Study Title: A **S**ingle arm, Multic**e**nter, Prospective, **C**linical St**u**dy on a Novel Minimally Invasive Posterio**r** Sacroiliac Fusion D**e**vice: **SECURE STUDY**

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Co- Investigator(s): up to 10 sites

Table of Contents

I. Purpose, Background and Rationale

The purpose of this post-market study is to evaluate data and evidence on the safety and efficacy of utilizing the LinQ system for sacroiliac disease. SI fusion has been a long-standing treatment for refractory SI joint disease that has failed conservative treatment. SI joint disease accounts for approximately 30-40% of all low back pain according to a recently published literature. Recently newer techniques have been developed to treat SI joint dysfunction in a less invasive method. A lateral approach utilizing three triangular titanium implants resulted in a statistically significant improvement in pain and disability when compared to conservative management for SI joint dysfunction. Although this approach is less invasive than a true open approach, it still carries significant risk and invasiveness. Risk of laterally placed screws into the spinal canal poses risk of neurological compromise. Non-weight bearing status, incisional pain, and recovery time are significant factors that must be acceptable to the clinician and patient.

Recently, an FDA approved posteriorly placed allograft into the mid-portion of the SI joint has shown significant promise as an alternative option to traditional or lateral SI fusion. The Linq system is a minimally invasive, percutaneous, single incision technique for SI fusion. Utilizing a posterior approach eliminates the risk of spinal canal compromises and improves the overall safety profile. Additionally, using a single incision and avoiding screws reduces invasiveness and significantly reduces recovery times. A recent abstract presented by Pyles on 20 consecutive patients showed an average 83% reduction in pain at 3 months with no serious adverse effects or complications using the Linq system[3]. The purpose of this multicenter, prospective, clinical series is to further establish the data, efficacy, and safety on the Linq system for chronic Sacroiliac Joint Disease.

II. Research Plan and Design

A. Study Objectives:

The purpose of this post-market study is to gather evidence documenting the performance and clinical outcomes associated with treatment of sacroiliac disease with the LinQ fusion procedure.

B. Study Type and Design

Multicenter Center, Prospective, Single arm Clinical study

C. Sample size, statistical methods, and power calculation:

Anticipated study enrollment will be ongoing patients for registry.

Power calculation based on paired T test, Alpha 0.05, Beta 0.2, Power 0.8, Effect Size 0.5, two sided yielded sample size of 34 patients. Assuming a 20 percent loss to follow up or study exit rate, fifty patients would be sufficient to achieve study aims.

Statistical methods would include paired T tests for quantitative measures which include VAS score, Oswestry Disability Index, and Promis-29.

D. Subject Criteria:

Inclusion criteria:

- Age 21-70
- Patient has lower back pain for >6 months inadequately responsive to conservative care
- Patient has at least 3 of 4 physical examination maneuvers specific for the SI joint (FABER, Gaenslen test, Stork/Gillete, and Yoman)
- Patient has improvement in lower back pain numeric rating scale (NRS) of at least 50% after injection of local anesthetic into affected SI joint(s) with confirmed arthrogram, within 30-60 min from injection
- Degenerative sacroiliitis as SIJ mediated in in the context of either radiographic evidence of SIJ degeneration, evident on computed tomography or Xrays or a history of prior lumbar fusion.
- SIJ disruption was defined in the study of as SIJ mediated pain in the context of asymmetric widening of SIJ on CT or Xrays or the presence of significant contrast leakage during diagnostic SIJ block
- Baseline Oswestry Disability Index (ODI) score of at least 30%
- Baseline Low back/buttock pain score of at least 50 on 0-100 mm visual analog scale
- Patient has signed study-specific informed consent form
- Patient has the necessary mental capacity to consent and participate and is physically able to comply with study protocol requirements
- Patient has medical insurance that covers this standard of care procedure and all other anticipated and unanticipated procedure related care.
- Patient's physician has decided that the best treatment for the patient's sacro-iliac disease is the LinQ system and the patient has agreed to the treatment.

Exclusion criteria:

- Inability to confirm that the pain is arising from the sacroiliac joint
- Current severe back pain due to other causes, such as lumbar disc degeneration, lumbar disc herniation, lumbar spondylolisthesis, lumbar spinal stenosis, lumbar facet degeneration, lumbar radicular pain, and lumbar vertebral body fracture
- SIJ pain secondary to inflammatory conditions, Other known sacroiliac pathology such as: Sacral dysplasia, Inflammatory sacroiliitis (e.g., ankylosing spondylitis or other HLA-associated spondylo-arthropathy), Tumor, Infection, Acute fracture, and Crystal arthropathy.
- Radicular pain extending beyond the buttock ≥ 30mm on VAS
- Has complete resolution of pain from the diagnostic SIJ injection lasting 30 days or more
- Has had an injection with corticosteroid into the index SIJ within the last 30 days
- Has had any neuraxial injection with corticosteroid within the last 30 days

- Has greater than 50% pain relief from diagnostic medial branch blocks at the L4/5 and/or L5/S1 levels
- Has had a sacral radiofrequency ablation within the last 6 months
- History of any hardware placement within the sacrum or sacroiliac joint. Fusion at L5/S1 is allowed if screws/hardware are not within THE Sacroliac joint. Any hardware or instrumentation that would obstruct the ability to access or place the Linq implant would be exclusionary.
- History of coccydynia or coccygectomy
- Clinical diagnosis of discogenic pain at L4/5 and/or L5/S1
- History of endometriosis or pudendal neuralgia
- History of recent (<1 year) major trauma to pelvis
- Chronic rheumatologic condition (e.g., rheumatoid arthritis)
- Any condition or anatomy that makes treatment with the Linq Implant System infeasible
- Use of medications known to have detrimental effects on bone quality and soft-tissue healing (metabolic bone disease, induced or idiopathic)
- Prominent neurologic condition that would interfere with physical therapy
- Current local or systemic infection that raises the risk of surgery
- Patient currently receiving or seeking worker's compensation, disability remuneration, and/or involved in injury litigation.
- Patient is participating in an investigational study or has been involved in an investigational study within 3 months prior to evaluation for participation
- Patient with insurance coverage that does not cover the SI fusion*
- Implanted intrathecal pain pump

Withdrawal/Termination criteria:

- Patient's participation will only be withdrawn by their request. There are no criteria for termination of participation due to safety.

E. Specific methods and techniques used throughout the study

Study Design: The PainTEQ study is a prospective, multi-site, prospective, single arm study intended to collect clinical data outcomes data associated with the treatment of sacroiliac disease with the LinQ fusion procedure. Data will be collected using self-report measures including the visual analog scale (VAS) for pain assessment where the participant is asked to place a line perpendicular to the VAS line at the point that represents their pain intensity. Using a ruler, the score is determined by measuring the distance (mm) on the 10-cm line between the "no pain" anchor and the patient's mark, providing a range of scores from 0–100. Other self-report questionnaires will be administered including the Oswestry Disablity Index (ODI) to measure low-back pain and disability, and the PROMIS 29 to measure physical, mental, and social health and well-being. The study team will also collect data including:

- Patient Satisfaction with Procedure
- Opioid consumption (Morphine Milligram Equivalents) at 1,3, 6, 12,18, 24 months.
- Serious adverse events and mortality as related to implantation of the device and events associated with recovery and rehabilitation
- Device related complications
- Satisfactory deployment (Defined as radiographic imaging of the implant within the SI joint. Procedure time
- Fluoroscopy time (in minutes)
- Blood loss
- Type of anesthesia (local; MAC; general)
- Patient demographics
    - Age
    - Gender
    - Race
    - BMI
    - Smoking (y/n)
    - Year of Pain
    - Underlying diagnosis: degenerative sacroiliitis/sacroiliac joint disruption
    - Prior lumbar fusion (y/n)
    - Prior treatments (PT, FA, SIJ injection)

1. Timeline: Patients included in the study return for follow-up visits at 7-14 days, 1, 3 months, 6, 12, 18, and 24months post-treatment. Primary endpoint will be 6 month time point.

2. No randomization as treatment with the LinQ system will be performed regardless of whether the patient agrees to be in the research.

F. Risk/benefit assessment:

As appropriate, address the following parameters as each relates to the individual subject in the study.

1. Psychological risk: minimal, less than 1%
2. Social risk minimal, less than 1%
3. Potential benefit of participating in the study
    a. To the individual subject and/or parent if any:
    Improvement in the following domains:
        a. Pain
        b. Physical functioning
        c. Emotional functioning
        d. Patient global rating of improvement and satisfaction
        e. Symptoms and adverse events
        f. Patient disposition
    b. To the population from which the subject is drawn: The study will provide

evidence to support a new treatment modality that is safe and effective. This

treatment modality also does not require repetition or multiple treatments unlike other treatments for sacroiliac joint dysfunction. It will also offer a salvage therapeutic option for patients who have failed other treatment modalities.

c. To science, society, and humanity in general: Advancement of minimally invasive musculoskeletal techniques that may significantly reduce associated morbidity, mortality, and overall cost of treatment for chronic musculoskeletal related pain.

G. Location where study will be performed: Multisite

H. Collaboration: Multisite

I. Single IRB Review for a Multi-site study:

IRB local approval

J. Personnel who will conduct the study, including:

1. Indicate, by title, who will be present during study procedure(s): Study coordinator, attending physician, company representative, fellow physician (when available).
2. Primary responsibility for the following activities, for example:
    a. Determining eligibility: PI, study attendings, senior trainees
    b. Obtaining informed consent: Attendings at the study site including co-investigators, senior trainees at study site, and/or research coordinators
    c. Providing on-going information to the study sponsor and the IRB: No Study Sponsors
    d. Maintaining participant's research records: Research coordinator
    e. Completing physical examination: Attendings and trainees at study site
    f. Taking vital signs, height, weight: Clinic staff
    g. Drawing / collecting laboratory specimens: Not applicable
    h. Performing / conducting tests, procedures, interventions, questionnaires: Attending physician and fellow physicians at study site
    i. Completing study data forms: Research coordinator
    j. Managing study database: Research coordinator

K. Adverse Event Monitoring

Adverse events and unanticipated problems will be ascertained and handled per standard of care as applies to any procedure. Problems that would be considered serious and reported to the IRB include infection, new skeletal fracture resulting from procedure, unanticipated post-operative admission, and neurologic injury and would be monitored for on an ongoing basis as per standard of care. The reporting timeframe would be within two weeks of incident to allow for appropriate additional diagnostic testing and treatment while maintaining study responsiveness to adverse events.

If patient experiences an adverse event or post-procedural problem, this will be treated per standard of care. This would include standard of care treatment of any related injury and potential device explanation. Patient may opt out of study at any time voluntarily. This would be monitored and discussed on an ongoing basis in the setting of an adverse event or post-procedural problem.

III. Subject Participation

A. Recruitment:

1. Potential study participants will come from the existing patient population of the investigators in each individual practice.

Recruitment can be performed by interventional pain providers and will be offered to anyone who is a candidate for the LinQ fusion procedure and meet the inclusion and exclusion criteria for the study. This research studies the LinQ system, a legally-marketed device, determined by that health care practitioner to be in the best interests of the patient. Patients will undergo treatment with the LinQ fusion procedure regardless of participation in the research. Therefore, the procedures being conducted because of the research are limited to data collection and the use of the LinQ system is not a research procedure.

B. Informed consent process and timing of obtaining of consent

The following study personnel may participate in the consent process: PI, co-Investigators, senior trainees, research assistants, and research coordinator.

After it has been determined that the patient is a candidate for LinQ fusion procedure and they meet the inclusion and exclusion criteria, the patient will be offered the opportunity to participate in this study. An IRB approved consent form will be used for this study and obtained on all study patients prior to collecting any study related information or documentation. All questions that the potential study patient has will be addressed. Participation in the study is voluntary, study patients may withdraw at any time.

The clinician will determine if the patient has the capacity to proceed with informed consent. Only patients with capacity to proceed with informed consent will be included in study. Minors are not allowed to participate in the study. A legally appointed guardian, closest family member, or individual with power of attorney may not serve as a substitute.

Alternatives to Participation:

Alternatives to participation in research study is to not take part in this research.

C. Costs to Subjects:

The patient will not incur any costs because of research. The LinQ procedure will be performed regardless of participation in the research and standard charges will apply for the LinQ procedure. Eligibility criteria include insurance coverage for study procedure.

D. How new information will be conveyed to the study subject and how it will be documented:

New information regarding treatment options or significant results that may affect care will be conveyed and applied by standard of care guidelines. Standard of care includes appropriate, HIPAA compliant communication mediums. This information will be documented in the medical record as it applies to the patient's treatment per standard of care.

Payment, including a prorated plan for payment:

The subject will be paid $250.00 at the 24 month visit for taking part in this research.

E. Payment for a research-related injury:

Study procedure is standard of care. Research-related injury will be handled as standard of care via accepted legal mechanisms, which include mediation, arbitration, or litigation for settlement.

IV. Data Collection and Protection

A. Data Management and Security:

Data will be collected from electronic medical record, during surgery, and self-report questionnaires. Confidentiality will be maintained by storing patient data on a cloud based secured, HIPPA compliant system. Identifiable data will not be sent outside any practice institution.

B. Procedures to protect subject confidentiality:

Patient identifiers may be included in master spreadsheet for reference to clinical chart if need arises for further review. Data will be de-identified with master spreadsheet containing patient identifiers linked to generated ID. A secondary spreadsheet will be generated containing pertinent study measures linked to the generated ID. The study coordinator will serve as the honest broker or buffer between master and secondary spreadsheets.

V. Data Analysis and Reporting

A. Statistical and Data Analysis:

Statistical analysis will include paired t-test of quantitative measures such as VAS pain score, Oswestry Disability Index, PROMIS 29, and quantitative secondary outcomes. ANOVA regression analysis will be performed to identify potential correlates of improved outcomes measures and adverse outcomes. IBM SPSS Statistics will be utilized to perform the analysis. Interim analysis will be performed on an anticipated monthly basis by a statistician. At no time will identifying information be transferred.

B. Outcome Measures:

i. Primary Outcome Measures

1. Binary success failure composite end point. A subject was considered a success if all of the following criteria were met

    a. Reduction from baseline VAS SIJ pain by at least 20 mm

    b. Absence of device related serious adverse events,

    c. Absence of neurologic worsening related to the lumbosacral nerve roots,

    d. Absence of surgical reintervention (removal, revision reoperation or supplemental fixation) for SIJ pain

ii. Secondary Outcome Measures

1. Improvement in baseline in VAS from baseline at 6 months
2. Oswestry Disability Index at 6 months follow up
3. PROMIS-29 at 6 months follow up
4. Patient Satisfaction with PGIC
5. Morphine milligram equivalent usage at all time points

C. Study results to participants:

Once final analysis completed, debriefing report will be given at follow up appointment or via telephone call. If no further contact maintained, copy of published manuscript will be sent to patients. Purpose of this will be to debrief patients as to study results.

D. Visit Schedule

	Screen	Baseline	Visit 1 Surgery	Visit 2 7-14 days post-surgery	Visit 3 1 month	Visit 4 3 months	Visit 5 6 months	Visit 6 12 months	Visit 7 18 months	Visit 8 24 months
	At least 7 days prior to Baseline	(within 4 weeks of surgery)		(+ 10 days)						
Informed Consent	x									
Inclusion / Exclusion Review	X	X								
Urine Pregnancy test (if required)	X									
Surgery Information			X							
VAS	x	X		x	x	X	x	x	x	x
PROMIS-29		X		X	X	X	X	X	x	x
ODI	X	x		x	x	X	x	x	x	x
Patient Satisfaction					x	x	x	x	x	x
Demographics & Medical History	X									
Opioid Medications		X		x	X	X	X	X	x	x
Adverse Events			x	X	X	X	X	X	x	x

E. Publication Plan

Plan will be for publication in peer reviewed medical journal.

Investigator Signature Page

My signature below affirms that I have read the PainTEQ Secure protocol and agree to implement and conduct this study according to the procedures specified in the protocol, in compliance with good clinical practices and all applicable laws and regulations.

SIGNATURE: _____ DATE:_____

NAME PRINTED: _____

INSTITUTION: _____

VI. Bibliography / References

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