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Clinical Safety and Performance of Sugita Titanium Aneurysm Clips

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Summary

Background. In spite of advantages for neuro-imaging, titanium aneurysm clips are not yet chosen for routine use for clipping of intracranial aneurysms, probably because their reliability has not been demonstrated in large numbers of cases. We assess reliability and safety of Sugita titanium aneurysm clips for routine clinical use in a large number of operated cases.

Method. Intra-operative performance and safety of Sugita titanium aneurysm clips were evaluated in 347 patients in our institutions. Aneurysms in 261 patients had ruptured; 86 patients had unruptured aneurysms.

Results. A total of 441 clips of 52 different types were used. No early or delayed complications occurred in relation to the titianium clips, such as deformity or slippage of a clip. Patient outcome according to the Glasgow Outcome Scale was similar to that when conventional cobalt-based aneurysm clips were used.

Interpretation. Reliability and safety of Sugita aneurysm clips were demonstrated in a large number of patients. The clips are suitable for routine use in aneurysm surgery.

Keywords: Aneurysm clips; intracranial aneurysm; subarachnoid haemorrhage; titanium.

Introduction

Neuro-imaging modalities including computed tomography (CT) and magnetic resonance imaging (MRI), and more recently three-dimensional CT angiography, MR angiography, and functional MRI, have enhanced the ability to demonstrate abnormalities in the central nervous system. However, images of the brain and surrounding structures in patients who have undergone clipping of intracranial aneurysms are degraded significantly by metal artifacts near the clips. Recently, three different makes of titanium aneurysm clips have been developed, resulting in significant improvement of imaging on MRI and CT compared with conventional cobalt-based clips [6, 8, 9, 10]. In spite of such advantages for neuro-imaging, titanium aneurysm clips are not yet chosen for routine use, probably because their reliability has not been demonstrated in large numbers of cases.

An assortment of Sugita aneurysm clips are now available in a titanium version [10]. We evaluated intra-operative performance and clinical safety of Sugita titanium aneurysm clips in 347 patients at our institutions.

Methods

Clips

Sugita titanium aneurysm clips are made of a titanium alloy termed 6-aluminium-4-vanadium-titanium (90% titanium, 6% aluminium, and 4% vanadium). The same double-coiled flat spring mechanism as the conventional clips is used to keep the advantage of Sugita clips, such as stable spring pressure and wide opening of blade. The bridge wire mechanism at the crossing part is also useful to prevent scissoring of the blade, i.e., vertical deformity of the clip blades resulting in ill-fitting when blades are closed. The blade and spring portion of the titanium clip are designed to be slightly larger than in conventional ones in order to achieve the same blade strength and spring force as with conventional clips [10]. A variety of clip sizes and shapes (52 different types) similar to conventional ones are available, including straight, curved, angled, bayonetted, and mini types (Fig. 1). Exceptions are fenestrated and ultralong clips, which now are under development. Titanium-coated appliers are used for clipping.

Patients

At Nagoya University and 12 affiliated hospitals, 347 patients with intracranial aneurysms (mean age, 58 years; range, 20 to 81) were treated by aneurysm neck clipping using Sugita titanium aneurysm clips from May 1996 to November 1998. Aneurysms had ruptured in 261 patients, while 86 patients had unruptured aneurysms (Table 1). Forty-eight patients had multiple aneurysms.

Locations of a total of 396 aneurysms, including ruptured, unruptured, and multiple lesions, included the anterior communicating artery (27.8%), middle cerebral artery (33.8%), internal carotid artery (29.5%), distal anterior cerebral artery (4.8%), and vertebrobasilar system in 3.8% (Table 1). By maximum diameter, 7 aneurysms (1.8%) were giant and 20 (5.1%) were large.

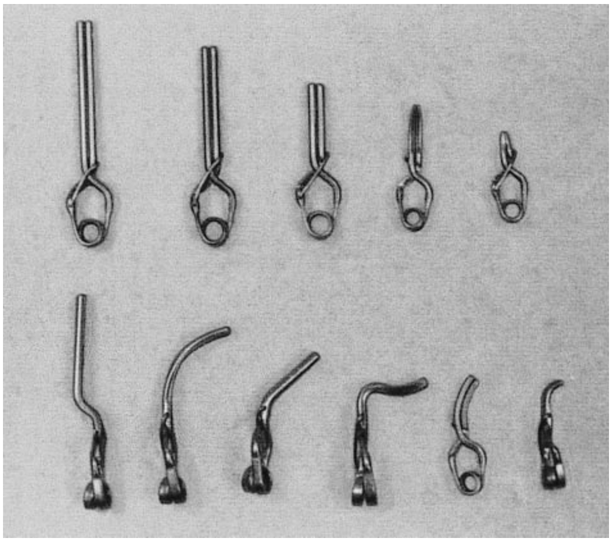

Fig. 1. Fifty-two Sugita titanium aneurysm clips of various sizes and configurations were available at the time of study, including straight, curved, angled, bayonetted, and mini types

Table 1. *Characteristics of 347 Patients Treated Using Sugita Titanium Clips*

	Ruptured aneurysm	Unruptured aneurysm
Number of patients	261	86
Location of aneurysm (%)		
ACoA	33.7	15.1
MCA	30.0	46.5
ICA	29.1	26.7
VB	1.9	9.3
dACA	5.4	2.3
Hunt & Hess grade (%)		
I	14.7	
II	37.3	
III	29.0	
IV	15.9	
V	3.2	
CT Fisher grade (%)		
1	5.2	
2	23.9	
3	51.8	
4	19.1	

ACoA Anterior communicating artery; *MCA* middle cerebral artery; *ICA* internal carotid artery; *VB* vertebrobasilar circulation; *dACA* distal anterior cerebral artery.

Among patients with subarachnoid haemorrhage, 14.7% were grade I, 37.3% were grade II, 29.0% were grade III, 15.9% were grade IV, and 3.2% were grade V according to the Hunt and Hess classification [3]. According to the Fisher CT classification, 51.8% of patients were grade III and 19.1% were grade IV [2].

Study Protocol

Patients underwent the accepted treatment for cerebral aneurysms with or without subarachnoid haemorrhage. Patients were evaluated with CT and four-vessel angiography to determine the anatomy of the aneurysms. Aneurysms were clipped using standard techniques. Titanium and cobalt clips were not used in combination because of the possibility of galvanic cell formation resulting in corrosion of the metals. Postoperatively, patients underwent the standard treatment and examinations including CT and angiography. Fasudil hydrochloride (AT877) was administered to most patients with subarachnoid haemorrhage to prevent cerebral vasospasm [14, 16]. Advantages of reduced clip artifacts in MRI, MR angiography, CT, and three-dimensional CT angiography were not focuses of this study.

Safety of Sugita titanium aneurysm clips was evaluated by surgical observations, clinical outcome and postoperative radiographs. Patient outcome was graded according to the Glasgow Outcome Scale (GOS) in patients after more than 3 months of follow-up [4]. Displacement or deformity of titanium clips was evaluated in anteroposterior and lateral radiographs immediately after and 1 month after surgery.

Results

Surgical Observations

Overall, 441 Sugita titanium aneurysm clips were placed in 366 patients with a follow-up period of 12 ± 6 months (mean $\pm$ SD). A single clip was used for 349 aneurysms. Multiple clipping was done for 43 aneurysms (2 clips for 39 aneurysms, 3 clips for 3 aneurysms, and 4 clips for 1 aneurysm). Number of each size of clip used was 225 standard-size clips (51.0%), 174 large clips (39.5%), and 42 mini-size clips (9.5%) (Table 2). Number for each clip shape were 241 straight clips (54.6%), 62 bayonet clips (14.1%), and 138 curved or angled clips (31.3%). The large array of titanium clips allowed selection of appropriate clips for each aneurysm in most cases, except when fenestrated clips were required. Clip applications and readjustments were uncomplicated in all cases. No clip malfunctioned during surgery. Scissoring of the clip blades never occurred in any clip types including miniclips in this series.

Table 2. *Size and Shape of Titanium Clips Used in This Study*

Shape	Size			Total
	Standard	Large	Mini	
Straight	154	74	13	241
Bayonetted	28	26	8	62
Angled or curved	43	74	21	138
Total	225	174	42	441

Values represent number of clips.

Table 3. *Clinical Outcome of 336 Patients 1 Month After Surgery*

GOS	Ruptured aneurysm	Unruptured aneurysm
Good recovery	167 (66.0)	78 (94)
Moderate disability	39 (15.4)	1 (1.2)
Severe disability	22 (8.7)	4 (4.8)
Vegetative state	3 (1.2)	0
Death	21 (8.3)	0
Total	253 (100)	83 (100)

Values represent number of patients and percentages (in parentheses) of total.

Subsequent Events

No rebleeding from the clipped aneurysms occurred except in one 65-year-old woman who developed rebleeding from an aneurysm of the anterior communicating artery 10 days after surgery and subsequently died. According to the surgeon's opinion, enlargement of the residual neck after incomplete clipping was the most likely cause of rebleeding. Since neither postoperative angiography, re-operation, nor autopsy could be performed for this patient, no direct evidence was obtained to resolve this issue.

No deformity or displacement of the clips was noted on radiographs either immediately after or one month after surgery. Even the patient with rebleeding, no deformity of the clip was evident from these studies, although the position of the clip had been shifted by an intracerebral haematoma.

In 253 patients with follow-up data after subarachnoid haemorrhage, 66.0% had good outcomes (GOS 1), 15.4% were moderately disabled (GOS 2), 8.7% were severely disabled (GOS 3), 1.2% were in a vegetative state (GOS 4), and 8.3% had died (GOS 5). In 84 patients treated for unruptured aneurysms, 94% had good outcomes, 1.2% were moderately disabled, and 4.8% were severely disabled. No deaths or vegetative states occurred. Postoperative epilepsy was noted in 8 patients in this study (2.3%). Among the patients with subarachnoid haemorrhage, postoperative epilepsy occurred in 6 (2.4%). No delayed complications occurred in relation to the titianium clips.

Discussion

We used 441 Sugita titanium aneurysm clips for the treatment of 347 patients with cerebral aneurysms and confirmed safety and reliability of the clips for routine clinical use. No complications were related to the titanium clips.

Postoperative image quality on MRI and CT is improved by use of titanium clips [1, 13, 17, 18]. Two different makes of titanium aneurysm clip (Spetzler and Yasargil) have been introduced in the last few years [6, 8, 9]. Sugita aneurysm clips, among the most commonly used, recently have become available in a titanium version [10, 15], and offer a significant advantage in reducing artifacts in postoperative imaging. Before routine clinical use of titanium aneurysm clips, their reliability and safety needs to be demonstrated in large numbers of well-studied cases.

The present study reported the largest number of patients in the literature to undergo operation for intracranial aneurysm with titanium aneurysm clips. Clinical results were comparable to those in patients with ruptured or unruptured aneurysms who were treated with conventional aneurysm clips [7, 14]. Shibuya *et al.* have reported clinical results involving cobalt-based clips in a multicenter trial of an antivasospastic agent, the myosin-light chain kinase inhibitor AT877, in 131 patients with subarachnoid haemorrhage [14]. Sixty-seven percent of patients had a good outcome (GOS 1), 8% were moderately disabled (GOS 2), 16% were severely disabled (GOS 3), 4% were in a vegetative state (GOS 4), and 5% died (GOS 5). The study protocol was similar to the present one, with both using AT877 as an anti-vasospastic agent. Outcomes were quite similar between the two studies. In asymptomatic, unruptured, intracranial aneurysms, King *et al.* have noted a 4.1% morbidity rate and a 1.0% mortality rate in a meta-analysis of 28 surgical series [7]. These results are also comparable to those in patients treated for unruptured aneurysms in the present study. Epilepsy occurred postoperatively in 8 of our patients (2.3%), which is not excessive compared with reported occurrences. Rose and Sarner have reported seizures in 10% of 1009 cases of ruptured intracranial aneurysm [12]. Limiting consideration to seizure onsets during the acute-care hospital stay, Kassell and Boarini have reported an occurrence rate of 3% to 5% in patients with SAH [5].

Mechanical reliability of Sugita titanium clips has already been demonstrated by Nagatani *et al.*, showing a closing force similar to that of conventional Sugita clips [10, 11]. However, the closing force had decreased by about 10% after 100 repeated clip openings, reflecting the physical properties of titanium. Scissoring of the blade, vertical deformity of the clip blades resulting in ill-fitting, never occurred in Sugita titanium clips probably owing to the double-coiled flat spring and the bridge wire mechanism at the crossing part of the blade. The bridge wire mechanism seemed to be stronger than the other mechanisms at the crossing part of the blade, such as box-rock mechanism.

One drawback of Sugita titanium aneurysm clips is that of having slightly thicker blades and a larger spring mechanism than conventional Sugita clips, and this bulk might limit access to the operative field from a narrow approach. Lack of a full array of clip types such as fenestrated clips, ultralong clips, and booster clips is an additional drawback at present.

In conclusion, the safety of Sugita aneurysm clips was demonstrated in a large number of patients, and they proved reliable for routine use in aneurysm surgery. Extended follow-up is expected to confirm long-term safety of these clips.

Appendix

This study was performed with the cooperation of the surgeons and the staff of the following neurosurgical hospitals: Anjo Kohsei Hospital, Chukyo Hospital, Handa City Hospital, Ichinomiya City Hospital, Kainan Hospital, Komaki City Hospital, National Nagoya Hospital, Okazaki City Hospital, Oogaki City Hospital, Shizuoka Kohsei Hospital, Toyohashi City Hospital, and Yokkaichi City Hospital.

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Comments

Takayasu *et al.* present their experience of clipping 396 aneurysms using Sugita titanium clips. The authors show, in a large series, their results with no significant clip related morbitity or complications.

The specific objective of the study was not achieved. The authors sought to analyze clip displacement, or deformity using plain radiographs post-operatively. We suggest that to study possible clip displacement or movement, cerebral angiography would be the study of choice to specifically document clip relationship to the aneurysm's neck.

Additionally, to document safety and reliability of titanium based aneurysm clips, longer term follow-up, rather than the two years in the current study would be needed.

The technique of clip placement across the neck of the aneurysm, in the experience of the senior commentator (Prof. M. G. Yasargil), is a far more crucial factor in predicting the long term aneurysm obliteration rather than the type of metal the clip is made of. Staged or stepwise clip placement, bipolar coagulation of the base of aneurysm, preservation of surrounding small perforators the selective use of temporary clips, needle puncture/excision of the fundus are all useful techniques to be considered in broad based aneurysms to achieve long term and aneurysmal obliteration while minimizing procedure related morbidity [1].

Magnetic Resonance Imaging (MRI) is becoming the main stay of central nervous system disease diagnosis. There will be greater emphasis in the future to use cranial bio-implants that have minimal distortion of MR images, low magnetic moment, and biocompatibility, such as titanium.

G. Yasargil and S. Abdulaauf

The growing use of MRI demands the utilization of biological implants made of materials without ferromagnetic properties, for safety reasons, as well as to minimize the artifacts image caused by the implant itself. Among these materials, the one in evidence nowadays is the titanium.

Until recently, most aneurysm clips on the market were made of cobalt alloys. Although these clips are compatible with MRI, they cause artifacts which reduce the quality of images, distort the structures to be shown and may compromise the diagnosis [1]. Besides that, it has been recently shown that a small percentage of these implants may become "contaminated" during handling, storage or resterilization, acquiring discrete ferromagnetic properties [3]. From the moment we begin to use higher power MRI equipments (up to 3.0 Tesla) [2], this issue becomes troublesome because of the high risk of interaction between the clips and the magnetic fields.

Since 1996 there have been released on the market 3 types of titanium clips – Spetzler (NMT-Neurosciences, USA), Yasargil (Aesculap, Germany) and Sugita (Mizuho, Japan) – all made of chemically pure titanium. The mechanical characteristics (opening and closure pressures) of these clips, as well as their biocompatibility, performance and safety are similar to those presented by cobalt alloy clips [5]. When compared, the image studies reveal that the titanium clips show superior image quality, besides being safer when exposed to MRI.

Despite the results published in small series [4, 6] titanium clips have a good intra-operative performance and clinical safety record. There was a lack of confirmation of this in a larger series of patients. Takayasu *et al.* analyzed a series of 347 patients with 441 titanium clips (Sugita) implanted for the treatment of intracranial aneurysms, confirming the safety and reliability of these implants. The two sole criticisms made about titanium Sugita clips are the thicker blades and lack of fenestrated and ultra long clips. The paper follows the pattern of clinical series with analysis of surgical results; however, the results shown in such a large series, together with the results in laboratory studies point to titanium clips as the first choice for the surgical treatment of intracranial aneurysms.

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