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Midterm Results of Aortic Repair Using a Fabric Neomedia and Fibrin Glue for Type A Acute Aortic Dissection

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Departments of Cardiovascular Surgery and Cardiology, Iwate Medical University Memorial Heart Center, Iwate Medical University, Morioka; Department of Cardiovascular Surgery, Kusatsu General Hospital, Shiga, Japan

Background. Controversy exists concerning the optimal surgical treatment of acute type A aortic dissection to reduce mortality rate and the need for reoperation. The goal of the present study was to evaluate midterm results of repair using a fabric and fibrin glue for acute type A aortic dissection.

Methods. From 1994 to 2005, 100 patients with acute type A aortic dissection underwent supracommissural graft replacement using a fabric as “neomedia” and fibrin glue. Mean patient age was 65.7 ± 11.3 years.

Results. Hospital mortality was 9%. All 91 survivors underwent follow-up evaluation for a mean period of 47.7 months. Aortic regurgitation was restored to non or mild in 46 survivors who had preoperative aortic regurgitation in the immediate period, and only one patient developed moderate aortic regurgitation in the midterm period. Survival at 1, 5, and 10 years including hospital mortality was 89.0 ± 3.1%, 75.2 ± 5.1%, and 59.2 ± 10.9%, respectively. Reoperation for aortic lesion was performed without mortality in three patients (residual dissection, n = 1; sinus of Valsalva dilatation, n = 1; acute redissection, n = 1). During two late reoperations, the fabric was observed to be firmly adherent to the dissected wall and maintained the shape of the aorta. Freedom from aortic reoperation was 98 ± 2% and 98 ± 2%, at 5 and 10 years, respectively.

Conclusions. Supracommissural aortic replacement using a fabric neomedia and fibrin glue resulted in low early and late mortality as well as a low reoperation rate.

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Although early outcomes after surgical treatment of acute type A aortic dissection have steadily improved over the last decade, the optimal method of surgical management remains controversial, particularly in regard to reducing mortality rates and the need for reoperation. One of the critical components of surgical correction of acute aortic dissection is the repair of the fragile aortic root, which can be accomplished by supracommissural graft replacement, valve-preserving aortic root replacement, aortic valve replacement with supracommissural replacement, and composite valve graft replacement. Preservation of the aortic valve has been recommended to minimize valve-related complications and to avoid anticoagulant therapy, which may delay false-lumen thrombosis downstream from the distal anastomosis of the aorta. Of the valve-preserving methods, supracommissural graft replacement is frequently selected because of technical simplicity and minimal invasiveness. However, patients who undergo supracommissural graft replacement are at a risk of requiring reoperation due to a variety of complications, including sinus of Valsalva dilatation [1–5], progressive aortic regurgitation [1, 3, 5–7, 8], redissection, or residual dissection at the aortic root [5, 6, 9].

Several reports have described the successful use of gelatine-resorcine-formalin (GRF) glue. However, other studies have described GRF glue-related redissection and tissue necrosis of the aortic root [10, 11]. We have performed supracommissural graft replacement using a fabric as “neomedia” and fibrin glue to prevent tissue damage and to reinforce the fragile aortic wall. The goal of the present study was to evaluate midterm results of this technique in patients with acute type A aortic dissection.

Patients and Methods
A total of 201 consecutive patients who underwent aortic replacement for acute type A aortic dissection at Iwate Medical University Hospital from 1994 to 2005 were reviewed retrospectively. This study was approved by our Ethics Committee, which waived the need to obtain informed consent. Aortic valve replacement with supracommissural graft replacement was performed in two patients with preexisting abnormalities of the aortic valve leaflets. One hundred eighty-five patients underwent supracommissural tube graft replacement only. Contra-
Table 1. Preoperative Clinical Characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>n = 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex, male</td>
<td>46</td>
</tr>
<tr>
<td>Cardiac tamponade</td>
<td>22</td>
</tr>
<tr>
<td>Aortic regurgitation</td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>31</td>
</tr>
<tr>
<td>Moderate</td>
<td>11</td>
</tr>
<tr>
<td>Severe</td>
<td>7</td>
</tr>
<tr>
<td>Myocardial ischemia</td>
<td>9</td>
</tr>
<tr>
<td>Limb ischemia</td>
<td>7</td>
</tr>
<tr>
<td>Cerebral ischemia</td>
<td>5</td>
</tr>
<tr>
<td>Intestinal ischemia</td>
<td>3</td>
</tr>
<tr>
<td>Chronic renal failure</td>
<td>2</td>
</tr>
<tr>
<td>Hypertension</td>
<td>72</td>
</tr>
<tr>
<td>DeBakey Type I</td>
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</tr>
<tr>
<td>DeBakey Type II</td>
<td>5</td>
</tr>
<tr>
<td>DeBakey Type III</td>
<td>21</td>
</tr>
</tbody>
</table>

indication for supracommissural graft replacement included Marfan syndrome (n = 6), destruction of the adventitia on the sinus of Valsalva (n = 4), annuloaortic ectasia (n = 2), and extension of dissection to the coronary ostia (n = 2). For these 14 patients, composite graft replacement was performed.

Of those patients who underwent supracommissural tube graft replacement only, 100 patients underwent repair of the aortic root using the fabric with fibrin glue and were enrolled in the present study. The remaining 85 patients underwent reconstruction of the aortic root using various techniques (GRF glue, n = 62; BioGlobue [CryoLife, Kennesaw, GA], n = 9; Teflon felts, n = 6; no glue, n = 8). Study participants consisted of 46 men and 54 women, ranging in age from 36 to 90 years, with an average age of 65.7 ± 11.3 years (median, 67 years). None of the patients were diagnosed Marfan syndrome. All patients underwent preoperative transthoracic echocardiography (TTE) to evaluate the aortic valve. Preoperative clinical characteristics of all patients are summarized in Table 1.

Surgical Technique

All operations were performed within 14 days after the onset of symptoms. Cardiopulmonary bypass was performed as previously described [12]. The femoral artery, the axillary artery, and (or) the innominate artery were cannulated (the femoral artery only, n = 64; the femoral artery and the axillary artery, n = 22; the axillary artery only, n = 13; the innominate artery only, n = 1). Open distal repair was performed under circulatory arrest in 98 patients. The remaining two patients underwent distal repair with an aortic clamp under mild hypothermia. No cerebral perfusion with deep hypothermic circulatory arrest was used in a rectal temperature of 21°C to 23°C; when circulatory arrest time was anticipated to be longer than 30 minutes, antegrade cerebral perfusion through the innominate, left common carotid, and left subclavian artery, was performed. Antegrade cerebral perfusion was done in 46 of 68 patients operated from 2002 to 2005. The mean cerebral perfusion time was 60.2 ± 31.0 minutes (range, 22 to 144 minutes). A left ventricular decompression line was inserted through the right superior pulmonary vein in all patients. During the cooling period, the ascending aorta was not clamped, except when ascending aortic clamping was necessary, to prevent left ventricular dilatation in patients with aortic regurgitation. Antegrade cold cardioplegia was used for myocardial protection. Next, the dissected aorta with the primary intimal tear was resected. The site of distal anastomosis was dependent on the extent of the intimal tear. For example, if the intimal tear extended to the aortic arch, the aortic arch was partly or totally replaced. Aortic arch replacement was performed in 59 patients (total arch replacement, n = 21; hemiarch replacement, n = 38). Then, the 0.61-mm-thick knitted polyester fabric (Bard Sauvage Fabric, Tempe, AZ) was placed between the dissected layers of the distal aorta, and the fibrinogen solution (human fibrinogen solution including human plasma-derived coagulation factor XIII and bovine aprotinin) and the thrombin solution (human thrombin solution including calcium chloride) of the fibrin glue set (Beriplast, Centeon, Germany or Bolheal, Chemo-Sero Therapeutic Institute, Japan) were applied to the fabric strip (10 to 15 mm width) (Fig 1A). The layers of the dissected aorta were compressed with surgical forceps for one to two minutes. Additional applications of the fibrin glue were often necessary to obliterate the false lumen. Since 2003, we have utilized a modified method involving soaking of the fabric strip in fibrinogen solution prior to placement within the false lumen, and thrombin solution was applied to the fibrinogen-soaked fabric (2–3 drops per 1 cm²) once it was in place [12]. Finally, the
layers of the dissected aorta were compressed with surgical forceps, a special clamp [13] and (or) the fingers (the thumb and the index finger). The modified method with fibrinogen-soaked fabric was performed in 57 patients. Since 2004, the geometrically fashioned fabric has been used instead of the fabric strip to obliterate the false lumen completely (Fig 1B).

A Hemashield graft (Boston Scientific, Natick, MA) was anastomosed using 4-0 polypropylene, and Teflon felt was placed on the outer surface of the aorta. After distal anastomosis, the proximal portion of the graft was clamped, and antegrade systemic perfusion from the side graft of the main graft was restarted. The procedure for the proximal aorta was performed during the subsequent rewarming. The aortic valve was resuspended by obliteration of the false lumen in the aortic root in the same manner as the distal aortic stump. Proximal anastomosis was performed at the level of the sinotubular junction after obliteration. Concomitant procedures included coronary artery bypass grafting in six patients, mitral valvuloplasty in one patient, femoro-femoral bypass in one patient, and fenestration of the femoral artery in one patient for leg ischemia. Operative data are summarized in Table 2.

Follow-Up

All survivors underwent follow-up, including review of outpatient hospital records and result of computed tomography (CT). Further, all patients with preoperative aortic valve regurgitation underwent transthoracic echocardiogram during follow-up. Aortic regurgitation was graded by measuring the proximal isovelocity surface area [14]. Mean follow-up among survivors was 47.7 ± 36.2 months (range, 6 to 160 months; median, 37 months).

Continuous data are presented as means ± standard deviation. Actuarial survival rates and freedom from reoperation were constructed using the Kaplan-Meier technique. Variability of the actuarial estimates was expressed as ± one standard error of the mean.

Results

Overall hospital mortality was 9% (9 of 100). The modes of death were the following: hypoxic cerebral damage as a result of preoperative cardiac tamponade (n = 2), myonephropathic metabolic syndrome as a result of lower limb malperfusion (n = 1), low cardiac output syndrome as a result of coronary malperfusion (n = 1), ischemic bowel as a result of intestinal malperfusion (n = 1), sepsis (n = 1), rupture of the descending thoracic aorta (n = 1), rupture of a left iliac artery aneurysm (n = 1), and pulmonary embolism (n = 1). Six of nine hospital deaths were closely related to preoperative complications. Ten patients experienced renal failure requiring temporary dialysis, and two patients experienced stroke postoperatively. Two patients underwent reexploration for postoperative bleeding. The mean ventilation time, the mean stay on the intensive care unit, and the mean hospital stay of the survivors were 110 ± 134 hours (median, 77 hours), 10.9 ± 10.9 days (median, 7 days), and 39.6 ± 16.8 days (median, 37 days), respectively.

Computed tomography performed within the first postoperative month revealed residual dissection near the proximal anastomosis in four patients. Three of these patients were observed medically because residual dissection was localized to a small area. The remaining patient had wide residual dissection and underwent reoperation on the 16th postoperative day. During the reoperation, three of the needle holes at the proximal suture line were noted to be elongated (3 mm to 5 mm in

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* Table 2. Operative Data

<table>
<thead>
<tr>
<th>Procedure</th>
<th>n = 100</th>
</tr>
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<tbody>
<tr>
<td>Operation time, minutes</td>
<td>463 ± 151</td>
</tr>
<tr>
<td>CPB time, minutes</td>
<td>209 ± 102</td>
</tr>
<tr>
<td>Circulatory arrest time, minutes</td>
<td>58.5 ± 25.6 (n = 98*)</td>
</tr>
<tr>
<td>Lowest rectal temperature, °C</td>
<td>20.4 ± 2.4 (n = 98*)</td>
</tr>
</tbody>
</table>

* patients with deep hypothermic circulatory arrest.

CPB = cardiopulmonary bypass.
length), possibly secondary to reduction of the size of 30 mm at the sinotubular junction level. Because the intima was fragile, the aortic root was replaced using a composite valve graft. The patient did well and was discharged on the 35th hospital day. One other patient underwent reoperation for mediastinitis on the 14th postoperative day. Irrigation of the mediastinum and an omental wrapping of the graft were performed, and the patient was discharged on the 55th hospital day. Computed tomography revealed no critical lesion in the remaining 86 survivors (Fig 2).

Follow-Up
Thirteen patients died during the follow-up period. Causes of late death were malignancy (n = 3), cerebral hemorrhage (n = 2), pneumonia (n = 2), ruptured abdominal aortic aneurysm (n = 2), cerebral infarction (n = 1), acute myocardial infarction (n = 1), renal failure (n = 1), and respiratory failure (n = 1). Actuarial survival rates at 1, 3, 5, and 10 years after the initial operation including hospital deaths were 89.0 ± 3.1%, 81.3 ± 4.2%, 75.2 ± 5.1%, and 59.2 ± 10.9%, respectively. When hospital deaths were excluded, survival was 97.8 ± 1.5%, 89.3 ± 3.6%, 82.7 ± 5.0%, and 65.1 ± 11.8%, respectively (Fig 3). On the other hand, 8 of 85 patients who underwent supracommissural tube graft replacement with other methods during the same period died in hospital, and actuarial survival rates at 1, 3, 5, and 10 years after the initial operation including hospital deaths were 84.7 ± 3.9%, 78.6 ± 4.5%, 72.3 ± 4.6%, and 66.4 ± 5.4%, respectively.

Follow-up contrast-enhanced CT was performed in all survivors except for three patients who died before the first follow-up CT. The mean time to follow-up CT was 39 ± 33 months (range, 6 months to 150 months; median, 30 months). There were no false aneurysms near the proximal anastomosis, and redissection of the aortic root occurred in one patient. Critical dilatation of the distal aorta was not recognized. One patient developed sinus of Valsalva dilatation, and three patients who had been observed medically for proximal residual dissections were stable. Residual dissection disappeared during the follow-up period in two patients. The remaining patients with residual dissection remained asymptomatic without dilatation of the aortic root.

Follow-up TTE was performed in 46 survivors who had aortic regurgitation preoperatively. The mean time to follow-up TTE was 37 ± 38 months (range, 4 months to 150 months; median, 25 months). The degrees of aortic regurgitation before operation, the immediate postoperative period, and midterm period are shown in Figure 4. Only one patient presented with moderate aortic regurgitation at last contact; she remained in stable condition and was treated medically. The remaining 45 patients had no or mild aortic regurgitation on most recent follow-up.

Reoperation
Two patients underwent reoperation during the follow-up period. One patient, a 48-year-old woman, required reoperation for sinus of Valsalva dilatation (from 42 mm to 58 mm) that developed over an 11-year period after the initial operation. The fabric strip (15-mm width) was inserted into the sinotubular junction but not the dissected sinuses at the initial operation. The preoperative echocardiography revealed the sinotubular junction of 28 mm without redissection of the aortic root and aortic regurgitation. During the reoperation, the dilatation was predominantly recognized in the sinuses and the fabric strip was noted to be firmly adherent to the dissected wall without dilatation of the sinotubular junction. The aortic root was repaired with the remodeling technique described by Yacoub and colleagues [15].

The other patient, a 49-year-old woman, was admitted with acute onset of chest pain at three months after initial aortic repair. Emergent operation was performed for acute redissection of the aortic root. A semicircular intimal tear on the sinus of the Valsalva was recognized along the proximal edge of the fabric strip that had been previously placed on the sinotubular junction. Because the sinotubular junction was obliterated firmly, there was
no redissection near the proximal anastomosis. The re-
dissected sinus with the new intimal tear was resected,
and the remaining sinus was repaired with fibrinogen-
soaked fabric. A woven Dacron graft was anastomosed in
a scallop-shaped configuration to match the noncoronary
sinus. Histologic analysis of resected specimens from
both patients did not reveal signs of aortic necrosis. The
postoperative courses of both patients were uneventful.
None of the patients required reoperations for lesions of
the distal thoracic aorta during follow-up. Actuarial free-
dom from aortic reoperation at 5 years and 10 years
after the initial operation was 98 ± 2% and 98 ± 2%,
respectively (Fig 5).

Comment
The present study demonstrated that repair of the aortic
root using a fabric neomedia and fibrin glue in patients
undergoing supracommissural aortic replacement re-
sulted in low in-hospital mortality (9.0%). This is in
contrast to the recently published data from the Interna-
tional Registry of Acute Aortic Dissection that described
an overall in-hospital mortality of 25.1% [16]. Most causes
of death in the present series were not due to technical
problems but, rather, due to preoperative complications
related to acute aortic dissection, which is consistent with
observations from other studies [4, 16–20]. Furthermore,
midterm survival at 5 years (excluding hospital deaths)
was 82.7 ± 5.0% in the present study. Recently, 5-year
survival rates of 80% to 94.9% have been reported [9, 16,
19, 20]. Considering that the mean patient age was higher
in the present study when compared with other studies
(65.7 years vs 58.0 to 58.3 years), midterm survival in the
present study appears to be acceptable.

Actuarial freedom from reoperation at five years after
initial surgery for acute type A aortic dissection ranges
from 74% to 94% [3, 4, 8, 9, 20]. In this series, freedom
from reoperation for survivors at five years was 98% ±
2%, and no reoperation was performed for aortic regur-
gitation. Development of postoperative aortic regurgita-
tion is a significant cause for reoperation after supracom-
missural graft replacement [1, 3, 5–7, 9]. The main
mechanism of aortic regurgitation in patients with acute
aortic dissection is dislocation and loss of commissural
support. While resuspending the commissures and the
reattachment of two dissected aortic walls can restore
valve function, aortic regurgitation can recur due to
redissection or development of aortic root dilatation
during the midterm period [2, 5, 21]. Graeter and col-
leagues [1] suggested that secondary development of root
dilatation may be due to incomplete healing or increased
wall tension in a dilated root. In the present series, only
one of 17 patients who had preoperative moderate to
severe aortic regurgitation developed moderate aortic
regurgitation during the midterm period. There are sev-
eral possible explanations for the low incidence of aortic
regurgitation in this study, including only one occurrence
of redissection at the proximal anastomosis, or the shape-
holding effect of the fabric neomedia, which was inserted
into the false lumen. Indeed, the fabric neomedia was
noted to have maintained its shape in those patients who
required reoperation. Bavaria and colleagues [22] re-
ported that the use of geometrically fashioned Teflon felt
or BioGlue as neomedia resulted in excellent outcomes,
with no reoperations on the aortic root at a mean of 14
months of follow-up. These findings suggest that Teflon
felt or fabric inserted into the false lumen yields excellent
midterm results in terms of maintaining the shape of the
dissected aortic wall.

In the present study, one patient required reoperation
for sinus of Valsalva dilatation without aortic regurgita-
tion. The fabric strip inserted at initial operation was
firmly adherent to the dissected wall without dilatation of
the sinotubular junction, and the dilatation was predo-
minate recognized in the unrepaired sinuses. In the light
of these findings, complete obliteration of the false lumen
using geometrically fashioned fabric might have pre-
vented sinus of Valsalva dilatation. Another patient un-
derwent reoperation secondary to a semicircular intimal
tear along the proximal edge of the fabric strip on the
sinus of Valsalva. The new intimal tear was revealed on
the dissected wall, into which the fabric strip was not
inserted. In the modified method with fibrinogen-soaked
fabric strip, the adhesive strength is not shown at the
place where there is no fabric strip. Geometrically fash-
ioned fabric should have been used to obliterate the false
lumen completely.

Aortic repair using fibrin glue for acute aortic dissec-
tion was previously described by Séguin and colleagues
[23]. While this technique was useful in sealing suture
holes, the adhesive strength of fibrin glue alone was
extremely weak. Since then, Morikawa and colleagues
[24] utilized a modified method of fibrinogen-soaked
absorbable mesh and the thrombin solution and reported
that this technique resulted in a sixfold enhancement of
the adhesive properties as compared with the conven-
tional layer method without the absorbable mesh. This is
consistent with results from the present study, in which a
fabric was used instead of the absorbable mesh. Actually,
the fabric was superior to the absorbable mesh in terms
of reinforcement of the dissected wall and prevention of
further damage to the fragile intima from the suture line.

The adhesive strength of fibrin glue is obviously less
than that of GRF glue. However, the adhesive strength of
the present technique was sufficient to maintain obliter-
ation of the false lumen in most patients. Indeed, prox-
imal residual dissections that were present during the
immediate postoperative period in three patients were
due to an insufficient volume of fibrin glue and an overly
short period and a disproportion of manual pressure
applied to the fabric and dissected wall. To soak suffi-
ciently a 5-cm² region of the fabric, 1 cm² to 1.5 cm² of
fibrinogen solution is required, and at least one minute is
needed to press the dissected aortic wall. In order to
avoid the disproportional press, the compression using
the thumb and the index finger has recently been per-
formed in addition to surgical forceps or a special clamp.
Further, there have not been any reports of toxic events
when using the fibrin glue [23, 25], which is consistent
with results from the present study. Finally, the use of the
fibrinogen-soaked fabric did not result in thromboembolic complication [26] as can occur with the GRF glue.

The remodeling technique or reimplantation technique has been used with good results for acute type A aortic dissection when conducted by an experienced surgeon. However, because surgeries for acute aortic dissection are often performed in emergency situations and in unstable patients, supracommissural graft replacement is preferred whenever feasible and appropriate because of its ease. The present study suggests that supracommissural graft replacement using a fabric neo-media with fibrin glue results in excellent outcomes for patients without preexisting lesions of the aortic valve and the aortic root, even if aortic regurgitation is moderate to severe.

One limitation of this study is the relatively short length of follow-up (47.7 ± 36.2 months) for the patients undergoing this technique. Pugliese and colleagues [8] reported that mean interval between initial repair and reoperation was 5.2 ± 3.1 years. Another limitation was that six different surgeons performed the surgeries over a 13-year period. However, the surgical principles employed by the various surgeons were similar.

In conclusion, supracommissural aortic replacement using a fabric neo-media and fibrin glue resulted in low early and late mortality as well as a low reoperation rate. Further, these data indicate that this technique possesses sufficient adhesive strength to obliterate the false lumen and maintain the shape of the dissected aortic wall without producing tissue toxicity. Further long-term follow-up is necessary to confirm these results.

References
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