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Device-specific Outcomes Following Endovascular Aortic Aneurysm Repair

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Abstract *Objective:* To compare aneurysm morphology, initial outcomes and mid-term results in patients receiving Talent or Zenith grafts for elective endovascular aneurysm repair (EVR).
Methods: Over a 6-year time period ending in 2007, 286 patients underwent elective EVR of infra-renal abdominal aortic aneurysms using Talent or Zenith devices. Patient demographics, aneurysm morphology and initial outcomes (primary-assisted technical success rates, 30-day limb occlusion, re-intervention and mortality) were compared using chi-squared tests or Student's *t*-tests. Kaplan–Meier curves were calculated to compare cumulative rates of freedom from type I or III endoleak, re-intervention, endograft patency and overall survival over mid-term follow-up.
Results: Adverse aneurysm morphology was more common in patients receiving Zenith stent grafts, with a greater proportion of shorter neck lengths ($<$10 mm, 12.9% vs 0%; $p \leq 0.001$) and severe neck angulation ($>60^\circ$, 25.0% vs 10.3%; $p = 0.002$). Equivalent primary-assisted technical success rates were achieved with both Talent and Zenith grafts (94.0% vs 96.1%; $p = 0.41$). A significant number of adjunctive procedures were required in both groups to obtain a proximal endograft seal, with relatively more procedures performed in the Talent group (28.6% vs 12.4%; $p = 0.003$). Early outcomes were similar for 30-day re-intervention (5.3% vs 3.9%; $p = 0.91$), 30-day limb occlusion (1.5% vs 2.6%; $p = 0.51$), 30-day morbidity (6.8% vs 11.8%; $p = 0.15$) and 30-day mortality (4.5% vs 3.9%; $p = 0.80$).

The cumulative incidence of freedom from re-intervention was $88.3 \pm 2.9\%$, $86.1 \pm 3.3\%$ and $84.1 \pm 3.9\%$ at 1, 2 and 3 years respectively. There were no significant differences between Talent and Zenith groups for re-intervention, type I or III endoleak or limb occlusion rates over the same time period. Overall patient survival was $88.4 \pm 2.85\%$ at 1 year, $83.7 \pm 4.0\%$ at 2 years and $78.9 \pm 5.5\%$ at 3 years.
Conclusions: Equivalent primary-assisted technical success rates can be achieved using either Talent or Zenith endografts for endovascular aneurysm repair, but operating teams should be prepared to perform additional adjunctive procedures to obtain a primary proximal seal with

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either stent. The Zenith endograft performed well in the context of less favourable pre-operative aneurysm morphology. Both Talent and Zenith endografts appeared equally durable in the medium term.

Introduction

Techniques of endovascular aortic aneurysm repair (EVR) have now become well established. Although early problems with commercial endografts resulted in several devices being withdrawn from the market, technology for currently used stent grafts is now relatively stable with improved outcomes.[1,2] To date, major randomised trials for EVR have primarily focused on comparing outcomes of EVR with open repair,[3,4] and there are no randomised trials comparing current devices for superiority of performance.

A single-centre comparative analysis of device-specific outcomes in Ancure, AneuRx, Excluder, Talent and Zenith devices was recently published by Ouriel et al.[5] Although overall survival was found to be diminished in the Zenith group, there were no significant differences in aneurysm-related death, type I or III endoleak or re-intervention rates. However, there did appear to be significant differences in frequency of limb occlusion and endoleak of any type between groups, with limb occlusion occurring most frequently with the Ancure device ($11 \pm 4.6\%$ at 12 months; $p = 0.009$) and endoleak of any type with the Excluder devices ($64 \pm 11\%$ at 12 months; $p = 0.003$).

The majority of infra-renal endovascular aneurysm repairs in Europe are performed using either the Zenith endograft (Cook Inc., Bloomington, IN, USA) or the Talent device (Medtronic, USA).[2,3,6] A comparison of these endografts was recently published in a post hoc analysis of data acquired through the UK EVAR trials.[6] Secondary intervention rate, aneurysm-related mortality and all-cause mortality for EVAR patients receiving Zenith or Talent endografts were investigated. No difference was found in the performance of either stent, but the perceived trend of results for endoleak and secondary intervention appeared to slightly favour patients with Zenith (vs Talent) endografts.

Although morphologic characteristics of the proximal aortic neck and size of the underlying aneurysm are known to influence the effectiveness of aneurysm exclusion and the durability of endograft attachment,[7,8] comparative studies of device-specific outcomes to date have reported little information regarding initial aneurysm morphology.

The aim of this study was to compare aneurysm morphology, initial outcome and mid-term results in patients receiving Talent or Zenith grafts for elective endovascular aneurysm repair (EVR).

Methods

Consecutive patients ($n = 310$) undergoing EVR at the St. George's Vascular Institute for infra-renal abdominal aneurysm, over a six-year period ending January 2007, were included in the study. During this time period, 24 EVRs were performed on patients for ruptured aneurysm or with sparsely used devices. These cases were excluded from further analyses, enabling a direct comparison between performances of Zenith ($n = 153$) and Talent ($n = 133$) endografts, under similar clinical circumstances. Numbers of procedures performed per year steadily increased, as did the ratio of Zenith to Talent devices implanted (Table 1). Device selection was performed using a multi-disciplinary process on an individual patient basis, with consensus opinion between vascular surgeons and radiologists. Endografts in both device groups were used outside their instructions for use (neck length >15 mm; angulation $<60^\circ$) in several patients. Zenith devices were selected for all patients with very short aneurysm neck lengths (<10 mm), and preferentially for patients with severely angulated aneurysm necks ($>60^\circ$).

Devices were compared using information obtained from a prospective database, used to record patient demographics, co-morbidities, aneurysm morphology, endograft details, operative outcomes, morbidity and mortality rates, and patient follow-up.

Aneurysm neck morphology was categorized by senior radiologists, reporting pre-operative computed tomography (CT), according to a recommended grading system for definition and categorisation of initial morphological aneurysm status.[9] Anatomical characteristics measured included neck length (>25 mm, 15–25 mm, 10–15 mm and <10 mm), diameter (<24 mm, 24–26 mm, 26–28 mm and >28 mm), angulation ($<30^\circ$, 30–45°, 45–60° and $<60^\circ$) and overall aneurysm size (<55 mm, 55–65 mm, 65–75 mm and >75 mm). Expert radiological opinion was used to decide upon suitability of iliac artery morphology for access purposes, with a global evaluation of adequate diameter (>7 mm), patency, tortuosity and extent of calcification. If iliac artery morphology was considered potentially inadequate for device delivery on the basis of CT findings, pre-operative diagnostic arteriography was performed. All patients underwent duplex and CT imaging prior to discharge, except those patients with significant renal insufficiency, where duplex scanning showed no evidence of type I or III endoleak. In these patients, CT scanning was delayed to six weeks post-operatively, and performed with a reno-protective regime of intravenous hydration combined with oral *N*-acetylcysteine. Further duplex imaging was obtained following discharge at six weeks,

Table 1 Endovascular devices used

Year	Talent (%)	Zenith (%)
2001–2002	5 (83.3)	1 (16.7)
2003	18 (51.4)	17 (48.6)
2004	30 (62.5)	18 (37.5)
2005	47 (50.0)	47 (50.0)
2006–2007	33 (32.0)	70 (68.0)

3 months, 6 months, 12 months and yearly thereafter, in combination with clinical history and examination.

Initial outcome measures of operative outcome included primary-assisted technical success rates, 30-day re-intervention, limb occlusion, and morbidity and mortality rates. Initial and ongoing rates of endoleak, re-intervention, limb occlusion and patient survival were compared to mid-term follow-up.

Reporting of all operative outcomes was based on recommended reporting standards for endovascular aneurysm repair.[10] Primary-assisted technical success was defined as the successful introduction and deployment of the device in the absence of surgical conversion, mortality, type I or III endoleak, limb occlusion, with or without unplanned adjunctive procedures. Type I endoleak was defined as perigraft blood flow caused by inadequate seal at either the proximal or distal graft ends. An endoleak caused by fabric disruption or component disconnection was classified as a type III endoleak. Conversion from endovascular to open repair was defined as primary if required at the original operation or secondary if performed on a subsequent occasion.

Deaths and morbidity occurring within 30 days of the operative procedure were considered procedure related. Deaths occurring after 30 days were defined as late deaths. Aneurysm-related deaths were defined as all deaths due to aneurysm rupture, a primary or secondary procedure, or surgical conversion. Causes of death were classified as verified (autopsy) or probable (consistent with reliable observation during the terminal illness). When these criteria could not be met, the cause of death was classified as indeterminate.[10]

Definitions for significant in-patient morbidity were based on standards published by the Ad Hoc Committee for Standardized Reporting Practices in Vascular Surgery of the Society for Vascular Surgery/American Association for Vascular Surgery.[10] Minimum inclusion criteria for significant (moderate to severe) systemic complications included cardiac (symptomatic requiring medical intervention), renal insufficiency (prolonged hospitalisation or dialysis), cerebrovascular (delayed recovery or CT confirmed cerebrovascular event), deep vein thrombosis (requiring medical intervention), pulmonary embolus (requiring medical intervention), coagulopathy (requiring transfusion therapy), bowel ischaemia (requiring intervention), gastrointestinal bleed (requiring endoscopic or surgical intervention), severe sepsis (documented infection with new organ dysfunction) and spinal cord ischaemia (delayed recovery or permanent deficit). Patient morbidity due to access site complications (haematoma, infection, false aneurysm or lymphocele requiring evacuation, debridement, repair or open drainage) and post-operative peripheral arterial complications requiring further intervention were also included.[10]

Statistical analysis

Comparative analyses of patient demographics and initial outcomes were performed using chi-square or Student's *t*-tests as appropriate. Ongoing risks for endoleak, re-intervention, limb occlusion and survival were defined in binary fashion for each type of endograft. Binary outcome events were analysed over the observed mid-term follow-up period using the Kaplan–Meier method.

Results

During the 6-year time period, 286 patients underwent elective EVR for infra-renal aortic aneurysm using Talent ($n = 133$) or Zenith ($n = 153$) devices, ranging in age from 43 to 89 years. Patient demographics, co-morbidities and initial operative outcomes are summarised in Table 2. Early morbidity and mortality rates were similar between device groups. Twelve patients (4.2%) died within 30 days of the initial procedure, including one patient due to aneurysm rupture and one patient due to retroperitoneal haemorrhage, both in the Talent group. Twenty-seven patients (9.2%) developed one or more significant procedure-related morbidities. Causes of 30-day morbidity and mortality are presented in Table 3.

Median length of follow-up was 16 months (range, 0–70 months). No patients required primary or secondary conversion to open repair during the course of the study and there were no device failures. Late mortality rates were similar between device groups. Out of twenty-eight late deaths during the study follow-up period, one known aneurysm-related death occurred in a patient receiving a Zenith endograft, who suffered an aneurysm rupture at two years following the primary procedure. Other causes for late death were pneumonia (8), myocardial infarction (4), malignancy (3), mesenteric ischaemia (1) and indeterminate (11).

Initial operative outcomes

Equivalent primary-assisted technical success rates were achieved in both Talent and Zenith groups (94.0% vs 96.1%; $p = 0.41$). Significantly more patients in the Talent group required primary adjunctive procedures to obtain a proximal seal (28.6% vs 12.4%; $p = 0.003$). Palmaz stent deployments were more common in the Talent group (21/133 vs 14/153; $p = 0.005$), but the numbers of patients requiring an aortic cuff extension were similar in both groups (10/133 vs 5/153; $p = 0.11$).

Early outcomes were similar between Talent and Zenith groups for 30-day re-intervention (5.3% vs 3.9%; $p = 0.91$), 30-day limb occlusion (1.5% vs 2.6%; $p = 0.51$), 30-day morbidity (6.8% vs 11.8%; $p = 0.15$) and 30-day mortality (4.5% vs 3.9%; $p = 0.80$).

Aneurysm morphology

Mean pre-operative aneurysm morphological diameters were similar between Talent and Zenith device groups, at 61.5 mm vs 62.7 mm; $p = 0.39$. After categorisation according to aneurysm morphological status, patients receiving Zenith stent grafts had a significantly greater proportion of aneurysms with adverse neck morphology, including shorter neck lengths (<10 mm, 12.9% vs 0%; $p < 0.001$) and severe neck angulation (>60°, 25.0% vs 10.3%; $p = 0.002$) (Fig. 1).

Table 2 Patient demographics and early outcomes

Demographics	Patient number (%)		*p*-Value
	Talent ($n = 133$)	Zenith ($n = 153$)	
Age	73.2 (7.44)[a]	73.5 (8.3)[a]	0.86
Male	119 (89.5)	139 (90.8)	0.71
Smoker	107 (80.5)	127 (83.0)	0.58
Diabetes	20 (15.0)	15 (9.8)	0.18
Hypertension	99 (74.4)	96 (62.7)	0.03
Hypercholesterolaemia	74 (55.6)	97 (63.4)	0.18
Coronary artery disease	62 (46.6)	75 (49.0)	0.68
Cerebrovascular disease	17 (12.8)	22 (14.4)	0.69
Chronic obstructive pulmonary disease	33 (24.8)	33 (21.6)	0.52
Renal failure	26 (19.5)	24 (15.7)	0.39
General anaesthesia	116 (87.2)	139 (90.8)	0.33
V-POSSUM	20.8 (5.4)[a]	20.7 (4.72)[a]	0.98
GAS	80.7 (10.4)[a]	82.7 (11.3)[a]	0.21
mCPI	1.82 (11.2)[a]	3.68 (11.5)[a]	0.21
CPI	1.84 (11.1)[a]	3.63 (11.5)[a]	0.16
Primary-assisted technical success	125 (94.0)	147 (96.1)	0.41
Proximal adjunctive procedures	38 (28.6)	19 (12.4)	0.003
30-day re-intervention	7 (5.3)	6 (3.9)	0.91
30-day limb occlusion	2 (1.5)	4 (2.6)	0.51
30-day mortality	6 (4.5)	6 (3.9)	0.80
30-day morbidity	9 (6.8)	18 (11.8)	0.15

V-POSSUM, Vascular Physiology and Operative Severity Score for the enUmeration of Mortality and Morbidity; GAS, Glasgow Aneurysm Score; mCPI, modified customised probability index; CPI, customised probability index.
[a] Mean (±SD).

In patients with severely angulated necks (>60°), 15 patients received a Talent endograft and 36 patients received a Zenith stent. The mean degree of angulation was greater in the Zenith group (76.1 ± 16.5 vs 67.5 ± 6.7; $p = 0.03$). Of these patients, eight (53%) receiving a Talent device developed a type I endoleak, compared to seven patients (19%) in the Zenith group ($p = 0.0005$). Eighteen patients in the Zenith group received a Zenith endograft in the context of an extremely short aneurysm neck (<10 mm), with a mean neck length of 7.2 ± 1.9 mm. Of these patients, seven (38.9%) developed type I endoleaks.

Table 3 Patient morbidity and mortality

	Patient number
Morbidity	
Myocardial infarction	5
Pneumonia	6
Renal impairment	7
Sepsis	2
Peripheral arterial	7
Wound debridement/drainage	3
Gastro-intestinal haemorrhage	1
Mortality	
Aneurysm rupture	1
Gastro-intestinal bleed	1
Ischaemic bowel	1
Myocardial infarction	3
Multi-organ failure	2
Pneumonia	3
Retroperitoneal haemorrhage	1

Mid-term results

The overall cumulative incidence of patients remaining free from type I or III endoleak was $93.5 \pm 2.2\%$ at 1 year, $90.2 \pm 3.0\%$ at 2 years and $85.1 \pm 5.2\%$ at three years, with similar results for each device group (Fig. 2). The corresponding cumulative results for patients remaining free from re-intervention over the same time period were $88.3 \pm 2.9\%$, $86.1 \pm 3.3\%$ and $84.1 \pm 3.9\%$. There were no significant differences between Talent and Zenith device groups for rates of re-intervention and limb occlusions over 36-month follow-up (Figs. 3 and 4). Overall patient survival was $88.4 \pm 2.85\%$ at 1 year, $83.7 \pm 4.0\%$ at 2 years and $78.9 \pm 5.5\%$ at 3 years. Both Zenith and Talent device patient groups had similar survival rates (Fig. 5).

Discussion

Modern endograft design has improved the results of endovascular aneurysm repair, but little data is available for comparison of device-specific outcomes to date. Although significant differences may exist between stent grafts of differing designs, current reported data would suggest that each stent graft has its drawbacks, and no single device can be regarded as ideal in all cases. This study provides a single-centre comparison of stent-graft

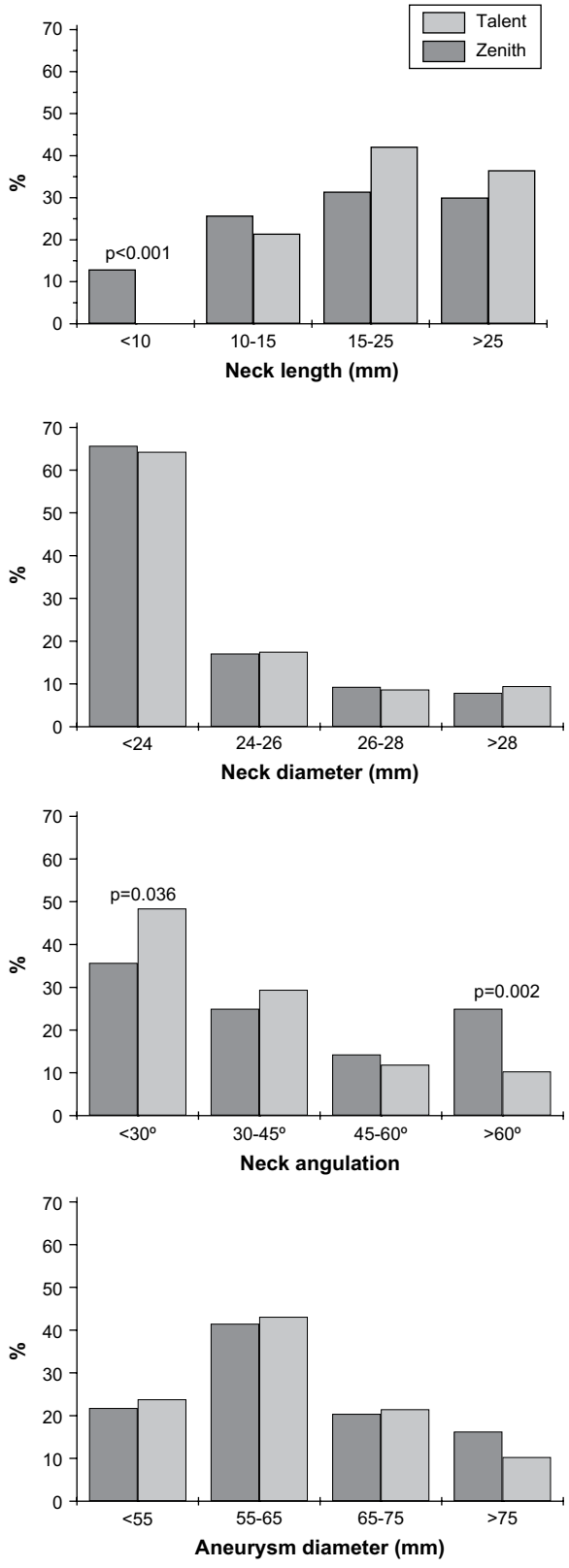

Figure 1 Comparison of aneurysm morphology in Talent and Zenith patient groups.

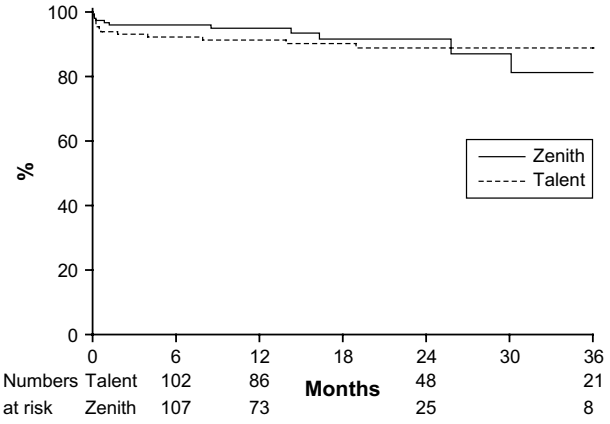

Figure 2 Freedom from type I or III endoleak over mid-term follow-up.

performance using prospectively collected data, but in the absence of randomisation, caution must be applied to the interpretation of results.

Zenith grafts were preferentially used for angulated or short aneurysm necks in this study. The Zenith device incorporates a bare proximal stent with 10 barbs for supra-renal fixation, whereas the fixation of Talent stents relies on radial force. In experimental studies on human cadavers, proximal fixation has been shown to be very secure with barbs, with the mean displacement force required to displace a Zenith endograft five times greater than that for Talent stents, at 24 N (23—26.5) vs 4.5 N (1.3—5.5) respectively.[10] However, it must be acknowledged that both Talent and Zenith grafts were used outside their instructions for use on several occasions in aneurysm morphology that they were not designed for.

Current reporting standards for endovascular repair recommend limited pre-operative classification criteria for aneurysms according to site, aetiology and clinicopathologic manifestations on the basis that over-classification can result in small patient subgroups that preclude meaningful data analysis. However, precise morphological categorisation is an essential inclusion in studies comparing device performance, as aneurysm diameter, proximal aortic neck diameter, infra-renal neck length and severe

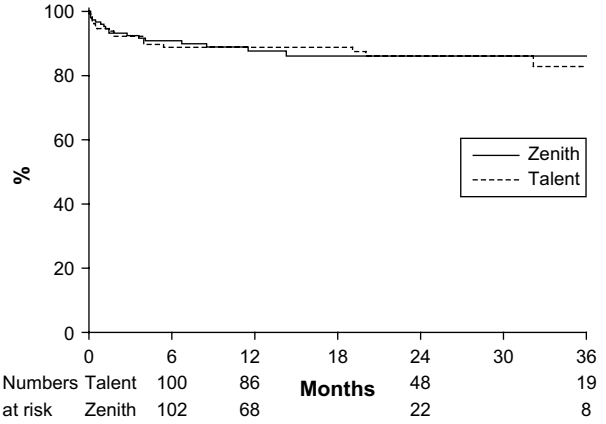

Figure 3 Freedom from re-intervention over mid-term follow-up.

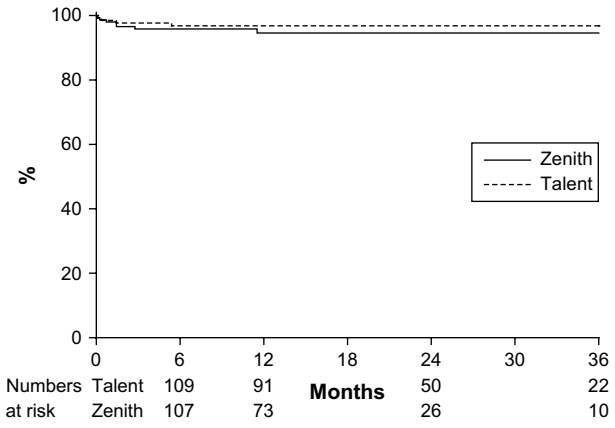

Figure 4 Freedom from limb occlusion over mid-term follow-up.

neck angulation are all known to significantly affect outcome following endovascular aneurysm repair.[11–13] In device-specific results from the UK EVAR trials, mean morphological characteristics of aneurysm size, neck diameter and neck length were reported, but not neck angulation.[5] Using mean values to represent morphological aneurysm characteristics can be misleading, as the numbers of patients with adverse anatomical characteristics are not precisely defined. The numbers of procedures performed on aneurysms with short necks (<10 mm) or severe angulation (>60°) may be more relevant in terms of interpreting device-specific outcomes.

The main factor affecting primary technical success in this study appeared to be adequate sealing at the proximal anchor zone. Our unit follows an aggressive protocol for the on-table assessment and management of type I endoleaks, which could explain why a significant number of patients in both groups required proximal adjunctive procedures to obtain a primary seal. All patients receive routine balloon dilatation at anchor zones followed by arteriography. For type I proximal endoleaks without graft malposition during stent deployment, a giant Palmaz stent dilated to 2 atm is used to encourage stent apposition to the proximal neck. However, if an endoleak appears to be due to graft migration during deployment, the graft is extended by using a proximal aortic cuff, generally oversized to prevent further endoleaks. Although patients with Talent devices required a greater number of proximal additional endovascular interventions, there were no observed differences in mid-term outcomes for either device groups. Similar findings are reported from the EUROSTAR registry, where the use of proximal aortic cuffs in 259 out of 6668 patients requiring EVR procedures did not influence outcome of endoleak of any type at 4 years.[14]

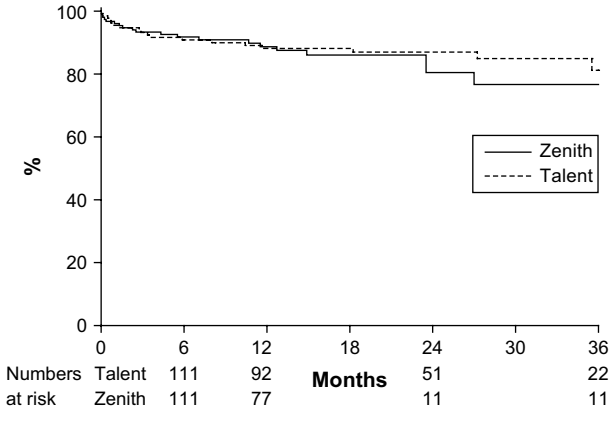

Figure 5 Patient survival over mid-term follow-up.

There were no significant differences in device performances over mid-term follow-up, with similar rates of type I or III endoleak, re-intervention, limb occlusion and overall survival. Although apparently lower cumulative incidences of secondary intervention were recently reported in 2846 patients on the EUROSTAR registry, at 6.0%, 8.7% and 12% at 1, 2 and 3 years respectively, the report excluded all re-interventions occurring within one month following the index endovascular procedure.[15] Our mid-term results included an initial 30-day re-intervention rate of 5%. Once this is taken into account, overall re-intervention rates in this study are entirely consistent with the EUROSTAR data.[16]

Overall patient survival has previously been reported to be diminished when using Zenith stents in a single-centre series assessing the performance of five devices (Ancure, AneuRx, Excluder, Talent and Zenith) in 703 patients undergoing EVR for infra-renal abdominal aneurysm repair.[4] Conversely, in the EVAR trials, the trend in all-cause mortality appeared to be greater in Talent stents.[5] Our study found no significant differences in all-cause mortality between device groups. Overall all-cause mortality in this study was 21% at three years, compared to 28% at four years in the EVAR I trial.[2]

In summary, this study suggests equivalent primary-assisted technical success rates can be achieved with both Zenith and Talent stents for endovascular infra-renal aneurysm repair. The Zenith stent performed well in the context of less favourable aneurysm morphology. Both stents required a significant number of proximal adjunctive procedures and operating teams should be adequately prepared for management of on-table proximal type I endoleaks. Talent and Zenith stents performed equally well in the medium term. Constant refinement and redesign of current endografts are likely to make adequately powered randomised trials unlikely to compare different stent designs, but device performance should be reported with adequate details of aneurysm morphology.

Conflict of Interest

The authors have no conflicts of interest.

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