ORIGINAL ARTICLE



A New Clip Generation for Microsurgical Treatment of Intracranial Aneurysms—The First Case Series

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- OBJECTIVE: Considerable effort has been made in order to reduce surgical invasiveness while maintaining optimal exploiting of the operative space in aneurysm surgery. One aspect of this evolution is represented by the Lazic (Peter Lazic GmbH, Tuttlingen, Germany) aneurysm clip system. The purpose of this study was to illustrate the new generation clip system in practiced aneurysm surgery.
- METHODS: A retrospective analysis of all aneurysm surgeries in our departments between December 2015 and January 2018 using the new D-Clip system was performed. Evaluation included standardized retrospective review of the main surgeon, the nursing staff, as well as an analysis of surgical video documentation by objective reviewers.
- RESULTS: Forty-five patients with 50 intracranial aneurysms underwent surgical clipping using the D-Clip system. A total of 64 permanent and 19 temporary D-Clips were applied. Nine clips needed to be replaced. All aneurysms could be occluded totally. Surgeons considered handling and manoeuvrability of clip application as feasible and good in all cases (100%), even under impaired visibility circumstances (14%). Objective video analysis revealed comparable results. Nursing staff scored handling and practicability of D-Clips equivalent to the preceding L-Clip generation. There were no intraoperative complications. Surgery-related postoperative morbidity was 6.7%.
- CONCLUSIONS: The new D-Clip system combines an attenuated design for minimally invasive clipping procedures with traditional mechanisms of common clip systems.

It therefore appears to be highly versatile in the context of variable different aneurysm morphologies and locations while maintaining high standard surgical safety and efficacy.

INTRODUCTION

reatment of intracranial aneurysms remains an interdisciplinary challenge, with an ongoing debate on whether microsurgical clipping or endovascular coiling results in the most favorable clinical outcome. After publication of the well known ISAT^I and BRATM²⁻⁴ results, various referring studies have been added to the current literature stating surgical clipping as the more effective method considering long-term occlusion rates, re-perfusion rates, and the need for re-treatment.⁴⁻⁵ Although endovascular techniques have been remarkably improved over time, especially considering technical features, there are still many individual constellations that require operative treatment.

In clipping procedures, considerable effort has been made to reduce surgical invasiveness, while enabling an effectively utilization of the surgical area. Besides the introduction of neuroendoscopy⁶ and the neurosurgical keyhole concept,⁷ the implementation of the Lazic aneurysm clip system (Peter Lazic GmbH, Tuttlingen, Germany) represents 1 aspect of the technical improvement in neurovascular surgery. The features and advantages of the L-Clip System have been reported previously,^{8,9} and the system has found its way into daily operative routine. The purpose of this study was to present the implementation of the new D-Clip system in treatment of intracranial aneurysms in a first consecutive case series.

Key words

- Aneurysm clip
- Clipping
- D-Clip
- Intracranial aneurysm
- Lazio
- Neurovascular surgery

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Citation: World Neurosurg. (2019) 130:e160-e165. https://doi.org/10.1016/j.wneu.2019.06.023

Journal homepage: www.journals.elsevier.com/world-neurosurgery

Available online: www.sciencedirect.com

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METHODS

From the first application in December 2015 to January 2018, a total of 46 patients with 50 intracranial aneurysms were surgically clipped using D-Clips in the neurosurgical departments of Saarland University Medical Centre (Germany) and of the Medical University of Vienna (Austria). In total, 64 D-Clips were applied. All data included in the present study was extracted from a prospectively maintained monocentric database. The main characteristics of the underlying study population can be found in Table 1. Inclusion criteria were a completely available data set of each individual patient including medical documentation, as well as a completely available video documentation of the surgery. All procedures were performed by the authors O.J., K.E., and F.G.

Aneurysm Characteristics	
Variable	n (%)
Patients	
Total	45 (100)
Male/female	12 (26.67)/33 (73.3
Mean age, years	56.87 ± 12.28
Aneurysms	
Total	50 (100)
Subarachnoid hemorrhage on admission	2 (4)
Previously coiled	4 (8)
Mean size, mm	5.4 × 4.5 × 4.8
Internal carotid artery	5 (10)
Ophthalmic artery	4 (8)
Anterior cerebral artery	1 (2)
Pericallosal artery	3 (6)
Anterior communicating artery	6 (12)
Middle cerebral artery	25 (50)
Posterior communicating artery	1 (2)
Basilar artery	1 (2)
Outcome	
Follow-up, months	9.6 ± 5.9
Surgery-related complications	3 (6.7)
Cerebrospinal fluid fistula	1 (2.2)
Wound healing disorder	1 (2.2)
Intracerebral hemorrhage	1 (2.2)
Reperfusion with requirement of retreatment	0 (0)

SAH, subarachnoid haemorrhage; mm, millimetre; ICA, internal carotid artery; OA, ophthalmic artery; ACA, anterior cerebral artery; AComm, anterior communicating artery; MCA, middle cerebral artery; PComm, posterior communicating artery; BA, basilar artery; CSF, cerebrospinal fluid; ICH, intracerebral haemorrhage.

General Study Design

All patients underwent digital subtraction angiography before surgery. Interdisciplinary evaluation of the radiologic and clinical findings was routinely performed. Of all patients undergoing surgery, only those who were clipped using D-Clips were included in further analyses. Immediately after the operation, the leading surgeon, as well as the nursing staff involved, documented handling and feasibility aspects with a standardized questionnaire for every single D-Clip applied. All clipping procedures were filmed and archived and afterwards additionally checked for the same criteria in a second step by an independent neurosurgeon. Clinical and radiographic outcome data were assessed at discharge and after 3 and 6 months, respectively, including postoperative digital subtraction angiography for proof of total aneurysm occlusion and impairment of involved vessels.

Surgical Technique

Surgical approach depended on the location of the aneurysm(s) in focus. Most patients were operated via supraorbital keyhole approach with an eyebrow incision. In some cases pterional or parasagittal craniotomy was performed. The detailed surgical technique of our institutes has been described previously. Additional neuroendoscopy with angled telescopes from o° to 70° (Karl Storz, Tuttlingen, Germany) was available at every time point of the operation. In all cases, intraoperative micro Doppler sonography and indocyanine green videoangiography was performed in order to control occlusion status and to detect accidental vascular impairment.

The Lazic D-Clip System

The D-Clips are made of non-ferromagnetic titanium and therefore are compatible with magnetic resonance imaging. Technical details of opening size and diameters are comparable with those of the L-Clips, as described in previous studies. The assortment includes temporary and permanent clips, both in regular and mini size. Thus, the variety is comparable to clip assortments of Sugita (Mizuho America Inc., California, USA), Yasargil (B. Braun Melsungen AG, Melsungen, Germany), or Lazic L-Clip systems. Closing pressures of the different D-Clips range within those of common alternative clip assortments:

- Standard clips (permanent): 150—180 g (±7.5% tolerance)
- Standard clips (temporary): 90–130 g (\pm 7.5% tolerance)
- Mini clips (permanent): 110–130 g (\pm 7.5% tolerance)
- Mini clips (temporary): 70–90 g (\pm 7.5% tolerance)

In order to imitate accustomed application manoeuvres, the D-Clip application digresses from the L-Clip's inverted grabbing mechanism by the applicator and moves back to the familiar grabbing from the outer sides of the clip (**Figure 1**). Despite the changed grabbing mechanism, clips can still be vertically adjusted within a range of $\pm 50^{\circ}$ (**Figure 2**).

Application, as well as removal, of both regular and mini clips can be performed with I applicator. Devices are delivered with a variable malleability, enabling an individual modification for each patient's anatomy. During the sterilization process the applicator

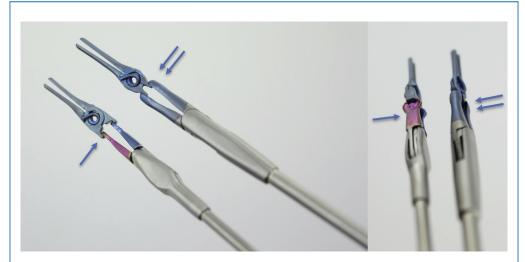


Figure 1. Comparison of the previous L-Clip grabbing mechanism (*single arrow*) with the new developed grabbing from the outer sides of the clip (*double*

arrow). The new D-Clip application refers to the conventional application mechanism as known from other common clip systems.

back-forms itself to its regular shape due to heating. An example can be seen in **Figure 3**. A schematic close-up illustration of the D-Clip within the applier and its relation to the aneurysm's anatomy is shown in **Figure 4**.

RESULTS

Demographic and Clinical Results

Surgical clipping using D-Clips was performed in 46 patients with a total of 50 aneurysms. Deployment of D-Clips in the our departments emerged from 1 application in 2015 to 28 applications in 2018. The most common location of the aneurysms was the middle cerebral artery (56%). Average aneurysm size was $5.5 \times 5.5 \times 4.8 \text{ mm}$ (1.3 \times 1.3 \times 1.4 mm to 30 \times 70 \times 30 mm). Two

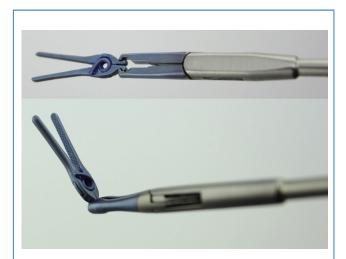


Figure 2. The new grabbing mechanism is realized without losing the variable vertical clip positioning within a range of $\pm 50^{\circ}$.

patients showed subarachnoid haemorrhage on admission with consecutive emergency clipping. All other patients underwent elective surgery for unruptured intracranial aneurysm. Four out of 50 aneurysms were previously coiled with need for operative retreatment. Detailed information on clinical features of the study population can be found in **Table 1**.

A total of 38 patients were operated via supraorbital keyhole approach. Six patients received modified pterional craniotomy and 2 patients underwent clipping via parasagittal approach. A total of 64 D-Clips were applied. Temporary clipping of proximal arteries was necessary in 18 procedures. Intraoperatively, all aneurysms could be totally occluded, confirmed by indocyanine green videoangiography and Doppler sonography. There were no intraoperative complications, such as rupture of the aneurysm or neurovascular compromise.

Retrospective Surgeon Analysis

In the retrospective reflection of the surgeons (Figure 5), all of the 64 clip applications were considered as feasible (100%). Despite an impaired visibility in 7 aneurysms (14.0%), manoeuvrability was considered good in all applications (100%). Nine D-Clips (14.0%) needed to be replaced. One of the replacements was performed under impaired visibility. All replacements were considered feasible and good (100%). A total of 18 temporary D-Clips were applied. All temporary clips were applied under favorable visualization. Handling and manoeuvrability of the temporary D-Clips was scored as good in all cases (100%). Nursing staff scored handling and practicability of the D-Clip system as equal to the L-Clip system in 62 applications (96.9%). One application (1.6%) was considered as more complicated, and 1 application (1.6%) was scored as easier.

Video Analysis

An entire video documentation of each procedure was available in all cases. Results of the analysis are shown in Figure 6. The

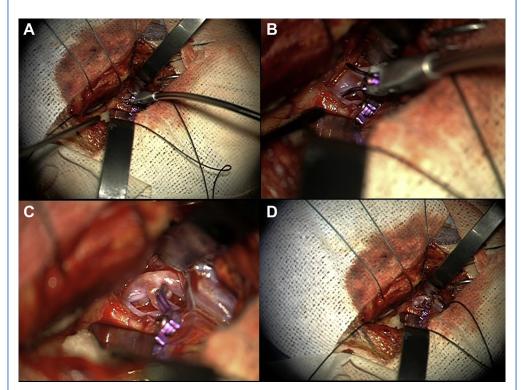


Figure 3. Exemplary case of a patient with a small middle cerebral artery aneurysm surgically clipped via supraorbital keyhole approach under usage of a new bayonet shaped Lazic D-Clip. The shaft of the applicator can be customized and adapted to the individual

anatomy (**A**, **B**). (**C**) The placed clip is shown. (**D**) Note the small anatomical field through the keyhole approach, where precise manoeuvres and a maximized utilization of anatomical space are essential.

objective analysts stated anatomical visibility during clip application as impaired in 12 aneurysms (18.8%). Handling and manoeuvrability of D-Clips was interpreted as good in 63 applications (98.4%). Performance of clip replacements was considered as feasible and good in all procedures (100%), even

though 2 situations were classified with impaired visibility circumstances (22%). Application and manoeuvrability of temporary clips was considered as feasible and good in all cases (100%).

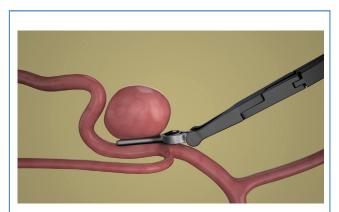


Figure 4. Schematic illustration of the D-Clip within the applier and its relation towards the aneurysm's anatomy. The clip can be vertically adjusted to facilitate the surgeon's trajectory within the operative field.

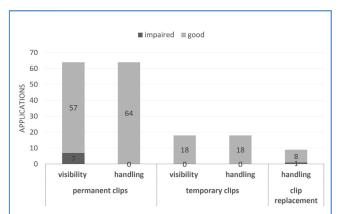


Figure 5. Results of the retrospective review by the surgeons. Handling of the D-Clip system was classified as good in the majority of all applications, even in situations with impaired operative visibility. The results are, respectively, for permanent clips, temporary clips, and clip replacements.

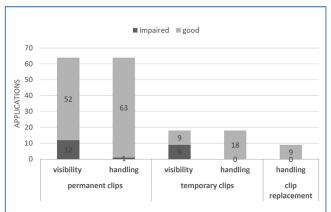


Figure 6. Results of the video analysis by objective reviewers. Comparable to the surgeons' analysis, the majority of the applications were considered as well practicable even in situations with impaired visibility. The results are respectively for permanent clips, temporary clips and clip replacements.

DISCUSSION

Even in times of an increasing relevance of endovascular treatment options for intracranial aneurysms, long-term analyses have shown that surgical clipping remains a safe and efficient therapy considering definitive treatment. 1,4,11-13 In this context, substantial effort has been made and various technical innovations have been invented to maximize surgical effectiveness. With the implementation of the keyhole approach concept for intracranial vascular lesions, manoeuvring within a very limited surgical field has become standard in daily operative routine. 7,14-17 With its slim, attenuated design, the L-Clip system with inverted grabbing mechanism addresses this aspect and has already proven its advances in modern, minimally invasive clipping procedures.8 Nevertheless, many neurovascular surgeons are still used to conventional clip systems such as Sugita or Yasargil. The presented Lazic D-Clip system combines its previously shown technical advances with a familiar feeling for the surgeon by reimplementing the traditional application mechanisms. This mechanism is realized without losing the

attenuated design, giving the surgeon maximum sight and manual manoeuvrability in a limited operative field.

In this study, handling and manoeuvring of the new generation clip system was evaluated by the surgeons themselves, nursing staff, and objective analysts. Concurring results suggest a comparable applicability of the D-Clip system in relation to its previous L-Clip generation. Perioperative complications also correspond to reported incidences of the previous system ⁸ (Table 1). Therefore, the D-Clip system seems to be capable to maintain a high standard surgical effectiveness.

Because morphologic variation of the clip's design range and technical modifications are comparable to those of its predecessor, the surgeon's choice remains highly configurable for the individual anatomic situation. Closing pressures given by the technical configuration of the D-Clip assortment turned out to be sufficient for a safe occlusion of a wide diversity of aneurysm morphologies. By maintaining I universal applicator for both clip application and removal, the instrumental set is kept clear and this simplifies the learning curve for training fellows, as well as ensuring an intuitive and safe use by the nursing staff.

The presented results have to be interpreted in a retrospective, subjective context of course. Nevertheless, our departments are very experienced with the use of Lazic Clip systems. Analysis of surgical turnover has shown a highly increasing number of applications of the new D-Clip system over the past 2 years. The application turned out to be compatible with conventional approaches, as well as endoscopic assisted keyhole approaches even to deeply located aneurysms at the skull base.

CONCLUSIONS

The new D-Clip system combines a streamlined design for minimally invasive clipping procedures with the traditional character of aneurysm clip systems. It is therefore highly versatile in context of variable different aneurysm morphologies and locations while maintaining high standard surgical safety and effectiveness for the individual patient.

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Conflict of interest statement: G. Fischer is a consultant for Peter Lazic GmbH, Tuttlingen, Germany. The remaining authors have no conflicts to report.

Received 23 April 2019; accepted 4 June 2019

Citation: World Neurosurg. (2019) 130:e160-e165. https://doi.org/10.1016/j.wneu.2019.06.023

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