Evaluation and Introduction of Non-Invasive Haemoglobin Testing for Blood Donor Screening

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“capillary” blood

= “lateral finger pulp vessels” blood

Capillary Hb versus Venous Hb

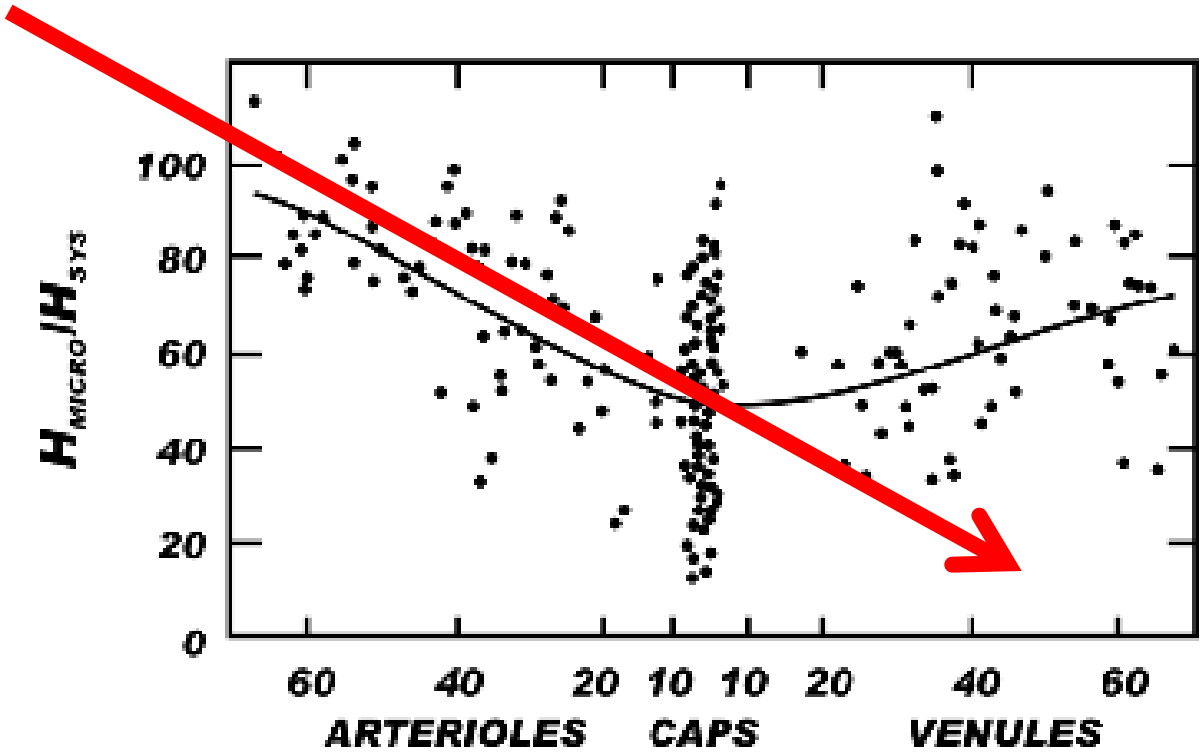
- Vox Sanguinis 2010, Tong et al.
  - 36, 258 paired samples
    - Capillary and venous haemoglobin levels in blood donors
    - Ranges : **12.0-12.4** g/dL (f), **13.0-13.4**g/dL (m).
    - Venous Hb levels were higher than capillary
      - Men 1.07 g/dL (SD 0.68g.dL), range -2.2 to +3.25g/dL (P<0.001)
      - Women 0.67 g/dL (SD 0.65g.dL(, range -2.5 to +5.4g/dL (P<0.001)

Mean Difference **between** Summer and Winter Hb Values

(Tong E *et al.* 2010)

	Mean difference in Summer	Mean difference in Winter	P value
Males n=10,496	0.88 (SD 0.134)	1.26 (SD 0.162)	<0.001
Females n=25,762	0.56 (SD 0.089)	0.78 (SD 0.081)	<0.001

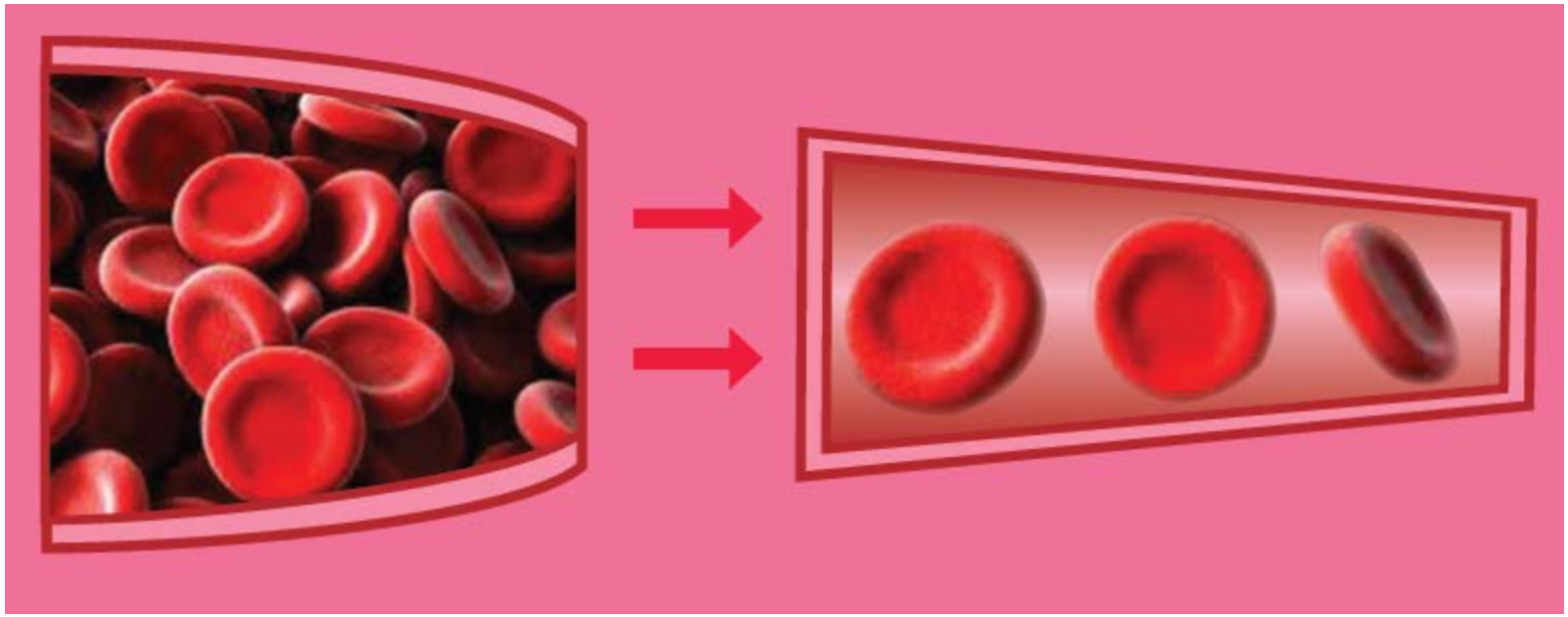
The Fåhraeus effect



Microcirculation laboratory, Penn State

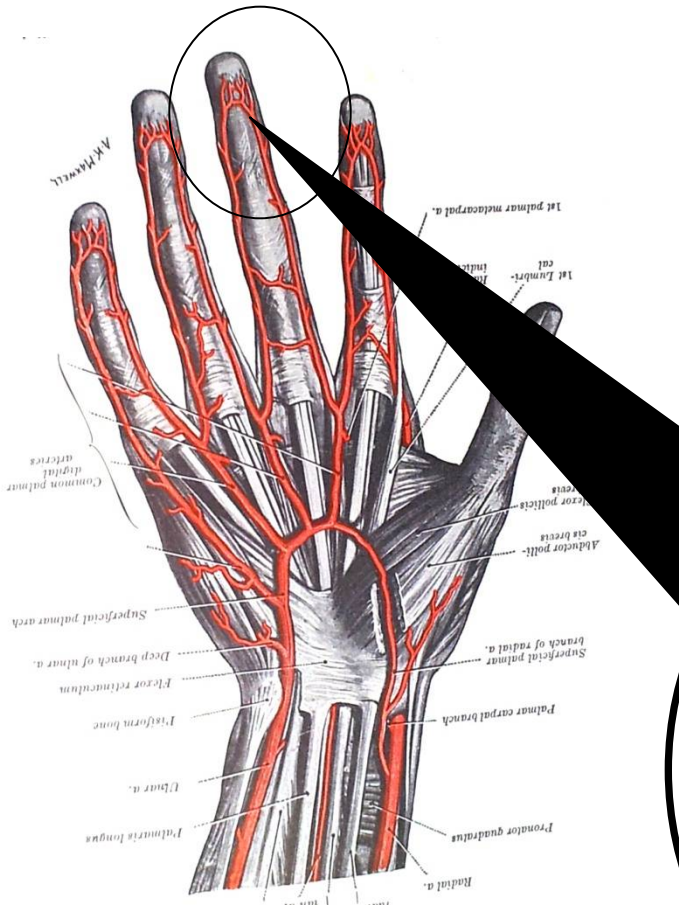
As arterioles narrow to < 300 microns, red cells thin out to a final mean Hct of about 20% in the capillaries

The Fåhraeus effect

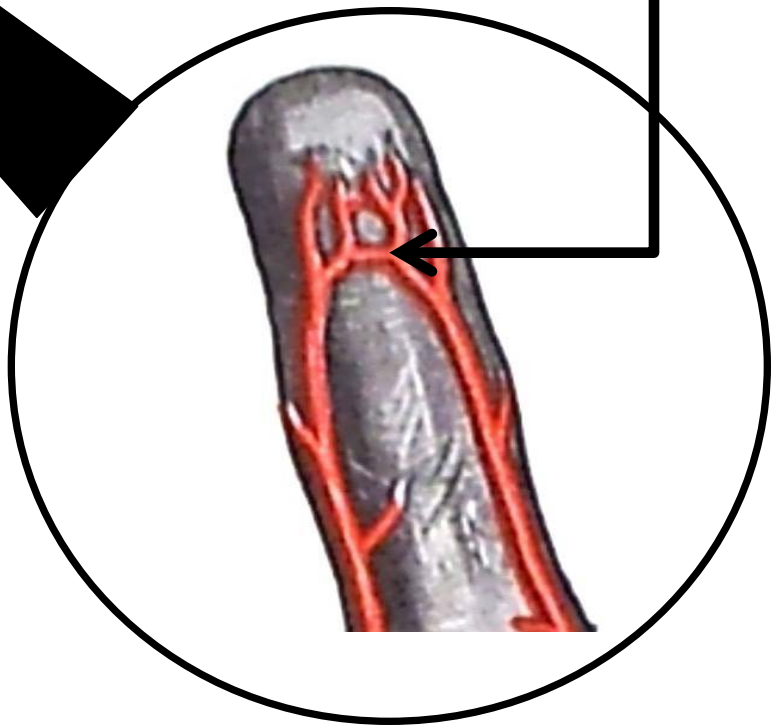


Our Hypothesis

- Blood in vessels >300µm in diameter will give higher mean Haemoglobin values



Arterial Arch believed to be below the Interphalangeal crease.



About 1 mm in diameter

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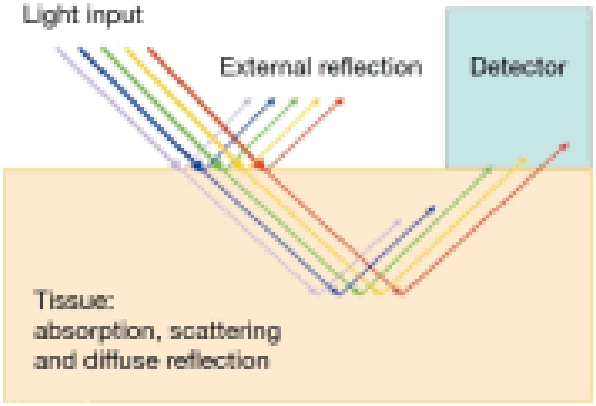
Non-invasive method

- The Haemospect® PS DD-00
  - Quantitative tissue reflectance spectroscopy (qTRS)
    - 500nm and 1000nm



Haemospect in use

Haemoglobin screening station

Donor’s seat

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The Study

- Two phase study
  - 1st phase; 175 comparative analysis
    - Capillary v Venous v Non-invasive
    - Men ≤ 14.5 g/dL
    - Women ≤ 13.5g/dL
  - 2nd phase; 945 donor trial
    - Venous v Non-invasive
    - Examined the false pass rate/deferral rate

Methods (Phase 1)

- Non-invasive (Haemospect PS-DD00)
  - Mean of 3 readings
- Capillary (HemoCue Hb 201+)
  - Finger stick Lancet technique
- Venous (Cell-DYN Sapphire)
  - Multi-parameter automated haematology analyser

Results (Phase 1)

Mean haemoglobin for potential donors, Male and Female combined (n=175)

Methods	Mean g/dL (SD)
Venous	13.99 (1.04)
Capillary	13.01 (0.84)
Non-invasive	13.71 (0.97)

Phase 2

- 945 donor trial
  - Non-invasive vs venous Haemoglobin

- False pass rate (venous haemoglobin reading < cut off value):
  - 23/945, or 2.4% (95% confidence interval 1.6 – 3.6%)

False Pass Rate

- 2.4% This Study
- 3.1% Ziemann, 2011
- 4.9% Mendrone, 2009
- 5.29% Patel, 2013

What does this mean?

- Impact on deferral rates

Year	Hb Deferral %	Min Hb (♂/♀)	Source
July/ Aug 2012	13.22%	12.5/13.5	Capillary
July/ Aug 2014	5.08%	12.5/13.5	Arterial Arch

Saved around 2000 units!

What does this mean?

- Hb screening - Earlier in donation process.

- Donors very pleased
  - Eliminates the finger stick method making for a more pleasant donation experience.

Conclusion

- Non-invasive method allows us to measure Hb in the area of the arterial arch.
- Hb measurement in this area is closer to the venous Hb than the distal capillary Hb.
- The Haemospect PS-DD00® Has been introduced by the IBTS nationally and has replaced the HemoCue Hb 201+.
- Deferral rates reduced to 5.08%
- Allows for Hb screening earlier in the donation process.

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References

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