Journal of Vascular and Interventional Neurology
Official journal of Zeenat Qureshi Stroke Research Center

The Orbit Galaxy XTRASOFT Coils: a Multicenter Study of Coil Safety and Efficacy in Both Ruptured and Unruptured Cerebral Aneurysms

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Abstract

Increase packing density with the use of softer three-dimensional (3D) coils has been indicated in reducing aneurysm recurrence. We are reporting a multicenter initial experience of using the Orbit Galaxy XTRASOFT which is a stretch-resistant, softer 3D coil in both ruptured and unruptured aneurysms. A total of 57 consecutive patients from five high-volume neurointerventional centers were reported where at least one Galaxy XTRASOFT coil was used during a procedure. There were 25 patients with ruptured aneurysm and 32 with elective coiling. The overall complication rate was 3.5%, one patient with nonoperative retroperitoneal hematoma and one patient with intraoperative rupture but with no neurological deficit. The occlusion rate of 90% or greater was achieved in 86% of the cases. The discharge modified Rankin score of 0 or 1 was achieved in 100% of the elective coiling and 65% in the ruptured cases. Early experience with Galaxy XTRASOFT coils for both ruptured and unruptured aneurysms appears to be safe with good aneurysm obliteration and low complication rate.

Abbreviations:

3D: 3-Dimensional

mRS: Modified Rankin Scale

Introduction

Arguably the greatest disadvantage of the endovascular treatment of cerebral aneurysms has been the high incidence of recurrence after coil embolization[1–3]. Over the past decade, the neurointerventional community, with industry support, has made considerable advancements in aneurysm coil design in an attempt to reduce the rate of recanalization after embolization. Such innovations in coil design stem from a large literature reporting on the biomechanical properties of different coil shapes, sizes, and core materials in vitro and in vivo.

Aneurysm recurrence has been correlated with lower coil packing density[4]. Studies have revealed higher packing density with three-dimensional (3D) coils[5,6] and with softer coils[7] compared to traditional helical coils. However, 3D coils are generally stiffer than helical coils, which can limit the number of 3D coils that can be placed, thereby reducing aneurysm packing. Orbit coils (Codman Neurovascular, Raynam, MA) were the first brand to offer 3D coils of all sizes, ranging from 2 to 20 mm. The 3D complex shape was designed to enhance conformability and concentric filling in order to produce a higher packing density. Orbit coils have a 3D conformation that results in random break deployment that may ease coil repositioning during embolization. Initial and midterm results in over 300 patients treated with Orbit coils indicated a high rate of complete aneurysm obliteration with a 16% recanalization rate[8,9]. How-

Published June, 2012.

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ever, the Orbit coil design had the unintended and unfortunate feature of poor stretch resistance, making these coils difficult to use and resulting in occasional coil malfunction. A new softer 3D coil, including a stretch-resistant iterative advance on the Orbit design, the Orbit Galaxy XTRASOFT (Codman Neurovascular, Raynam, MA), was approved by the Food and Drug Administration in May 2010 and released for use in the United States in July 2010 and Europe in September 2010. To date, no published literature exists describing the safety or efficacy of the Galaxy coil in ruptured or unruptured cerebral aneurysms. We report a multicenter initial experience using the Galaxy XTRASOFT coils in both ruptured and unruptured aneurysms to guide neurointerventionists in their use of this new coil.

Material and Methods

Five high-volume neurointerventional centers were queried to report consecutive cases of all patients with cerebral aneurysms who were treated with at least one Galaxy XTRASOFT coil during endovascular coil embolization between the dates of July 2010 and November 2010. Centers were asked to provide demographic data (age, gender, Fisher Grade and Hunt--Hess Grade, if applicable), procedural data, aneurysm morphometrics and location, use of heparin or antiplatelet agents, synchronous use of assist devices such as balloon and/or stenting, and outcome data. All intraprocedural and periprocedural complications were recorded. Outcome data included percent aneurysm occlusion (classified as 100%, 95--99%, 90--94%, 80--90% and < 80%) and the discharge modified Rankin Score (mRS).<auq>Author: Please check whether the acronym “mRS” stands for “modified Rankin Score,” “modified Rankin Scale,” or both.</auq> Angiographic occlusion and outcome was determined by each individual center and self-reported. The institutional review boards at each participating center approved the use of the device as well as the collection and sharing of registry data among these centers. Data are reported as mean ± standard error of the mean.

Results

A total of 57 patients received Galaxy coils for aneurysm embolization between July and November 2010 at participating study centers. Forty-one patients were female (72%). The mean age was 57 ± 12 years (ranges 20--79 years). Twenty-five patients had a ruptured aneurysm (44%); the remaining 32 patients underwent elective coil embolization. Table 1 displays admission Fisher and Hunt--Hess grades for the 25 ruptured aneurysm patients. The mean aneurysm size was 6.9 ± 3.4 mm (range 1--25 mm). The mean unruptured aneurysm size (mean 7.0 ± 3.3 mm) was slightly larger than ruptured aneurysm size (mean 6.7 ± 4.8 mm). The mean neck size was 3.4 ± 1.4 mm (range 1.5--6.9 mm); the neck size of unruptured aneurysms (mean 3.7± 1.6 mm) was once again larger than those of ruptured aneurysms (mean 2.9 ± 1.0 mm). All of the treated aneurysms were considered saccular in shape. There were no mycotic, dissecting, or fusiform aneurysms that were treated in this study.

Three treatments utilized balloon assistance (all ruptured aneurysms) and 15 patients required stent assistance (all unruptured aneurysms). Galaxy coils were used alone in 16 patients (28%) and in combination with other coils in 41 patients (72%). This included using Galaxy coils as a lead coil (typically in small ruptured aneurysms), as well as using Galaxy as finishing coils following the use of a different coil type. Periprocedural complications were reported in only two patients (3.5%): one patient developed a nonoperative retroperitoneal hematoma from a high femoral artery access site and a second patient sustained aneurysmal rerupture during coiling that did not result in neurological deficit. The patient was discharged home within 10 days of the procedure.

Aneurysm occlusion and discharge mRS are displayed in Table 3. Upon completion of embolization, 44% of the aneurysms achieved 100% obliteration and 86% had occlusion greater than or equal to 90%. Ninety-four percent of patients with unruptured aneurysms had a discharge mRS of zero. Of the patients with ruptured aneurysms, 64% had a discharge mRS of either 0 or 1. One patient died from sequelae of the subarachnoid hemorrhage that was not treatment related.

Discussion

There has been considerable research over the past decade evaluating the inherent biomechanical properties of various coil shapes, sizes, and coatings in regard to enhancing aneurysm occlusion[10–12]. Although there is limited evidence suggesting superiority of one type of coil over the others[12,13], it is well understood that increased aneurysm occlusion at time of coil embolization reduces the future risk of coil compaction, aneurysm recanalization, and aneurysm re-rupture[2,14]. Higher coil packing density has been associated with lower aneurysm recurrence, likely given its close relationship with aneurysm occlusion and inverse relationship to coil compaction[4]. In addition, aneurysm recurrence is more common after coiling of ruptured aneurysms compared

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to unruptured aneurysms[15,16]. This association is likely secondary to less aggressive treatment measures taken in recently ruptured aneurysms than in elective cases, as well as reluctance of the treating physician to use stent assistance due to the inherent risks of the necessary antiplatelet agents in these patients. New coils must therefore harbor properties that promote aneurysm occlusion through enhanced aneurysm filling and increased packing density while expressing a satisfactory safety profile in those with both ruptured and unruptured aneurysms.

The Galaxy coils share a similar random loop, 3D design with the Orbit coils, although they are purported to lack the original coil's sensitivity to stretching. Stretching occurs when the primary wind of a coil is lost, creating a progressive unwinding of the coil and potentially leading to coil material being left in normal vasculature. A reasonable analogy is that of a pulled thread on a sweater, which when attempted to be removed or manipulated, only unwinds further. When a coil stretches, it can potentially lead to devastating complications if it is unable to be safely removed. When in its correct shape, the platinum wire that makes up the Galaxy coil is wound into a 0.012-in platinum coil that is attached to a delivery tube. This 0.012-in coil diameter results in more coil volume per equal length of coil, as compared to typical 0.010 finishing coils. The coils are available in 2--4 mm diameter and 1.5--10 cm in length. Galaxy coils are specifically designed to produce true random loops with a soft finish while being stretch resistant. As such, they are primarily used at the termination of embolization as "space finders" that will contour to, and fill, vacancies within the coil mass.

Galaxy coils were introduced into the United States in July 2010 and in Europe in September 2010. There are no published accounts to date of the safety or efficacy of the Galaxy coils when used for aneurysm embolization. In our series, the Galaxy coils were used both in isolation (28%) and in combination with other coils. Initial radiographic obliteration was 95% or better in 75% of patients. These results were achieved with a low complication rate (3.5%). Only one intraoperative rehemorrhage occurred, and this event resulted in no clinical sequelae. Aneurysm occlusion and outcome data are comparable to other recent studies evaluating various coil technologies[10,17,18]. Most notably, not a single incidence of coil stretching was encountered. While the overall number of cases in this study are relatively low, they represent a reasonable volume of cases with a very "real life" proportion of stent- and balloon-assist procedures, both of which have been anecdotally associated with a possible increased risk of stretching. While the moderate number of patients and retrospective nature of the data collection limit the findings in this study, they quite strongly demonstrate the relative safety of the Galaxy coil and confirm that there are no major concerns with the coils' performance of safety profile.

Short-term radiographic and clinical outcomes appear comparable to other series of coil embolization. In the International Subarachnoid Aneurysm Trial, 74% of patients with ruptured aneurysms treated with coil embolization had a 2-month mRS of 2 or less[19]; in our series, 72% of patients with ruptured aneurysms and 86% of all patients had a discharge mRS of 2 or less. More recent data of both ruptured and unruptured aneurysms from the HELPS trial demonstrated an 18-month mRS of 2 or less in 78% of patients treated with hydrogel-coated coils and 88% of those treated with bare platinum coils[10]. In this series, angiographic occlusion of 90% or more was observed in 86% of patients. Immediate[20] and midterm[21] (mean 175 days) occlusion data after Enterprise stent-assisted coil embolization revealed 76% and 88% of patients with greater than 90% occlusion, respectively. Six-month angiographic data from the Cerecyte Coil Trial (unpublished data) revealed angiographic occlusions of 85% in the Cerecyte arm and 87% in the bare platinum arm[22]. Given the natural history of aneurysm occlusion after coil embolization and the clinical improvements seen in patients in the weeks--months following subarachnoid hemorrhage, it is likely that the Galaxy coil data presented herein will have a comparable safety and efficacy profile compared to other larger series with longer follow-up.

It should be noted that the data generated for this investigation are self-reported and not adjudicated by an independent core lab. While certainly independent data review would have been ideal, the resources and funding to perform such an evaluation were not available. However, in any case it is critical that, whether self-reported or adjudicated, we, as a specialty, strive to record our technical and clinical outcomes with each new iterative technology, and thereby avoid the propagation of poor outcomes should they become evident. It should be stressed that in the current regulatory environment, iterative coil technology changes do not need clinical data prior to FDA approval. This is not necessarily a bad thing, as it greatly increases the rate of technological advancement. However, that knowledge puts all the more pressure on the medical community to do its very best to critically self-evaluate these new technologies as soon as is reasonably possible.

Table 1.

Hunt--Hess and Fisher grades for the 25 patients with ruptured aneurysms.

Grade	N	Percent (%)
Hunt--Hess	25	--
1	11	44.0
2	2	8.0
3	9	36.0
4	1	4.0
5	2	8.0
Fisher	25	--
1	4	16.0
2	3	12.0
3	12	48.0
4	6	24.0

Table 2:

Aneurysm location and size.

Factor	N	Percent (%)
Aneurysm Location	57	--
Internal carotid artery	--	--
Ophthalmic	5	8.8
Superior hypophyseal	2	3.5
Supraclinoid (dorsal wall or not specified)	7	12.3
Posterior communicating	7	12.3
Carotid terminus	1	1.8
Cavernous segment	1	1.8
Anterior communicating artery	16	28.1
Middle cerebral artery	4	7.0
Posterior Circulation	--	--
Posterior inferior cerebellar artery	3	5.3
Basilar trunk or basilar---not specified	4	7.0
Superior cerebellar artery	2	3.5
Basilar apex	4	7.0
Not reported	1	1.8
Aneurysm Size (mm)	57	--
Less than 7	32	56.1
7--12	22	38.6
13--25	3	5.3

Table 3.

Angiographic aneurysm occlusion and discharge mRS of patients treated with Galaxy coils.

Factor	Ruptured Aneurysms		Unruptured Aneurysms		All Aneurysms	
	N	Percent	N	Percent	N	Percent
Initial Aneurysm Occlusion	25	--	32	--	57	--
100 %	14	56.0	11	34.4	25	43.9
95--99%	6	24.0	12	37.5	18	31.6
90--94%	2	8.0	4	12.5	6	10.5
80--89%	0	0	0	0	0	0
Partial	1	4.0	3	9.4	4	7.0
Not reported	2	8.0	2	6.3	4	7.0
Discharge Modified Rankin Score	25	--	32	--	57	--
0	2	8.0	30	93.8	32	56.1
1	14	56.0	1	3.1	15	26.3
2	2	8.0	0	0	2	3.5
3	4	16.0	0	0	4	7.0
4	1	4.0	0	0	1	1.8
5	1	4.0	0	0	1	1.8
6	1	4.0	0	0	1	1.8
Not reported	0	0	1	3.1	1	1.8

Conclusion

This study is the first to assess the feasibility of the Galaxy XTRSOFT coils for the endovascular treatment for both ruptured and unruptured aneurysms. In this series of more than 50 patients, Galaxy XTRASOFT coils were used safely in patients with good aneurysm obliteration and a low complication rate.

References

1. Molyneux A, Kerr R, Stratton I, et al. International Subarachnoid Aneurysm Trial (ISAT) of neurosurgical clipping versus endovascular coiling in 2143 patients with ruptured intracranial aneurysms: a randomised trial. *Lancet* 2002;360:1267–74.
2. Raymond J, Guilbert F, Weill A, et al. Long-term angiographic recurrences after selective endovascular treatment of aneurysms with detachable coils. *Stroke* 2003;34:1398–403.
3. Murayama Y, Nien YL, Duckwiler G, et al. Guglielmi detachable

coil embolization of cerebral aneurysms: 11 years' experience. *J Neurosurg* 2003;98:959–66.

4. Sluzewski M, van Rooij WJ, Slob MJ, Bescos JO, Slump CH, Wijnalda D. Relation between aneurysm volume, packing, and compaction in 145 cerebral aneurysms treated with coils. *Radiology* 2004;231:653–8.
5. Wakhloo AK, Gounis MJ, Sandhu JS, Akkawi N, Schenck AE, Linfante I. Complex-shaped platinum coils for brain aneurysms: higher packing density, improved biomechanical stability, and midterm angiographic outcome. *AJNR Am J Neuroradiol* 2007;28:1395–400.
6. Piotin M, Iijima A, Wada H, Moret J. Increasing the packing of small aneurysms with complex-shaped coils: an in vitro study. *AJNR Am J Neuroradiol* 2003;24:1446–8.
7. Piotin M, Liebig T, Feste CD, Spelle L, Mounayer C, Moret J. Increasing the packing of small aneurysms with soft coils: an in vitro study. *Neuroradiology* 2004;46:935–9.
8. Lubicz B, Leclerc X, Gauvrit JY, Lejeune JP, Pruvo JP. Three-dimensional packing with complex orbit coils for the endovascular treatment of intracranial aneurysms. *AJNR Am J Neuroradiol* 2005;26:1342–8.
9. Hirsch JA, Bendok BR, Paulsen RD, Cognard C, Campos J, Cronqvist M. Midterm clinical experience with a complex-shaped detachable platinum coil system for the treatment of cerebral aneurysms: Trufill DCS Orbit detachable coil system registry interim results. *J Vasc Interv Radiol* 2007;18:1487–94.
10. White PM, Lewis SC, Gholkar A, et al. Hydrogel-coated coils versus bare platinum coils for the endovascular treatment of intracranial aneurysms (HELPS): a randomised controlled trial. *Lancet* 2011;377:1655–62.
11. Khan, SN.; Nichols, C.; Depowell, JJ.; Abruzzo, TA.; Ringer, AJ. *Clin Neurol Neurosurg*. 2011. Comparison of coil types in aneurysm recurrence.
12. White PM, Raymond J. Endovascular coiling of cerebral aneurysms using "bioactive" or coated-coil technologies: a systematic review of the literature. *AJNR Am J Neuroradiol* 2009;30:219–26.
13. Kurre W, Berkefeld J. Materials and techniques for coiling of cerebral aneurysms: how much scientific evidence do we have? *Neuroradiology* 2008;50:909–27.
14. Johnston SC, Dowd CF, Higashida RT, Lawton MT, Duckwiler GR, Gress DR. Predictors of rehemorrhage after treatment of ruptured intracranial aneurysms: the Cerebral Aneurysm Rerupture After Treatment (CARAT) study. *Stroke* 2008;39:120–5.
15. Tan IY, Agid RF, Willinsky RA. Recanalization rates after endovascular coil embolization in a cohort of matched ruptured and unruptured cerebral aneurysms. *Interv Neuroradiol* 2011;17:27–35.
16. Nguyen TN, Hoh BL, Amin-Hanjani S, Pryor JC, Ogilvy CS. Comparison of ruptured vs unruptured aneurysms in recanalization after coil embolization. *Surg Neurol* 2007;68:19–23.
17. Linfante I, DeLeo MJ, Gounis MJ, Brooks CS, Wakhloo AK. Cerecyte versus platinum coils in the treatment of intracranial aneurysms: packing attenuation and clinical and angiographic midterm results. *AJNR Am J Neuroradiol* 2009;30:1496–501.
18. Ishii A, Murayama Y, Nien YL, et al. Immediate and midterm outcomes of patients with cerebral aneurysms treated with Matrix1 and Matrix2 coils: a comparative analysis based on a single-center experience in 250 consecutive cases. *Neurosurgery* 2008;63:1071–7.discussion 7-9
19. Molyneux AJ, Kerr RS, Yu LM, et al. International subarachnoid aneurysm trial (ISAT) of neurosurgical clipping versus endovascular coiling in 2143 patients with ruptured intracranial aneurysms: a randomised comparison of effects on survival, dependency, seizures, rebleeding, subgroups, and aneurysm occlusion. *Lancet* 2005;366:809–17.
20. Mocco J, Snyder KV, Albuquerque FC, et al. Treatment of intracranial aneurysms with the Enterprise stent: a multicenter registry. *J Neurosurg* 2009;110:35–9.
21. Mocco, J.; Fargen, KM.; Albuquerque, FC., et al. *Neurosurgery*. 2011. Delayed thrombosis or stenosis following Enterprise-assisted stent-coiling: is it safe?: Midterm results of the Interstate Collaboration of Enterprise Stent Coiling.
22. Molyneux A, Fox AJ, Sneade M, Mehta Z. Cerecyte Coil Trial: the angiographic outcome of endovascular coiling in patients with ruptured and unruptured intracranial aneurysms treated with cerecyte coils compared with bare platinum coils. Results of a prospective randomized trial. 2010Abstract presented at: