

## Our experiences with proximal aortic anastomosis assist device in coronary artery bypass graft surgery

*Koroner arter baypas greft cerrahisinde proksimal aortik anastomoz destek cihazı ile deneyimlerimiz*

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### ABSTRACT

**Background:** This study aims to report our experiences with the proximal aortic anastomosis assist device during coronary artery bypass grafting.

**Methods:** Between January 2006 and May 2010, a total of 26 patients (23 males, 3 females; mean age 72.6±5.8 years; range 55 to 81 years) who underwent bypass surgery using the proximal aortic anastomosis assist device in our clinic were retrospectively analyzed. The indications for the utilization of the device were the presence of proximal aortic calcifications and atherosclerotic plaques in coronary artery bypass graft surgery and insufficient proximal aortic exploration additionally in redo coronary artery bypass graft surgery. Embolic events, neurological complications, the length of intensive care unit stay, and mortality rate were recorded.

**Results:** Off-pump single-vessel or two-vessel coronary artery bypass grafting without cardiopulmonary bypass was performed in 19 patients, while off-pump three-vessel coronary artery bypass grafting under cardiopulmonary bypass was performed in seven patients. Six patients underwent redo coronary artery bypass grafting. No neurological complications, embolic events or mortality were observed in any patients.

**Conclusion:** Proximal aortic anastomosis assist devices considerably facilitate proximal anastomosis in indicated patients undergoing coronary artery bypass grafting. We believe that the utilization of these devices may also reduce the proximal anastomosis site-related complications which may occur during coronary artery bypass grafting.

**Keywords:** Coronary artery bypass grafting; Enclose II anastomosis assist device; proximal anastomosis; proximal aortic anastomosis assist device.

### ÖZ

**Amaç:** Bu çalışmada koroner arter bypass greftleme sırasında proksimal aortik anastomoz destek cihazı ile deneyimlerimiz sunuldu.

**Çalışma planı:** Ocak 2006 - Mayıs 2010 tarihleri arasında kliniğimizde proksimal aortik anastomoz destek cihazı kullanılarak baypas ameliyatı yapılan toplam 26 hasta (23 erkek, 3 kadın; ort. yaş 72.6±5.8 yıl; dağılım 55-81 yıl) retrospektif olarak incelendi. Proksimal anastomoz destek cihazı kullanım endikasyonları, koroner arter baypas greft ameliyatında proksimal aortta kalsifikasyon ve aterosklerotik plak varlığı ve redo koroner arter baypas greft ameliyatında ilaveten yetersiz proksimal aortik eksplorasyondur. Embolik olaylar, nörolojik komplikasyonlar, yoğun bakım ünitesinde kalış süresi ve mortalite oranı kaydedildi.

**Bulgular:** On dokuz hastaya kardiyopulmoner baypas olmaksızın atan kalpte tek damar veya iki damar koroner arter baypas greftleme yapılırken, yedi hastaya kardiyopulmoner baypas eşliğinde atan kalpte üç damar koroner arter baypas greftleme yapıldı. Altı hastaya redo koroner arter baypas greftleme yapıldı. Hastaların hiçbirinde nörolojik komplikasyon, embolik olay veya mortalite gözlenmedi.

**Sonuç:** Koroner arter baypas greftleme yapılan endikasyonlu hastalarda, proksimal aortik anastomoz destek cihazları proksimal anastomoz için büyük kolaylık oluşturmaktadır. Bu cihazların kullanımının koroner arter baypas greftleme sırasında meydana gelebilecek proksimal anastomoz yeri ile ilişkili komplikasyonları da azaltacağı kanaatindeyiz.

**Anahtar sözcükler:** Koroner arter baypas greftleme; Enclose II anastomoz destek cihazı; proksimal anastomoz; proksimal aortik anastomoz destek cihazı.



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It is critical to evaluate preoperative risk factors to avoid postoperative neurological complications of coronary artery bypass grafting (CABG) such as stroke and cognitive dysfunction. It is well-established that advanced age, diabetes mellitus, hypertension, acute myocardial infarction, cerebrovascular incident, carotid artery disease, left ventricular dysfunction, chronic kidney disease, pulmonary disease, atherosclerotic proximal aorta, low cardiac output syndrome, and atrial fibrillation (AF) are significantly associated with neurological complications after CABG.<sup>[1]</sup>

In addition, the major intraoperative risk factors include aortic cross-clamping and ascending aorta manipulation.<sup>[2,3]</sup> Therefore, the surgeon must be careful about the nature of the ascending aorta and it must be ensured that there is no plaque in the ascending aorta before aortic clamping. It has been shown that side-clamping before proximal anastomoses (double-clamping technique) accounts for 28% of the embolic events after CABG.<sup>[4]</sup> The Enclose II anastomose device (Novare Surgical Systems, Inc., CA, USA), the proximal aortic anastomosis assist device, has been specifically designed to facilitate the anastomoses of the grafts to the proximal aorta during the beating heart CABG surgery.<sup>[5]</sup> It also helps the surgeon to complete the proximal anastomoses without aortic side-clamping.<sup>[6]</sup>

In this article, we aimed to report our experiences with the proximal aortic anastomosis assist device during CABG surgery.

## PATIENTS AND METHODS

Between January 2006 and May 2010, a total of 26 patients (23 males, 3 females; mean age 72.6±5.8 years; range 55 to 81 years) who underwent bypass surgery using the proximal aortic anastomosis assist device (Enclose II Anastomose Device; Novare Surgical Systems, Inc., CA, USA) in our clinic were retrospectively analyzed. The indications for the utilization of the device were the presence of proximal aortic calcifications and atherosclerotic plaques in CABG surgery and insufficient proximal aortic exploration additionally in redo CABG surgery. The ascending aorta was examined for any plaque or calcification by palpation intraoperatively. Embolic events, neurological complications, the length of intensive care unit (ICU) stay, and mortality rate were recorded.

The Novare Enclose device (Novare Surgical Systems) (Figure 1) consists of two parallel horizontal arms connected by a perpendicular, rectangular-shaped plastic housing. The lower arm is fixed in position; however, it's the distal tip can open into a diamond-shaped membrane turning a lever attached to the side

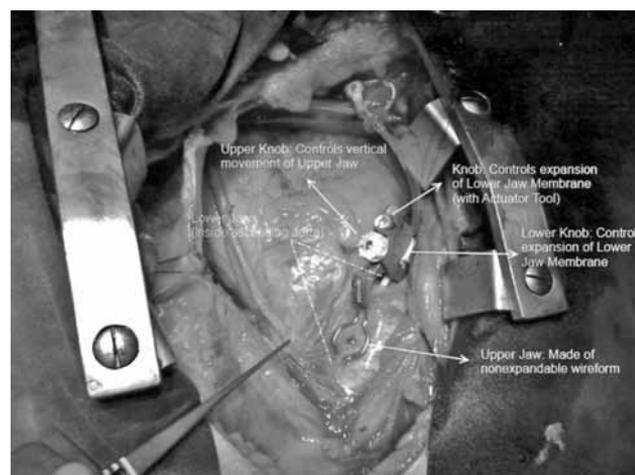
of the plastic housing. In the novel lower profile of the device (Novare Enclose II), a knob located on the superior aspect and operated by a special driver has replaced this lever and the membrane is set lower to preclude possible injuries. The back end of this arm is connected to the plastic tubing with a plastic stopper at the end. Plastic tubing is connected to a metal bar inside the lower arm which lies on top of the membrane and acts as a scaffold. In addition, there are two tiny holes on the superior aspect of this metal bar which allow blood to flow back to the attached plastic tubing. The upper arm is mobile. The distal end divides into two fork-like, diamond-shaped curved metal arms. The proximal end of the upper arm is attached to the plastic housing through a pivot and can be raised or lowered by means of a control knob at the superior aspect of the plastic housing. This allows the aortic wall at the proximal anastomosis site to be sandwiched between the two arms, thus achieving a bloodless field when a punch hole is made for the proximal anastomosis.<sup>[7]</sup>

All patients underwent isolated CABG surgery. All operations were performed under general anesthesia with median sternotomy. On-pump and off-pump CABG surgery techniques were used. The Enclose II anastomose device was used for the proximal anastomosis in accordance with the literature data.<sup>[7]</sup>

## RESULTS

Demographic characteristics of the patients and preoperative risk factors are shown in Table 1.

Off-pump single-vessel or two-vessel CABG without cardiopulmonary bypass was performed in 19 patients, while off-pump three-vessel CABG under cardiopulmonary bypass was performed in seven



**Figure 1.** The proximal anastomosis assist device (intraoperative view).

**Table 1. Demographic data and preoperative risk factors of the patients**

	n	%	Mean±SD	Min.-Max.
Age (years)			72.6±5.8	55-81
Body mass index			30.3±6.0	21-43
Ejection fraction (%)			34.1±7.1	25-45
EuroSCORE			6.0±2.7	3-13
Gender				
Male	23	88.5		
Diabetes mellitus	7	26.9		
Hypertension	16	61.5		
Chronic obstructive pulmonary disease	4	15.4		
Smoking	20	76.9		

SD: Standard deviation; Min.: Minimum; Max.: Maximum.

patients. Six patients underwent redo coronary artery bypass grafting.

The mean length of ICU stay was 1.2±0.4 days. No serious complications including neurological and embolic events, low cardiac output, prolonged duration of mechanical ventilation, renal failure requiring dialysis or revision surgery were observed. There was no in-hospital mortality.

## DISCUSSION

Coronary artery bypass grafting is one of the most commonly performed operations throughout the world.<sup>[8]</sup> Despite recent improvements in the cardiopulmonary bypass techniques, neurological complications still stand as one of the major causes of mortality and morbidity after CABG surgery.<sup>[8]</sup> Cerebral impairment is one of the main complications of CABG surgery which increases postoperative morbidity.<sup>[9]</sup> The incidence of neurological impairment after CABG has been reported to range between 0.4 and 13.8%.<sup>[1]</sup> Cerebral impairment may occur in two different types: type 1 can be seen as stroke, transient ischemic attack, and coma, whereas; type 2 can be seen as new deterioration in intellectual function, disorientation, confusion, agitation, disorientation, memory deficit, or seizure without evidence of focal injury.<sup>[1]</sup> The incidence of postoperative cognitive decline was 53 percent at discharge, 36 percent at six weeks, 24 percent at six months, and 42 percent at five years.<sup>[10]</sup> The manipulation of the affected and plaqued aorta is the main cause of the stroke after macro-embolizations from the atheromatous debris of these plaques.<sup>[11]</sup> In addition, intraoperative micro-embolizations of cerebral vessels play an important role in the postoperative cerebral dysfunction.<sup>[12]</sup>

The plaques of the ascending aorta noticed during surgery may pose a challenge for the proximal

anastomosis of the vascular grafts. The side-clamping of the plaqued areas may lead to aforementioned complications. In such cases, it is reasonable to perform proximal anastomosis without removing the aortic cross-clamp or with the aid of the proximal anastomosis assist device. On the other hand, it should be remembered that all devices which are applied to the ascending aorta may cause microembolisms during surgery and these microembolisms mostly occur while inserting and removing these devices.<sup>[2,3,12]</sup> Barbut et al.<sup>[11]</sup> reported that the majority of the postoperative microembolism cases had severe proximal aortic atherosclerosis and the separation of the debris mostly occurred during declamping. Therefore, it is suggested that the conventional method of double aortic clamping may increase postoperative neurological complications such as stroke, while single clamping may reduce these undesired adverse events.<sup>[3]</sup> Based on our experience, we believe that one of the main advantages of using a proximal aortic anastomosis assist device is that there is no need for aortic side-clamping. As a result, the risk of neurological complications which may occur by manipulating the plaqued aorta can be reduced.

On the other hand, some surgeons prefer single aortic clamping than double clamping due to neurological complications of the side clamping. Nisanoğlu et al.<sup>[8]</sup> reported that single clamping, although not sufficient individually, was favorable against the double clamping in elderly and atherosclerotic patients. Similarly, Us et al.<sup>[13]</sup> showed that single clamping significantly reduced the postoperative neurological complications in patients aged ≥70 years.

Furthermore, transcranial Doppler ultrasound findings confirmed that the avoidance of aortic side-clamping significantly reduced the intracranial microembolisms.<sup>[12]</sup> Therefore, we can suggest that the Enclose II device assistance in the proximal graft anastomosis can also reduce these microembolisms.<sup>[12]</sup>

Moreover, Akpınar et al.<sup>[6]</sup> published a report showing that the Enclose II device reduced cerebral microembolisms in beating heart CABG patients. In some redo CABG surgeries, the exposure of the proximal aorta may not be as clear as it is intended. In such cases, the proximal anastomosis device may facilitate help the surgeon to conduct the anastomoses easily. Also, Boova et al.<sup>[14]</sup> reported similar findings with the Novare Enclose proximal assist device, which was found to be safe facilitating suture construction of the proximal aortocoronary graft anastomosis. In our patients who underwent redo operations, this device also offered an easy way for the proximal anastomosis, when the exploration of the ascending aorta was complicated. It may also reduce the operation time and increase the comfort of the surgeon during surgery. As it is highly practical to use, we utilize this device in our daily off-pump CABG operations. We also believe that the main reason of the lack of neurological complications in our patients is lesser traumatization of the ascending aorta by the proximal anastomosis assist device.

On the contrary, Arai,<sup>[15]</sup> in his editorial paper, reported that the major drawback of the Enclose II anastomosis device was that it necessitated an alternate access site and some degree of aortic trauma might occur during the insertion and manipulation of the device. Nevertheless, being able to perform more than one anastomosis through a single insertion port is an advantage compared to other anastomosis assist devices. On the other hand, we have been using the proximal anastomosis assist device for four years for aforementioned indications and we have not been so far observed any complications such as stroke, embolism, or death.

In conclusion, technological improvements in cardiac surgery make the life of the surgeon much easier. Therefore, proximal aortic anastomosis assist devices considerably facilitate proximal anastomosis in indicated patients undergoing coronary artery bypass grafting. We believe that the utilization of these devices may also reduce the proximal anastomosis site-related complications which may occur during coronary artery bypass grafting.

#### **Declaration of conflicting interests**

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