

OPINION ARTICLE

A Japanese Semi-Custom-Made Najuta Fenestrated Stent-Graft System is a Cutting-Edge, Innovative Endovascular Technique

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Abstract

Although aortic medicine has generally undergone remarkably huge and ultrarapid progress in recent decades, practically in every medical discipline, concerning the most up-to-date both basic and clinical understanding (bench to bedside translational research) and multidisciplinary aortic disease treatment modalities, aortic pathology still has very high mortality and morbidity rates worldwide (particularly aortic aneurysm), making further medical advances an urgent and mandatory key medical focus. The previous 30 years, and even a bit more, were a time of the witnessed

creation of numerous very useful and versatile technical apparatuses used for the endovascular stent-graft restoration of Thoracic Aortic Aneurysms (TAA). This text argues (pro and contra arguments) and highlights the unique biomechanical characteristics of the cutting-edge radiological armamentarium, the Japanese semi-custom-made Najuta fenestrated stent-graft (SB-Kawasumi Laboratories, Inc., Kanagawa, Japan), the structural arrangement, angiological methods, and provides a concise but thorough analysis of treatment outcomes based on the most current literature data. It also provides a brief description of its wall structure, main clinical implications with workflow, shortcomings, and, lastly, documented advantages.

Key Words: *Najuta stent-graft system; Thoracic aortic aneurysm; Endovascular treatment; Complex anatomy*

Introduction

In the past decenary, the scientific community has advocated for the aorta to be viewed more as an independent target organ, suggesting a holistic medical strategy towards understanding aortic diseases, as a more practical approach. The term aortic aneurysm refers, generally speaking, to a pathological dilatation of the normal aortic lumen (at least 1.5 times higher diameter than

the expected normal diameter of a given normal aortic segment), involving one or concomitantly several different wall segments [1,2]. TAA remains, even today, a potentially highly fatal disease (approximate prevalence is around 7/100,000 subjects per year), with devastating consequences, characterized by abnormal dilation of the thoracic aorta (ascending, arch, or descending thoracic aorta), whereby the

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structural integrity of the arterial vessel wall is compromised, and its endovascular treatment is in practice, still quite difficult [1].

Main Discussion

In TAA treatment, there are more treatment options, or possibilities within the so-called most updated therapeutic landscape: vascular surgery as the first option, still being considered as the gold standard, interventional radiology, hybrid procedures, and conservative pharmacotherapy [3]. Vascular surgical treatment for TAA and aortic dissection usually and traditionally means, graft or stent-graft positioning through initial thoracotomy and/or laparotomy, which although in the most situation have better longer results – mainly in the term of overall survival, has also very significant flaws (i.e., significantly impacts patients physical and mental state due to numerous factors such as surgical incision spot and sternotomy, potential long lasting bleeding time, lengthy operation time, general anaesthesia and its risk, often high likelihood for pharmacoresistant intrahospital infections, and sometimes the need for surgical cardiopulmonary bypass grafting, etc.) [3,4,5]. Endovascular stent and/or stent-graft repair was therefore developed in the interventional radiology community (namely the first known documented and official clinical case report on the stent-grafts implementation was published in the year of 1988 by the Ukraine doctors – more precisely by Volodos et his coworkers) primarily to minimize the intrusiveness and traditional risks accounted for open vascular surgery (primarily for thoracic and abdominal aortic chronic steno-occlusive and aneurysmatic diseases), and secondary as an acceptable therapeutic option for subjects who are for some reasons (mainly to weak performance state) considered high-risk or even contraindicated (absolute or relative contraindications) for open vascular surgery [3,4,6].

Devise Description

The Najuta stent-graft technical approach/

strategy, on the other hand, is a well-composed original combination of a self-expandable stainless-steel Z-stent specifically adapted for various vascular interventions (large diameters, high rigidity, high radial force, and large interstices that prevent occlusion of venous and arterial tributaries) and a synthetic, thin, expanded polytetrafluoroethylene graft (more precisely, a metallic stent bonded to a graft), and involves covering the pathological segment with a stented artificial graft (Figure 1). However, in Thoracic Endovascular Aortic Repair (TEVAR) for supra-aortic arch diseases, special attention must be given to preserving the supra-aortic arch branch vessels (the brachiocephalic artery, the left common carotid artery, and the left subclavian artery) and ensuring their proper hemodynamic function [3,7]. Standard stent-grafts also often require additional and sometimes complicated long-lasting procedures (i.e., bypass surgery, chimney technique, debranched technique, parallel graft technique, in addition to in situ fenestration, etc.) that are considered high-risk in patients with poor health conditions, to reconstruct the supra-aortic arch offshoot vessels. The Japanese semi-custom-made Najuta fenestrated stent graft (SB-Kawasumi Laboratories, Inc., Kanagawa, Japan) was constructed, aiming to address this important technical issue in a completely endovascular manner, with the possibility to obtain a long proximal sealing length, thanks to the fenestrated and scalloped design [5]. It is a 3D Japanese semi-custom-made patient-specific fenestrated stent-graft system, made by sewing an ultrathin woven polyester graft (Ube Industries, Tokyo, Japan) onto a self-expanding stainless-steel stent (Gianturco Z stent; Cook Medical, Bloomington, IN, USA), with a score of different-sized fenestrations aimed primarily to protect the supra-aortic arch offshoot arteries, and in more complicated clinical scenarios, offers a far simpler approach to preserving the arch vessels without the absolute necessity of complex and much riskier surgical branched techniques (Figure 2) [8].

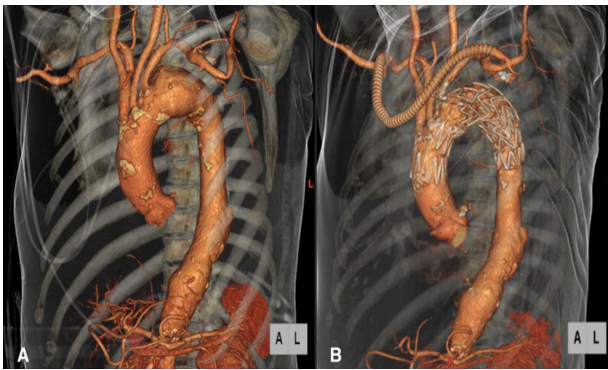


Figure 1) Depiction of a distal aortic arch fusiform aneurysm, which also involved the left subclavian artery origin, from the left anterolateral projection angle. The first is preoperative CT angiography, as the left image, and postoperative CT angiography, as the right image, with the example of debranching bypass and exclusion of the aneurysmatic dilatation using the custom-made Najuta thoracic stent-graft system [9].



Figure 2) Another practical example of a semi-custom-made Najuta fenestrated stent-graft unique biomechanical structure. The white arrow represents a third fenestration in order created with the idea to maintain the left common carotid artery blood flow. Overall, both the second and proximal sections of the third (white arrow) fenestrations also protect the brachiocephalic artery. The most proximal fenestration was created practically to exclude the chance of complicated unintentional distal migration of a stent-graft covering the brachiocephalic artery [10].

Clinical Outcome

Another crucial strength of the Najuta stent-graft system is that it is considered particularly effective for the lesion at the aortic arch lesser curvature, where the TEVAR technique, using a general type-tube stent graft, is very often unsuccessful, presumably mainly due to a short proximal neck [7,8]. On the other hand, such aneurysmatic dilatations are, in most instances, far more successfully treated with the Najuta stent-graft system, again presumably due to its

technical advantages (a longer landing zone and increased proximal neck length thanks to the created multiple fenestration, etc.) [8]. In line with previous, Sato H. et al in a retrospective study analysis, in a two different Japanese institution, with total 37 involved subjects, after mean follow-up period of 2.9 ± 2.9 years, reported a very good results with a very high technical success rate of 97.3% (36 of 37 respondents; mean proximal neck length from the left common carotid artery was 20.1 ± 5.3 mm. 10 patients with type Ia endoleaks - 27.8%, 6 with stroke - 16.7%, and 1 with paraplegia - 2.8% as postoperative complications) (Figures 3 and 4) [11]. Of note, on the other side, although some technical issues in the Najuta system have been reported, Italian Najuta registry collaborators, in a technical note, gave some practical advice in the form of five bail-out procedures or evidence-based strategies (positioning of a coaxial extra-stiff guidewire; positioning of a long introducer sheath down to the aortic root from the right brachial access; inflation of a balloon inside the ostia of the supra-aortic vessels; inflation of a balloon inside the aortic arch - coaxial to the device, and transapical access technique), in resolving those problems [12].

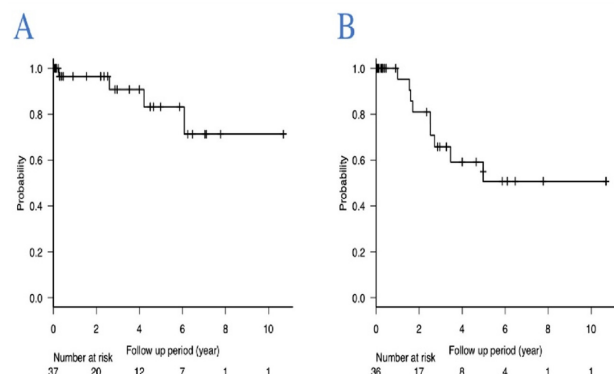


Figure 3) Kaplan–Meier statistical survival curves graphically estimating the median overall survival rates and the rates of exclusion from aorta-interconnected complications (i.e., aneurysmal enlargement, stent-graft migration, rupture, retrograde type A dissection, etc.) after TEVAR using the Japanese Najuta fenestrated stentgraft system. (A) Median overall survival rates at 1, 3, 5, and 7 years were 96.4%, 90.8%, 83.2%, and 71.3%, respectively. (B) Rates of absence from aorta-associated complications at 1, 3, 5, and 7 years were 90.5%, 65.8%, 50.7%, and 50.7%, respectively [11].

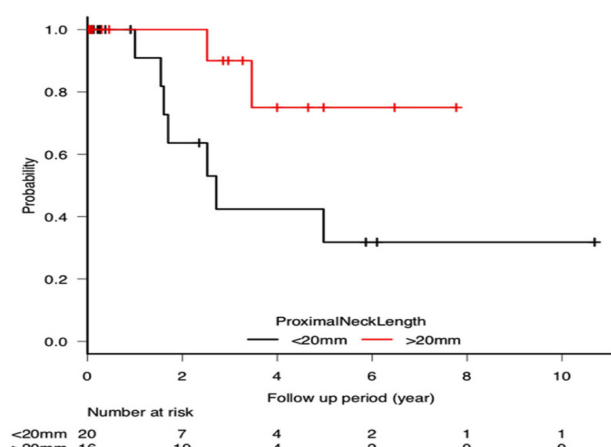


Figure 4) Another kaplan–meier statistical curvature estimating the precise rates of absence from aortaconnected events in the two classes separated and grounded on the proximal neck length from the left common carotid artery of 2 cm (cut-off value) as key criteria. The class with less than 2 cm distance had statistically significantly lower rates of absence from aorta-connected incident (final log-rank test analysis: $P=0.046$; therefore, since the P value is less than 0.05, rejecting the null hypothesis and meaning a statistically significant difference in event rates) [11].

Comparative analysis with limitations and complications

Previously mentioned vascular surgical interventions (i.e., chimney and debranched technique, parallel graft technique in addition to in situ fenestration, triple-barrel chimney graft technique, etc.) do not involve graft implementation for arch aneurysms treatment while preserving the supra-aortic offshoot circulation, and therefore, due to their potential complication, can be considered as surgical options for TAA, but not as first-choice therapy. Nevertheless, in the chimney technique, type Ia endoleak has a high incidence, presumably due to the gap between the main and chimney graft (the type Ia endoleak occurrence has been reported as a major flaw, ranging from 20% to 40%) [13]. Opposed to the previous, the prevailing problem with the debranched technique is that, although arterial tributary bypass can provide adequate and competent proximal landing distance, but the surgical procedure for the left common carotid and the brachiocephalic arteries may have stroke as a sequela, documented in a very concerning incidence of approximately 1% to 27% cases [14].

On the other hand, the approximate stroke incidence associated with the Najuta stent-graft system was documented to be around 0% to 5%, which is generally significantly lower than that of the other aforementioned techniques [15]. In a large multicentric study from Japan (collected data from 35 high-volume Japanese centers), from Yokoi Y. et associates, reporting their institutional experience with a relevant total number of 383 examiners undergoing total endovascular arch repair with the fenestrated custom-made device Najuta stent-graft, 30-day mortality and stroke rate were exceptionally low, at 1.6% and 1.8%, respectively [16]. Nevertheless, these structural apparatus systems also have significant drawbacks, i.e., nonconformity of 2.5 cm length stents and their low radial force due to the stent's lack at the fenestrated lesion. The proximal sealing can frequently be inappropriate in practice, even if the proximal landing zone is from the ascending aorta. Hence, type Ia endoleak occurrence was increased compared with other tools, documented as an approximate range between 4% to 33% [15,17]. Kurimoto with his co-workers had a very similar study design comparable to the previously mentioned article from Sato H. with colleagues, both which analysed Najuta stent-graft implementation effects for 37 subjects with arch aneurysms; the incidence of type Ia endoleaks was 32.4%, and the statistical rates of absence from aorta-interrelated events (aneurysmal enlargement, stent-graft migration, rupture, retrograde type A dissection, etc.) at 2 and 5 years were 88.5% and 56.5%, in the first study, versus Sato H. et al. manuscript, whereas in contrast, these main results are quite similar (Figures 3 and 4). The incidence of type Ia endoleaks was 27.8%, with the rate values at 2 and 5 years being 81.0% and 50.7%, respectively [10,11]. Additionally, in a head-to-head comparison, the first study yielded generally better results with longer follow-up, including improved stent-graft patency, albeit with a slightly higher incidence of type Ia endoleaks. Moreover, groups with a proximal neck length of less than 2 cm showed an increased aorta-connected complication rate

in the chronic phase of follow-up time, and even a short proximal neck length was identified as an independent risk factor for type Ia endoleaks. Therefore, a distance less than 2 cm is definitely the clinical limitation for treatment and a cut-off value, as it is inappropriate for proximal sealing; and every instruction for use should advocate eluding it for widespread use due to its drawbacks.

To summarize the previous paragraph, I would note that the Najuta stent-graft is a very important, acceptable, and safe treatment modality for subjects at high risk for total arch replacement and surgical procedures, such as debranched or chimney techniques, particularly when the proximal neck length from the left common carotid artery exceeds 2 cm (cut-off value) [10,11].

Lastly, regarding the cost-benefit analysis, although this device system has high initial device costs, it ultimately brings significant economic cost savings by reducing, and in some cases, completely avoiding expensive complications and extended hospitalizations [17,18]. Noteworthy is that both the economic, technical, and medical shortcomings of this system, as well as generally custom-made devices, at this moment are the long production time (approximately 4-8 weeks), which still significantly limits their application in the most urgent medical cases. Hopefully, future manufacturer developments will resolve those issues (it could potentially be managed with so-called parallel grafts, obtainable off-the-shelf and at a lower market price, only with a disadvantageous higher type I endoleaks incidence – i.e., gutter endoleak type; additionally, the new innovative design with inner branches could potentially accelerate their future construction as off-the-shelf custom-made devices) [19].

Conclusion

To sum up, in my final remarks, I would like to add that the main advantages of the Najuta stent-graft system, as proven and documented in evidence-based medicine publications,

compared with other endovascular, angi- or surgical techniques, are:

- TAA restoration.
- Aortic arch repair and distal aortic arch corrections.
- Patient-specific individual customization and approach (the preliminary pre-shape of the stent-graft can be optimized for each present clinical case, in both a fusiform or saccular aneurysm, by altering each stent connection location to approximate as much as possible the three-dimensional-3D real aortic arch flexion angle, allowing the best possible matching with the patient's individual anatomical state).
- Efficient also for highly complex and versatile anatomy (a rigid three-dimensional skeleton structure, short aneurysmal neck, tortuous aortic arch, compromised seal zone, shaggy aorta, bovine type of aortic arch as a variety, and other aortic anomalies, etc.).

Prevention of some serious postinterventional complication that occurs more often in alternative treatment regimens (type I-III endoleaks, particularly Ia endoleaks subtype, bird-beak configuration, strokes, paraplegia, paraparesis, retrograde type A dissection, distal stent-graft induced new entry, distal stent-graft migration, respiratory failure, congestive heart failure, etc.). Noteworthy, this stent-graft system and construction idea, with some adjustments, of course, has very high potential to further expand in a term of anatomical indications to be widely used also for other arteries (i.e., not only the thoracic aorta, but also visceral and peripheral arteries, etc.), and perhaps even to be a valid alternative for kissing stents in the management of arterial bifurcation diseases. Consequently, a large, multicenter, prospective cohort study (optimally both interventional and observational study types) with a long follow-up time, examining its durability, should be put in place to answer all these raised actual questions. What is certain, at this moment, is that this

technique, since its first clinical approval in Japan in 2013, although not yet used in my home country, Serbia, at present, is definitely very actively shaping the interventional radiology

community intercontinentally and beyond that has still perspective and room for further improvement.

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