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Executive Summary

EarliPoint HEALTH

Eye-Tracking–Based Measurement of Social Visual Engagement Compared With Expert Clinical Diagnosis of Autism

What Was Studied

- Whether an objective eye-tracking test of toddlers' social visual engagement can aid diagnosis and quantify abilities in specialty clinics across the US.

Why it Matters

- Families often notice concerns before age 2, yet diagnoses are delayed until 4–5 years—with even longer delays for racial/ethnic minority, rural, and lower-income families.
- Gold-standard tools are accurate but slow and specialist-dependent. A faster, objective test could expand capacity and speed access to supports.

How the Study Worked

- Design: Multisite, prospective, double-blind diagnostic study at 6 US clinics, designed to support FDA clearance.
- Participants:
  - 499 toddlers enrolled ages 16-30 months (mean 24:1)
  - 95.2% success rate in data collection (475/499)
- Eye-tracking test: Children watched short social videos. Automated devices recorded gaze; algorithms output:
  - Categorical result (autism vs non-autism), plus
  - Indices for social disability, verbal ability, and nonverbal ability.
- Clinical comparison: gold standard expert autism diagnosis using validated assessments
  - Expert clinicians also noted their own certainty of diagnosis: less than fully certain in ~30% of cases (140/475).

Diagnostic Accuracy

- AUC 0.90
- Sensitivity 78.0%, Specificity 85.4%, AUC 0.90 (when clinicians certain)
- Plain take: High accuracy, replicated in different independent clinics across the US; surprisingly high expert clinician uncertainty in their own diagnoses (~30%) highlights potential benefit of an objective test.

How Well Did It Track Abilities?

- Accurately predicts expert clinical assessments that take hours to administer:
  - Social disability (ADOS-2 total): r = –0.75
  - Verbal ability (Mullen): r = 0.65
  - Nonverbal ability (Mullen): r = 0.65
- Eye-tracking test explained ~74–75% of variance in gold standard assessments.

Practical Takeaways

- Safe, effective, automated; run by clinic staff with ~1 hour training.
- Automated cloud-based processing; reports generated quickly after testing.

Eye-Tracking–Based Measurement of Social Visual Engagement Compared With Expert Clinical Diagnosis of Autism

- Even expert clinicians giving gold standard assessments can be less than fully certain of correct diagnosis in ~30% of children.
- An objective test, measuring same behaviors in the same way for every child tested, can aid efficient accurate autism diagnosis.

Equity Note

In this sample, clinicians' diagnoses were associated with some children's race and ethnicity (a statistical sign of potential bias); objective eye-tracking results were free from bias and had no association with race or ethnicity.

Limitations

- The eye-tracking test is a diagnostic test, not a screening test.
- The eye-tracking test was designed to aid early diagnosis, in young children 16 through 30 months of age.

Bottom Line

- A feasible, objective biomarker that complements clinicians: solid accuracy in routine clinics and meaningful tracking of social, verbal, and nonverbal abilities—promising for earlier, more efficient assessment.
- Data from this multisite clinical trial led to FDA clearance of EarliPoint: the first objective FDA-cleared test to aid in early diagnosis and assessment of autism in children ages 16 through 30 months.