	30.2 ± 5	n.s.

Table.1: Demographic data of both groups

Table 2

	V-Group	Q-group	p
Capsule (min)	3.39 ± 0.9	2.93 ± 0.82	0.019
Subcutaneous (min)	3.76 ± 0.86	3.35 ± 0.98	n.s.
Global (min)	7.15 ± 1.38	6.28 ± 1.52	0.01
Flexion (°)*	102.4 ± 12.41	100.9 ± 5.93	n.s.
Extension (°)*	-1.6 ± 3.85	1.5 ± 3.79	n.s.
Superficial infection	1 (2.3%)	3 (7.5%)	n.s.
Deep infection	0 (0%)	0 (0%)	n.s.
Dehiscence	1 (2.3%)	2 (5%)	n.s.
Suture breakages	0 (0%)	17 (41%)	< 0.001

*= Range of motion measured at 1-month postoperatively

Table.2: Variables studied in both groups (±SD)