

# Stent graft repair of subclavian and axillary vascular injuries: The Groote Schuur experience

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**Background.** Trauma-related subclavian and axillary vascular injuries (SAVIs) are generally associated with high morbidity and mortality rates in the surgical literature. There is an emerging trend towards increasing use of stent grafts (covered stents) for repair, with evidence limited to small case series and case reports.

**Objectives.** To report on the clinical and device-related outcomes of stent graft repair of trauma-related SAVIs at a single institution.

**Methods.** A retrospective chart review of all patients with trauma-related SAVIs requiring stent graft repair was performed. Outcome measures included technical success, mortality, amputation rate, device-related complications (early and late), and reintervention rates (early and late).

**Results.** A total of 31 patients was identified between June 2008 and October 2013 (30 males, 1 female). Mean age was 27.9 years (range 19 - 51). All 31 patients sustained a penetrating injury (93.5% stab, 6.5% gunshot injuries). There were 21 subclavian and 10 axillary artery injuries. Five patients (16%) were HIV-positive. Nine patients (29%) were shocked on presentation. Early results (30 days): There were no periprocedural deaths. Primary technical success was 83.9% (26/31). Five patients required adjunctive interventional or operative procedures. There were no early procedure-related complications, reinterventions or open conversions in this study. Overall, suboptimal results were seen in five patients (one type I endoleak and four type II endoleaks). Follow-up results (>30 days): Nineteen patients (61.3%) were available for follow-up. Mean duration of follow-up was 55.7 weeks (range 4 - 240). Overall stent graft patency was 89.5% (17/19). Four patients (21.1%) had an occluded stent graft. Stent graft salvage was possible in two patients. Three type II endoleaks were seen on follow-up. Late reinterventions were performed in five patients (26.3%). Conversion to an open procedure was not required in any patient. There was one late death and one major amputation of a stented limb in a patient who had sustained severe soft-tissue injuries during the follow-up period.

**Conclusion.** Perioperative, early and intermediate results suggest that stent graft repair of select trauma-related SAVIs is relatively safe and effective. Axillary arteriovenous fistulas remain a particular challenge using this treatment modality. Larger prospective studies are required to define the utility of stent grafts for select trauma-related SAVIs better.

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Despite the paucity of long-term, durable data, stent graft repair has emerged as a safe and feasible alternative to open repair of trauma-related subclavian and axillary vascular injuries (SAVIs). Surgical treatment is often attended by high morbidity and mortality rates (5 - 30%).<sup>[1,2]</sup> Indeed, some have suggested that stent graft repair should be considered as first-line treatment for trauma-related SAVIs.

Peripheral stent grafting evolved as a complementary treatment strategy since 2008 at Groote Schuur Hospital, Cape Town, for select patients with vascular trauma.

## Methods

All patients considered endosuitable were counselled about the procedure, and the need for diligent follow-up was emphasised.

Consent was obtained from all patients. The procedure was performed either in an interventional angio suite under local anaesthesia or in the operating theatre (OR) under general anaesthesia. Estimation of stent graft diameter and length was obtained from preoperative imaging modalities that included catheter angiography, duplex ultrasound (DUS) or computed tomography angiography (CTA). A range of stent grafts of different diameters and lengths was available at the time of the procedure. Access for deployment was obtained via percutaneous or 'cut-down' (femoral or brachial) approaches. When using femoral access, long systems were utilised (guidewires; balloon and stent catheters; long, appropriately sized sheaths). Heparin was given prior to lesion crossing and stent graft deployment in all cases. We maintained the habit of balloon moulding, a requirement for some older-generation

devices, of all stent grafts post deployment using low inflation pressures (2 - 3 atm).

A completion angiogram was performed in all cases. For patients with percutaneous femoral approaches, a short exchange sheath was inserted and secured. The sheath was removed after 4 hours to allow for normalisation of clotting times, and a compression dressing was applied after obtaining compression haemostasis. All patients received aspirin (long term) and clopidogrel (4 weeks) post stent graft insertion.

After institutional research ethics committee approval of clinical audit of vascular trauma, those patients who had undergone stent graft repair of a trauma-related peripheral vascular injury were identified from a prospectively maintained vascular database and angiography unit patient records. Only patients with SAVIs were included in this study. A retrospective chart review was then performed. All possible attempts were made to contact patients with no or incomplete follow-up. Interval history, pulse status and a DUS evaluation were documented at all follow-up visits. Where indicated, patients also had either CTA or catheter angiography on follow-up. Data captured included demographic, clinical, diagnostic and procedural details. Outcome measures included technical success, mortality, amputation rate, device-related complications (early and late), and reintervention rates (early and late).

## Results

A total of 31 patients was identified for the study. The vast majority (93.5%) were male (29/31). Altogether, there were 21 (67.7%) black patients and 10 patients of mixed ethnicity. The mean age was 27.9 years (range 19 - 51). All 31 patients sustained a penetrating injury (29 stab wounds and 2 gunshot wounds). There were no blunt or iatrogenic injuries identified in this study. There were 21 subclavian and 10 axillary vascular injuries (23 acute and 8 chronic, defined as >2 weeks). The vascular pathology on imaging identified 23 false aneurysms, 5 arteriovenous fistulas and 3 arterial dissections (Table 1). One patient with a transected proximal (ostial) vertebral artery, with a false aneurysm and an arteriovenous fistula, was included as

**Table 1. Vascular pathology related to penetrating trauma**

| Vascular pathology | Subclavian   |                | Axillary     |                |
|--------------------|--------------|----------------|--------------|----------------|
|                    | Acute, n (%) | Chronic, n (%) | Acute, n (%) | Chronic, n (%) |
| False aneurysm     | 14 (45.2)    | 3 (9.7)        | 4 (12.9)     | 2 (6.5)        |
| AVF                | 1 (3.2)      | -              | 1 (3.2)      | 3 (9.7)        |
| Dissection         | 3 (9.7)      | -              | -            | -              |
| Total              | 18 (58.1)    | 3 (9.7)        | 5 (16.1)     | 5 (16.2)       |

AVF = arteriovenous fistula.

**Table 2. Patient demographic and clinical features**

|                                 | n (%)          |
|---------------------------------|----------------|
| Age (years), mean (range)       | 27.9 (19 - 51) |
| Males                           | 30 (96.8)      |
| HIV-positive                    | 5 (16.1)       |
| Shocked on initial presentation | 9 (29.0)       |
| Active bleed                    | 6 (19.4)       |
| Admission haemoglobin <10 g/dL  | 11 (35.5)      |
| Diminished/absent pulse status  | 11 (35.5)      |
| Haematoma                       | 20 (64.5)      |
| Bruit/thrill                    | 8 (25.8)       |
| Odynophagia                     | 3 (9.7)        |
| Haemo- and/or pneumothorax      | 13 (41.9)      |
| Upper limb swelling             | 2 (6.5)        |
| Distended veins                 | 2 (6.5)        |
| Thromboembolism                 | 6 (19.4)       |
| Brachial plexus injury          | 4 (12.9)       |
| Spinal cord injury              | 1 (3.2)        |
| Fracture clavicle               | 1 (3.2)        |
| Fracture 1st rib                | 1 (3.2)        |
| Head injury                     | 1 (3.2)        |
| Maxillary fracture              | 1 (3.2)        |
| Fracture scapula                | 1 (3.2)        |

a subclavian injury. Five patients (16%) were found to be HIV-positive (not all were tested).

The demographic and clinical features are listed in Table 2. Nine patients (29%) were shocked on presentation. Six patients (19%) presented with an active bleed, of which five required a wound tract Foley catheter balloon tamponade of the bleed. The balloon catheter shaft was knotted to prevent any inadvertent deflation of the bulb. The mean injury severity score was 22.84 (range 16 - 34).

A total of 32 peripheral stent grafts was deployed in 31 patients (31 arterial and

1 venous). All stent grafts used were self-expandable: Haemobahn (3); Viabahn (5) and heparin-bonded Viabahn (23) (W L Gore and Associates, USA). A single Fluency stent graft was used (Bard, USA). Intentional stent graft coverage of the vertebral origin was performed in three patients after confirming contralateral vertebral or circle of Willis patency. Eleven patients required stent grafting across the costoclavicular space.

In all cases only a single stent graft was needed for each injury. In a single case, an additional stent graft was required in the axillary vein to treat a persistent arteriovenous fistula (AVF) following

the arterial stent grafting. Stent graft diameters ranged from 6 to 10 mm. Most stent grafts were 50 mm in length (28/32) and were deployed using percutaneous femoral access (20/31). One patient required a femoral cut-down to deploy a large 10 × 50 mm subclavian stent graft. Nine patients had a stent graft deployed in the OR via retrograde brachial access (all cut-downs). Altogether, 16 procedures were performed in the OR and 15 in the angio suite. One patient had a hybrid procedure in the OR performed via an open axillary-brachial approach (Figs 1 and 2).

Two patients had simultaneous trans-catheter coil embolisation of adjacent arteries following stent grafting. One patient had a left axillary-distal brachial artery bypass using an arm vein, for a symptomatic long-segment total chronic occlusion, at the time of the stent grafting of a distal subclavian chronic false aneurysm. Four patients required transbrachial embolectomies. A retrograde transbrachial approach to stent grafting was employed in these cases. The mean duration of the procedure was 102.9 minutes (range 35 - 360).

Two patients required evacuation of large haematomas, of which one was infected. Five patients required removal of the Foley catheter and evacuation of the haematoma. These supplementary procedures were generally performed in the OR 48 hours after stent graft repair.

#### Periprocedural results (30 days)

There were no perioperative (30 days) deaths or amputations in this study. Technical success was 83.9% (26/31), and was defined as endoluminal revascularisation without endoleaks or any residual stenosis over 30% at the completion of the procedure. Suboptimal results were seen in five patients. One patient had a type I endoleak (inadequate seal) following stent grafting of a proximal subclavian false aneurysm with a short proximal neck under 10 mm. Serial follow-up ultrasound (US) scans revealed resolution of the type I endoleak and thrombosis of the false aneurysm at 1 month. Four patients had residual type II endoleaks (continued sac or fistula perfusion via side branches) following stent graft repair (one acute and three chronic axillary AVFs): one patient had a residual type II endoleak despite transcatheter

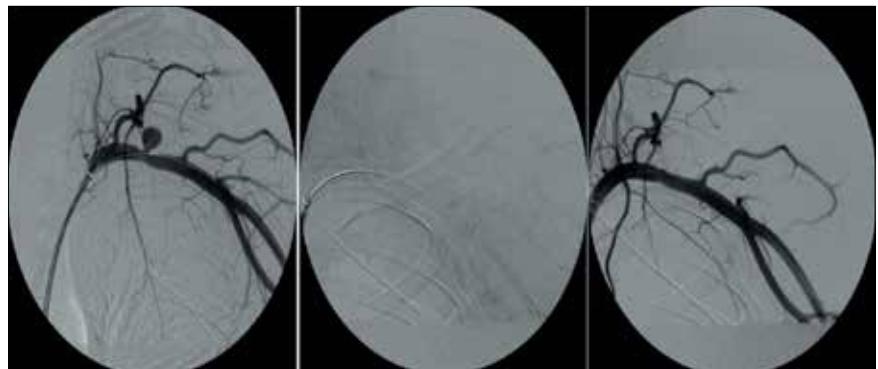


Fig. 1. Distal left subclavian false aneurysm repaired with peripheral stent graft.

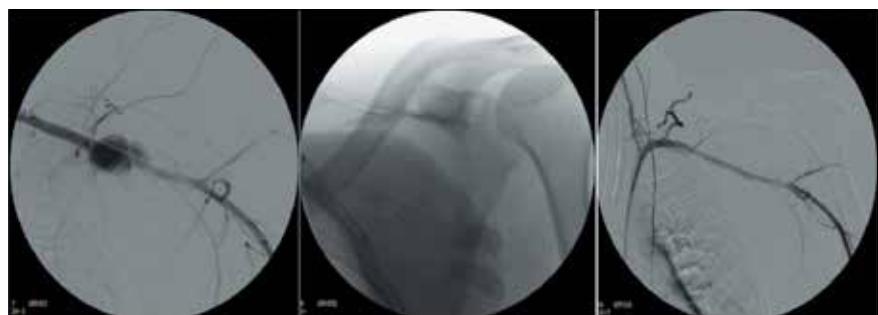


Fig. 2. Stent graft repair of a large left axillary artery false aneurysm.

coiling; the other three patients had late retrograde filling of the sac or vein via small remote tributaries. It was decided to observe these patients with serial US scans with a view to staged treatment if the type II endoleaks persisted.

There were no procedure-related complications, reinterventions or open conversions in this study at 30 days. One patient had stab-wound sepsis, requiring debridement. One patient had a loculated haemothorax requiring a thoracotomy for evacuation. Only four patients required intensive care unit (ICU) admission (mean length of stay 3 days). Mean postprocedure length of hospital stay was 4.5 days (range 1 - 48).

#### Follow-up results (>30 days)

Nineteen patients (61.3%) presented for follow-up. The mean duration of follow-up was 55.7 weeks (range 4 - 240). All patients had a DUS at follow-up. Angio-imaging was performed in 10 patients (3 CTA, 7 catheter angiography). Overall stent graft patency was 89.5% (17/19).

Four patients had an occluded stent graft: two of the patients were asymptomatic; one had arm claudication; and one presented with acute upper limb ischaemia. Three of these four patients had distal subclavian

injuries requiring stent grafting across the costoclavicular space (1 Fluency; 1 standard Viabahn and 1 heparin-bonded Viabahn) and one patient had a distal axillary stent graft (heparin-bonded Viabahn).

Three type II endoleaks were identified on follow-up (1 vertebral AVF; 2 axillary AVF). The vertebral origin injury treated as a subclavian injury initially had a good technical result. The patient defaulted on follow-up and presented much later with an established vertebral AVF (asymptomatic). Only two of the four axillary AVF patients with residual type II endoleaks presented themselves for follow-up. Both had persistent type II endoleaks feeding into the AVF.

Late stent graft stenosis was identified in three patients with DUS surveillance. Two of these patients had a subclavian angiogram. Both had mild stenoses (<30%) not requiring any intervention. The third patient, with a moderate-to-high-grade stent graft stenosis identified on DUS, had mild arm claudication and was scheduled for an angiogram. He was admitted a week later with trauma-related severe soft-tissue injuries (80% body surface area) and Rutherford grade III acute ischaemia of the stented upper limb.

Late reinterventions (>30 days) were performed in five patients (26.3%). For patients with an occluded stent graft, salvage was possible in two patients. The first patient with arm claudication had a transbrachial stent graft thrombectomy and high-pressure balloon angioplasty of a distal edge stenosis with a good technical result. The second patient with the acute limb ischaemia had a stent graft thrombectomy and high-pressure balloon angioplasty of a distal edge stenosis with a technically good result. Forearm fasciotomy, however, revealed non-viable compartments. The remaining two patients with occluded stent grafts had select subclavian angiography. Both had well-collateralised chronically occluded stent grafts that defied attempts at crossing. These two patients have remained asymptomatic.

The HIV-positive patient with the persistent left vertebral AVF was found to have right vertebral and basilar artery occlusive disease precluding transcatheter embolisation. He underwent surgical ligation of the vertebral artery (V2) followed by transvenous transcatheter coil embolisation of the vertebral vein.

The stent graft-treated acute distal axillary AVF with type II endoleak had no identifiable vessels amenable to transcatheter embolotherapy. Percutaneous duplex-directed intrasac thrombin injection with balloon occlusion of the adjacent axillary vein proved unsuccessful. A 13 mm covered stent was deployed into the axillary vein across the fistula as a last-resort 'bail-out' option, with a good technical result.

The patient who had a stentgraft repair of a complex chronic distal axillary AVF, with multiple postprocedural type II endoleaks, had a scheduled transfemoral transcatheter coil embolisation of multiple feeding axillary branches. Late retrograde filling of the sac and AVF via nondescript small remote branches could still be demonstrated on completion angiography. The patient remained asymptomatic with no pulsatile mass or thrills but a soft flow murmur. This was treated expectantly.

Eleven patients had a stent graft deployed across the costoclavicular space; six patients returned for follow-up. Three of the eleven patients had an occluded stent graft (1 Fluency; 1 Viabahn; 1 heparin-bonded Viabahn), as detected on DUS. One stent graft in a symptomatic patient was salvaged, as described in the late interventions above. The other two patients remained asymptomatic.

Seven patients had a distal axillary stent graft. Of the five of these patients followed up, two developed stent graft stenosis: one mild (<30%) and one moderate to severe (50 - 70%). Both had heparin-bonded Viabahn stent grafts.

Five patients were found to be HIV-positive. Two were on antiretroviral treatment. Of the three of these patients followed up, only one developed a mild stent graft stenosis. This patient had a distal axillary stent graft (heparin-bonded Viabahn) and was not on antiretroviral treatment.

Conversion to an open bypass procedure was not required in any of our patients. There was one late death, associated with multiple organ failure, and one major amputation of a stented limb in a patient who sustained >80% body surface area soft-tissue injuries. Stent graft salvage did not prevent amputation in the setting of advanced limb ischaemia.

## Discussion

Subclavian and axillary vascular injuries are generally attended by high morbidity and mortality rates in the surgical literature (5 - 30%).<sup>[1,2]</sup> Peripheral stent graft treatment of SAVIs has obvious merits compared with operative treatment. The stent graft procedure is minimally invasive, with less blood loss. In addition, it avoids surgery in anatomically challenging confined spaces with crowded critical structures; there is reduced iatrogenic brachial plexus and venous injury; no sternotomy is required; there is less need for ICU admissions; and the procedural times and the postprocedure length of hospital stay are shorter. There are, however, a few issues regarding stent grafting for SAVIs that merit consideration.

While the 30-day, early and intermediate results are reassuring, the long-term durability of these stent grafts remains a concern. Only results from diligent long-term follow-ups will address these concerns. This is likely to prove difficult, considering that follow-up of civilian trauma patients is notoriously poor. Indeed, many of these patients have compelling reasons for not wanting to be found. Unreliable contact details and tracking of patients in unhospitable communities remain a challenge. Some patients are serial victims of interpersonal violence. The life expectancy of these trauma patients remains speculative.

As noted in our experience, vertebral artery and distal axillary injuries are prone to early and late complex arteriovenous fistula formation. Adjunctive and sometimes novel interventional treatment is necessary and may prove just as challenging as primary surgical treatment. Transcatheter embolotherapy may not be totally corrective in some patients, despite directly addressing the clinical insult of these lesions. Whether this remains so in the long term or whether this is merely a bridge to surgery remains to be defined. An incidental finding was that salvage axillary vein stent grafting across the AVF provided a good technical result. It remains to be defined whether this is durable in the long term.

Intentional coverage of dominant vertebral arteries should be avoided. Subclavian injuries close to dominant vertebral arteries are best addressed surgically, where possible.

Supported by early reports with good safety and efficacy data,<sup>[3-6]</sup> the current evidence is limited to case reports and small case series.<sup>[7]</sup> There is, however, an evolving trend towards increasing utility of stent grafts to treat vascular trauma.<sup>[8,9]</sup> A systematic review by DuBose *et al.*<sup>[10]</sup> identified 32 published case reports and case series between 1996 and 2012. A total of 160 patients with SAVIs were stent grafted (150 subclavian; 10 axillary). Initial success was 96.9% (155/160). Six procedure-related complications and one procedure-related death were reported. Stent graft patency was 84.4% for a variable follow-up period (from hospital discharge to 70 months).

The largest series to date, as reported by Du Toit *et al.*<sup>[11]</sup> described 57 patients who underwent stent graft repair of penetrating subclavian injuries (1997 - 2007). There was one access-related complication requiring surgery and one perioperative death. Three patients had symptomatic early graft occlusion (<30 days). Twenty-five (44%) patients were followed up. There were two subsequent trauma deaths unrelated to the stent grafts. Five patients (20%) had significant stent graft stenosis that was managed successfully with endovascular intervention. Two patients (12%) had occluded stent grafts treated conservatively.

Limited comparisons between stent graft and open repairs show less blood loss, shorter operating times and fewer brachial plexus injuries in favour of stent grafts.<sup>[12-14]</sup> The reported early technical failure rates with surgery appear to be similar (~5%).<sup>[11]</sup> It is reassuring that the early and late conversion rates to open surgery remains consistently negligible in patients treated with stent grafts. The endosuitability of patients with subclavian injuries is ~50%.<sup>[15]</sup> Stent grafting is contraindicated in patients requiring surgery for associated injuries, e.g. tracheal or oesophageal injuries and infected haematomas. In our experience, large uninfected haematomas may be evacuated safely after 48 hours following stent graft repair. Advances in endovascular device technology and techniques are rapidly eliminating the technical constraints identified in earlier studies.

## Conclusion

Stent graft treatment is evolving as a complementary treatment strategy for SAVIs, and more studies will better define its role in this setting. Future directions should identify patients most likely to benefit in well-designed prospective studies.

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# The influence of diabetes mellitus on early outcome following carotid endarterectomy

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**Background.** There are few studies that look at the influence of diabetes mellitus on early outcome following carotid endarterectomy (CEA). Those available have reported conflicting results, with some showing poor outcome and others similar outcome to those without diabetes mellitus.

**Objective.** To assess the influence of diabetes mellitus on early outcome following CEA.

**Methods.** Clinical data on patients who had CEA over a 5-year period were acquired from a prospectively maintained computerised database. They were divided into two groups, namely diabetics and non-diabetics.

**Results.** Two hundred and sixty-four charts were analysed. There were no significant differences in patient demographics and risk factors for atherosclerosis between the two groups. The majority (71%) of patients had CEA for symptomatic carotid disease. Carotid shunting was performed selectively, and significantly more diabetic patients had CEA under the protection of a carotid shunt ( $p=0.0469$ ). Postoperative strokes, transient ischaemic attacks and deaths were not significantly different between the two groups.

**Conclusions.** Diabetes mellitus had no influence on the early surgical outcome following carotid endarterectomy.