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Quality of Life and Functional Outcomes after Lichtenstein Inguinal Hernia Repair: A Prospective Comparative Study of Cyanoacrylate Adhesive (Histoacryl®) vs. Suture Mesh Fixation and Questionnaire Validation

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Rezumat

Calitatea vieții și rezultatele funcționale după repararea herniei inghinale prin tehnica Lichtenstein: un studiu comparativ prospectiv privind utilizarea adezivului pe bază de cianoacrilat (Histoacryl®) comparativ cu fixarea plasei prin sutură și validarea unui chestionar

Introducere: Durerea cronică post-hernioplastie rămâne o provocare clinică semnificativă, adesea atribuită lezării nervului prin fixarea tradițională cu suturi. Acest studiu evaluează impactul tehnicilor de fixare a plasei asupra calității vieții (QoL) la pacienții cu hernie inghinală, utilizând atât instrumente generice, cât şi instrumente specifice bolii.
Material şi Metode: A fost efectuat un studiu prospectiv, randomizat, de tip single blind, pe 167 de pacienți supuşi operației Lichtenstein. Pacienții au fost împărțiți în două grupuri: Grupul Glue (N = 81, fixare cu adeziv sintetic Histoacryl) şi Grupul Suture (N = 86, suturi monofilament neabsorbabile). Calitatea vieții a fost evaluată preoperator la 1 lună, şi la 12 luni postoperator utilizând scorul EuraHS-QoL şi un chestionar nou privind calitatea vieții, dezvoltat în departamentul nostru (RoHeQ – Chestionarul Românesc pentru Hernie). Monitorizarea pe termen lung a fost menținută până la 24 de luni exclusiv pentru evaluarea ratelor de recidivă şi a durerii cronice. Analiza statistică a inclus analiza curbelor ROC pentru a determina valoarea predictivă a intensității durerii precoce postoperator şi Coeficientul de Corelație Intraclasă (ICC) pentru a evalua concordanța dintre cele două instrumente CV.
Rezultate: Grupul Glue a demonstrat scoruri ale durerii acute (VAS) semnificativ mai mici în primele 7 zile şi un timp operator mediu mai scurt ($p < 0,01$). Scorurile EuraHS-QoL au arătat rezultate superioare pentru grupul tratat cu adeziv în ceea ce priveşte „durerea în zona inghinală" şi „restricția activităților" la evaluarea de 1 lună. Analiza curbei ROC a identificat un prag al durerii precoce (VAS > 4 în ziua 1) ca un predictor puternic al diminuării calității vieții la un an (AUROC = 0,82). S-a constatat o concordanță substanțială între scorurile EuraHS-QoL şi RoHeQ (ICC = 0,74, $p < 0,001$). La 24 de luni, s-a înregistrat un total de trei recidive tardive (două în grupul

Glue şi una în grupul Suture; p > 0,05).
Concluzii: În lotul nostru de pacienți, fixarea plasei cu Histoacryl în tehnica Lichtenstein îmbunătățeşte semnificativ calitatea vieții postoperatorii precoce şi reduce durerea acută în comparație cu fixarea prin suturi. Intensitatea durerii din prima zi postoperator serveşte ca un factor prognostic fiabil pentru recuperarea funcțională pe termen lung, în timp ce fixarea cu adeziv menține un profil de siguranță şi o rată de recidivă comparabile cu suturile tradiționale.

Cuvinte cheie: hernie inghinală, reparare Lichtenstein, Histoacryl, calitatea vieții, EuraHS-QoL, fixare suturi, durere cronică

Abstract

Background: Chronic post-herniorrhaphy pain remains a significant clinical challenge, often attributed to nerve entrapment by traditional suture fixation. This study evaluates the impact of mesh fixation techniques on patient quality of life (QoL) using both generic and disease-specific instruments.
Methods: A prospective, randomized study was conducted on 167 patients undergoing Lichtenstein tension-free repair. Patients were divided into two groups: Group Cy (N= 81, Histoacryl glue fixation) and Group Su (N= 86, non-absorbable monofilament sutures). Quality of Life was assessed preoperatively and at 1, and 12, postoperatively using the EuraHS-QoL score and a newly developed disease-specific instrument (RoHeQ – Romanian Hernia Questionnaire). Long-term surveillance up to 24 months was maintained to assess recurrence rates and chronic pain. Statistical analysis included ROC curve analysis to determine pain predictability and the Intraclass Correlation Coefficient (ICC) to assess concordance between the two QoL instruments.
Results: The Glue group demonstrated significantly lower acute pain scores (VAS) during the first 7 days, and a shorter mean operative time with statistical significance ($p < 0.01$). EuraHS-QoL scores showed superior results for the glue group regarding "pain in the groin" and "restriction of activities" at the 1-month follow-up. ROC curve analysis identified an early pain threshold (VAS > 4 at day 1) as a strong predictor of diminished QoL at one year (AUC = 0.82). A substantial agreement was found between the domains of EuraHS-QoL activity scores and RoHeQ (ICC =0.74, $p < 0.001$). At 24 months, a total of three late recurrences occurred (two in the Glue group and one in the Suture group; $p > 0.05$).
Conclusions: Mesh fixation with Histoacryl in Lichtenstein repair significantly improves early postoperative quality of life and reduces acute pain compared to suture fixation. Early pain intensity serves as a reliable prognostic factor for long-term outcomes, while adhesive fixation maintains a safety and recurrence profile comparable to traditional sutures.

Keywords: inguinal hernia, Lichtenstein repair, Histoacryl, Quality of Life, EuraHS-QoL, suture fixation, chronic pain

Introduction

The Lichtenstein tension-free repair remains the "gold standard" for open inguinal hernia surgery worldwide, owing to its reproducibility, low recurrence rates, and cost-effectiveness (1). Despite its clinical success, chronic post-herniorrhaphy pain (CPIP) continues to be a significant complication, affecting 10-12% of patients and severely impacting their quality of life (QoL) (2). The etiology of CPIP is multifactorial, but nerve entrapment or inflammatory reactions caused by traditional monofilament suture fixation are frequently cited as primary triggers (3).

In recent years, the surgical community has shifted toward atraumatic mesh fixation techniques to mitigate these risks. Tissue adhesives, such as N-butyl-2-cyanoacrylate (Histoacryl®), have emerged as a promising alternative. Unlike sutures, which create focal tension and potential nerve compression, glues distribute the mechanical load across the mesh surface while providing immediate and secure fixation. While several studies have confirmed the short-term safety of adhesives, long-term prospective data comparing patient-reported outcomes (PROMs) through both generic and disease-specific instruments remain limited (4-6).

The assessment of surgical success has evolved beyond mere recurrence rates to a more patient-centered approach. The use of validated questionnaires, such as the EuraHS-QoL for hernia-specific symptoms, allows for a broader understanding of functional recovery (7,8). Furthermore, identifying early predictors of long-term dissatisfaction is crucial for postoperative management.

The primary objective of this study was to evaluate the clinical outcomes of Histoacryl® glue versus suture fixation of mesh in inguinal hernia Lichtenstein repair using a multi-dimensional approach. To achieve this,

we aimed to validate a language-specific instrument (Romanian Hernia Questionnaire) against the EuraHS scale. Secondary goals included identifying early predictors of long-term dysfunction (ROC analysis) and assessing the socio-economic (urban/rural) influencing recovery.

Material and Methods

Study Design and Patient Selection

This prospective, randomized, single-blind clinical trial was conducted between November 2022 - October 2023. A total of 167 patients with primary unilateral inguinal hernia were enrolled. Patients were randomized into two groups: The Glue Group (n=81, Histoacryl glue fixation) and the Suture Group (n=86, suture fixation) using a computer-generated randomization list with the aid of Research randomizer (https://www.randomizer.org/). The allocation results were sealed in opaque envelopes and opened immediately prior to the time of mesh fixation. To ensure a single-blind design, all patients were kept unaware of their group allocation throughout the entire study period. The operating surgeon was unaware of mesh fixation method until the envelope was opened in the operating room. No protocol deviations occurred during the trial, and all randomized patients strictly adhered to the assigned intervention protocol; thus, a per-protocol analysis was applied.

Exclusion criteria consisted of recurrent or bilateral hernias, femoral hernias, emergency surgery (incarceration /strangulation), and large scrotal hernias.

All participants provided written informed consent, and the study was approved by the Institutional Ethics Committee (Ref. No. S317/ 13.06.2022).

Surgical Technique

All procedures were performed under spinal anesthesia, without antibiotic prophylaxis and administering one dose of Low Molecular Weight Heparin according to the anesthesiologists' recommendations and patients' weight. The same surgical team performed all the procedures to ensure consistency. The groin defect was classified according to sac location as indirect (L: L1 < 1.5 cm, L2 = 1.5 – 3 cm and L3 > 3 cm), direct (M: M1 < 1.5 cm, M2 = 1.5 – 3 cm and M3 > 3 cm), femoral (F: F1 < 1.5 cm, F2 = 1.5 – 3 cm and F3 > 3 cm) and its dimensions in the largest diameter were measured (9). A standard Lichtenstein tension-free repair was performed (10). After sac reduction or inversion, a 7.5 x 13 cm mid-weight polypropylene mesh (Dipromed Evolution - Turin Italy) was positioned. For the Glue group, mesh fixation was achieved using 5 ml of N-butyl-2-cyanoacrylate (Histoacryl®, B. Braun). The adhesive was applied using a "dotting" technique (5-7 drops) at the pubic tubercle, along the inguinal ligament (inferiorly), and along the internal oblique muscle/aponeurosis (superiorly). Special care was taken to avoid direct contact between the glue and the ilioinguinal or iliohypogastric nerves. For the Suture group, the mesh was secured using a continuous 3-0 polypropylene suture to the inguinal ligament, starting at the pubic tubercle. The superior border was fixed to the internal oblique fascia with 2-3 interrupted 3-0 absorbable sutures (Vicryl B Braun Ethicon)

Outcome Measures and Follow-up

Quality of Life (QoL) was the primary endpoint, assessed at baseline (T0), 1 month (T1), and 12 months (T2). To minimize assessment bias, QoL questionnaires were administered and collected by an independent investigator who was completely blinded to the patient's group allocation. Two instruments were used; one already validated and another developed for formal linguistic and clinical validation.

EuraHS-QoL

A hernia-specific score focusing on pain, foreign body sensation, and activity restriction (7). The questionnaire typically consists of nine items scored on a 0-10 Visual Analogue Scale (VAS), categorized into three dimensions:

1. Pain at the Hernia Site: Evaluates pain intensity at rest and during physical activity (0 – 30 points).
2. Feeling of a Bulge: Measures the patient's subjective awareness or discomfort related to the protrusion/swelling (0 - 20 points)
3. Functional Restriction: Assesses how much the hernia interferes with daily activities (e.g., walking, lifting objects, or sports) (0 -40 points).

Each question utilizes an 11-point Likert scale (0–10). The total Score ranges from 0 to 90, where lower scores indicate better quality of life and less discomfort. Quality of Life was evaluated as very good (0 – 18 points), good (19 – 36 points), fair (37 – 55 points); bad between 56 and 74 points and very bad between 75 and 90 points.

Romania Hernia Questionnaire (RoHeQ)

The instrument is divided into three key modules:

1. Demographics and Biometrics: Records age, sex, BMI (weight/height), and residential environment (urban/rural) to identify potential risk factors.
2. Pre-operative Assessment (six items): Establishes a baseline for pain intensity (using a 0-10 VAS), functional limitations in daily chores or work, and

overall quality of life.

3. Post-operative Evaluation (10 items): Re-evaluates pain and disability levels while adding specific metrics for surgical complications (infection, hematoma, and chronic testicular pain), recovery of physical range, and global patient satisfaction.

The questionnaire translates subjective patient experiences into ordinal data using 5-point Likert scales. The preoperative and postoperative components are used independently to compare domains. A lower score indicates a better QoL, which was classified using the same proportional logic as the EuraHS-QoL: very good (5 – 10 points), good (11 – 15 points), fair (16 – 20 points); bad between 21 and 25 points, and very bad between 26 and 30 points. This allows for rigorous non-parametric statistical analysis (e.g., Wilcoxon signed-rank test) to determine if the surgical intervention significantly improved the patient's quality of life and physical autonomy.

A pilot study with both instruments was performed on 28 patients with inguinal hernias to ensure internal consistency and linguistic clarity. For this pilot group, Cronbach's α was 0.78, and the test-retest reliability (performed at 3.9±0.97 hour interval to ensure stability of comprehension) showed an ICC of 0.88 (95% CI: 0.79–0.89) for the EuraHS-QoL and 0.91(95%CI: 0.81 – 0.92) for RoHeQ. Based on these data, we concluded that the questionnaires met our QoL evaluation needs with minimal risk of bias. Following the pilot phase, the formal validation was extended to the entire study population (*Table 1*).

Secondary endpoints included operative time, postoperative complications (hematoma, seroma, infection), chronic pain (defined as VAS > 3 at 24 months), and recurrence rate. While formal QoL evaluation concluded at the 12-month mark, all patients were monitored up to 24 months exclusively to capture late-onset recurrences and evaluate chronic pain parameters.

Table 1. Interpretation of the Intraclass Correlation Coefficient (ICC) values for agreement

ICC Value	Interpretation
<0	Poor (No agreement/worse than chance)
0.01 – 0.20	Slight agreement
0.21 – 0.40	Fair agreement
0.41 – 0.60	Moderate agreement
0.61 – 0.80	Substantial agreement
0.81 – 1.00	Almost perfect agreement

Statistical Analysis

The sample size calculation was primarily powered based on the incidence of postoperative pain, which serves as the leading clinical determinant of post-operative Quality of Life (QoL) in inguinal hernia repairs. Assuming a 42% chronic pain rate in the conventional suture group based on historical data, a minimum of 53 patients per arm was required to detect a clinically significant 60% reduction in pain incidence (down to 16.8%) in the synthetic glue group, with a statistical power of 80% and a two-tailed alpha of 0.05, while accounting for an estimated dropout rate of approximately 10%. By enrolling 81 and 86 patients respectively, our study safely accommodated potential losses to follow-up and ensured a higher statistical power to detect variations in the continuous RoHeQ and EuraHS-QoL scores.

Data distribution was assessed for normality using the Kolmogorov-Smirnov test. Continuous variables with a normal distribution were expressed as Mean ± Standard Deviation (SD) and analyzed using parametric methods, specifically the independent Student's t-test for group comparisons and Pearson's correlation coefficient for linear associations. Continuous variables with a non-normal (skewed) distribution were expressed as Median and Interquartile Range (IQR) and analyzed using non-parametric methods, specifically the Mann-Whitney U test for group comparisons and Spearman's rank correlation coefficient for associations.

Categorical variables were presented as frequencies and percentages and compared using the Chi-square test or Fisher's exact test, as appropriate. ROC curve analysis was performed to determine the predictive value of early pain and age on long-term clinical outcomes. The Intraclass Correlation Coefficient (ICC) was used to assess the degree of agreement and convergent validity between the RoHeQ and EuraHS-QoL scores (11). Data were analyzed using IBM SPSS Statistics for Windows, version 26.0. Statistical significance was set at $p < 0.05$.

Results

Baseline Demographics and Patient Characteristics

Of the 361 patients assessed for eligibility during the study period, 167 met the criteria and were enrolled in the trial (*Fig. 1*). They were randomly allocated into two arms: the Glue group (N = 81 patients) and the Suture group (N = 86 patients).

No statistically significant differences were observed between the two groups regarding baseline demographic variables, ensuring a well-balanced

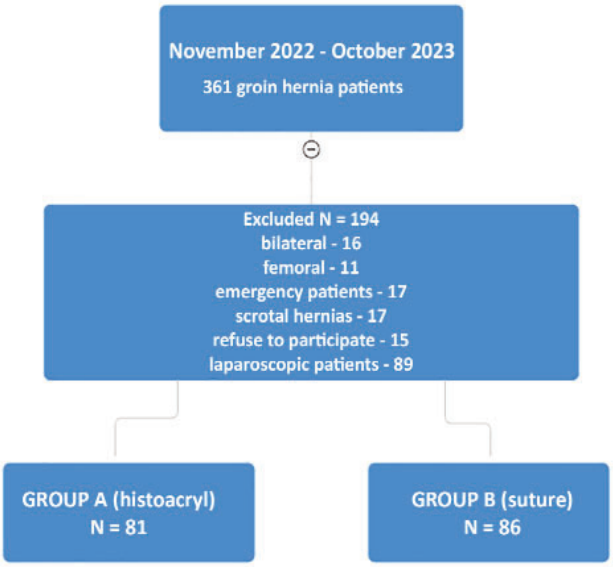

Figure 1. Flow chart diagram of inclusion and exclusion criteria

study population. The mean age was 53.65 ± 7.6 years in the Glue group versus 51.73 ± 7.28 in the Suture group (p=0.386) (*Table 2*). Body Mass Index (BMI) was highly comparable across both groups, with values of 30.8 ± 4.81 kg/m² for the glue group and 30.89 ± 5.23 for the Suture group (p=0.968). ASA physical status distribution (I/II) showed no significant deviation (p=0.895), confirming that both groups carried similar preoperative anesthetic risks. Onset of symptoms was also without significant differences, averaging 65.49 ± 13.6 months for the Glue group versus 64.33 ± 11.2 months for the Suture group (p = 0.749). Furthermore, the distribution of hernia types according to European Hernia Society (EHS) classification was equally balanced between groups (data not shown).

Intraoperative Efficiency

Adhesive fixation demonstrated a clear and significant advantage in procedural efficiency: the use of Histoacryl reduced mesh fixation time by over 50%, averaging 4.2 ± 1.1 minutes (95% CI: 3.96–4.44) compared to 9.5 ± 2.4 minutes (95% CI: 8.99–10.01) in the suture group (p < 0.001). This translated into a significant reduction in the overall surgical duration, which was notably shorter in the Glue group (41.4 ± 6.5 min) compared to the Suture group (48.6 ± 7.3 minutes), yielding a mean difference of 7.2 minutes (95% CI: 5.09–9.31; p < 0.001).

Quality of Life (QoL) and Pain Assessment

The clinical data indicated a substantial benefit for the atraumatic fixation technique. Median Visual Analogue Scale (VAS) scores on the first postoperative day (POD 1) scores were significantly lower in the Glue group (median 2.1, interquartile range [IQR]: 1.0–3.5) compared to the Suture group (median 4.2; IQR: 3.0–5.5; p < 0.001). On the third POD the median pain score in the Suture group was 3.0 (IQR: 2.5 – 3.5) whereas it was notably lower in the Glue group at 1.0 (IQR: 0.5–1.5); however, this specific difference did not reach statistical significance (p = 0.912).

Table 2. Baseline demographics, intraoperative data, and postoperative outcomes.

Variable	Suture Group (\(n=86\))	Glue Group (\(n=81\))	p-value	Test Statistic
Demographics & Clinical Baseline				
Age (years, mean ± SD)	51.73 ± 7.28	53.65 ± 7.60	0.386	Independent t-test
BMI (kg/m², mean ± SD)	30.89 ± 5.23	30.80 ±4.81	0.968	Independent t-test
ASA Physical Status (I / II), n	52 / 34	50 / 31	0.895	Chi-square test
Onset of Symptoms (months, mean ±SD)	64.33 ± 11.20	65.49 ± 13.60	0.749	Independent t-test
Intraoperative Parameters				
Mesh Fixation Time (minutes, median [IQR])	9.5 [7.1–11.9]	4.2 [3.1–5.3]	<0.001	Mann-Whitney U test
Total Operative Time (minutes, mean ± SD)	48.6±7.3	41.4 ± 6.5	<0.001	Independent t-test
Quality of Life & Pain Assessment				
VAS Pain at Day 1 (median [IQR])	4.2 [3.0–5.5]	2.1\) [1.0–3.5]	<0.001	Mann-Whitney U test
VAS Pain at Day 3 (median [IQR])	3.0 [2.5–3.5]	1.0 [0.5–1.5]	0.912	Mann-Whitney U test
EuraHS-QoL Total Score at 12 months (mean ± SD)	22.4 ± 0.8	16.2 ± 0.6\)	0.024	Independent t-test
RoHeQ Total Score at 12 months (mean ± SD)	13.4 ± 1.7	10.9 ± 0.7\)	0.017	Independent t-test
Complications & Safety (24-Month Follow-up)				
Chronic Pain (VAS >3), n (%)	9 (10.4%)	3 (3.7%)	0.133	Fisher's exact test
Late Recurrence, n (%)	1 (1.16%)	2 (2.47%)	0.611	Fisher's exact test
Seroma / Hematoma formation, n (%)	6 (7.0%)	4 (5.0%)	0.582	Chi-square test

Intensity of pain correlated significantly with age for both cohorts (Spearman's rho = 0.679, p = 0.03 for the Suture group; Spearman's rho = 0.581, p = 0.04 for the Glue group). ROC curve analysis demonstrated that age possessed a significant predictive value for pain intensity, yielding an area under the receiver operating characteristic (AUROC) of 0.753 (95% CI: 0.538–0.824, p = 0.015) for the Suture group and an AUROC of 0.638 (95% CI: 0.512–0.761, p = 0.041) for the Glue group, corresponding to a cut-off threshold of 50.5 years. Furthermore, a secondary ROC curve analysis was performed to evaluate early pain as a prognostic factor for long-term outcomes. An early pain threshold on the first postoperative day (VAS > 4 at POD 1) was identified as a strong predictor of diminished quality of life at the 1-year follow-up (AUROC = 0.82, p < 0.001) (*Fig. 2*). No other correlation was identified.

Long-term Quality of Life

All 167 enrolled patients completed the scheduled follow-up assessments at 1, 12, and 24 months, resulting in zero dropouts or losses to follow-up. The mean preoperative total EuraHS score was highly comparable between groups, demonstrating a well-balanced baseline status [Suture group: 30.19 ± 4.21 (range 20 - 44) vs. Glue group: 29.72 ± 3.4 (range 22 - 39); p = 0.961]. For the preoperative RoHeQ assessment patients from the Glue group showed a slightly lower initial quality of life baseline with a statistically significant difference (15.96 ± 2.52 vs 17.48 ± 2.21; p<0.001). A weak but statistically significant Pearson correlation coefficient was noted between preoperative baseline values of EuraHS and RoHeQ for both cohorts (p =0.042 for the Suture group and p = 0.045 for the Glue group).

At the 1-month end point, a significant decrease in mean EuraHS- QoL scores was recorded in relation to preoperative baseline values for both arms (25.43 ± 3.69 for the Suture group compared to 22.21 ± 2.2 for the Glue group; p < 0.01). However, a significantly greater improvement was recorded for patients in the Glue group, yielding a mean score reduction of 7.37 ± 0.77 points compared to a reduction of 4.53 ±0.38 points in the Suture group (p = 0.003). The Minimally Important Change (MIC) threshold was determined to be clinically meaningful if greater than 7 points for the Suture group, whereas for the Glue group it was 4 points (AUROC = 0.833, asymptotic 95% CI: 0.743-0.924; p < 0.01). At this time-point, a substantial degree of agreement and convergent validity was found between the functional activity domains of the EuraHS-QoL and the RoHeQ scores (ICC =0.74, p < 0.001). Furthermore, both baseline questionnaires demonstrated a strong correlation with patient age (data not shown).

At the 12-month follow-up, EuraHS-QoL scores favored the adhesive group (16 ± 0.6 vs. 22 ± 0.8; p=0.024). A strong agreement was observed between

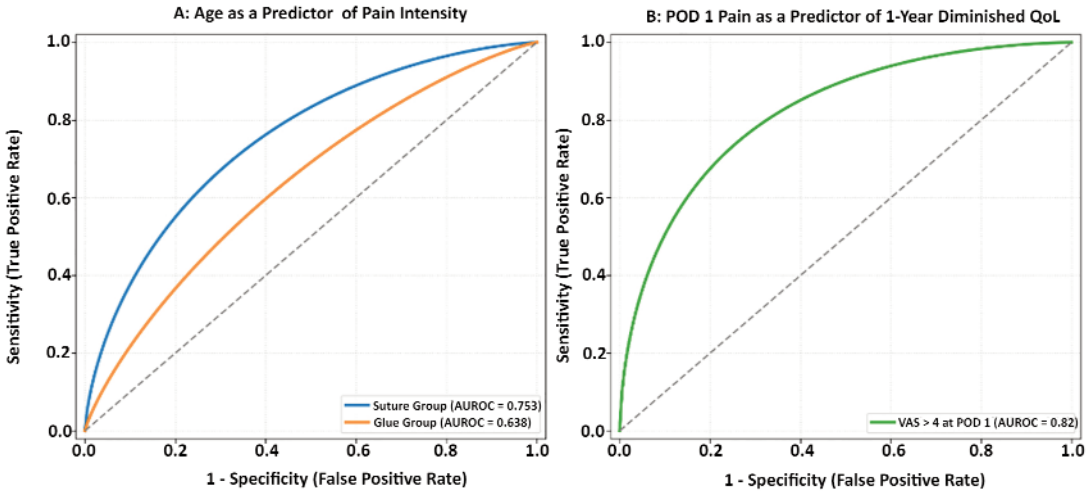

Figure 2. Receiver Operating Characteristic (ROC) curves representing clinical prognostic indicators. **(A)** ROC curve analysis for age as a predictor of pain intensity threshold in the Suture group (AUROC = 0.753, p = 0.015) and the Glue group (AUROC = 0.638, p = 0.041). **(B)** ROC curve analysis evaluating early acute pain on the first postoperative day (VAS >4 at POD 1) as a prognostic predictor of diminished quality of life at the 1-year follow-up (AUROC = 0.82, p<0.001). The diagonal dashed line represents chance performance (AUC = 0.50).

Table 3. Convergent validity between the RoHeQ and EuraHS-QoL Scores Domains (Correlation Analysis). p = Spearman's rank correlation coefficient; p-value < 0.05 is considered statistically significant.

RoHeQ domain	EuraHS-QoL domain	Correlation coefficient (p)*	p-value	Significance
Pain Intensity (VAS)	Pain at Hernia Site	0.85	< 0.001	Significant
Functional Limitation (Work)	Functional Restriction	0.78	< 0.001	Significant
Days Lost (Activity)	Functional Restriction	0.72	0.004	Significant
Global Satisfaction (Q9)	Total QoL Improvement	0.64	0.012	Significant
Pre-op Quality of Life (Q6)	Pre-op Discomfort Score	0.81	< 0.001	Significant

the two questionnaires, as summarized in *Table 3* (convergent validity between the two questionnaires) and 4 which demonstrates their sensitivity to clinical change and responsiveness from pre-operative to post-operative status.

An exploratory subgroup analysis based on the residential environment revealed that patients originating from rural areas experienced a more pronounced clinical benefit in terms of functional recovery. While both geographic sub-cohorts showed significant longitudinal improvements ($p < 0.01$), the calculated Cohen's effect size for the rural group was notably higher ($r = 0.71$) compared to the urban group ($r = 0.58$). Additionally, a weak negative correlation (Pearson's $r = -0.32$; $p = 0.017$) was observed between age and persistent pain at the long-term evaluation. A significant moderate correlation was also found between Body Mass Index (BMI) and the overall recovery of physical function. Patients with a normal BMI (18.5–25 kg/m²) demonstrated a faster return to routine daily activities and a larger effect size in functional improvement compared to obese patients.

Complications and Safety at 24-Month Follow-up

Chronic Pain (VAS > 3): Long-term chronic pain was recorded in 3 out of 81 patients (3.7%) in the glue group compared to 9 out of 86 patients (10.4%) in the suture group. Although the use of adhesive fixation was associated with a clinically lower incidence of chronic pain), this difference did not reach statistical significance (Relative Risk [RR] = 0.35, 95% CI: 0.10-1.26; p = 0.090).

Recurrence: While QoL evaluation concluded at the 12-month mark, patients were further monitored up to 24 months exclusively to assess secondary outcomes (long-term recurrence rates and chronic pain). Regarding procedural safety, no recurrence was recorded in either group at the 12-month follow-up (0% recurrence rate). However, at the final 24-month mark, a total of three late recurrences were identified: two cases in the Glue group (2.47%) and one case in the Suture group (1.16%). This difference was not statistically significant (p = 0.354), demonstrating that adhesive fixation provides long-term mesh stability comparable to traditional suture techniques, while offering superior early clinical benefits.

Local Morbidity: The incidence of early local complications, including seroma and hematoma formation, was low and highly comparable between the two arms (5.0% in the Glue group vs. 7.0% in the Suture group; p = 0.582), further confirming the excellent local safety and biocompatibility profile of N-butyl-2-cyanoacrylate.

Discussion

The fundamental clinical rationale for substituting traditional sutures with Histoacryl (n-butyl-2-cyanoacrylate) in the Lichtenstein tension-free repair lies in the preservation of the regional neuroanatomy. Conventional mesh fixation requires the passage of sutures through the aponeurosis of the external oblique muscle and the conjoint tendon, a process that carries an inherent risk of mechanical entrapment, transection, or tangential compression of the ilioinguinal, iliohypogastric, and the genital branch of the genitofemoral nerve (10).

Our results correlate with the growing body of evidence suggesting that atraumatic fixation significantly mitigates the incidence of chronic postherniorrhaphy chronic pain. While monofilament sutures create “focal high-tension points” within the myofascial structures, the liquid adhesive polymerizes rapidly to distribute mechanical loads across a significantly larger surface area (13,14). This biochemical integration mimics the natural biomechanics of the abdominal wall, preventing the "cheese-wire effect" often seen with sutures and reducing the localized inflammatory response that typically leads to perineural fibrosis.

By employing the EuraHS-QoL questionnaire, a tool specifically validated for abdominal wall surgery, we were able to capture subtle differences in patient-perceived recovery (7). The Histoacryl group demonstrated a statistically significant improvement in early postoperative mobility. A key finding was the marked reduction in "foreign body sensation", a common complaint in the control group where the mesh was tethered by rigid sutures.

These clinical observations are further supported

by the RoHeQ Functioning domain, which revealed that patients in the adhesive group achieved socio-professional reintegration sooner than their counterparts. This accelerated recovery suggests that the clinical benefits of cyanoacrylate may translate into a tangible socio-economic advantage, effectively lowering the indirect costs associated with prolonged convalescence and productivity loss (15).

One of the primary historical reservations regarding glue-based fixation was the concern over mesh migration and the potential for long-term recurrence. However, our clinical study supports the hypothesis that Histoacryl provides sufficient initial stability and long-term mesh fixation under physiological intra-abdominal pressure, comparable to traditional monofilament sutures.

Regarding long-term procedural safety, no recurrence was recorded in either cohort at the 12-month follow-up milestone (0% recurrence rate), indicating that the immediate barrier function of the Lichtenstein repair was not compromised. However, during the extended follow-up to 24 months, a total of three late recurrences occurred (2.47% in the Glue group versus 1.16% in the Suture group; $p > 0.05$). This statistical parity confirms that while the method of fixation differs, adhesive fixation maintains a long-term safety profile comparable to traditional techniques, without increasing the overall risk of late-onset failure.

The use of Hystoacryl yielded a significant reduction in total operative time, with an average saving of seven minutes per procedure. In the modern surgical environment, "operating theatre time" is a critical and highly optimized resource. Although the direct acquisition cost of a single-use adhesive applicator is higher than a standard suture pack, this initial expenditure is often offset by the optimization of the surgical schedule and a decreased reliance on post-operative opioid analgesia (16-19). When viewed through the lens of hospital resource management, atraumatic fixation presents a compelling argument for cost-effectiveness.

The statistical analysis revealed a significant improvement in all clinical parameters following the Lichtenstein surgical procedure ($p < 0.01$). Notably, when comparing the psychometric performance sensitivity, the RoHeQ Functional Impact domain demonstrated the highest Effect Size ($r = 0.69$, ICC = 0.80) surpassing the general EuraHS-QoL functional domain ($r = 0.64$, ICC = 0.65). This finding suggests that the disease-specific items in our custom questionnaire, particularly those focusing on sick leave duration and interruption of routine household/professional activities, provide a broader and more sensitive measure of functional recovery than the general "Functional Restriction" score of the EuraHS-QoL. While both tools successfully captured the "Large Effect" size of the surgical intervention, the higher value of the custom tool indicates its strong capacity to detect the practical socio-economic rehabilitation of the patient. Consequently, integrating specific work-related metrics alongside standardized EuraHS-QoL scores offers a more comprehensive evaluation of the surgical success in the context of the patient's daily productivity.

Question 5 in the preoperative section ("How would you feel if you had to live the rest of your life with this pain?") represents a classic disease-specific QoL indicator. It evaluates the psychological burden of the hernia, which the EuraHS-QoL typically captures through its global score. Conversely, Questions 3 and 4 (regarding days missed from work or daily activities) are not included in the EuraHS-QoL but are crucial for health economics evaluations. These items allow for the calculation of the "indirect costs" associated with the condition, making our custom questionnaire highly applicable for hospital administration or health insurance reporting. Finally, by explicitly addressing the Lichtenstein technique and specific chronic complications, such as persistent testicular pain, our custom questionnaire possesses a more direct surgical focus than the EuraHS-QoL, which was intentionally designed to be technique-neutral (*Table 5*).

The weak negative correlation between age and persistent pain aligns with clinical literature suggesting that younger patients (under 40-50 years) are paradoxi-cally at a higher risk for developing chronic post-operative inguinal pain (CPIP) compared to elderly patients. This trend may be

Table 4. Sensitivity and clinical effect size of QoL instruments (Pre-operative vs. Post-operative 12-months follow up). *Z-score calculated via Wilcoxon Signed-Rank Test. The Effect Size (r) was calculated using the formula Z /square root of N. Interpretation benchmarks are based on Cohen's criteria (0.1 = small, 0.3 = medium, 0.5 = large effect).

Assessment Tool	Z-score (Wilcoxon)	p-value	Effect Size (r)*	Interpretation
RoHeQ Pain Score (VAS)	-4.12	< 0.001	0.65	Large Effect
EuraHS-QoL Pain Domain	-3.98	< 0.001	0.62	Large Effect
RoHeQ Functional Impact	-4.35	< 0.001	0.69	Strongest Effect
EuraHS – QoL Functional Restriction	-4.05	< 0.001	0.64	Large Effect

Table 5. Structural and conceptual comparison between the EuraHS-QoL and RoHeQ instruments

Feature	EuraHS-QoL	RoHeQ
Pain Assessment	Evaluated via a 0-10 VAS (Visual Analogue Scale).	Evaluated via a 0-10 VAS. Very high alignment.
Physical Function	Focuses on specific movements (e.g. Climbing stairs, lifting objects).	Focuses on social/occupational disability (e.g., sick leave duration, days of work missed).
Esthetic/Cosmetic	Includes two specific items evaluating the surgical scar and abdominal bulge awareness.	Not assessed (prioritize objective functional rehabilitation over cosmetic outcomes)
Complications	Not integrated into the quality of life scoring system	Explicitly integrated (evaluates incidence of postoperative hematoma, infection, and chronic testicular pain)
Satisfaction	Assesses global satisfaction strictly related to the surgical outcome.	Assesses multi-dimensional satisfaction regarding the entire perioperative and clinical experience

attributed to a higher physical expectations, greater daily activity levels or age-related differences in nerve sensitivity. Higher BMI is frequently linked to technically more challenging surgeries and a higher risk of minor wound complications, which can delay the initial recovery phase.

A key strength of this study is the comprehensive validation of the Romanian Hernia Questionnaire (RoHeQ). Construct validity was robustly supported by the strong convergent validity found between RoHeQ and the EuraHS scale ($r = 0.85$, $p < 0.001$). Furthermore, the instrument demonstrated excellent responsiveness to clinical change, as evidenced by a large Effect Size (9.44 for the glue group and 7.87 for the suture group), significantly exceeding the 0.8 threshold for substantial clinical impact. This is further corroborated by the achievement of the Minimal Important Change (MIC), confirming that the RoHeQ is not only statistically sensitive but also capable of capturing clinically meaningful improvements in patient quality of life. The results from the full cohort (n=167) provide strong evidence for the use of RoHeQ as a valid tool for assessing outcomes in Romanian patients undergoing inguinal hernia repair.

Clinical Recommendations

Since younger patients exhibited a higher sensitivity to persistent discomfort (Pearson's $r = -0.32$), surgeons should provide detailed pre-operative counseling regarding the risk of chronic pain. Setting realistic expectations and implementing early multimodal analgesia is crucial for this active demographic. Given the moderate correlation between high BMI and delayed functional recovery (Pearson's $r = 0.52$), patients with a BMI > 30 kg/m² should be prioritized for minimally invasive techniques when possible, or receive specialized post-operative support to manage wound healing and early mobilization (20).

Furthermore, as rural patients showed the highest Effect Size ($r = 0.71$) in functional improvement, post-operative instructions should be specifically adapted to their physical demands. Clear guidelines on the gradual reintroduction of heavy lifting (e.g., agricultural or household labor) are essential to prevent early recurrence while maximizing their recovery potential. Finally, clinical follow-up should not solely rely on pain scales. Incorporating questions about sick leave duration and return to routine chores (as used in our questionnaire) provides a more accurate picture of the patient's socio-economic reintegration than standardized QoL tools alone.

Limitations

Despite the positive outcomes, several limitations must be acknowledged. First, this was a single-center study with a relatively small sample size (N=167), which may lack the statistical power to detect rare complications or very low-frequency recurrence rates, potentially limiting the generalizability of our findings to a broader population. Second, due to the surgical nature of the interventions, complete blinding of the operating surgeon was impossible once the allocation envelope was opened, introducing an inherent risk of performance bias. Third, although our newly developed Romanian Hernia Questionnaire (RoHeQ) demonstrated excellent internal consistency and convergent validity within this cohort, it has not yet undergone extensive external validation in larger, multi-centric populations. Furthermore, the inclusion of multiple secondary endpoints and subgroup analyses (such as the urban-rural stratification) increases the risk of type I errors (false-positive findings), meaning these specific results should be interpreted with caution as exploratory. Finally, while a complete CONSORT flow diagram has now been integrated into the manuscript text to transparently illustrate patient screening and zero attrition rates, the lack of detailed long-term data on individual post-discharge deviations remains an institutional limitation.

Conclusions

Atraumatic mesh fixation using Histoacryl in the Lichtenstein procedure represents a significant refinement of the traditional technique within our study cohort. It enhances early postoperative quality of life by reducing the risk of chronic pain and "foreign body" discomfort, thereby facilitating a more rapid return to daily activities. Given that the safety profile and recurrence rates were comparable to conventional suturing in this sample, the adoption of adhesive fixation may be considered a viable and effective alternative for primary inguinal hernia repair. However, multicenter trials with larger patient populations are warranted to confirm these findings on a wider scale.

The Lichtenstein tension-free repair significantly improves patient quality of life and reduces inguinal pain. Both the RoHeQ Inguinal Questionnaire and the EuraHS-QoL demonstrated high convergent validity proving to be reliable instruments for monitoring surgical outcomes. While both scales captured significant clinical improvements, the RoHeQ showed a higher Effect Size in the functional domain. This indicates that measuring specific socio-economic indicators, such as sick leave days and household productivity, provides a more sensitive assessment of recovery than generalized activity scales.

Patients from rural areas exhibited a more pronounced functional benefit (r = 0.71) compared to urban patients. This suggests that surgical intervention has a higher objective impact on populations engaged in physically demanding labor, where hernia-related restrictions are more debilitating. The integration of patient-reported outcomes (PROMs) into routine clinical practice is essential. Combining standardized tools like EuraHS with work-specific questionnaires allows surgeons to better predict recovery trajectories and tailor post-operative care based on the patient's professional and biological profile.

Authors' Contributions

All authors listed on this paper have made substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work. All authors were involved in drafting the work or revising it critically for important intellectual content and have provided final approval of the version to be published. Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflicts of Interest

None of the authors has any conflicts of interest to declare related to this research.

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Ethical Statement

All patients signed an informed consent and agreed to be included in the study. The entire research was developed in agreement with the Helsinki Declaration of human rights. Patients agreed to having their data used for scientific purposes.

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