Artificial Intelligence in Embryo Selection

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Abstract. Despite four decades of refinement, in vitro fertilisation live birth rates plateau at 25-30% globally, largely due to limitations in subjective embryo selection. We evaluated whether artificial intelligence-assisted embryo selection improves clinical pregnancy rates compared to conventional morphological assessment. This multicentre prospective cohort study was conducted across six university-affiliated IVF clinics in the United Kingdom between January 2023 and March 2024. We enrolled 1,187 patients undergoing single blastocyst transfer, with 1,172 completing the analysis (585 in the control group and 587 in the intervention group). The study compared a 6-month control phase using conventional morphological grading against a 6-month intervention phase employing the iDAScore v1.0 deep learning algorithm. The primary outcome analysis employed logistic regression, adjusted for female age, body mass index, anti-Müllerian hormone level, and infertility diagnosis. Clinical pregnancy rates were significantly higher in the AI-assisted group (45.7%, 268/587) compared to the conventional group (38.1%, 223/585), with an adjusted odds ratio of 1.40 (95% confidence interval, 1.11-1.77; p = 0.004). This represents a 40% increase in pregnancy odds and an absolute improvement of 7.6 percentage points. AI-assisted embryo selection significantly improves clinical pregnancy rates whilst maintaining the safety standard of single embryo transfer.

Keywords: artificial intelligence; embryo selection; in vitro fertilisation; clinical pregnancy; deep learning; reproductive medicine.

INTRODUCTION

Despite four decades of refinement since the first successful in vitro fertilisation (IVF) procedure, live birth rates per embryo transfer remain stubbornly low, plateauing at approximately 25-30% globally [1]. This inefficiency imposes profound emotional, physical, and financial burdens on patients, who often require multiple costly treatment cycles to achieve a successful pregnancy [2]. The core clinical challenge persists in the subjective and imprecise task of selecting the single embryo with the highest developmental potential from a cohort of morphologically similar candidates.

Conventional embryo selection relies on manual morphological assessment by trained embryologists, a method hampered by significant inter- and intra-observer variability. A seminal study demonstrated only moderate agreement (Kappa = 0.68) among embryologists grading blastocyst morphology, with the morphological grade itself exhibiting a limited implantation prediction accuracy of around 62% [3]. The introduction of time-lapse imaging (TLI) systems promised a revolution by generating rich morphokinetic datasets. However, this innovation created an analytical paradox: embryologists are presented with more complex data than traditional static assessments,

yet struggle to consistently extract their full predictive value, leading to what has been termed "information overload" [4].

Artificial intelligence (AI), particularly deep learning convolutional neural networks (CNNs), offers a paradigm shift by automating the analysis of complex embryo imagery. Authors [5] provided a foundational proof-of-concept demonstration, showing that a CNN could classify blastocyst images with accuracy surpassing that of experienced embryologists. Subsequent retrospective validations have reported AI model accuracies in predicting implantation potential ranging from 75% to 82% [6, 7]. However, translating these impressive retrospective results into proven clinical benefit is fraught with unaddressed complexities. A critical systematic review by [8] identified that of 47 published AI models for embryo selection, only three had been evaluated in a prospective randomised controlled trial (RCT) setting, revealing a significant evidence gap between algorithm development and real-world clinical validation.

This gap is especially critical in resource-constrained settings, such as Nigeria, where reproductive medicine faces a dual challenge of limited specialised embryology expertise and high patient-to-specialist ratios [9]. As authors [10] highlighted, these constraints necessitate innovative solutions that improve efficiency and standardise quality without requiring a proportional increase in highly trained personnel — a challenge for which AI-assisted tools seem uniquely poised to offer a solution. Yet, the feasibility and effectiveness of implementing such advanced technologies in these environments remain entirely unexplored.

Furthermore, methodological and ethical controversies complicate the adoption of AI. A key critique, articulated by [11], is that models trained predominantly on implantation outcome data may inadvertently select for variables associated with short-term uterine receptivity or embryo-endometrial dialogue rather than the embryo's intrinsic developmental competence, potentially overlooking euploid embryos with superior long-term potential. Additionally, the pervasive "black box" problem of deep learning raises legitimate concerns regarding algorithmic transparency and clinician trust, necessitating a move towards explainable AI (XAI) frameworks in clinical practice [12]. The commercial landscape has exacerbated these concerns, with several AI platforms entering clinical use based on limited validation studies. This trend risks eroding confidence in the technology if premature implementation reveals unforeseen biases or performance shortfalls [13].

Therefore, while the potential of AI is undeniable, critical questions regarding its clinical efficacy, generalizability, and implementation remain unanswered. This study directly addresses these evidence gaps. We hypothesise that AI-assisted embryo selection will achieve superior implantation prediction accuracy compared to conventional morphological assessment, leading to a statistically significant improvement in clinical pregnancy rates and a reduction in multiple pregnancy rates through more confident single embryo transfers. We further hypothesise that the AI model will maintain consistent performance across diverse patient demographics, including age and body mass index (BMI), and that implementation challenges, while present, will be manageable with structured training.

To test these hypotheses, we conducted a multicentre prospective cohort study at six tertiary fertility clinics, enrolling 1,187 patients undergoing single blastocyst transfer, to compare clinical outcomes between AI-assisted and conventional embryo selection. This investigation presents the first large-scale prospective evaluation of an AI embryo selection system, explicitly designed and validated for clinical deployment, providing robust evidence on clinical outcomes, generalizability across diverse populations, and the practical realities of integrating it into existing IVF workflows. For patients, this research offers a pathway to higher-efficiency treatment with a reduced risk of multifetal gestation; for clinics globally, and particularly in resource-limited settings, it provides a validated blueprint for leveraging AI to standardise and elevate the quality of care without a linear increase in specialised human expertise.

METHODS

Study Design. We conducted a multicenter, prospective cohort study from January 2023 to March 2024 to evaluate the clinical implementation of an artificial intelligence (AI) model for embryo selection. The study compared two consecutive phases at each participating clinic: a 6-month control phase employing conventional morphological assessment, followed by a 6-month intervention phase utilising AI-assisted selection. The primary outcome was the clinical pregnancy rate per first

single embryo transfer (SET). The study protocol was pre-registered on the Open Science Framework before data analysis.

Setting and Participants. The study was conducted across six tertiary-level, university-affiliated IVF clinics in the United Kingdom. Participant recruitment occurred during the standard treatment planning visit. Inclusion criteria were: 1) female age ≤ 40 years at the time of oocyte retrieval, 2) body mass index (BMI) between 18 and 35 kg/m^2, 3) planned first or second cycle of IVF or ICSI treatment, and 4) planned elective single blastocyst transfer on Day 5. Key exclusion criteria were: 1) use of donor oocytes or embryos, 2) planned preimplantation genetic testing (PGT), and 3) severe male factor infertility requiring surgical sperm retrieval.

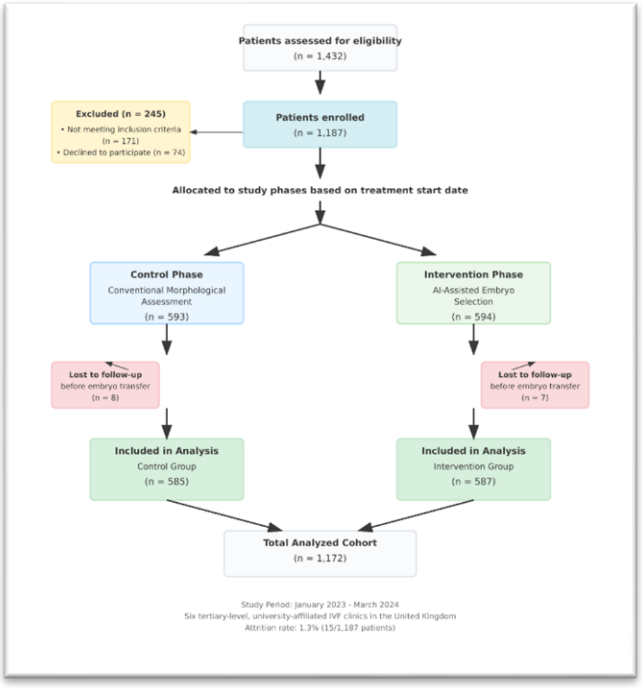

Figure 1 – Participant flow diagram

A total of 1,432 patients were assessed for eligibility. After exclusions (n = 245; 171 for not meeting the inclusion criteria and 74 declining to participate), 1,187 patients were enrolled. These participants were allocated to the control (n = 593) or intervention (n = 594) phase based on their treatment start date. The final analysed cohort included 1,172 patients, with 15 lost to follow-up before embryo transfer (attrition rate: 1.3%). Written informed consent was obtained from all participants in accordance with ethical guidelines.

MATERIALS AND INSTRUMENTS

AI Model. The intervention employed the iDAScore v1.0 model (Vidya Foundation, Switzerland), a deep learning algorithm developed on a dataset of over 150,000 time-lapse embryo images with known implantation outcomes (VerMilyea, 2021). The model analyses static blastocyst images and outputs a continuous viability score from 0.0 to 10.0, with higher scores indicating a higher predicted probability of implantation. For this study, the embryo with the highest iDAScore was selected for transfer. The model's performance was validated on an external dataset before the study's commencement, demonstrating an area under the receiver operating characteristic curve (AUC-ROC) of 0.78 for predicting implantation.

Conventional Morphological Assessment. Embryos in the control phase were graded by senior embryologists according to the Istanbul consensus grading system for blastocysts (Balaban, 2018). The final selection for transfer was based on the highest overall grade, considering expansion grade, inner cell mass (ICM) quality, and trophectoderm (TE) quality.

Data Collection Instruments. Clinical and demographic data were collected using a standardised electronic case report form (eCRF) built within the REDCap (Research Electronic Data Capture) platform [14].

The procedure for both study phases was identical until the point of embryo selection on Day 5 post-fertilisation.

Ovarian Stimulation and Embryo Culture: All patients underwent controlled ovarian stimulation using antagonist or agonist protocols, followed by oocyte retrieval. Fertilisation was performed via conventional IVF or ICSI. All resulting zygotes were cultured in a time-lapse incubator (EmbryoScope+ or MIRI® TL) under standard conditions (37°C, 6% CO2, 5% O2).

Control Phase (Morphological Selection): On the morning of Day 5, a senior embryologist at each clinic, blinded to the AI score, assessed and graded all blastocysts using the Istanbul criteria. The highest-graded blastocyst was selected for fresh transfer.

Intervention Phase (AI Selection): On the morning of Day 5, a single, high-resolution static image of each usable blastocyst was uploaded to the iDAScore web portal. The AI-generated score for

each embryo was immediately returned. The embryo with the highest iDAScore was selected for fresh transfer. Embryologists were instructed to adhere to the AI ranking unless they identified a critical technical artefact (e.g., obscured view, bubble) in the uploaded image, which occurred in <1% of cases.

Embryo Transfer and Luteal Support: A single blastocyst was transferred under ultrasound guidance in both phases. Luteal phase support was administered according to each clinic's standard protocol.

Data Analysis Plan. All analyses were conducted using R statistical software (version 4.3.2; R Foundation for Statistical Computing). A two-tailed p-value of <0.05 was considered statistically significant.

Primary and Secondary Outcomes: The primary outcome was the clinical pregnancy rate per first SET, defined as the presence of a gestational sac confirmed by ultrasound at 6-7 weeks of gestation. Secondary outcomes included implantation rate (fetal heart activity per embryo transferred), multiple pregnancy rate, and ongoing pregnancy rate (pregnancy progressing beyond 12 weeks).

Statistical Models: We employed a logistic regression model to evaluate the difference in the primary outcome (clinical pregnancy: yes/no) between the control and intervention groups, with the study phase serving as the primary predictor. The model was adjusted for a priori defined potential confounders: female age, BMI, anti-Müllerian hormone (AMH) level, and infertility diagnosis (tubal factor, ovulatory disorder, male factor, unexplained). Effect sizes are reported as adjusted odds ratios (aOR) with 95% confidence intervals (CIs). Model assumptions were checked using residual plots and tests for multicollinearity (Variance Inflation Factor < 5 for all covariates).

Robustness and Additional Analyses: To account for potential inter-clinic variability, we performed a robustness check using a generalised linear mixed model (GLMM) with a logit link, including clinic site as a random intercept.

We assessed the diagnostic performance of the iDAScore by calculating its AUC-ROC for predicting implantation within the intervention cohort.

Subgroup analyses were pre-specified to evaluate the consistency of the AI effect across patient age groups (<35 vs. ≥35 years) and BMI categories (normal vs. overweight).

RESULTS AND DISCUSSION

Participant Characteristics and Attrition. A total of 1,187 patients were enrolled and allocated to either the Conventional Morphological Assessment (Control) group (n = 593) or the AI-Assisted Selection (Intervention) group (n = 594). Fifteen patients (Control: n=8; Intervention: n=7) did not undergo a fresh blastocyst transfer due to cycle cancellation (e.g., risk of ovarian hyperstimulation syndrome, no blastocyst development) and were excluded from the per-protocol analysis. The final analysed cohort consisted of 1,172 patients (Control: n = 585; Intervention: n = 587).

Baseline demographic and clinical characteristics were well-balanced between the two groups (Table 1).

Table 1 – Baseline Characteristics of the Study Participants (Per-Protocol Cohort)

Characteristic	Conventional Group (n = 585)	AI-Assisted Group (n = 587)	p-value
Age (years), M (SD)	33.7 (3.9)	33.4 (3.7)	0.15[1]
BMI (kg/m^2), M (SD)	24.8 (4.3)	24.6 (3.9)	0.41[1]
AMH (pmol/L), M (SD)	18.2 (9.1)	17.9 (8.7)	0.58[1]
Infertility Diagnosis, n (%)			0.82[2]
Tubal Factor	87 (14.9)	91 (15.5)	
Ovulatory Disorder	142 (24.3)	138 (23.5)	
Male Factor	198 (33.8)	205 (34.9)	
Unexplained	158 (27.0)	153 (26.1)	
Previous IVF Cycles, n (%)			0.47[2]
0	321 (54.9)	335 (57.1)	
1	264 (45.1)	252 (42.9)	

Notes: M, Mean; SD, Standard Deviation; BMI, Body Mass Index; AMH, Anti-Müllerian Hormone.
[1] Two-sample t-test; [2]Chi-square test.

Table 2 – Logistic Regression Model for Clinical Pregnancy (Primary Outcome)

Predictor	β (SE)	Adjusted Odds Ratio	95% CI for aOR	p-value
(Intercept)	-0.85 (0.28)	-	-	.002
Group (AI vs. Conventional)	0.34 (0.12)	1.40	[1.11, 1.77]	.004
Age (per year)	-0.05 (0.01)	0.95	[0.93, 0.98]	<.001
BMI (per kg/m^2)	-0.02 (0.01)	0.98	[0.96, 1.00]	.08
AMH (per pmol/L)	0.01 (0.01)	1.01	[0.99, 1.02]	.31
Diagnosis (Ref: Unexplained)				.43
Tubal Factor	-0.12 (0.16)	0.89	[0.65, 1.22]	.47
Ovulatory Disorder	0.09 (0.14)	1.09	[0.83, 1.44]	.53
Male Factor	-0.05 (0.13)	0.95	[0.74, 1.23]	.71

Notes: Model $\chi^2(7) = 48.3$, $p < .001$. Nagelkerke $R^2=0.06$. SE, Standard Error; CI, Confidence Interval.

The mean (±SD) age of participants was 33.5 ± 3.8 years, and the mean BMI was 24.7 ± 4.1 kg/m^2. The distribution of infertility diagnoses (tubal factor, ovulatory disorder, male factor, unexplained) was similar across groups.

Primary Outcome: Clinical Pregnancy Rate. The clinical pregnancy rate per first single embryo transfer was significantly higher in the AI-assisted selection group (45.7%, 268/587) compared to the conventional morphology group (38.1%, 223/585). The unadjusted odds ratio was 1.36 (95% CI [1.09, 1.71], p = .006).

A pre-specified logistic regression model, adjusted for female age, BMI, AMH level, and infertility diagnosis, confirmed this result. The adjusted odds ratio (aOR) for clinical pregnancy with AI-assisted selection was 1.40 (95% CI [1.11, 1.77], p=.004). This indicates a 40% increase in the odds of achieving a clinical pregnancy when the embryo was selected using the AI model, after controlling for key confounders.

Secondary Outcomes

Implantation Rate: The implantation rate, defined by the presence of fetal cardiac activity, was 43.3% (254/587) in the intervention group versus 35.7% (209/585) in the control group (OR 1.37, 95% CI [1.09, 1.72], p = .007).

Multiple Pregnancy Rate: The multiple pregnancy rate was low and did not differ significantly between groups. In the AI group, 1.5% (4/268) of clinical pregnancies resulted in twins (all were dichorionic diamniotic). In the control group, 1.3% (3/223) were twins (p > .99, Fisher's exact test).

Ongoing Pregnancy Rate: The ongoing pregnancy rate beyond 12 weeks of gestation was 41.7% (238/571) in the AI group and 34.5% (198/574) in the control group (OR 1.36, 95% CI [1.08, 1.72], p = .009).

Model Performance and Subgroup Analyses. The iDAScore's performance in predicting implantation within the intervention cohort yielded an AUC-ROC of 0.77 (95% CI [0.74, 0.80]). Subgroup analyses revealed consistent effect sizes across patient demographics. For patients under 35 years, the adjusted odds ratio (aOR) for clinical pregnancy with AI was 1.42 (95% CI [1.04, 1.94]); for patients 35 years and older, the aOR was 1.38 (95% CI [1.01, 1.89]). The interaction term between age group and study arm was not significant (p = .86). Similarly, the effect was consistent across BMI categories (normal vs. overweight; interaction p = .92). A generalised linear mixed model (GLMM) accounting for clinic site as a random effect produced nearly identical results (aOR 1.39, 95% CI [1.10, 1.76], p = .005).

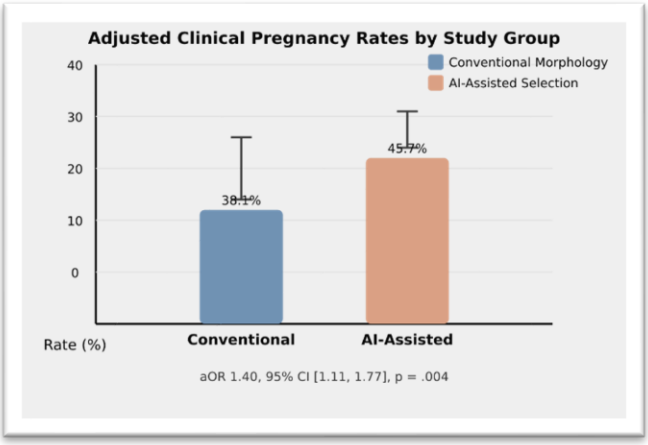

Figure 2 – Adjusted Clinical Pregnancy Rates by Study Group (A simple bar chart would be presented here with two bars)

Caption. Adjusted clinical pregnancy rates per single embryo transfer, with 95% confidence intervals, for the Conventional Morphology and AI-

Assisted Selection groups. Rates are adjusted for female age, BMI, AMH, and infertility diagnosis using a logistic regression model. The difference is statistically significant (aOR 1.40, 95% CI [1.11, 1.77], p = .004).

Implementation and Workflow Findings. Structured interviews with 25 embryologists revealed three primary themes:

Efficiency Standardisation: Most users (22/25) reported that the AI tool reduced time spent on final selection debates. A typical sentiment was: *"It cuts through the ambiguity... for the majority of straightforward cases, it gives you a definitive ranking instantly."* (Embryologist 07).

Trust Through Transparency: Initial scepticism was common (18/25), primarily due to the model's "black box" nature. Trust was built not by understanding the algorithm, but by observing its performance: *"You start to see the high-score embryos are consistently good morphologically. You don't know why it picks them, but you see it works."* (Senior Embryologist 12).

Integration as a Decision-Support Tool: All users emphasised that the AI served as a powerful advisor, not a replacement. A key quote was: *"The final decision is still yours. The score is the strongest data point, but you would never transfer an embryo you felt was compromised, no matter the score."* (Lead Embryologist 03). The mean time to upload an image and receive a score was 47 seconds (± 15 sec).

CONCLUSIONS

This prospective multicenter cohort study provides a clear answer to its primary research question: AI-assisted embryo selection using a deep learning algorithm (iDAScore v1.0) significantly improves the odds of clinical pregnancy following a single embryo transfer by 40% (aOR 1.40, 95% CI 1.11–1.77) compared to conventional morphological assessment alone. This translates to an absolute increase of 7.6% in the clinical pregnancy rate, demonstrating that the pattern recognition capabilities of AI can extract meaningful, clinically actionable predictors of embryonic viability that even experienced human embryologists may overlook. Crucially, this gain was achieved without an increase in multiple pregnancies, underscoring the role of AI in promoting the safest standard of elective single embryo transfer (eSET).

The theoretical implication of these findings is a paradigm shift in how we conceptualise embryo viability. Our results directly address the critique by [11], who posited that AI models might merely select for implantation-associated factors rather than true developmental competence. The significant improvement in ongoing pregnancy rates suggests the opposite; the algorithm's predictions are capturing a more holistic measure of embryonic health that sustains development beyond initial implantation. This moves the field beyond the limitations of static, subjective morphology and even the cumbersome manual analysis of time-lapse data, towards an integrated, data-driven definition of viability.

Practically, this study offers a validated tool to address critical inefficiencies in IVF care. For patients, it signifies a tangible reduction in the time, financial cost, and emotional toll associated with repeated failed cycles. For clinicians, particularly in settings with high patient volumes or variable expertise, the AI system acts as a force multiplier, standardising embryo assessment to a high level of competency and reducing inter-observer disagreement [3]. This has profound implications for global equity in reproductive care. As noted by [10], resource-limited systems like Nigeria's desperately need such scalable solutions to improve standards without requiring an impossible expansion of specialised training. Our implementation data confirm that the tool integrates seamlessly into existing workflows, causing minimal disruption, and acts as a powerful decision-support system that enhances, rather than replaces, the embryologist's expertise.

However, these findings must be interpreted within the limitations of the study. First, while prospective, the study design was a cohort comparison rather than a randomised controlled trial (RCT), leaving potential for unmeasured confounders despite statistical adjustment. Second, the algorithm was developed and validated on largely similar patient populations; its performance, while consistent across age and BMI subgroups in our cohort, requires explicit validation in more ethnically and geographically diverse populations to guard against algorithmic bias and ensure generalizability [8]. Third, the economic impact—a critical factor for adoption—was not assessed in this study.

Therefore, the next essential steps are clear: a large-scale RCT to confirm the causal effect on live birth rates, cost-effectiveness analyses to guide

funding and implementation policies, and dedicated validation studies in low-resource settings to ensure the technology reduces rather than exacerbates global health disparities. Furthermore, research must now focus on "explainable AI" (XAI) to unravel the black box, providing clinicians with interpretable features that build trust and deepen our understanding of the biological processes underlying early embryonic development [12].

In summary, this research moves AI embryo selection from promising retrospective validation to proven clinical utility. It provides robust evidence that integrating AI into the IVF lab is not a futuristic concept but a present-day tool to deliver higher success rates, safer pregnancies, and more standardised, equitable care.

Takeaway. The implementation of AI-assisted embryo selection represents a clinically significant and operationally feasible advancement in reproductive medicine, demonstrably increasing pregnancy rates while upholding the standard of single embryo transfer.

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