

Recipient-Site Complications and Six-Month Graft Retention Following Follicular Unit Extraction with a Vector-10™ CVD Lab-Grown Diamond Blade

A Retrospective Analysis at a Hair Restoration Hospital

Abstract

Background: Chemical vapour deposition (CVD) lab-grown diamond has recently been introduced as a recipient-site incision instrument in follicular unit extraction (FUE), following internal laboratory testing together with independent third-party validation, demonstrating superior edge durability and initial sharpness relative to sapphire. Patient-level clinical outcome data for this instrument have not previously been reported.

Methods: This retrospective, single-arm cohort study included 30 patients who underwent primary FUE with the Vector-10™ CVD Lab-Grown Diamond blade (Vector-10™) at a single hair restoration hospital in March 2026, each followed for 6 months. This analysis represents a 6-month assessment of an ongoing observational follow-up designed to evaluate outcomes through 12 months. The primary outcome was a pre-specified composite of clinically significant recipient-site complications. The secondary outcome was 6-month graft retention, assessed using a standardized photographic method at a fixed reference area. A subset of patients additionally received hyperbaric oxygen therapy (HBOT) as part of a non-randomized, patient-preference-based adjunct.

Results: The clinically significant recipient-site complication rate was 10.0% (3/30; 95% CI 3.5–25.6%). No complications occurred in the HBOT subgroup (0/12) versus 16.7% (3/18) in the non-HBOT subgroup; this difference did not reach statistical significance given the limited sample size (Fisher's exact $p = 0.26$). Mean 6-month graft retention was 94.4% (SD 4.1%), declining with increasing Norwood-Hamilton grade.

Conclusions: In this 6-month analysis, clinically significant recipient-site complications following FUE with the Vector-10™ were infrequent, with an incidence slightly above some published benchmarks that is discussed in the context of the small cohort size. Six-month graft retention is reported as a preliminary measure pending 12-month assessment. The lower complication incidence observed in the HBOT subgroup is hypothesis-generating and warrants prospective confirmation. No comparative claim regarding the Vector-10™ relative to other blade materials can be made from this single-arm design.

Keywords: *follicular unit extraction; CVD lab-grown diamond; recipient-site complications; graft retention; hyperbaric oxygen therapy; retrospective cohort*

1. Introduction

Follicular unit extraction (FUE) has become the predominant surgical approach to hair restoration, and the instrumentation used to create recipient-site channels is recognised as a determinant of tissue trauma, healing, and ultimately graft survival [1,2]. Recipient-site instrumentation has progressed through successive material generations: stainless steel, synthetic sapphire, and, most recently, chemical vapour deposition (CVD) lab-grown diamond. The transition from steel's U-shaped incision profile to sapphire's V-shaped geometry has been associated with reduced tissue displacement and lower recipient-site trauma [3,4].

The Vector-10™ CVD Lab-Grown Diamond blade (Vector-10™) represents the most recent instrument in this progression, engineered to a Mohs hardness of 10, with the manufacturer specifying an edge radius refined to the Ångström scale [3]; this specification reflects manufacturer-reported data and was not independently re-measured for the present study. Repeated-use testing demonstrated that the Vector-10™ maintained substantially greater initial sharpness and sharpness longevity than sapphire, with full structural integrity preserved across 150,000 repetitions, in testing conducted internally [5] and corroborated by independent third-party validation [6]. These findings establish a mechanistic rationale, reduced cumulative cutting force across a session, for a potential reduction in per-incision tissue trauma. However, this evidence is confined to in vitro mechanical testing on a rubber substrate; no patient-level clinical outcome data for the Vector-10™ have previously been reported, and the validation studies themselves note that in vitro repetition counts may not correspond directly to clinical use [5,6].

Recipient-site complications following FUE, while mild and self-limited, occur in a meaningful minority of patients across large clinical series [7]. Reported graft survival varies considerably, generally falling between 85% and 95% at 12 months depending on surgeon experience, technique, and patient factors [7,8]. Establishing baseline patient-level safety and early outcome data for a newly introduced instrument, even in the absence of a comparator arm, is a necessary first step before comparative or confirmatory studies can be designed.

This study aimed to describe the incidence of clinically significant recipient-site complications, as the primary outcome, in a consecutive cohort of patients undergoing primary FUE with the Vector-10™ at a single hospital, and to report 6-month graft retention as a preliminary secondary outcome. A non-randomized exploration of whether adjunctive hyperbaric oxygen therapy (HBOT) was associated with a difference in complication incidence was also undertaken.

2. Methods

2.1 Study Design and Setting

This was a retrospective, single-arm cohort study conducted at Vera Clinic, Istanbul, Turkey. All procedures were performed using the Vector-10™. Patients underwent primary FUE with the Vector-10™ between 23 and 31 March 2026, following the instrument's introduction into clinical use, and were each followed for 6 months; the 6-month assessment for the final enrolled patient was completed on approximately 30 September 2026. This analysis represents a 6-month assessment of an ongoing observational follow-up designed to evaluate outcomes through 12 months; the 12-month analysis will be reported separately once follow-up is complete. All procedures were performed by the same senior hair transplant doctor and surgical team, eliminating inter-surgeon variability as a source of confounding. This

study does not include a comparator blade arm; no claim of superiority or non-inferiority relative to sapphire, steel, or any other instrument is made or implied.

2.2 Participants

Eligible patients were adults aged 18 years or older who underwent primary FUE with the Vector-10™ at the study center during the recruitment window, operated on by the same surgical team, and who reached the 6-month assessment.

Exclusion criteria were: recipient-site channels created under a mixed-blade protocol; transplantation limited to non-scalp sites (eyebrow, beard, or moustache); a concurrent adjuvant procedure other than HBOT performed outside the clinic's standard protocol; a prior transplantation performed at another facility, where the current procedure represented a revision or completion case; or incomplete intraoperative documentation or data-use consent.

Of 40 consecutively screened patients, 7 were excluded on eligibility grounds (mixed-blade protocol, n = 1; non-scalp recipient site, n = 2; prior transplantation at another facility, n = 1; incomplete documentation, n = 3), yielding 33 eligible patients. A further 3 patients (9.1%) were lost to follow-up before the 6-month assessment, yielding a final analytic cohort of 30 patients.

2.3 Standard of Care and the HBOT Subgroup

All patients received the clinic's standard post-operative protocol, consisting of platelet-rich plasma (PRP) and low-level laser therapy (LLLT), administered uniformly across the cohort; these are therefore reported as a fixed procedural feature rather than a confounding variable. Within this cohort, a subset of patients additionally elected to receive hyperbaric oxygen therapy (HBOT), delivered in-house via a multiplace hard-shell chamber at individualized pressures up to 2.5 ATA, limited to one or occasionally two sessions in the immediate post-operative period. Allocation to HBOT was based on patient preference rather than randomization or blinded assignment; this is a non-randomized comparison and is treated as such throughout, including in the statistical approach and interpretation.

2.4 Outcome Measures

Primary outcome: clinically significant recipient-site complications. A pre-specified composite outcome was defined, limited to clinically significant complications localized to the recipient site, that is, events requiring clinical intervention or exceeding the expected post-operative healing course: folliculitis requiring treatment, cystic reaction, ingrown hairs, delayed healing (crusting persisting beyond 21 days), and prolonged post-operative oedema (persisting beyond 72 hours). Expected, self-limiting post-operative findings, including transient early erythema and minor crusting within the normal healing window, were regarded as part of the expected post-operative course and were not counted as complications. Systemic or donor-site events (e.g., temporary shock loss, donor-site scarring) were likewise not included, as they are not attributable to recipient-site incision technique. Complications were identified from post-operative team communications (video calls and patient-submitted photographs), extracted retrospectively by a single trained data extractor using a standardized coding form.

Secondary outcome: 6-month graft retention. Because the study population includes a high proportion of international patients who return to their home country within one week of surgery, in-person trichoscopic assessment was not feasible at 6 months. Graft retention was instead assessed using a

standardized photographic method: a fixed reference area was marked and documented intraoperatively, with the corresponding baseline graft count recorded. At 6 months, patients, guided in real time by the clinic's post-operative care team via video call, photographed the same reference area under standardized conditions. Surviving follicular units within the reference area were counted from these images by the clinical team. Graft retention was calculated as (follicular units counted at 6 months / follicular units transplanted into the reference area at baseline) $\times$ 100. This approach follows the principle of a fixed, standardized reference area established in prior graft-survival methodology [9], adapted here to a remote photographic protocol in place of in-person trichoscopy. This outcome is reported as a preliminary measure: 6 months precedes the 12–18 month interval typically required for final graft-survival stabilization, and the figure may therefore not yet reflect final retention. The reliability of photographic hair-counting methodology, including its inherent observer- and image-quality-dependent limitations, has been described previously [10]; these limitations are addressed in Section 4.1.

2.5 Data Sources

Baseline demographic and surgical data (age, sex, Norwood-Hamilton stage, graft count) were extracted from structured fields in the clinic's electronic patient records system. Six-month outcome data (photographic graft counts, complication events) were extracted from the post-operative care team's remote follow-up communications by a single trained data extractor.

2.6 Statistical Analysis

This study was descriptive in design. Continuous variables are reported as mean $\pm$ standard deviation (SD). Categorical variables are reported as n (%). The primary complication rate is reported as a proportion with a 95% confidence interval (CI) calculated using the Wilson score method, appropriate for small samples and small proportions. The association between HBOT and the composite complication outcome was assessed using Fisher's exact test, selected over the chi-square test given the small expected cell counts. Given the modest cohort size, the study was not powered for formal hypothesis testing of subgroup differences, and no multivariable modelling was performed; these constraints are discussed in Section 4.1. A two-sided $p < 0.05$ was considered statistically significant. Analyses were performed using Python (SciPy 1.x).

2.7 Ethical Considerations

This study relied exclusively on existing, de-identified clinical records; no additional visits, tests, or interventions were performed for research purposes. Patients were informed at the time of treatment that anonymized clinical data collected during standard follow-up could be used for research and quality-improvement purposes. Given the retrospective, fully de-identified nature of the dataset, this analysis was conducted as an internal institutional registry review rather than a prospective research study; prospective ethics committee approval under the Declaration of Helsinki was therefore not applicable, though the analysis adhered to the Declaration's principles regarding confidentiality and data protection for retrospective, de-identified data.

3. Results

3.1 Participants

Of 40 consecutively screened patients, 30 met all eligibility criteria and completed the 6-month assessment (follow-up rate 90.9% of eligible patients). Mean age was 38.4 years (SD 9.2). The cohort comprised 25 men (83.3%) and 5 women (16.7%). Mean graft count transplanted was 2,880 (SD 610). Norwood-Hamilton stage distribution is presented in Table 1.

Table 1. Baseline characteristics of the analytic cohort (N = 30)

Characteristic	Value
Age, years, mean (SD)	38.4 (9.2)
Sex, male, n (%)	25 (83.3)
Sex, female, n (%)	5 (16.7)
Graft count, mean (SD)	2,880 (610)
Norwood II–III, n (%)	13 (43.3)
Norwood III vertex–IV, n (%)	12 (40.0)
Norwood V, n (%)	5 (16.7)
HBOT subgroup, n (%)	12 (40.0)
No-HBOT subgroup, n (%)	18 (60.0)

3.2 Recipient-Site Complications (Primary Outcome)

Three of 30 patients experienced a clinically significant recipient-site complication meeting the pre-specified definition, giving a rate of 10.0% (95% CI 3.5–25.6%) (Table 2). No complication required surgical re-intervention. Events comprised folliculitis requiring treatment (n = 1), delayed healing (n = 1), and prolonged post-operative oedema (n = 1).

Table 2. Clinically significant recipient-site complications within 6 months (N = 30)

Complication	n	%
Folliculitis requiring treatment	1	3.3
Delayed healing (>21 days)	1	3.3
Prolonged post-operative oedema (>72 h)	1	3.3
Any clinically significant complication	3	10.0

3.3 HBOT Subgroup Comparison

No clinically significant complications were observed among patients who received HBOT (0/12, 0%), compared with 3/18 (16.7%) among those who did not (Table 3). While the direction of this difference is notable, it did not reach statistical significance given the limited sample size (Fisher's exact p = 0.26). As allocation to HBOT was based on patient preference rather than randomization, and as the study was not powered for subgroup comparison, this observation should be interpreted as hypothesis-generating rather than confirmatory of a treatment effect; potential selection bias is addressed in Section 4.1.

Table 3. Clinically significant complication incidence by HBOT status

Group	N	Complications, n (%)	p
HBOT	12	0 (0.0)	0.26
No HBOT	18	3 (16.7)	–

3.4 Six-Month Graft Retention (Secondary Outcome)

Mean 6-month graft retention was 94.4% (SD 4.1%). Retention declined with increasing Norwood-Hamilton grade (Table 4), consistent with the established inverse relationship between baseline disease severity and graft outcome reported elsewhere [7,8]. As noted in Section 2.4, this figure is a preliminary measure and may not yet reflect final retention assessed at 12 months.

Table 4. Six-month graft retention by Norwood-Hamilton grade

Norwood Grade	n	Graft Retention, Mean % (SD)
II–III	13	95.4 (3.7)
III vertex–IV	12	94.2 (4.1)
V	5	92.0 (4.8)
Overall	30	94.4 (4.1)

4. Discussion

The principal finding of this 6-month analysis is that, in a consecutive single-arm cohort, FUE performed with the Vector-10™ CVD Lab-Grown Diamond blade was associated with a 10.0% rate of clinically significant recipient-site complications at 6 months, with a preliminary 6-month graft retention of 94.4%. The clinically significant complication rate (10.0%) exceeds the range reported in some large clinical series (1.2–4.7%) [7], despite the narrow, intervention-based definition applied here. This is plausibly attributable to the small cohort size, in which each event carries a weight of more than three percentage points, together with reliance on remote photographic and verbal reporting rather than in-person examination, which may increase rather than decrease the likelihood of capturing minor events. This difference is noted rather than minimized. No event required surgical re-intervention. For context, a mean 6-month graft survival of 92.0% has previously been reported for follicular unit transplantation using implanter-based placement [9]; the present point estimate (94.4%) is numerically similar to, and marginally higher than, this figure, though differing techniques and cohort sizes preclude direct comparison, and no comparative claim is intended. The figure also remains subject to the reduced sensitivity of photographic assessment relative to in-person trichoscopy for detecting fine, early-regrowth follicles [10]. Whether this early point estimate is maintained, increases, or declines toward 12 months cannot be inferred from a single interim time point; this trajectory will be characterized directly once the planned 12-month assessment of this cohort is complete.

This single-arm design does not permit certain conclusions. Laboratory testing of the Vector-10™, conducted internally [5] and corroborated by independent third-party validation [6], demonstrated substantially greater edge durability and initial sharpness relative to sapphire under in vitro conditions, providing a plausible mechanistic basis for reduced per-incision tissue trauma. The present study was not designed to test this hypothesis: in the absence of a concurrent comparator arm, the figures reported here cannot be interpreted as evidence that the Vector-10™ outperforms, matches, or underperforms any other blade material. They represent a descriptive clinical baseline, the first patient-level outcome data for this instrument, against which future comparative studies can be designed and powered.

No clinically significant complications were observed in the HBOT subgroup, a direction consistent with an existing randomized controlled trial, which found that clinical-pressure hyperbaric oxygen therapy combined with hair transplantation was associated with reduced post-operative follicular shedding and reduced folliculitis and itching relative to no adjunctive therapy [11]. This observation arises from a

non-randomized, unblinded comparison in which allocation reflected patient preference, and the study was not powered to detect a subgroup difference; patients who elected to undergo an additional therapy may differ systematically from those who did not, in ways not captured by the variables recorded (e.g., health-seeking behaviour or baseline anxiety about complications). It should accordingly be regarded as hypothesis-generating rather than as evidence of a causal HBOT effect.

4.1 Limitations

Several constraints should be considered. First, and most fundamentally, this is a single-arm study; no comparator blade group was included, and no comparative or superiority claim regarding the Vector-10™ can be drawn from these data. Second, this is a 6-month analysis; the secondary graft-retention outcome precedes the 12–18 month interval required for final graft-survival stabilization and is therefore reported as a preliminary measure that may not yet reflect final retention. For this reason, graft retention was positioned as a secondary rather than primary outcome, with the primary outcome (recipient-site complications) chosen because it can be validly ascertained within the 6-month window. Third, the analytic cohort is small ($N = 30$), which limits statistical power; the HBOT subgroup comparison in particular was underpowered and did not reach significance despite a notable directional difference. Fourth, the secondary outcome was assessed using a standardized photographic method rather than in-person trichoscopy, necessitated by the predominantly international, remotely-located patient population; this method carries inherent limitations related to image standardization, observer counting reliability, and the potential under-detection of fine or lightly pigmented regrowth [10]. It also cannot definitively distinguish regrowing transplanted follicles from any pre-existing native follicles within the reference area unless that area was confirmed to be completely bald at baseline; to the extent residual native hair was present, reported retention may be overestimated. Fifth, allocation to HBOT was non-randomized and based on patient preference, introducing potential selection bias; additionally, the HBOT protocol applied here (one, occasionally two, sessions) was brief relative to protocols described elsewhere in the hyperbaric wound-healing literature, and the biological plausibility of a measurable effect from such limited exposure has not been independently established. Sixth, complication ascertainment relied on remote photographic and verbal reporting rather than in-person clinical examination, which may under-detect subtle or non-visible events.

4.2 Future Directions

The findings of this 6-month analysis will be followed by completion and reporting of the 12-month outcomes for the present cohort, to characterize final graft survival.

5. Conclusions

In this retrospective, single-arm 6-month analysis of 30 patients, FUE performed with the Vector-10™ CVD Lab-Grown Diamond blade was associated with a low absolute number of clinically significant recipient-site complications; the corresponding rate was modestly above some published benchmarks, a difference discussed in relation to the small cohort size. Six-month graft retention is reported as a preliminary measure pending 12-month assessment. No comparative claim relative to other blade materials is supported by this design. The absence of clinically significant complications in the HBOT subgroup is hypothesis-generating.

Disclosures

Ethics Approval: This study relied exclusively on existing, de-identified clinical records; no additional visits, tests, or interventions were performed for research purposes. Given the retrospective, fully de-identified nature of the dataset, prospective ethics committee approval was not applicable; the analysis adhered to the principles of the Declaration of Helsinki regarding confidentiality and data protection for retrospective, de-identified data.

Conflict of Interest: All authors are affiliated with Vera Clinic, where the study was conducted and where the Vector-10™ is used under an exclusive clinical partnership. The clinic provided patient records and follow-up infrastructure. The authors declare no other competing interests. Data analysis and manuscript preparation were conducted independently of marketing, sales, or commercial decision-making functions of the clinic.

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Data Availability: De-identified data supporting the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: All phases of this analysis, including conceptualization, data interpretation, and manuscript preparation, were conducted by Vera Clinic Academy. The final version was approved for publication by the institution.

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