The effect of suture materials and techniques on the outcome of repair of the rotator cuff

A PROSPECTIVE, RANDOMISED STUDY

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In a prospective, randomised study on the repair of tears of the rotator cuff we compared the clinical results of two suture techniques for which different suture materials were used. We prospectively randomised 100 patients with tears of the rotator cuff into two groups.

Group 1 had transosseous repair with No. 3 Ethibond using modified Mason-Allen sutures and group 2 had transosseous repair with 1.0 mm polydioxanone cord using modified Kessler sutures. After 24 to 30 months the patients were evaluated clinically using the Constant score and by ultrasonography.

Of the 100 patients, 92 completed the study. No significant statistical difference was seen between the two groups: Constant score, 91% vs 92%; rate of further tear, 18% vs 22%; and revision, 4% vs 4%. In cases of further tear the outcome in group 2 did not differ from that for the intact repairs (91% vs 91%), but in group 1 it was significantly worse (94% vs 77%, p = 0.005).

Overall, seven patients had complications which required revision surgery, in four for pain (two in each group) and in three for infection (two in group 1 and one in group 2).

The main factors influencing the results of repairs of the rotator cuff are the size of the tear, fatty muscle infiltration and atrophy. Biomechanical testing has shown the significant effect of both suture techniques and materials on mechanical strength and the subsequent rate of failure. Gerber et al. drew attention to the importance of suture techniques and materials in tendon-to-bone repair of tears of the rotator cuff and reported that a modification of the Mason-Allen suture with non-absorbable suture material provided the most secure reconstruction. No clinical study, however, has supported these laboratory data. Previous reports of open repair of the rotator cuff had showed good results even with biomechanically inferior suture techniques.

Inspired by the work of Gerber et al., a modification of the Mason-Allen suture with non-absorbable braided No. 3 Ethibond provided better results than a modified Kessler suture with 1.0 mm absorbable braided PDS cord. We focused particularly on the rate of further tears, revisions, infections and the clinical results as determined by the score of Constant and Murley.

Patients and Methods

We prospectively randomised into two groups 100 patients who were undergoing open repair of the rotator cuff. Group 1 received non-absorbable braided No. 3 Ethibond (0.7 mm diameter) and a modified Mason-Allen technique with 1.0 mm absorbable braided PDS cord and a modified Kessler technique.

None of the listed parameters regarding demographic data and additional surgical procedures were significantly different in the two groups (Table I).

The inclusion criteria were repairable, non-traumatic, full-thickness Bateman types 1 to 3 tears of the rotator cuff (1 cm to 5 cm in largest diameter), which were suitable for direct tendon-to-bone repair. Exclusion criteria were previous shoulder surgery, the presence of an os acromiale, a neurological deficit in the
upper limb, cervical disc disease, systemic diseases involving the locomotor system (rheumatoid arthritis, lupus erythematosus, scleroderma, Marfan’s syndrome, the Ehlers-Danlos syndrome), metastatic malignancy before erythematosus, scleroderma, Marfan’s syndrome, theing the locomotor system (rheumatoid arthritis, lupus erythematosus, scleroderma, Marfan’s syndrome, the

Operative technique.

Samilson and Prieto

Ehlers-Danlos syndrome), metastatic malignancy before erythematosus, scleroderma, Marfan’s syndrome, theing the locomotor system (rheumatoid arthritis, lupus erythematosus, scleroderma, Marfan’s syndrome, the

Table I. Clinical details and diagnosis-related data of both groups

<table>
<thead>
<tr>
<th></th>
<th>PDS*</th>
<th>Ethibond</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men:women</td>
<td>32:12</td>
<td>36:13</td>
<td>NS (0.39)‡</td>
</tr>
<tr>
<td>Right:left side</td>
<td>28:15</td>
<td>33:16</td>
<td>NS (0.88)§</td>
</tr>
<tr>
<td>Mean age in yrs at surgery (range)</td>
<td>57 (41 to 71)</td>
<td>56 (38 to 69)</td>
<td>NS (0.80)§</td>
</tr>
<tr>
<td>Mean follow-up in mths (range)</td>
<td>27 (24 to 30)</td>
<td>26 (24 to 29)</td>
<td>NS (0.10)§</td>
</tr>
<tr>
<td>Median follow-up in mths</td>
<td>27</td>
<td>26</td>
<td></td>
</tr>
<tr>
<td>Size of tear</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bateman17</td>
<td>1</td>
<td>12</td>
<td>NS (0.83)‡</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>17</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>16</td>
<td>18</td>
</tr>
<tr>
<td>Lateral clavicle resection (%)</td>
<td>34 (77)</td>
<td>40 (82)</td>
<td>NS (0.60)‡</td>
</tr>
<tr>
<td>Biceps tenodesis</td>
<td>10</td>
<td>9</td>
<td>NS (0.60)‡</td>
</tr>
<tr>
<td>Rupture of long head of biceps</td>
<td>2</td>
<td>4</td>
<td>NS (0.47)‡</td>
</tr>
<tr>
<td>Sliding incision</td>
<td>32</td>
<td>34</td>
<td>NS (0.72)‡</td>
</tr>
<tr>
<td>Workers’ Compensation Board</td>
<td>4</td>
<td>5</td>
<td>NS (0.85)‡</td>
</tr>
</tbody>
</table>

* PDS, polydioxanone
† NS, not significant
‡ chi-squared test
§ Mann-Whitney U test

Ethibond/PDS sutures were prepared and sliding incisions were closed with simple side-to-side sutures using absorbable braided sutures. While the arm was in neutral position, the transosseous sutures were then tied without tension and, using a 2=1=1=1=1 knot, over a bony bridge of more than 1 cm.

The post-operative rehabilitation protocol was identical in both groups. The patient used an abduction pillow for six weeks, except for the periods of physiotherapy, continuous passive movement or body care. No active shoulder movement was allowed for six weeks, but passive physiotherapy and continuous passive movement were started on the first post-operative day and continued for six weeks. After discharge from hospital, the continuous passive movement took place at home (twice daily, for a total of 30 minutes) and the physiotherapy (three times a week) in a medical centre. After six weeks, active physiotherapy (centre-based supervised) and an active at-home self-exercise programme which excluded strengthening components were started.

Randomisation. During surgery, at the point when the surgeon was certain that he would be able to effect a complete closure of the defect of the rotator cuff without using tendon transfers, a nurse placed the patient’s name at the next free position on a computer list. The position on the computerised randomisation list indicated whether Ethibond or PDS should be used. Clinical details regarding the size of the tear, number of sutures, additional procedures and the quality of the tendon were recorded.

Rating of the results. The clinical assessment at the time of follow-up included active and passive ranges of movement and evaluation of the Constant score.16 The strength of abduction was measured in a sitting position with the forearm in pronation, 90° of abduction and 30° of anteversion in the scapular plane. Strength was analysed with a Mecmesin myometer (Mecmesin Ltd, Nottingham, UK) fixed at the wrist over a period of five seconds. Three measurements were made alternately for each arm and the mean value was taken for further calculations. In addition, the score of each patient was related to the age- and gender-adjusted normal values.15 The patients were also asked whether they would agree to have the same operation performed again and how they would subjectively grade their result on a scale from one to six, one being excellent, six being poor.

Sonographic assessment. Ultrasound of the reconstructed cuff was performed using a 7.5 MHz linear transducer (Type Sonoline Elegra; Siemens AG, Erlangen, Germany). As described by Hedtmann and Fett,19 standard planes in the coracoacromial window with images of the tendons of supraspinatus, infraspinatus and subscapularis in two planes were used for assessment of the reconstructed cuff. The criteria for a recurrent tear were the absence of the cuff, a gap in the reconstruction in two planes, and bulging and/or gaping within the reconstruction during dynamic examination. Simple differences of echogenicity were not rated as criteria for a recurrence of a tear.20 The ultrasonographic
examination was done by the first author (TDB) who was blinded to the type of operative procedure and to the result of the clinical assessment. In the four cases of revision surgery, the sonographic diagnosis was confirmed at the time of revision surgery. Prickett et al\(^\text{21}\) found a surgically confirmed accuracy of 89\% for ultrasound in assessing the rotator cuff post-operatively.

**Statistical analysis.** As proposed by Bortz\(^\text{22}\), in order to detect a medium effect size, the group size was set to 50 patients. A power analysis was performed expecting a difference of greater than ten in the age and gender-related Constant score with an SD of 20. A sample size of 50 in each group was found to be adequate.

For all analyses, alpha was set to 0.05, beta to 0.8 and the confidence interval (CI) at 95\%. The individual scores pre- and post-operatively were tested using the Wilcoxon test for dependent samples. The differences in the absolute and the age-adjusted Constant score between the patients of both groups were tested using the Mann-Whitney U test for independent samples. Further comparisons regarding the incidence of re-ruptures, deep infections and ‘drop-outs’ were analysed using the chi-squared test.

In order to identify a predictor for a good clinical result (Constant score) a linear regression model which included hand dominance, Workers’ Compensation Board (WCB), age, gender, the size of the defect (Bateman) and the type of suture used was applied.

**Results**

Of the 100 patients initially enrolled, two with PDS reconstruction had to be excluded during the post-operative period because of C5 nerve root entrapment and fibromyalgia syndrome. In these cases, this was not related to the operative procedure. Five patients (one Ethibond, four PDS) did not wish to attend the follow-up examination after two years, but agreed to a telephone interview. Their subjective assessment indicated two excellent, two good and one moderately successful result. Because we could not assess the Constant score and could not perform an ultrasound examination of these five patients, they were registered only in the subjective results and not included in the statistical analysis. After two years 93 patients were available for follow-up assessment, 44 with PDS reconstruction and 49 with Ethibond.

The minimum, mean, median and maximum follow-up times were 24, 27, 25 and 30 months for the PDS and 24, 26, 25 and 29 months for the Ethibond group.

**Subjective.** Forty-five (94\%) of the 48 patients with PDS reconstruction and 46 of the 50 (92\%) with Ethibond reconstruction would agree to have the same operative procedure again. Of the 48 patients with PDS reconstruction 40 (83\%) rated their result as excellent or good and 41 (82\%) of the 50 with Ethibond reconstruction rated their result as excellent or good. Six patients (12\%) in both groups rated their result as satisfactory, and two (4\%) of the PDS group and three (6\%) of the Ethibond group as poor.

**Objective.** The mean Constant score of the entire study group was 77 (92\% when adjusted for age and gender). The rate of sonographically diagnosed re-tears was 18\% (eight of 44) for the PDS group and 22\% (11 of 49) for the Ethibond group. The difference was not statistically significant (\(p = 0.648\)). The pain reported on a visual analogue scale from zero to 15 (15 = pain free) was 12.9 in the PDS and 13.1 in the Ethibond group (\(p = 0.648\)).

Consequently, with a Constant score of 76 (91\%) for the PDS and 78 (92\%) for the Ethibond groups, the overall results did not show a significant difference (\(p = 0.329\)). In those with a recurrent tear, patients with a PDS reconstruction had a mean Constant score of 91\% and showed no significant difference (\(p = 0.648\)) from those whose reconstruction remained intact (Constant score 91\%). However, patients with a recurrent tear after Ethibond reconstruction had a mean Constant score of 77\%, which was significantly (\(p = 0.005\)) lower than that of 94\% for those whose reconstruction remained intact (Fig. 1).

**Linear regression analysis of conditions affecting the outcome.** Hand dominance, Workers’ Compensation Board and the size of the defect and the suture material and type did not significantly affect the result when measured by the age- and gender-adjusted Constant score (Table II).

The Constant score showed that only age and gender had a significant effect on the results. More precisely, an age-
and gender-adjusted Constant score made it apparent that the risk of less favourable results is significantly increased for patients who are both female and younger (Table II).

**Complications.** In each of the two groups, two patients (4%) required revision surgery because of persistent pain. Two isolated tears of the supraspinatus were found in the PDS group and reconstructed again within six months of the initial surgery. During revision, no remaining suture material was found. In the Ethibond group, one patient with a symptomatic re-tear, diagnosed at follow-up, underwent reconstruction again and one, seven months after the initial surgery, had a lateral clavicular resection as well as removal of scar tissue and Ethibond suture material at the greater tuberosity. The reconstruction of the rotator cuff was intact at revision. In the patient with the further tear the Ethibond sutures and the knots were found to be intact and the further tear therefore must be due to failure of tendon tissue. In the Ethibond group, two low-grade infections caused by *Staphylococcus epidermidis* and in the PDS group, one low-grade infection caused by *Neisseria* species led to revision within three weeks of the initial surgery. At the follow-up examination there was no clinical evidence of persisting infection and the C-reactive protein levels were normal.

**Discussion**

Open repair of the cuff is a well-established procedure for the treatment of tears. The overall results of our study, with a mean Constant score of 77 points (92% when adjusted for age and gender), are similar to the data reported by Kronberg and Brostrom in which the mean Constant score was 77, Romeo et al, Galataz et al, Gazielly et al. Our results are slightly better than those reported by Motycka, Kriegleder and Landsiedl (72%), Plafki et al (81.4%), Yel et al (82%) and Knudsen et al (71%).

A number of studies indicated that an increase in the tear beyond a certain size as assessed by MRI or ultrasound, increased the probability of a less favourable outcome. However, it should be noted that Sonnabend and Watson, in a review of 667 cases, found that the size of the tear was not an indicator of patient satisfaction. Cofield et al found a correlation between the age and the size of the tear with older patients having larger tears. Harryman et al reported that older patients and patients with larger tears had more recurrent defects. The design of our study with its exclusion criteria reduced both the influence of the size of the tear, especially massive tears, and the involvement of the subscapularis.

Wolfgang reported that the results of repairs of the rotator cuff in older patients were less good than those in younger patients, but this is not to be supported by more recent studies. In a retrospective study, Watson and Sonnabend found that patients younger than 55 years of age were more likely to have worse results. These findings are similar to those in our study in which older women had a statistically significantly higher Constant score when adjusted to include gender and age. When our results are compared with those of Constant and Murley and Thomas, Dieball and Busse, this may be attributable to the significantly higher Constant score for our population of women aged 46 years and older and men aged 60 years and older. Since there was no difference in the age and gender distribution in either of our groups, our study is not affected.

In 1994 Gerber et al reported that a modification of the Mason-Allen suture technique improved the ultimate tensile strength for sutures in the tendon of infraspinatus in sheep. In addition to this new modification, they recommended a plate-augmentation device at the bone attachment. Their work greatly implicated suture techniques and materials in the rate of re-tears after repair of the rotator cuff. Caldwell et al drew attention to the importance of the placement of the transosseous sutures at least 1 cm below the tip of the greater tuberosity and at least 1 cm apart.

A number of recently-published papers have examined the use of suture materials and tendon-grasping techniques mainly for arthroscopic techniques or for comparing suture anchors and transosseous sutures. The tendon-to-bone repair of torn rotator cuffs has three points of weakness: the tendon-suture interface, the thread and the suture-to-bone interface. The benefit of the Mason-Allen stitch is the firmness of its hold in the tendon while its disadvantages are its tendency to rupture at the knot and its effect on tissue viability. The modified Kessler No. 1 suture shows less ultimate tensile strength and has less cycles to failure. With regard to suture materials only those which are braided and absorbable demonstrate *in vitro* mechanical properties similar to those of braided polyester.

To our knowledge, there is no information in the literature regarding suture and tendon-grasping techniques for transosseous repair of the rotator cuff. Only Machner et al presented data which compared a transosseous technique with an anchor technique, and no statistical difference in clinical outcome was found. Surprisingly, the data of our prospective, randomised study cannot support the experimental data found by Gerber et al. The non-absorbable braided No. 3 Ethibond suture with a modified Mason-Allen technique (Constant score 92%) had the same rate of re-tear and overall clinical results (p = 0.362) as the Kessler suture with a 1.0 mm absorbable braided PDS cord (Constant score 91%). So far, the mechanical *in vitro* data have not been confirmed in the clinical setting.

The only significant difference (p = 0.005) was indicated when sonographically confirmed re-tears in patients with non-absorbable sutures (Constant score 77% vs 94% in intact reconstructions) were compared with re-tears in patients with absorbable sutures (Constant score of 91% in both re-tears and intact reconstructions (p = 0.648)).

Because of the small number of patients, we can only speculate that the inferior results after failed repair with
non-absorbable suture material were due to mechanical irritation of the non-absorbable suture material in the subacromial space, as was found in the two cases of revision surgery in this group. Since no histological data are available our study cannot determine whether re-tears are related to mechanical failure of the suture, failure of the tendon, failure of the bone, or tendon necrosis.

We, therefore, conclude that although basic science studies support the use of special suture techniques and non-absorbable materials, their advantages are unproven in the clinical setting in terms of both clinical outcome and rate of recurrence. Absorbable suture material may have advantages in repair of the rotator cuff when the quality of the tendon is poor.

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References