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#### Araştırma Makalesi | Research Article

# FOLDED STENT: THE THIRD GENERATION TRICK TO IMPROVE THE MICROVASCULAR STENTING TECHNIQUE

FOLDED-STENT: MİKROVASKÜLER STENTLEME TEKNİĞINİ GELİŞTİRMEK İÇİN ÜÇÜNCÜ NESİL YÖNTEM

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#### ABSTRACT

**Objective:** Although microsurgical vessel anastomoses have become a routine procedure today, they are still among the difficult techniques to apply. The most important step in the success of the technique is the clear presentation of the vessel lumen. In this study, we aimed to describe a new technique that will provide an easier anastomosis by keeping the lumen open during microvascular anastomoses.

**Methods:** Four groups were formed using the chicken wing radial artery, which is an inanimate animal model. One of these was the control group who underwent standard microvascular repair. The second and third groups that followed were those in which two previously defined intravascular stenting techniques were applied. The fourth group was the Folded stent group that we just defined.

**Results:** Anastomosis time was found to be significantly longer when compared to other groups in our newly defined technique. This time was an average of 3 minutes. No significant difference was observed in terms of the number of sutures used in anastomoses. No posterior wall suture complication was observed in any specimen.

**Conclusion:** It has been seen that the "Folded-Stent" technique can be used safely like other stenting techniques in terms of keeping the lumen open during anastomosis and preventing the adhesion of the vessel walls. In clinical practice, it is an advantageous technique that can be used to prevent posterior wall suturing of small vessels, especially during venous repairs.

Keywords: Vascular anastomosis, microsurgery, stent, suture

#### ÖZ

Amaç: Mikrocerrahi damar anastomozları günümüzde rutin bir işlem haline gelmesine rağmen halen uygulanması zor teknikler arasındadır. Tekniğin başarısındaki en önemli adım damar lümeninin net olarak gösterilmesidir. Bu çalışmada mikrovasküler anastomozlarda lümeni açık tutarak daha kolay anastomoz sağlayacak yeni bir tekniği tanımlamayı amaçladık. Yöntem: Cansız bir hayvan modeli olan tavuk kanadı radial arter kullanılarak dört grup oluşturuldu. Bunlardan biri standart mikrovasküler onarım yapılan kontrol grubuydu. Takip eden ikinci ve üçüncü gruplar, önceden tanımlanmış iki intravasküler stentleme tekniğinin uygulandığı gruplardı. Dördüncü grup ise yeni tanımladığımız Folded stent grubuydu. Bulgular: Yeni tanımlanan tekniğimizde anastomoz süresi diğer gruplara göre anlamlı olarak daha uzun bulundu. Bu süre ortalama 3 dakikaydı. Anastomozlarda kullanılan sütür sayısı açısından anlamlı bir farklılık gözlenmedi. Hiçbir örnekte arka duvar sütür komplikasyonu gözlenmedi.

**Sonuç:** "Folded-Stent" tekniği, anastomoz sırasında lümenin açık kalması ve damar duvarlarının yapışmasını önlemesi açısından diğer stentleme teknikleri gibi güvenle kullanılabilir olduğu görülmüştür. Klinik pratikte özellikle venöz onarımlar sırasında küçük çaplı damarların arka duvar dikilmesini önlemek için kullanılabilecek avantajlı bir tekniktir.

Anahtar Kelimeler: Vasküler anastomoz, mikrocerrahi, stent, sütür

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#### Introduction

With the possibility of microsurgical vessel repair, many operations that once seemed impossible, such as replantation of severed limbs, and free tissue transplants, have become possible.<sup>1</sup> However, although microsurgical vessel repair is a routine procedure, it is still a difficult technique to apply today.<sup>2</sup> The most important of these difficulties and the situation that causes vascular anastomosis is the suturing of the posterior wall. At the same time, an appropriate number of sutures should be placed homogeneously at equal intervals throughout the vessel lümen.<sup>3,4</sup>

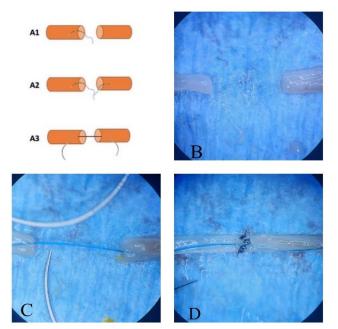
These problems become an even greater problem with veins because their walls stick together more easily than those of arteries. As a result, some authors have developed the technique of intravascular stenting (IVaS), which consists of placing a nylon monofilament suture in a vein to act as a temporary stent.<sup>5</sup> Studies comparing this technique with traditional sutures have reported difficulties with stent insertion and removal, especially thrombosis like complications due to stent related trauma to the vessel Wall.<sup>6</sup> Therefore, the "clip stent" technique was recommended to improve the IVaS technique.<sup>7</sup> In this technique, the double-needle monofilament suture is placed in the lumen of both ends of the vascular anastomosis and then the needle is passed through the vessel wall and pulled out from both sides, and the anastomosis is completed with the help of this stenting. An advantage of this technique is that stent removal is not traumatic. The disadvantage is that it causes leaks in each of the two remaining holes after needle removal.<sup>7</sup> It has been proposed to develop the "clip stent" technique to perform microsurgical anastomoses, by showing that it can be applied as a single needle with a technique called "pull out stent", which can be improved by removing the needles and placing and removing the stent with one hole in two places.<sup>8</sup> In this study, we further developed these two techniques, which were developed to keep the vessel lumen open during microsurgical vessel anastomosis, and defined a new technique we named "folded stent". To validate our hypothesis, we performed an experimental study by completing arterial anastomoses in the chicken wing radial artery, which is a commonly used microsurgical application model, with clip stent, pull out stent, and newly defined folded stent techniques.

#### Methods

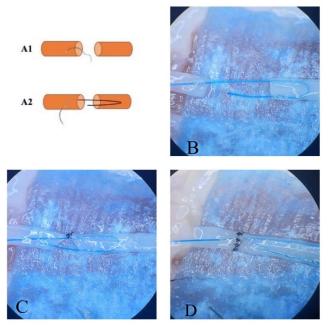
This study was planned using the chicken wing radial artery microsurgery training model, which is a non-living microsurgery training model. Ethics committee approval was not obtained for the study, since there is no need for ethical committee approval in studies with non-living animal models.

All anastomoses were performed by an experienced orthopedic and traumatology specialist, who routinely performs hand and microsurgery operations. Our study was performed on 40 standard microsurgical anastomosis models. While preparing the anastomosis, the injured vessel model was created by finding the radial artery in the muscle cleavages, following the skin incision with a longitudinal incision so that the radius bone of the chicken wing remains on the surgeon's side. The mean diameter of the proximal part of the artery was 0.5 mm after the removal of the adventitia. Four groups, each containing ten anastomosis models, were formed. In group I (control group), the artery was repaired using standard end-to-end anastomosis with simple spaced sutures (10-0 nylon, Ethilon, Johnson & Johnson) . Group II was also repaired with end-to-end anastomosis using the 'clip-on stent' technique (Figure 1). In Group III, the artery was repaired by end-to-end anastomosis with the pull-out stent technique (Figure 2), and in Group IV, the artery was repaired using the newly defined "folded stent" technique. All anastomoses were performed using a stereo microscope (Soif Optical Instruments, China) with up to 40x magnification. The "Folded-stent" technique consisted of three steps (Figure 3). First, a curved 6-0 nylon monofilament was inserted, and folded into the arterial lumen. This stent was removed from the wall on one side by inserting it into the lumen and then the other end into the contralateral lumen. The second step consisted of the anastomosis with simple cut 10-0 nylon sutures (Ethilon, Johnson & Johnson). The third step consisted of removing the stent and closing the exit hole with a 10/0 nylon suture if leakage was detected. The results were recorded in terms of measuring the time to perform an anastomosis (in minutes), evaluating the homogeneous distribution of the sutures, evaluating the anastomotic transition and leaks by injecting methylene blue (Figure 4) into the vascular system, and finally, whether suturing should be applied to the stent removal site.

Differences between the four groups were statistically evaluated for each of three quantitative variables (time to completion, number of stitches per anastomosis including exit hole in groups II, III, and IV, number of leaks) and one qualitative variable (whether or not leak). Considering the sample size, non-parametric Kruskal-Wallis and Wilcoxon tests were used at a significance level of 0.05.



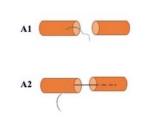
**Figure 1.** A1, A2 and A3 a schematic explanation of the Clip stent technique. B. The prepared state of the arteries used in the model for repair, C. The application of the Clip stent technique before anastomosis, D. The completed anastomosis with the Clip stent.

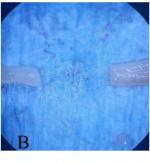


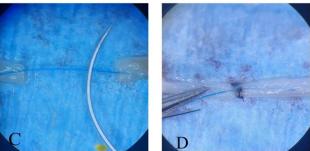
**Figure 3.** A1 and A2 a schematic explanation of the Folded stent technique. B. The application of the Folded stent technique before anastomosis, C. The application of the first suture of Folded stent technique, D. The completed anastomosis with the Folded stent.

#### Results

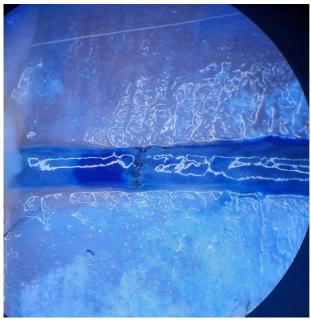
The results for each group are shown in Tables 1-4, respectively. The shortest anastomosis time was in group I, followed by group III, then group II and finally group IV. The difference between Groups I and II (p=0.0051), groups







**Figure 2.** A1 and A2 a schematic explanation of the Pull-out stent technique. B. The prepared state of the arteries used in the model for repair, C. The application of the Pull-out stent technique before anastomosis, D. The completed anastomosis with the Pull-out stent.



**Figure 4.** Appearance after injection of methylene blue for evaluation of anastomotic patency.

I and III (p=0.0069), and groups I and IV (p= 0.0051) was statistically significant when compared to the control group Group I. The mean time per anastomosis was longer. The number of sutures was  $6.6\pm0.51$  in group I,  $6.5\pm0.52$  in group II,  $6.6\pm0.51$  in group II, and  $6.5\pm0.52$  in group IV. When compared with the control group, there was no statistically significant difference between the groups (group II p=0.338, group III p=0.404, group IV p=0.404) in the terms of sutures. In Groups II and III, an additional 1 suture was required in a specimen to close the exit hole of the stent. In this respect, the difference was not statistically significant (p = 0.368). The number of

o leaks per anastomosis was 0 in group I, 2 specimens in group II, 1 specimen in group III, and 0 in group IV. Leakage rates were not significantly different in any group compared to the control group (p=0.472). It was observed that the anastomosis permeability was positive, since the

Table 1.End-to-endanastomosesperformedwithoutstenting

Specimen No	Time (min)	Stictches (n)	Leaks (n)	Patency (+/-)
1	14	7	0	+
2	13	6	0	+
3	15	7	0	+
4	17	7	0	+
5	19	7	0	+
6	11	6	0	+
7	16	7	0	+
8	10	6	0	+
9	12	6	0	+
10	18	7	0	+
Mean±SD	14.5±3.02	6.6±0.51		

SD: Standard Deviation, Min: Minutes

 $\ensuremath{\textbf{Table 3.}}\xspace$  End-to-end an astomoses performed with "Pull-out Stent"

Specimen No	Time (min)	Stictches (n)	Leaks (n)	Patency (+/-)
1	20	6	0	+
2	18	6	0	+
3	23	7	0	+
4	28	7	0	+
5	17	6	0	+
6	27	7	1	+
7	25	7	0	+
8	16	6	0	+
9	29	7	0	+
10	22	7	0	+
Mean±SD	22.5±4.69	6.6±0.51		

Mean±SD22.5±4.696.6±SD: Standard Deviation, Min: Minutes

#### Discussion

The development of microsurgical techniques made it possible to repair vessels with a diameter of 1 mm, followed by supermicrosurgical techniques with vessel repairs of 0.5 mm and less. Anastomosis of increasingly smaller blood or lymphatic vessels can be performed with these techniques.9-11 The development of techniques has prompted the quest to develop more powerful microscopes<sup>12</sup>, finer instruments, and more accurate suturing techniques. In this context, some authors have tried to develop methods to facilitate the removal of these delicate sutures. IVaS, "Clip-stent" followed by "Pull-out stent" techniques have been described in recently published studies.<sup>7,8</sup> The IVaS technique is based on a technique in which a silastic tube is inserted into the vascular lumen to facilitate suturing of vessels larger than 1 mm.<sup>5</sup> Although there are no studies showing the superiority of IVaS, it can be applied according to the surgeon's preference.<sup>6</sup> The "clip stent" technique was

methylene blue crossed the anastomosis line in all anastomoses since the anastomosis was permeable. There was no significant difference between the groups (p=1).

 
 Table 2. End-to-end anastomoses performed with "Clip-Stent"

Specimen No	Time (min)	Stictches (n)	Leaks (n)	Patency (+/-)
1	18	6	0	+
2	24	7	0	+
3	17	6	0	+
4	27	7	0	+
5	29	7	1	+
6	28	7	1	+
7	19	6	0	+
8	26	7	0	+
9	20	6	0	+
10	23	6	0	+
Mean±SD	23.1±4.38	6.5±0.52		

SD: Standard Deviation, Min: Minutes

 
 Table 4. End-to-end anastomoses performed with "Folded-Stent"

Specimen No	Time (min)	Stictches (n)	Leaks (n)	Patency (+/-)
1	21	6	0	+
2	24	6	0	+
3	26	6	0	+
4	25	6	0	+
5	34	7	0	+
6	33	7	0	+
7	31	7	0	+
8	35	7	0	+
9	23	6	0	+
10	30	7	0	+
Mean±SD	28.2±5	6.5±0.52		

Mean±SD 28.2±5 6.5±0.5 SD: Standard Deviation, Min: Minutes

developed due to the complications and difficulties encountered during the removal of the stent during IVaS application.<sup>7</sup> This "Clip-stent and Pull-out stent" technique has many advantages.<sup>8</sup> The possibility of damage to the vascular intima during anastomosis is reduced. In the IVaS technique, the stent must be removed before all the sutures in the anastomosis are completed, whereas in these two stent techniques, the sutures can be made with the stent in place. In addition, vascular clamps may be released while the stent is in place to check for leakage at the anastomosis. In the event of a leak, additional sutures can be made without the risk of transfixing the vessel wall. The disadvantage of the "Clip-stent" technique is that it requires two passes through the vessel wall with two needles. Holes formed can cause leaks, therefore requiring additional stitches. For this reason, the "Pull-out stent" technique has been developed, which transforms these holes into one rather than two holes. However, the "Folded-Stent" technique, which we described in our study, is a third-generation application that improves

these techniques, and while providing the advantage of a single exit hole, it ensures that the vessel lumen is seen more clearly and remains open. At the same time, when evaluated in terms of damage to the vascular intima, it has the same advantages as the "Pull-out stent" technique. The most important step in the successful application of microsurgical vessel anastomosis is proper visualization of the lumen and no sutures to the posterior wall. Although a significant increase in the application time was observed in this newly defined technique compared to other techniques, it caused an increase of three minutes in the longest anastomosis time. Considering the advantages of making the anastomosis more ideal and seeing the lumen better, the "Folded-stent" technique is an advantageous technique in terms of anastomosis quality. In general, the benefits of stenting are better patency of vascular anastomoses, more regular sutures, and fewer posterior wall sutures.<sup>5,7,8</sup> The main disadvantage is leakage from the needle exit hole as its diameter constantly exceeds that of the suture, which can cause parietal tears. A "Pull out stent" is theoretically better than a "Clip-stent" because it uses a needle-free suture and enters the vessel wall through a single hole. Because the diameter of 4/0 nylon is smaller than the diameter of the needle, the hole obtained after placing an inclined suture through the vessel wall is smaller than that of the needle. Reducing the number of holes in the wall is expected to reduce the risk of leakage, as well as the advantage of better visualization of the lumen in the "Folded-stent" technique. In practice, we think that all of our results were not statistically significant because they were applied in an experimental model by an experienced surgeon. For example, the time to anastomose with the "Pull out stent" was significantly shorter than with the "Clip-stent", but the "Folded-stent" technique was longer than the others. Although the leak rate was not significantly different from one group to the next, the "Pull out stent" and "Folded-stent" had less leakage than the "Clip-stent". Apart from these techniques, there is a theoretical risk of stent migration in the IVaS technique, which is the standard first stenting technique. Other techniques, the third generation of which were developed with our technique, do not have this risk. However, there is a theoretical risk of thrombosis due to the perforation holes in the stent, as in the "Clipstent". Considering the clinical applications, the veins are the veins that have the most difficulty in revealing the lumen of the veins. At the same time, the risk of posterior wall suture is more common in vein repairs. We believe that the "Folded-stent" technique, which we have just defined in routine clinical applications, especially during vein repair, will benefit the surgeon in terms of anastomosis quality.

The most important limitation of our study is that it is difficult to evaluate anastomotic quality in a non-living animal model. Although anastomotic permeability can be better evaluated from animal studies, our main aim in this study is to introduce a new technique in which the vessel lumen can be seen more clearly by the surgeon, not anastomotic permeability.

#### Conclusion

In the non-living animal model, the "Folded-Stent" technique provides advantages like other stenting techniques in terms of keeping the lumen open during the anastomosis and preventing the adhesion of the vessel walls. It is an advantageous technique that can be used in clinical practice, especially during venous repairs, to prevent posterior wall suturing of small caliber vessels.

#### **Compliance with Ethical Standards**

Ethics committee approval is not required for the study

#### **Conflict of Interest**

The authors declare no conflicts of interest.

#### **Author Contribution**

ÇP: Study idea, hypothesis, design, material preparation, data collection and analysis, writing the first draft of the article, critical review of the article finalization and publication process

#### **Financial Disclosure**

None

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