

## Performance of GelitaSpon Rapid3 during use in open vascular surgery

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### INTRODUCTION

Gelita-Spon® Rapid<sup>3</sup> is a fast-acting gelatin-based hemostatic sponge developed by Gelita Medical as a novel alternative to traditional hemostats. The rapid portion of the Gelita-Spon® Rapid<sup>3</sup> name refers to: (1) the quick application of the product out of the packaging; (2) how quickly it absorbs fluid upon application; and (3) how quickly the body reabsorbs it. Unlike other topical hemostats that are slow to be absorbed within the body or require removal at a later date, Gelita-Spon® Rapid<sup>3</sup> is readily biodegradable and decomposes within days with little risk of encapsulation.

Over a period of two years, Gelita-Spon® Rapid<sup>3</sup> was used in over 400 procedures conducted by Dr. McDonald of the Royal Victoria Hospital. These procedures included but were not limited to: repairs of aorto-abdominal and endovascular aneurysms; aortic, carotid, femoral and popliteal endarterectomies; aorto bifemoral and femoral-popliteal bypasses. The patients undergoing these procedures covered a spectrum of ages, a multitude of co-morbidities and many different medications.

The primary aim of this study was to evaluate the performance and safety of Gelita-Spon® Rapid<sup>3</sup> as used in vascular surgery given its use in across a broad selection of individuals.

### MATERIALS AND METHODS

The sample period used for this study was two years and includes procedures from December 2011 to December 2013. In most of Dr. Sandy McDonald's surgeries throughout this timespan, Gelita-Spon® Rapid<sup>3</sup> was used in place of other topical or active hemostats in vascular procedures at the Royal Victoria Hospital of Barrie, Ontario, Canada. Only procedures that used Gelita-Spon® Rapid<sup>3</sup> were considered in this current study. Procedures in which the Rapid3 hemostatic agent was used include endarterectomies of the aorta, carotid, femoral and popliteal arteries; bypasses involving the aorta and bifemoral and femoral and popliteal arteries; repair of stenotic arteries and aneurysms in the abdominal aorta (predominantly) or femoral artery; grafts, patches and angioplasties; and combinations of many of the above disorders. All of these procedures were performed under open conditions.

Rapid3 was used to quell bleeding and oozing of arterial anastomoses. The application of the novel hemostat was performed in the same manner as the previously used hemostat, Surgicel. Once the package was opened, the scrub nurse would cut the hemostat into 3 or 4 strips that would then be applied to the anastomosis using forceps. The hydrophilic properties of Gelita-Spon® Rapid<sup>3</sup> required that a clean, dry instrument be used to place the hemostat as it would begin absorbing fluid immediately upon exposure to moisture on the surface of the gloves. Care was taken to gently apply pressure to the repaired vessel for at least one minute, at times a longer period depending on the procedure and the amount of oozing or bleeding. Prior to closing the incision, protamine sulfate was administered to counteract the effects of heparin. The incision was then closed with the hemostat left in place on the anastomosis.

If complications had arisen, an ultrasound may have been taken prior to the follow-up visit to Dr. McDonald's clinic, Barrie Vascular Imaging. No occurrences took place, therefore all patients next saw

Dr. McDonald four weeks post operation, where the patients underwent ultrasound imaging of their repair at Dr. McDonald's clinic in Barrie.

## RESULTS

In the span of two years, Rapid3 was used in 450 cases performed at the Royal Victoria Hospital. All procedures using Gelita-Spon® Rapid<sup>3</sup> were performed under open conditions. These procedures include: endarterectomies of the aorta, carotid, femoral and popliteal arteries; bypasses involving the aorta and bifemoral, and femoral and popliteal arteries; repair of stenotic arteries and aneurysms in the abdominal aorta (predominantly) or femoral artery; grafts, patches and angioplasties; and combinations of many of the above disorders.

### Handling properties

Gelita-Spon® Rapid<sup>3</sup> has excellent handling properties irrespective of the procedure for which it is used. The packaging is easily opened and the hemostat is easily cut and handled within the OR. Being able to use the hemostat right out of the package saves valuable time for the operating room staff, which is imperative for use in vascular procedures, particularly those involving major arteries and those located so near the heart. The nurses responsible for cutting the hemostat into smaller portions reported no trouble doing so. The hemostat was cut easily and cleanly without folding over the scissors.

The hemostat was easily placed and showed excellent adherence to the site of anastomosis. The Rapid3 was grasped with a pair of forceps, and its semi-rigid dry state allowed for a high degree of maneuverability during placement. Once placed, Rapid3 was easily manipulated to conform to the contours of the vessel for optimal placement. Even after fluid absorption, the hemostat retained its strength and was easily repositioned, allowing for optimal placement prior to closing.

### Hemostatic properties

Gelita-Spon® Rapid<sup>3</sup> is an effective, fast-acting hemostatic sponge, making it an effective tool during vascular surgery. It successfully induced hemostasis at the site of vascular anastomoses during a range of procedures involving major arteries. Upon application to the site of the anastomosis, Rapid3 was held for approximately one to two minutes to halt bleeding and oozing. Although it was held for that duration, it appeared to have induced hemostasis before application of pressure was ceased. It was observed to quickly absorb fluids from the site and held them within, improving visibility to the repair site and surrounding tissues.

The infection and rebleed rates remained low and thus were unchanged from those seen with previous products. Any complications pertaining to the use of a hemostatic agent (eg. bleeding, encapsulation, tumour mimicking, etc.) would have been observed with an ultrasound, however no complications were seen. There was also no evidence to suggest heightened foreign body reactions or infection pertaining to the Rapid3. Thus, the next observation of the anastomotic site was four weeks post-op, and by that time the Gelita-Spon® Rapid<sup>3</sup> had long since been reabsorbed.

### Additional remarks

Gelita-Spon® Rapid<sup>3</sup> was ready to use out of the package without preparation and induced hemostasis faster than other hemostatic agents previously used. These aspect of its performance made it especially appealing for use in vascular procedures. Additionally, once exposed to blood or plasma, Rapid3 did not

change colour as previously used products had, and it maintained its shape while wet, making it easier to reposition if needed.

## CONCLUSION

Gelita-Spon® Rapid<sup>3</sup> has been observed to be an effective, fast-acting hemostatic agent that is ready to use right out of the package. The hemostat began working immediately upon contact with fluid, and was still easily handled when saturated. Relative to previously used hemostatic agents, there was no difference observed in infection rate or post-operative bleeding at the site of anastomosis, thus precluding the need for additional imaging. Given the lack of complications or adverse reactions, and absence of the hemostat during ultrasound imaging performed four weeks post-operatively, Dr. McDonald concluded it was completely resorbed after every usage. Gelita-Spon® Rapid<sup>3</sup> confers advantages over other hemostatic agents without any additional drawbacks, a statement underscored by the absence of complications in 450 vascular procedures in which it was used over a two year period.