

From the surgeon’s perspective... Dr. Scott clinical experience Q&A



SURGEON

John David Scott, MD,
FACS, FASMBS
Greenville, South Carolina



GORE® BIO-A® Tissue Reinforcement – Clinical experience: Hiatal hernia repair with concomitant sleeve gastrectomy

Between 2014 and 2018, 374 patients in his practice received GORE® BIO-A® Tissue Reinforcement (120 of these performed by Dr. Scott)

Mesh related complications:	none reported
Hiatal hernia recurrences:	none reported
Time points for follow up:	1 week, 1 month, 3 months, 6 months Every 6 months for the first 2 years Then annually for the lifetime of the patient

How many patients with hiatal hernias have you repaired with GORE® BIO-A® Tissue Reinforcement?

“For the entire practice since 2014: **374 paraesophageal hernia repairs** (I have personally done over 120 of these repairs). In my lifetime, including those hernias fixed between 2008–2013 (before this current dataset) I have performed 200 repairs.”

How long is your follow-up for your GORE® BIO-A® Tissue Reinforcement hiatal hernia repair patients?

“Our intention is to follow our bariatric patients for life. The schedule is for post-operative follow-up at one week, one month, three months, six months, then every six months for the first two years; then every year thereafter.”

How many hiatal hernia recurrences have you had in your GORE® BIO-A® Tissue Reinforcement bariatric patient population?

“To my knowledge there have been **zero operative revisions** performed for hiatal hernia recurrence on those patients. The bariatric procedure re-operative rate has been 10%.”

Have you had any mesh related complications in your GORE® BIO-A® Tissue Reinforcement hiatal hernia repairs?

“We have not observed any complications directly related to the placement and usage of the GORE® BIO-A® Tissue Reinforcement at the hiatus.”

Why did you start using GORE® BIO-A® Tissue Reinforcement?

“We wanted the additional confidence that our suture hiatoplasty was going to be secure enough to allow for better healing of that repair. Having the GORE® BIO-A® Tissue Reinforcement scaffolding present has given us more confidence that repair was being bolstered. We saw success when using PGA:TMC web material during our staple line reinforcements during bariatric procedures so we felt it would be beneficial for hiatal repairs. This gave us confidence in the near term that it would cut down on recurrences in that area of the hiatoplasty. We have always had confidence in Gore products overall, no fears of mesh migration into the esophagus or that it will disappear overnight.”



Why do you prefer GORE® BIO-A® Tissue Reinforcement over other products?

“The GORE® BIO-A® Tissue Reinforcement is there long enough to be effective and then is not there to add any additional risk to the procedures. We have heard a lot of horror stories about using permanent mesh in that location leading to central complications: repeated motion in that area could lead to mesh migration into the esophagus or too much of an inflammatory reaction at the GI junction. We wanted a product that would support the healing process and be there during that critical healing process.

*Other non-permanent materials we tried in the past did not give us that confidence and seemed flimsy or more prone to complications, risk factors, etc. Biologics seemed to not add value, while some saw encapsulation and an inconsistent absorption period. **The GORE® BIO-A® Tissue Reinforcement absorption profile was something we could depend on, due to its uniform construction and consistent, reliable absorption profile.** GORE® BIO-A® Tissue Reinforcement gave us confidence in our repairs and we felt risks were reduced while benefits gained for the patients and the repairs.”*

Would you consider GORE® BIO-A® Tissue Reinforcement easy to handle and / or deploy in a trocar for hiatal hernia repairs?

“Yes, GORE® BIO-A® Tissue Reinforcement is easy to use and easy to get in through a trocar. Ease of use, in my opinion, is the right combination of compliance to get in to the trocar but then maintains its shape well to allow for ease of handling and placement once in the abdominal cavity. I will wet / soak the device then trim it. It is easy to trim and shape to what I need specific to my dissection and the case.”

In what percentage of your patients do you use a mesh to reinforce the crural closure?

“I use mesh in all cases unless the defect is smaller than 2 centimeters. I would use it in cases of large posterior defects too. I universally choose to reinforce sleeve patients because reherniation is higher in that patient population.”

Could you describe your technique to achieve a tension free crural defect closure?

“I would recommend a complete dissection of the hernia sac back into the abdominal cavity. Also getting three to four centimeters of esophageal length. We do not use relaxing incisions to bring the two leaves of the crura together. With good length, you should be able to bring them back together.”

GORE® BIO-A® Tissue Reinforcement, hiatal configuration: Designed for ease of use in Hiatal / Paraesophageal hernia repairs



Hiatal configuration conforms to the anatomy.



Easy to handle and manipulate.



Easy to insert and deploy through the trocar.

10
YEARS
positive
clinical results

10 YEARS EFFECTIVE CLINICAL USE

Complex and high-risk AWR cases
Hiatal / Paraesophageal hernia repair
Demonstrated economic value

- MORE than 150 publications
- LOW recurrence rates in hiatal hernias
- LOW recurrence rates in complex ventral hernias
- OVER 1,700 patients in the clinical literature
- TARGETED absorption period avoids the risk for long-term mesh-related complications
- LOWER cost alternative to other non-permanent products

Do you have any other thoughts for an effective crural closure?

“If I’m worried about tension of the suture repair, I will absolutely use GORE® BIO-A® Tissue Reinforcement. That has worked very well for bigger defects (anything over five to six centimeters diameter then need to think about how to bolster the suture repair). These are large in my opinion and you should start to figure out ways to bolster that area. Also, suturing through the diaphragmatic fascia in addition to the muscle to solidify the repair before covering with the GORE® BIO-A® Tissue Reinforcement is a good way to approach the repair.”

Do you use other Gore products in your practice?

“Yes. We started using GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement for staple line reinforcement in sleeves and bypasses. We have a lot of confidence in that product being used in our bypasses. Also, for abdominal wall hernia repairs we use GORE® BIO-A® Tissue Reinforcement for retromuscular placements.”

What is the range of hiatal defect sizes that you have repaired?

“I repair anything bigger than two to three centimeters. The largest defect size is an eight centimeter diaphragmatic defect (upside down stomach situation).”

Patient considerations or characteristics for hiatal repairs – are your patients concerned about the use of mesh in hernia repairs in general?

“Since there are risks with surgery, we discuss those with all of our patients, including risks of dissection, benefits, how it would affect GERD, reflux, etc. If patients ask about the mesh or express concerns, we tell them that GORE® BIO-A® Tissue Reinforcement is a bioabsorbable material and will not erode into an organ, so these fears are not a significant concern with this mesh and/or specific to a hiatal hernia repair with GORE® BIO-A® Tissue Reinforcement.”



GORE® SEAMGUARD®
Bioabsorbable Staple Line
Reinforcement



John David Scott, MD, FACS, FASMB,
Greenville, South Carolina



The observations provided reflect the individual experience of the physician and the patients treated. Individual patients present a range of variables that may affect the device and size selections made by the physician, as well as the outcomes and results. Licensed Healthcare Providers are responsible for making decisions about patient care and the appropriate use of medical technologies.



W. L. GORE & ASSOCIATES, INC.

Flagstaff, AZ 86004

+65.67332882 (Asia Pacific) 800.437.8181 (United States)

00800.6334.4673 (Europe) 928.779.2771 (United States)

goremedical.com

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