Application of a Novel Bioabsorbable Tonsil Patch®

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ABSTRACT

The *real* and *perceived pain* associated with tonsillectomy has resulted in voluminous research to find the "*Eldorado*" for tonsillectomy – the elusive but long sought after "painless tonsillectomy." [1]

The current study is a limited feasibility trial of a *truly novel* material for use during tonsillectomy as a tonsil patch®. The primary purpose was to determine feasibility and to understand how to handle the material. A secondary goal was to understand what, if any, impact there would be on postoperative pain reduction.

Biodesign® (SurgiSIS) 4-layer tissue grafts (COOK Medical, Bloomington, IN) were placed in the tonsillar fossa after tonsillectomy. *Biodesign® (SurgiSIS)* is a collagen matrix derived from the small intestine of pigs. The tonsillectomies were performed as isolated procedures or in conjunction with other surgeries to treat obstructive sleep apnea. All patients were adult patients.

The study goals were met in determining feasibility. Clinically, patients were experiencing about a 50% reduction in pain with noted fewer call-backs to the office for post-operative pain medication. Later results recorded with a standardized visual analog scale (VAS) confirmed anecdotal experience.

This study provides encouraging evidence that a non-energy based device may provide an "out of the box" solution for this perplexing problem in Otolaryngology.

Further study is warranted to explore whether *Biodesign® (SurgiSIS)* can improve postoperative pain and reduce bleeding after tonsillectomy.

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INTRODUCTION

A MEDLINE® search for "postoperative tonsillectomy pain" from the year 2002 to 2012 results in 610 citations. The problem of postoperative tonsillectomy pain is a real and vexing problem for patient, practitioner and industry alike.

Industry has generally approached the problem of post-tonsillectomy pain with a myriad of dissectors developed specifically for the procedure. There are at least ten different tools to accomplish the procedure. Coblation® (ArthroCare ENT, Austin, TX) is currently the most common instrument used to perform tonsillectomy (27.5%); however, the benefits still remain doubtful.[2,3]

Surgeons have addressed the issue of postoperative pain with a combination of tools and techniques; topical application, local infiltration, intravenous/oral/rectal administration of drugs; speech therapy; diet and activity modification[4]; imagery-induced relaxation[5]; and acupuncture.[6] Studies have also addressed the possibility of ethnicity as a discrepancy for post-operative pain.[7]

A few studies have addressed the basic pathophysiology of wound healing by attempting to cover the post-operative site with various materials.[8-10]

The current pilot trial attempts to address the basic issue of wound healing with a novel, bioabsorbable non-cadaveric tissue graft.

METHODS AND MATERIALS

4-layer *Biodesign® (SurgiSIS)* was used as a postoperative dressing after tonsillectomy. During this feasibility pilot trial, tonsillectomy was performed as an isolated procedure or as a combined procedure with a palatoplasty for obstructive sleep apnea (OSA). Additional procedures to address multi-level obstruction were performed as well to include midline glossectomy.

All tonsillectomies were performed using the Peak® electrosurgical dissector (Peak Surgical). All fossae were injected with 0.25% Bupivicaine with 1:100,000 epinephrine at the conclusion of the tonsillectomies.

4-layer *Biodesign® (SurgiSIS)* was fashioned in approximately 4.5cm x 2.5cm ovoid patches (figure 1) from a single sheet of 4x7cm *Biodesign® (SurgiSIS)*. In order to accommodate two patches from the supplied material, the patches were oriented 45º off the vertical axis. A surgical marking pen was used to dye the tissue. A series of six to eight 2.0 Vicryl® sutures were placed in the sub-mucosal muscular layer of the tonsillar pillars (palatopharyngeal and palatoglossal muscles). A single 2.0 Vicryl® was placed deep within the tonsillar bed (superior pharyngeal constrictor) (figure 2).

The pillars were initially closed with either 2.0 chromic® placed in the mucosa or closed with a *Biodesign® (SurgiSIS)* bolster (figure 3).

RESULTS

Ten patients (twenty sides) underwent successful placement of 4-layer *Biodesign® (SurgiSIS)* in this feasibility pilot trial.

Handling of the *Biodesign® (SurgiSIS)* was fairly straight forward. However, in placement the suture would at times "drag" the patch away from the tonsillar fossa. If placed in a bloody or wet surgical field, this made handling of the tissue more difficult.

In the first several cases, learning proper placement and securing of the graft proved challenging. Initial placement was performed by securing with 2.0 Vicryl® in the muscle of the submucosal layer of the tonsillar pillars (figure 2). This was followed with mucosal closure using 2.0 chromic suture. As with many tonsillectomies, shearing forces would pull these sutures out. The second technique used was the same as the first method; however, a *Biodesign® (SurgiSIS)* bolster was used in an attempt to prevent shearing (figure 3). This proved no more successful than the first technique and required a significant amount of time.

The final method of placement was submucosal tacking into the palatopharyngeal and palatoglossal muscles (respectively) with a single suture placed within the superior pharyngeal constrictor while leaving the tonsillar fossa open (no closure of the pillars).

Total time for placement near the end of the series approximated 8 minutes per side.

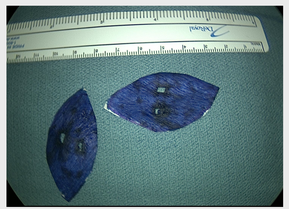

Figure 1. Biodesign® preparation

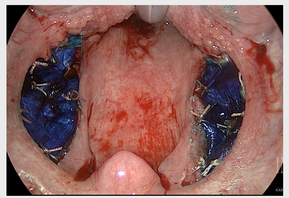

Figure 2. Placement w/o bolster

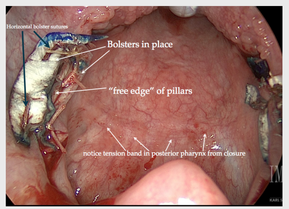

Figure 3. Intraoperative placement w/bolster

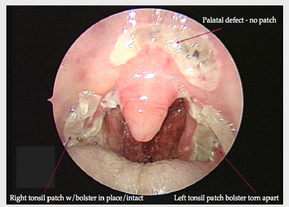

Figure 4. Post-op day 2 with bolster.

RESULTS

Patients were seen within 3 days of tonsil patch® placement and then again at about 2 weeks.

There were no cases of adverse reaction or aspiration of the *Biodesign® (SurgiSIS)* material. Closure of the tonsillar pillars with or without the bolster resulted in uniform failure of the closure; however, there was no evidence of non-adherence of the graft.

The last two patients of the series were provided post-operative pain logs and a standardized visual analog scale (VAS) to record their pain level.

The patient in Figure 5 (post-op day #2) was reporting pain on the VAS of 4-5. She presented to the clinic for evaluation and demonstrated minimal pain with swallowing water.

The second patient reported a pain level of 3-4 on the VAS on post-operative day #4.

Patient #6 was able to compare his procedure to his wife's tonsillectomy done approximately five years before and they both commented on the difference in the pain level he experienced (improved).

There were no cases of post-operative bleeding.

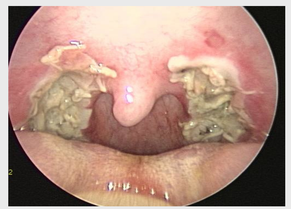

Figure 5. Post-op day 2 without bolster

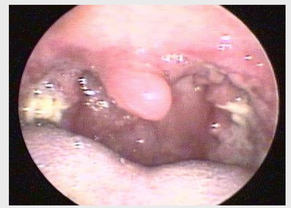

Figure 6. Post-op day #15

DISCUSSION

This study demonstrates the feasibility of using a bio-absorbable tonsil graft. Further, these results are consistent with previously reported results using Alloderm® as a peritonsillar graft resulting in about a 50% reduction in pain.[8] Problems with Alloderm® include cost, its cadaveric origin, and orientation (dermal side vs. non-dermal side).

Biodesign® (SurgiSIS) has been used for many years for hernia repairs, pelvic slings, and soft-tissue repair in the abdominal and pelvic regions. It has had limited use in other ENT operative sites.[11,12] In the oropharyngeal operative site, pain reduction related to tissue grafting is thought to be the result of providing a protective environment for re-epithelization.[8]

A major benefit to *Biodesign® (SurgiSIS)* over Alloderm® is its derivation from a non-cadaveric origin. Native tissue in-growth occurs within 24 hours with vascular in-growth occurring within 7 days. Total incorporation into the native tissue occurs within 3 weeks. In a five year study *Biodesign® (SurgiSIS)* demonstrated that it is easily absorbed, supports early and abundant new vessel growth and serves as a scaffold for the constructive remodeling of fascial and related tissues, and remains durable for long-term support.[13] Wiedeman concluded, "The morphological findings point to outstandingly good biocompatibility of *Biodesign® (SurgiSIS)* …without any foreign body or inflammatory reaction.[14]

CONCLUSIONS

The study demonstrates the feasibility of using *Biodesign® (SurgiSIS)* as a tonsil patch®. Pain reduction appears similar to previous attempts to cover the tonsillectomy site with a tissue graft.

For *Biodesign® (SurgiSIS)* or any other grafting material to be desirable, a specific closure device must be developed to reduce operative time. The grafts must be engineered for tonsillectomy to reduce cost. And it must be durable throughout the healing process.

Further clinical evaluation to confirm the effectiveness of the *Biodesign® (SurgiSIS)* technology in pain reduction as a tonsil patch® would be beneficial. Given its unique properties, other uses within Otolaryngology should be explored as well.

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