

Trigger Finger Release with UltraGuideTFR™ and Real-Time Ultrasound Guidance: Clinical Summary

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Introduction

Trigger finger, or stenosing tenosynovitis, is a common hand condition with a lifetime prevalence of 2-3% among the general adult population and 5-20% among diabetics.¹⁻⁴ Over 300,000 trigger finger release (TFR) procedures are performed annually in the United States to alleviate symptoms in patients with severe or refractory disease.^{1,5-7} The primary goal of a TFR surgery is to release the A1 pulley and resolve the mechanical symptoms.^{1,7} Traditional or classic open TFR is typically performed through a 1-2 cm transverse, longitudinal, or oblique palmar incision and has a reported success rate of 90-100%.^{1,8,9} However, many patients experience prolonged recovery periods due to pain, stiffness, or wound/scar sensitivity despite successful resolution of the triggering symptoms.^{7,10-14}

Trigger finger release using ultrasound (US) guidance was initially described by Jou and Chern in 2006.¹⁵ The primary goal of TFR using US guidance is to successfully resolve triggering while promoting a faster recovery.¹⁵⁻¹⁹ Since then, over 15 peer reviewed publications have reported clinical results on over 700 digits (>600 patients) treated with TFR using US guidance, with a clinical success rate of 98% at up to 18-month follow-up.¹⁵⁻¹⁹ Among these studies noted, there were no infections, tendon ruptures, bowstringing, or permanent nerve injuries in the long, ring, index or small fingers.¹⁵⁻¹⁹ In addition, a recently published, single surgeon, prospective randomized trial (Level 1 study) comparing TFR with US guidance to classic open TFR without US guidance demonstrated that patients treated with TFR using US guidance recovered significantly faster with respect to discontinuation of analgesics, restoration of normal motion, return to normal activities and QDASH scores.¹⁹

The Sonex Health patent pending UltraGuideTFR device was specifically designed to provide physicians with a simple, elegant, safe, and effective tool to perform TFR with or without US guidance (Figure 1). UltraGuideTFR is not indicated for trigger thumb release. Please see the Instructions for Use for a complete listing of the indications, contraindications, warnings and precautions. UltraGuideTFR consists of an ergonomic Introducer Handle attached to a curved Introducer containing a Blade Track. When using US guidance, the Introducer is passed through a small incision in the proximal palmar crease region and advanced into the tendon sheath and under the A1 pulley. Once the position of the Introducer is confirmed relative to the A1 pulley, flexor tendons, and surrounding neurovascular structures, the Blade Handle is removed from its Post and the Blade advanced along the Blade Track into the sheath and deep to the A1 pulley. The retrograde cutting Blade is then activated and the tendon sheath and A1 pulley are incised under direct US visualization. Following the release, the Introducer is used to probe the A1 pulley to ensure a complete release. The skin is typically closed with adhesive strips (e.g., Steri-Strip™). TFR with UltraGuideTFR and real-time US guidance can be performed in a variety of clinical settings, including an office procedure room using only local anesthesia.



Figure 1. UltraGuideTFR (Sonex Health, Inc., Eagan, MN).

Clinical Experience²⁰

The first TFR procedure using UltraGuideTFR with real-time US guidance was performed on January 21, 2022.

- Over 1,000 procedures completed by 43 different physicians
- All fingers treated – long, ring, index and small, including simultaneous procedures.
- Procedures performed in the procedure room/office setting, ASC and OR, and 97% performed using only local anesthesia.*
- Post-operative discomfort typically managed with acetaminophen or NSAIDs as necessary; no opioids required.
- Patients generally allowed to resume activities as tolerated (at the physician’s discretion).
- Those physicians who participated in a limited market release of the UltraGuideTFR device performed over 100 TFR procedures with US guidance, and rated the performance of the device and the procedure on a scale of 1-5 (1 = strongly disagree and 5 = strongly agree) with the following results:*

 - Easy to use = 4.98
 - Easy to perform the procedure = 4.98
 - Will use with future TFR patients = 4.98

*UltraGuideTFR Limited Market Release data on file (n=100). Sonex Health, Inc. April 20, 2022.

Outcomes

- The following is a summary of outcomes from TFR procedures performed with UltraGuideTFR using real-time US guidance as recorded in the Sonex Health APEX-TFR database (unpublished):²⁰
 - Median intra-operative pain score (0-10, 0 = no pain, 10 = worst pain possible) was 1.0 (n=110 fingers), with most patients identifying the local anesthesia needle as the most painful part of procedure.
 - 95% of all patients returned to normal daily activities within 3 days, increasing to 98% within 7 days (n=128).
 - 86% of employed patients returned to work within 3 days, increasing to 98% within 7 days (n=50), including 15 light and heavy manual laborers.
 - Median self-reported Quinnell Scale (0=normal, 4=locked) reduced from 2.0 pre-operatively (n=164 fingers) to 0.0 at 2 weeks (98 fingers), 1 month (105 fingers), 3 months (99 fingers), and 6 months (63 fingers).
 - Significant improvement in QDASH scores (Figure 2a).
 - By 2 weeks, 36% of wounds/scars were rated as excellent (indistinguishable from surrounding skin), and an additional 58% were rated very good (barely noticeable, minimal difference from surrounding skin) (Figure 3).

Over 97% of patients were very satisfied or satisfied with their wound/scar at all time points.

*APEX-TFR = Assessment of the Patient Experience-TFR. Real-world data measuring the short-term and long-term patient experience following trigger finger release with UltraGuideTFR and real-time US guidance. Data current and reflects full cohort as of 1-December-2022, unless otherwise indicated.

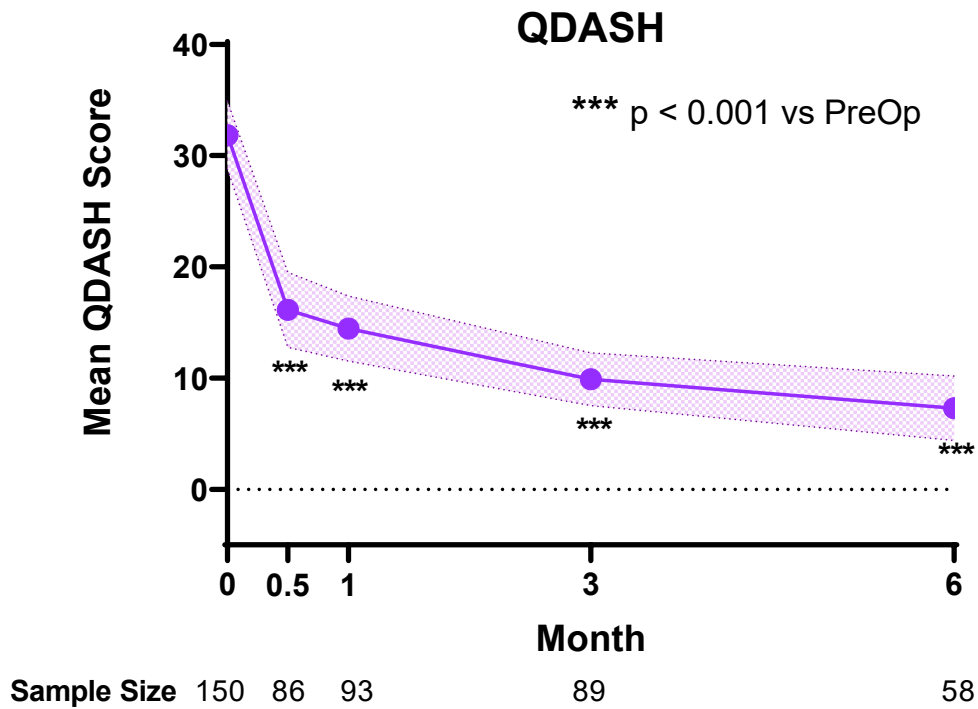


Figure 2a. Mean QDASH scores following TFR using UltraGuideTFR with real-time US guidance (lower scores = better outcomes). Compared to pre-op, QDASH scores were significantly reduced at all time points ($p < 0.001$), and QDASH score reductions exceeded minimally clinically important differences at all time points. Note that the results are comparable to the US group in a recently published prospective, randomized trial, as shown in the Figure 2b.²⁰ All values represent means \pm 95% CI. Data compiled from 13 different physicians. APEX-TFR database, December 1, 2022.

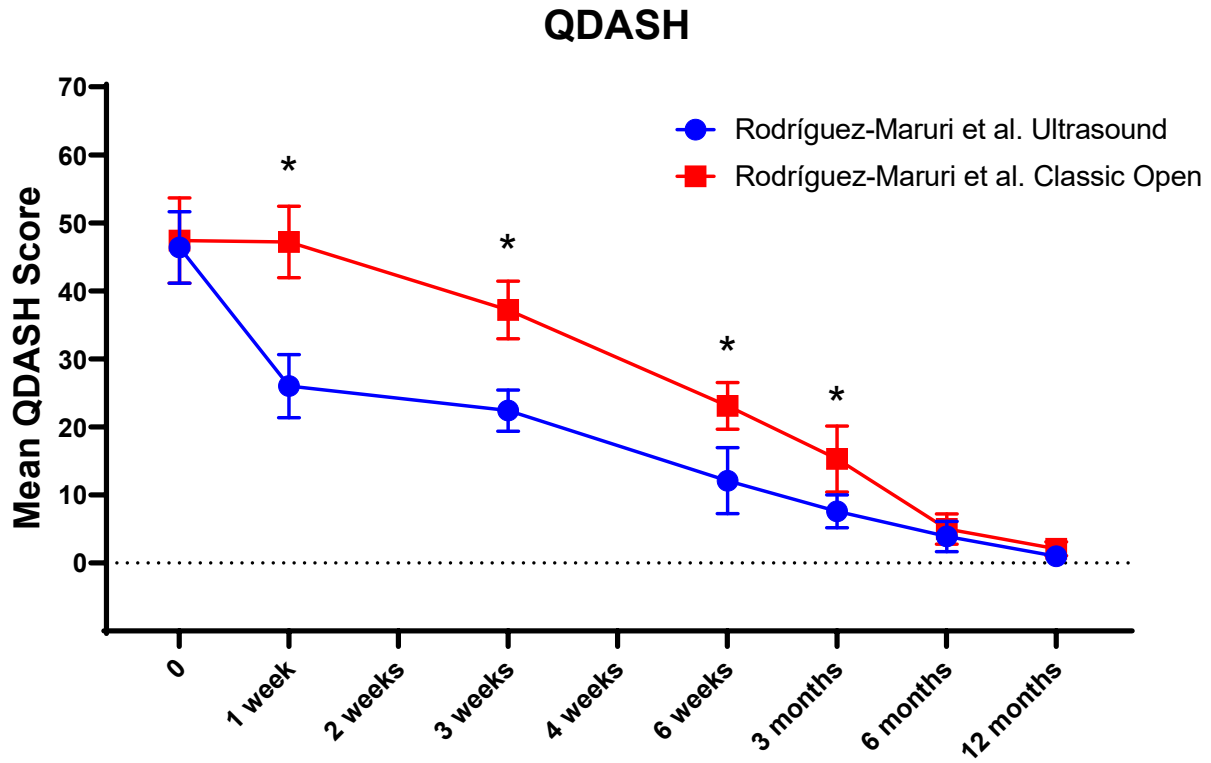


Figure 2b. QDASH scores following classic open TFR without US guidance (red line) and TFR using US guidance (blue line) (lower scores = better outcome). Data reproduced from a prospective, randomized trial (Level I) comparing the two techniques.¹⁹ Patients treated with TFR using US guidance recovered significantly faster during the first 6 weeks as compared to classic open TFR (asterisks, $p < 0.05$). All values represent means \pm 95%CI.

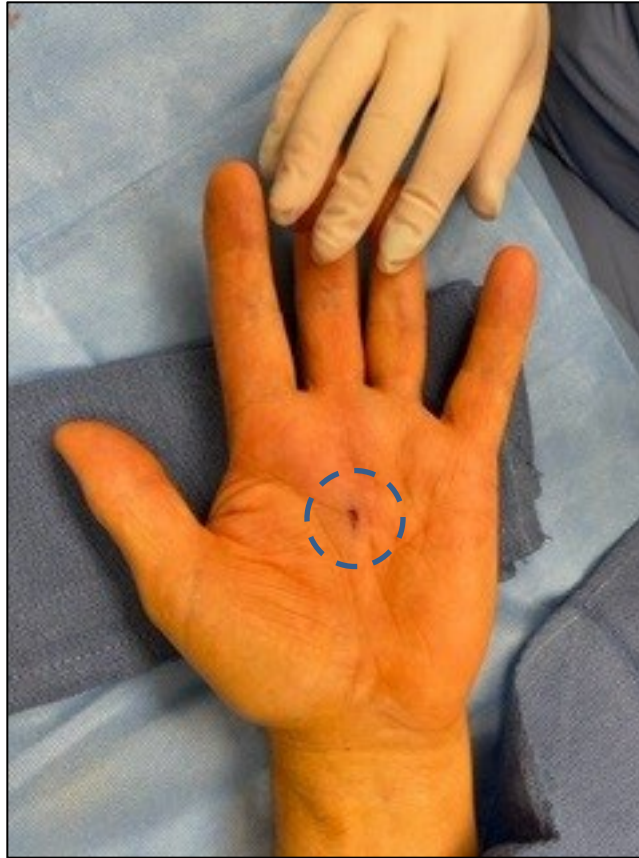


Figure 3. Wound following TFR using UltraGuideTFR with real-time US guidance taken immediately following the procedure. 95% of wounds were closed with adhesive strips (UltraGuideTFR Limited Market Release data on file (n=100), Sonex Health, Inc. April 20, 2022).

Presentations

- AAHS 2023 Podium Presentation accepted for AAHS 2023 – “Clinical Results of Trigger Finger Release Using Ultrasound Guidance (TFR-US) In Multiple Practice Settings ,” by Richard Schaefer, MD, Alan Blackburn, MD, Brett Kindle, MD, Craig Chappell, DO, Joseph McGinley, MD, Douglas Hoffman, MD. Case series reporting on 150 patients (164 fingers) treated by 13 different physicians with up to 6 months follow-up. To be presented at AAHS, January 2023.
- ASSH 2022 Eposter – “Trigger Finger Release Using Ultrasound Guidance: Initial Experience from Multiple Sites,” by Richard Schaefer, MD, Douglas Hoffman, MD, Brett Kindle, MD. *Initial case series reporting on 36 patients (40 fingers - 4 index, 18 long, 17 ring, and 1 small) treated by 8 different physicians using local anesthesia and a small (3-4 mm) transverse palmar incision. Over 2/3 of patients were treated in the clinic setting. Wounds were typically dressed with adhesive strips or skin glue plus a light dressing. Follow-up was available for 32 patients/34 fingers at 1wk, 22 patients/26 fingers at 2wks, 13 patients/13 fingers at 1mo, and 12 patients/12 fingers at 3mos. No complications occurred. Median return to activity was 2 days and among the fully employed patients the median return to work was 3 days. All patients reported resolution of triggering, with the median Quinnell Score reducing from 2 pre-op to 0 at day 7 and remaining at 0 through 3 months. Mean QDASH scores decreased from 33.2 pre-op to 15.5 at 2wks, 16.2 at 1mo, and 17.8 at 3mos. Mean global satisfaction (1=very dissatisfied, 5=very satisfied) was 4.6 at 2wks, 4.5 at 1mo, and 4.3 at 3mos. All 8 physicians graded the ease of device use and confidence performing TFR-US as 5/5 (5=very confident), despite these being their first cases with the device. The authors concluded that TFR using UltraGuideTFR with US guidance can be safely implemented by multiple physicians with diverse ultrasound experience with excellent short-term results and a high degree of patient and user satisfaction.*

Conclusion

TFR performed using US guidance has an established track record of safety and efficacy in the peer-reviewed literature, including a Level 1 study documenting superior earlier outcomes compared to traditional or classic open TFR without US guidance. The UltraGuideTFR device provides a unique combination of safety and usability features to facilitate TFR with US guidance. The initial clinical experience performing TFR with UltraGuideTFR and real-time US guidance has been excellent based on over 1,000 procedures performed by a diverse group of operators in multiple practice settings, including procedure rooms.

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