Eclipse® Total Shoulder Arthroplasty System

On July 26, 2019, the Eclipse total shoulder arthroplasty system received clearance from the US Food and Drug Administration. Used to treat primary and posttraumatic osteoarthritis, the Eclipse system has been on the market outside the US for more than 14 years. The system’s novel cage screw and calcium-phosphate–coated trunnion replace the humeral head without violating the intramedullary canal.

- Bone-preserving anatomic humeral head placement
- Compressive fixation of cage screw and trunnion to the cortical rim of the humeral metaphysis reduces the stress-shielding often observed in stemless arthroplasty
- More than 20,000 implantations since 2005
- Nine-year outcome study published in the Journal of Shoulder and Elbow Surgery
- Compatible with Univers VaultLock®, pegged, and keeled glenoids
- Bone preservation and easy removal provide for a stable revision, when necessary

HYMOVIS® High Molecular Weight Viscoelastic Hyaluronan

HYMOVIS hyaluronic acid is the only 2-injection regimen on the market for the treatment of pain in patients with osteoarthritis of the knee who have failed to respond adequately to conservative nonpharmacologic therapy or simple analgesics.

Key features and benefits of HYMOVIS:

- A hydrogel with greater viscosity, elasticity, and increased joint residence time
- Withstands mechanical stress and shear
- Increased joint lubrication with reduced friction
- Natural hyaluronan, not cross-linked to formaldehyde or cinnamic acid
- Long-lasting efficacy

HYMOVIS is redefining pain relief for osteoarthritis patients everywhere with just 2 convenient injections.

References

1. HYMOVIS [package insert]. Fidia Pharma USA; October 2016.
**FlipCutter® III Drill**

The new, innovative FlipCutter III drill is an adjustable, variable-size, all-in-one guide pin and reamer that allows minimally invasive socket creation from the inside-out. Designed for the ultimate in convenience and utility, the FlipCutter III drill:

- Can ream sizes 6 mm and 7 mm to 12 mm, including half-sizes, through a small 3.5 mm hole
- Helps reduce inventory and minimize the costs associated with opening multiple drills during a procedure
- Has a unique design with 2 different cutting edges, a distal edge for drilling and a proximal edge for retrograde reaming
- Each edge has been specifically engineered to improve performance during each step

**Synergy Matrix™ Video Integration**

Arthrex continues to bring a new level of efficiency to the OR. The Synergy Matrix video integration system is the world's first OR integration platform capable of supporting the 4K video signal produced by the Synergy UHD4™ camera system and distributing it to multiple displays within the OR and facility. The next-generation platform expands on the success of the Synergy Matrix system with the inclusion of an integrated touch panel that improves system performance and reliability, simplifies the user experience, and offers a more robust room-to-room communication and source-sharing experience.

The Synergy Matrix video integration system’s enhanced capabilities include:

- Programmable room presets allowing users to select the room’s audio and video sources and in-room displays with a single touch.
- In-room cameras can be fully controlled from the tablet. Presets allow for quick configuration of the camera positions for scenarios like patient privacy.
- Improved control over which outside rooms have viewing capabilities of internal sources allows users to grant permission for a specific time range or remove access as needed.
- Enhanced remote support reduces OR downtime through proactive system monitoring of the health of integrated ORs.
- Arthrex can upgrade and service each system independently via remote support.

**Suture augmented versus standard anterior cruciate ligament reconstruction: a matched comparative analysis.**


- This retrospective study of 60 patients with a 2-year follow-up compared outcomes between standard anterior cruciate ligament reconstruction (ACLR) using hamstring auto- or allografts with suture augmentation (*Internal Brace™* ligament augmentation using FiberTape® and TightRope® suture) and ACLR without suture augmentation.
- The study concluded that ACLRs with *Internal Brace* ligament augmentation demonstrated improved patient-reported outcomes measures (PROMs), less pain, and a higher percentage of earlier return to preinjury activity level when compared with standard hamstring ACLRs without evidence of overconstraint.
- Postoperative average daily (0.60 ± 1.25 vs 1.66 ± 1.90) and maximum daily pain were significantly lower in the suture augmentation group (*P* < .014).

- The SA group had improved PROMs (*P* < .05) and maximum pain scores (*P* = .001).
- Patients in the SA group had a significantly earlier return to preinjury level than the ACLR group (9.17 ± 3.94 vs 12.88 ± 3.94; *P* = .002).
- The SA group had a higher percentage of preinjury activity level than the ACLR group (93.33% ± 13.22% vs 83.17% ± 17.69%; *P* = .010).
FiberTape® Cerclage Mechanical Properties

- This study was performed to define the mechanical properties of FiberTape cerclage (a tensionable, suture-based cerclage) and benchmark them against 18 ga stainless steel wire, which is commonly used in cerclage procedures like humeral fixation during shoulder arthroplasty.
- The FiberTape cerclage proved to have higher load-to-failure and initial tension, and produced half the displacement compared to stainless steel wire cerclage.
- This mechanical performance, in addition to easy intraoperative handling, less radiographic interference, and no risk of metallosis, makes FiberTape cerclage a viable alternative for cerclage procedures.

FiberLink™ SutureTape

FiberLink and TigerLink™ SutureTape is a 1.3 mm suture with a closed loop on one end. Create cinch stitches by simply passing the suture through tissue and feeding the free suture limb through the loop for tensioning. Lock the cinch stitch into position to create a knotless repair using PushLock® or SwiveLock® suture anchors. The cinch stitch knotless repair can be used for soft-tissue fixation of the glenoid labrum, rotator cuff dog-ear compression, or biceps repair using the Loop ‘N’ Tack™ surgical technique. FiberLink and TigerLink sutures can also be used to shuttle multiple sutures at once with the Scorpion™ suture passer.

- 1.3 mm SutureTape loop with a single, round suture tail; simplifies tension control of soft tissue
- Improved tissue compression with tape design
- 21% more resistant to pull-through in soft tissue compared to #2 suture
- Knotless repair with SwiveLock or PushLock suture anchors
Virtual Implant Positioning™ (VIP) System

Web-based, preoperative planning with the VIP system helps surgeons plan anatomic and reverse shoulder arthroplasty procedures using patients’ CT scans in 3-dimensional space. All Arthrex shoulder arthroplasty glenoid options can be used with the system, including the Univers VaultLock® glenoid system for anatomic shoulder replacement, and the Univers Revers™ shoulder systems for reverse shoulder arthroplasty.

- A recent web portal upgrade now allows for visualization of the articulating surfaces and screw trajectory for implant positioning. An upgrade for backside seating and maximum gap offset between the implant’s backside and the patient’s bone interface will be released in the near future.

- A next-generation, reusable glenoid targeter is also scheduled to launch in December 2019. This device will be more ergonomically designed and will allow surgeons to calibrate the entire device in one step. In conjunction with the glenoid targeter, a Nitinol pin will be released, which will allow for easier insertion of the cannulated glenoid preparation instrumentation while maintaining the desired trajectory.

The iBalance® UKA Adjustable Spacer Block

The iBalance UKA adjustable spacer block further improves operative efficiency and reproducibility when it comes to assessing the tension of the MCL during partial knee replacement. The expandable device can seamlessly transition into your existing surgical technique and minimize the in-and-out actions of current static spacer blocks.

Simply use a lamina spreader to consistently open the self-retaining spacer block in both flexion and extension to determine the prefemoral resection gap. Both distal femoral and posterior femoral cutting blocks slide on in the conventional manner, creating the appropriate composite spaces.
FDL and FHL Implant Systems

The new FDL and FHL Implant Systems allow surgeons to use the tension-slide technique to quickly and effectively treat a multitude of pathologies in the foot and ankle. The standard in distal biceps repair, the tension-slide technique now joins TightRope® button fixation as another tenodesis product with proven technology for the foot & ankle market. Available in 4 sizes, the FDL and FHL Implant Systems are conveniently packaged for ease of use for surgeons, facilities, and technology consultants.

Key features and benefits:

• **Maximize Tendon-to-Bone Contact** – Using the tension-slide technique, surgeons can easily draw the tendon to the base of the tunnel and against the cortex using a pulley-type mechanism
• **Low-Profile Fixation** – Allows for passage through a small hole
• **Excellent Load-to-Failure** – FHL - 299N ultimate load-to-failure, FDL - 259N ultimate load-to-failure.\(^1\) In addition, cortical button fixation removes the variability of bone quality.
• **Convenience Pack** – No need to have instruments in the room and can move quickly to the procedure
• **Disposable Graft Tendon Sizer Kit** – Use to determine which size implant system to open

Compression FT Screws

The Compression FT family of screws now offers 5 diameters and 91 screw lengths to fit various orthopedic applications throughout the body. The Compression FT screws come in 2.5 mm micro, 3.5 mm mini, 4.0 mm standard, 5.0 mm large, and 7.0 mm XL diameters. Longer screws and new caddies for the micro, mini, and standard sizes are also available.

• Headless design allows for minimal risk of impingement or soft-tissue irritation
• Variable-stepped thread pitch and tapered proximal profile allow for gradual compression and promote bone union
• Cannulation allows for accurate placement for percutaneous and open indications

InternalBrace™ 2.0 Ligament Augmentation for Lateral Ankle Instability

Introducing the new InternalBrace 2.0 ligament augmentation system—surgeons can now drill, tap, and implant using the new talus offset guide. The upgraded system increases surgical versatility with more size and material options, in addition to the new radiopaque marker and laser line window to determine the SwiveLock® implant location. The new cannulated drills and taps in the InternalBrace 2.0 ligament augmentation system allow surgeons to take a percutaneous or minimally invasive approach. The biologic advantages of the collagen-coated FiberTape® suture and JumpStart® antimicrobial dressing complete this comprehensive ligament augmentation system.

Reference

\(^1\) Arthrex, Inc. Data on file (APT 04032). Naples, FL; 2019
Why use ArthroFLEX for augmentation?
- Has demonstrated improved clinical outcomes
- Provides improved strength to help protect repair and allow healing
- Proven to reduce retear rates
- Has high ultimate load and suture retention strength

Despite advances in surgical technology, repairs of large (3 cm to 5 cm) to massive (>5 cm) rotator cuff tears result in retear rates of 30% to 63%. These retears frequently occur at the suture-tendon junction and can be attributed to tension at the repair site and the quality of tendon being repaired. In hopes of augmenting the initial repair to reduce the possibility of failure, surgeons may use biological scaffolds, such as the ArthroFLEX decellularized bio-implant to provide a mature collagen scaffold as a framework for host cell repopulation, as well as improved healing rates.

Patient Selection
- In the setting of full-thickness rotator cuff tears that have enough tissue elasticity to be mobilized fully to the footprint and not be overly tensioned, but the cuff tissue is thinned or potentially inadequate.
- For revision cases, when the rotator cuff tendon has been shortened through attrition or tearing.
- In cases where augmentation will provide more surface area for the stress of the repair to be distributed evenly and allow for thickening of the tissue.

Anchor Placement and Suture Passing
- The medial row anchors should be placed at the articular margin and edges of the tear.
- 4-, 6-, or 8-anchor SpeedBridge configurations can be used with this construct.
- The distance between the anchors must be accurately measured.
- The sutures should be passed roughly 3 mm lateral to the musculo-tendinous junction, but equidistant through the cuff as the anchors are spaced anterior and posterior.
- For most anterior and posterior medial row anchors, the eyelet sutures should be retained for the eventual double-pulley; eyelet sutures of the inner anchors can be removed if 6-or 8-anchor SpeedBridge configurations are performed.

Measuring for Graft Preparation
- The arthroscopic measurement probe can be used to measure the anterior to posterior distance between the passed FiberTape® sutures.
- Alternatively, the SCR measuring guide may be used.
- The anterior-posterior length of the graft is calculated by adding 10 mm to both sides.
- Medial-lateral distance of the graft is typically 15 mm to 20 mm.
Graft Preparation
- Typically, an ArthroFLEX® 201 is used (surgeons may opt for the thinner ArthroFLEX 101 or the thicker ArthroFLEX 301).
- Prepunch holes based on the obtained measurements with a 14 ga needle to create uniform holes in the graft to aid in passing the FiberTape® suture limbs.
- Number of prepunched holes is dependent on whether construct will be a 4-anchor (2 holes), 6-anchor (3 holes), or 8-anchor (4 holes) SpeedBridge™ configuration.

Preparation of the ArthroFLEX graft

Optional: Reduction of lateral dog-ear flaps with FiberLink sutures

Graft Preparation
• Typically, an ArthroFLEX® 201 is used (surgeons may opt for the thinner ArthroFLEX 101 or the thicker ArthroFLEX 301).
• Prepunch holes based on the obtained measurements with a 14 ga needle to create uniform holes in the graft to aid in passing the FiberTape® suture limbs.
• Number of prepunched holes is dependent on whether construct will be a 4-anchor (2 holes), 6-anchor (3 holes), or 8-anchor (4 holes) SpeedBridge™ configuration.

Preparation of the ArthroFLEX graft

Optional: Reduction of lateral dog-ear flaps with FiberLink sutures

Passing/Introducing the Graft
- After passing each suture set through its respective graft hole, the double-pulley system can be created by tying one eyelet suture limb from the anterior and posterior suture sets.
- The graft may be pushed through the Passport Button™ cannula using a Back Grasper or a KingFisher® FiberTape retriever/grasper.
- Take care not to twist the graft during insertion.

Passing/Introducing the Graft
• After passing each suture set through its respective graft hole, the double-pulley system can be created by tying one eyelet suture limb from the anterior and posterior suture sets.
• The graft may be pushed through the Passport Button™ cannula using a Back Grasper or a KingFisher® FiberTape retriever/grasper.
• Take care not to twist the graft during insertion.

Introduction of the ArthroFLEX graft to final position

Completed repair

Optional: Reduction of lateral dog-ear flaps with FiberLink sutures

References
Joshua S. Dines, MD, usually treats shoulders, elbows, and knees in his sports medicine practice at the Hospital for Special Surgery. But he noticed that he was treating lower extremities injuries, including Achilles tendon ruptures, more often.

“A lot of these injuries occur when playing sports. And from a patient perspective, they get injured playing a sport, they have to choose a doctor. In their minds, this becomes a sports medicine-type injury. A lot of these patients get seen by sports medicine specialists,” he said.

Dr. Dines spoke with Arthrex’s Vice President of Global Medical Education, Christopher Adams, MD, recently about treating Achilles injuries and how his perspective changed when he became a patient himself.

Dr. Adams wondered if Dr. Dines had criteria for treating these injuries operatively or nonoperatively. Dr. Dines said it depended on the patient’s age and activity level.

“Younger, more active, athletic patients benefit from surgical repair. There’s a lower rerupture rate, a better return to strength and, along those lines, a better return to sport,” he said.

According to Dr. Dines, as medicine evolves and our understanding of biomechanics and treatment options improves, more procedures can be done percutaneously, causing less morbidity to the body. “Anything we can do to improve wound healing is a victory,” he said. Estimating he does about 10 to 15 Achilles tendon repair procedures each year, Dr. Dines said he anticipates he will see more in the future.

“People are staying active and so there is a higher incidence of Achilles ruptures,” he said. “The other thing is some of the newer studies are getting more extensive at looking at the outcomes, and that only benefits the surgical repair.”

Dr. Dines has first-hand knowledge of this injury. Last year, he tore his Achilles playing tennis.

“What was your rationale in deciding what was the best technique for you? Patients ask us all the time, ‘What would you do if you were in my situation?’ This is the perfect case. What did you do?” Dr. Adams asked.

Dr. Dines said the first decision he had to make was whether to treat it operatively or nonoperatively. His rationale for surgery, he said, was the same advantages he observed treating his own patients.

“The techniques are better. I wanted to be active. I wanted as low a rerupture rate as possible. I want it to be as strong as possible so I can get back to playing sports. When you took those into account, surgery became an easy decision,” he said.

Dr. Dines said his concern about wound healing led him to consider the PARS technique over an open Krakow procedure.

The technique to repair the Achilles has evolved from tying knots using the PARS technique to using the Achilles Midsubstance SpeedBridge™ repair to fixate SwiveLock® anchors into the calcaneus.

“I don’t think one is better than the other. I think there are applications for both. The knotless SpeedBridge technique gets rid of some of the issues with PARS like the knot stacks, and you don’t have to worry about reproducibility of surgeons tying knots because it becomes a knotless construct. It also works really well when you have a distal tear when there’s not a lot of tendon on the calcaneus.

But I don’t think the PARS technique is going away. I think the PARS technique is good for more proximal tears. As we go forward, I think there is a role for each of these. It is going to be case-by-case dependent and surgeon dependent.”

References

For more information on Achilles tendon ruptures: https://arthrex.info/STO-achilles-tendon
**FiberTag® TightRope® Implant**

The FiberTag TightRope implant facilitates attachment of single-ended grafts, such as quad tendon grafts, to ACL TightRope RT and ABS implants. FiberTag suture is integrated into the TightRope implant for a strong, consistent connection between the suture and TightRope loop. A simplified suturing technique, along with innovative packaging and the new GraftClamp graft preparation instrument, makes preparing quadriceps tendon grafts faster and more reproducible than ever.

1. Load the suture card onto the GraftClamp instrument. Then pierce one tooth of the GraftClamp instrument through the FiberTag suture. Clamp the GraftClamp instrument approximately 2 mm from the end of the graft.

2. Place the first needle pass approximately 20 mm from the end of the graft. Then perform SpeedWhip™ stitches, working toward the TightRope implant and ensuring the FiberTag suture is captured with each needle pass.

3. After placing 2 SpeedWhip stitches through the FiberTag suture, pass the needle through the slot in the suture card, ensuring the needle passes over the TightRope implant. Repeat the SpeedWhip rip-stop technique with 2 additional passes.

4. Cut one suture just below the splice near the needle to aid in burying the knot. Wrap the suture limbs around the graft and tie a knot. Use the needle to bury the knot in the graft. Cut the excess suture.

5. The FiberTag TightRope suture card can now be removed from the GraftClamp instrument. Unwrap the sutures from the suture card cleat and remove the TightRope implant loops from the retaining slots in the card.

6. FiberTag TightRope graft preparation is now complete and the opposite end of the graft can be prepared in the desired manner.
What’s in My Bag?

Featuring Brian S. Cohen, MD (Chillicothe, OH)

FiberTape® Cerclage System

The FiberTape® cerclage system replaces metal cables and wires traditionally used for fracture fixation, providing better compression and ultimate load. The cerclage system contains FiberTape and TigerTape™ cerclage sutures along with various passing instruments, a tensioner, and an instrument tray. Here, Dr. Cohen shares his experience using the FiberTape cerclage system.

Q: How long have you been using FiberTape cerclage and why did you move away from using metal wires/cables for fracture stabilization applications?

A: FiberTape cerclage system has been a part of my surgical “toolbox” since it was released approximately 2 years ago. Prior to its release, I used a nonmetallic, synthetic cable with a metal-locking mechanism. I moved away from the traditional metal wires/cables for fracture fixation and over to the FiberTape cerclage because the previous single-passing only device was difficult to pass and “lock,” was visible on X-ray, and was not low profile.

Q: What procedures are you primarily using FiberTape cerclage for?

A: The FiberTape cerclage is used for procedures that previously required wires and cables. Cases that are amenable to FiberTape cerclage depend on the fracture pattern (long oblique or spiral) and include:

- Long-bone and clavicle fractures
- Revision joint replacement (specifically total shoulder and total hip)
- Patella fractures
- Allograft fixation to host bone
- Plate fixation to bone
- Preliminary fracture fixation to minimize the need for bulky bone-holding reduction clamps

Q: Are there applications where you believe FiberTape cerclage is a better solution than the previous technology of cables and wires? Why?

A: Because of its lower profile, the FiberTape cerclage is ideal for preliminary fracture fixation, because the plate will sit over the FiberTape cerclage as if it was not there.

It can be passed easily and multiple times and it has a simplistic locking mechanism, which all help to make cerclage fixation easier for deep, hard-to-reach fractures.

Q: What do you find is most beneficial when using suture material instead of metal cable systems or wires?

A: The benefit of using FiberTape cerclage is that it is invisible on X-ray, low profile, easily passed, easily secured, and easily removed with a suture scissor or scalpel if adjustments need to be made.

Q: What are some technique pearls you can share to enhance the use of FiberTape cerclage?

A: The biggest challenge I faced when I first started to use the FiberTape cerclage was pulling the tape through the locking mechanism. I found initially that the cinching device could be used as a “mechanical” knot pusher if the conjoined suture end (prior to cutting) was passed into the torque wheel and turned to pull the tape through the locking mechanism. Subsequently, I discovered that this can be easily accomplished if each tape limb is tensioned using a back-and-forth technique.

Reference
As one of the first adopters of the Arthrex NanoScope visualization system, the first medical-grade, 3-in-1, 1.9 mm chip-on-tip single-use camera system, I can say this is a game changer for orthopedics.

In traditional scopes, the camera and light source is within the camera housing. With the NanoScope system, the camera and light are on the tip. This technology is an important innovation and stands out from the competition by allowing for better resolution and a smaller diameter scope. Also, the scope tube can flex slightly to access areas of the joints that are often hard to visualize.

The image quality is excellent, consistent, and free of distortion. The chip-on-tip technology with the LED light at the tip decreases bright spots and provides a natural, high quality view of the joint. There is no edge distortion and the whole screen visualizes well.

The 1.9 mm diameter NanoScope sheath is more robust than and a huge improvement over other small scope systems. It makes it easier to get around a joint. It's almost like putting a spinal needle in the joint place; one can see how much easier it is to move around joints such as the shoulder, elbow, and knee. A smaller capsular, skin, and muscle trocar allows for less “skin-capsule distress,” meaning it is much easier to move around the joint than with a traditional 5 mm to 6 mm scope sheath. This is dramatically apparent as you drive the NanoScope camera around on your first case.

Also, compared to the traditional 30° scopes, difficult areas of the anatomy are actually easy to view with the NanoScope system. There is really no area that I cannot reach in the joint. The straight-on view provides a wider, 120° field of view. The scope is ergonomic and well-designed. It is light and easy to control, and it feels good in your hand. Decisions about trajectory and insertion, followed by “driving around” the joint for diagnostic capabilities, are intuitive.

I use the NanoScope system in several areas of my practice. It's extremely useful in the operating room for cases that require a scope, including shorter cases as well as open procedures that need a scope first. You can also use it for scar debridement postsurgery, cartilage or injury assessment, review a joint or to supplement an MRI, and for repairs in the shoulder, elbow, and small joints. In addition, the in-office scope applications are numerous.

Arthrex has also created a wide range of Nano instrumentation in addition to the visualization system. The 2 mm single-use instruments are the next generation in tissue resection and extraction. They are designed to facilitate safe introduction into most tight joint spaces without the need for a limb holder.

The disposable instruments are lightweight, well-designed, and sharp. They work well and allow you to do many of the cases that we do on a daily basis without any concern. You can always use backup instruments if necessary, but I haven't found it to be a need in the cases we perform with the NanoScope system.
Anatomic Total Shoulder Arthroplasty (TSA) Virtual Implant Positioning™ (VIP) Preoperative Planning System vs TSA Without Planning

Purpose
To report the early clinical outcomes of pain, function, and quality of life comparing patients who underwent anatomic total shoulder arthroplasty (TSA) with Arthrex implants (Univers™ II and Apex) and preoperative planning using the VIP™ system to patients who underwent anatomic TSA with Arthrex implants and no planning.

Method
Patients enrolled in the Surgical Outcomes System™ global registry who underwent anatomic TSA with Arthrex implants (Univers II and Apex) with preoperative planning using the VIP system or patients who underwent anatomic TSA with Arthrex implants and no planning were included. Standard patient-reported outcomes questionnaires for VAS, ASES Shoulder Function, and SANE were administered at standard time points postoperatively. Results were reported from presurgery to 5 years postsurgery. The number of patients included per time point is shown below.

<table>
<thead>
<tr>
<th>Time Point</th>
<th># Compliant TSA VIP System Patients/# Total Patients</th>
<th># Compliant TSA No Planning Patients/# Total Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presurgery</td>
<td>139/165</td>
<td>539/768</td>
</tr>
<tr>
<td>6 months</td>
<td>111/152</td>
<td>516/705</td>
</tr>
<tr>
<td>1 year</td>
<td>99/133</td>
<td>471/638</td>
</tr>
<tr>
<td>2 years</td>
<td>28/43</td>
<td>342/504</td>
</tr>
<tr>
<td>5 years</td>
<td>N/A</td>
<td>73/120</td>
</tr>
</tbody>
</table>

Trend Conclusion
Based on these results, the pain, function, and quality-of-life scores for patients who have undergone anatomic TSA with Arthrex implants and preoperative planning using the VIP system trend toward better outcomes than the scores of patients who have undergone anatomic TSA with Arthrex implants and no plan. However, no claims can be made on the potential of these results without further analysis to determine statistical significance.

Reference