Title: Prospective Clinical Evaluation of High-Purity Type I Collagen in Select High-Risk Hernia Repair Scenarios

NCT No: NCT07360691

Date: March 16, 2026

INTRODUCTION

Hernia repair is among the most frequently performed general surgical procedures worldwide, with synthetic mesh reinforcement significantly reducing recurrence rates compared with primary suture repair alone [1,2]. Despite these advances, mesh-related complications such as surgical site infection, chronic inflammation, mesh extrusion, persistent pain, and the need for mesh explantation continue to pose substantial clinical challenges [3–5]. These issues are particularly pronounced in contaminated or potentially contaminated fields and in patients with multiple comorbidities, where permanent synthetic mesh implantation may exacerbate morbidity [6,7].

Synthetic meshes function as permanent foreign bodies and may provoke prolonged inflammatory responses, fibrosis, and bacterial biofilm formation. In high-risk settings such as emergency hernia repair, re-operative abdominal wall surgery, diabetes, obesity, smoking, immunosuppression, and prior mesh infection, the risk of postoperative complications is significantly increased [4–7]. Consequently, surgeons often face a dilemma between accepting higher recurrence rates with suture repair and the potential morbidity associated with synthetic mesh placement.

Biologic meshes have emerged as selective alternatives in such complex scenarios. These materials, typically derived from collagen-rich extracellular matrices, are designed to provide temporary structural support while facilitating host tissue integration, angiogenesis, and gradual remodelling [8–10]. Compared with permanent synthetic meshes, biologic scaffolds demonstrate reduced inflammatory response and greater resistance to infection, making them attractive adjuncts in contaminated or high-risk operative fields [9,10]. However, variability in source tissue, processing techniques, cross-linking, and degradation profiles has resulted in heterogeneous clinical outcomes, limiting their widespread adoption [8].

High-purity type I collagen (HPTC), marketed as Surgicoll-Mesh®, is a bioengineered collagen scaffold composed of more than 97% native type I collagen. It is manufactured using proprietary purification processes that remove immunogenic proteins, elastin, and lipids while preserving the native triple-helical collagen structure [11,12]. Unlike heavily cross-linked biologic meshes, HPTC remains un-crosslinked and resorbable, allowing controlled enzymatic degradation and progressive replacement by organized host tissue rather than persistent foreign material.

The regenerative and anti-inflammatory properties of high-purity type I collagen have been demonstrated across multiple clinical applications. Prospective studies and randomized

controlled trials have reported improved tissue quality, accelerated healing, reduced inflammation, and favourable safety profiles in chronic wounds, venous leg ulcers, diabetic foot ulcers, and complex reconstructive settings [13–16]. These findings suggest that HPTC functions not merely as a passive scaffold but as a biologically active matrix capable of modulating the healing microenvironment.

In the context of abdominal wall reconstruction, early clinical reports have suggested that collagen-based meshes may be particularly useful as biologic reinforcement in infected or high-risk hernia repairs, facilitating wound resolution and tissue integration while minimizing mesh-related morbidity [9,10,17]. However, much of the existing evidence is retrospective, heterogeneous, and limited by small sample sizes, underscoring the need for prospective evaluation using standardized outcome measures.

Feasibility and early-outcome studies play a critical role in the clinical evaluation of biologic materials intended for adjunctive use. Such studies allow systematic assessment of safety, handling characteristics, wound behavior, and short-term clinical outcomes while avoiding overinterpretation of efficacy [18]. They also provide essential data on outcome variability and procedural practicality that inform the design of future comparative or randomized trials.

The present prospective, single-arm clinical study was therefore designed to evaluate the early safety, feasibility, and short-term clinical outcomes of high-purity type I collagen used as a biologic reinforcement in selected hernia repair scenarios where permanent synthetic mesh placement is considered undesirable. The study focuses on early postoperative outcomes, including wound healing, surgical site infection, pain trajectory, and short-term integrity of repair, with the aim of generating hypothesis-generating data to guide future controlled investigations.

MATERIALS AND METHODS

Study Design and Setting

This study was designed as a prospective, single-arm clinical study evaluating the early safety, feasibility, and short-term clinical outcomes of high-purity type I collagen (HPTC; Surgicoll-Mesh®) used as a biologic reinforcement in selected hernia repair scenarios. The study was conducted at a tertiary care teaching hospital with experience in complex abdominal wall reconstruction and biologic mesh application.

The study design and operative principles were informed by the authors previously published clinical experience using high-purity type I collagen in infected and high-risk hernia scenarios, which demonstrated favourable wound outcomes and acceptable early durability in a retrospective case series [19]. The present study was undertaken to prospectively evaluate early outcomes using standardized inclusion criteria, outcome measures, and follow-up protocols.

Institutional Ethics Committee approval was obtained prior to patient enrolment. All procedures were conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines. Written informed consent was obtained from all participants after explaining the nature of the biologic material, its intended role as reinforcement, and the scope of early outcome evaluation.

Patient Selection

Adult patients aged 18 to 75 years undergoing elective or semi-elective hernia repair were screened for eligibility. Inclusion was restricted to clinical scenarios in which permanent synthetic mesh placement was considered undesirable due to local or systemic risk factors. These included patients with contaminated or potentially contaminated surgical fields (Centers for Disease Control wound class II or III), prior mesh infection or explantation, recurrent hernia with compromised soft tissue, diabetes mellitus, obesity, smoking history, immunosuppression, or advanced age with poor tissue quality.

Hernia types included ventral, incisional, and selected inguinal hernias where biologic reinforcement was deemed appropriate by the operating surgeon. Patients with active generalized sepsis, gross faecal contamination, loss of abdominal domain requiring staged reconstruction, known hypersensitivity to collagen, pregnancy, malignancy involving the abdominal wall, or inability to comply with postoperative follow-up were excluded.

Surgical Technique and Application of High-Purity Type I Collagen

All procedures were performed under general or regional anesthesia using standard aseptic technique. Hernia repair was undertaken using established principles of tension-free closure, with primary fascial approximation wherever feasible. Limited component separation techniques were employed when required to achieve midline closure without undue tension. High-purity type I collagen mesh was prepared according to manufacturer instructions and hydrated in sterile saline prior to implantation. The collagen scaffold was used strictly as a biologic reinforcement and not as a bridging material. Depending on defect location and surgeon preference, the mesh was placed in an onlay or sublay position, ensuring complete coverage of the repaired fascial defect with adequate overlap onto healthy tissue.

The collagen mesh was secured using interrupted or continuous absorbable sutures, taking care to avoid excessive tension or folding. Particular attention was paid to achieving intimate contact between the mesh and host tissue to facilitate cellular infiltration and integration. Closed-suction drains were placed selectively based on wound characteristics and removed according to standard clinical criteria. Skin closure was performed in layers.

Postoperative Care and Follow-Up

Postoperative management followed institutional protocols, including appropriate antibiotic coverage based on wound classification and comorbid risk factors. Patients were encouraged to ambulate early and were advised to avoid heavy lifting for a minimum of six weeks. Wound assessments were performed during inpatient stay and at scheduled outpatient visits. Clinical follow-up was conducted at two weeks, four weeks, and eight weeks postoperatively. These time points were selected to capture early wound behaviour, pain trajectory, and immediate postoperative complications, consistent with feasibility and early-outcome study objectives.

Outcome Measures

The primary outcomes of interest were safety and feasibility, defined by successful implantation of the collagen mesh, absence of intraoperative technical difficulty, and absence of collagen-related adverse events. Secondary early clinical outcomes included surgical site infection, wound seroma or dehiscence, postoperative pain assessed using the Visual Analog Scale, and early clinical integrity of repair assessed by physical examination.

Outcomes were recorded prospectively using standardized case record forms. Surgical site infections were classified according to Centres for Disease Control criteria.

Statistical Analysis Plan

Given the exploratory nature of this early-outcomes study, no formal sample size calculation for efficacy was performed. Continuous variables were summarized as mean ± standard deviation or median with interquartile range, depending on data distribution. Categorical variables were expressed as frequencies and percentages.

Changes in pain scores over time were analysed using paired t-tests or Wilcoxon signed-rank tests, as appropriate. Statistical significance was defined conservatively as $p < 0.05$. All analyses were considered exploratory and hypothesis-generating. Statistical analysis was performed using standard statistical software.