Testing & Technical Hurdles

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SMTL

About SMTL

- Provide testing and technical services on medical devices to
  - the NHS in Wales & Welsh Government
  - the UK Health Service (NHS SC)
  - Industry
- 16 staff, including pharmacists, microbiologists, technicians
- UKAS accredited for testing
- Sit on
  - MHRA CSD
  - Standards: BSI, CEN, ISO
  - SALG
  - WG WNCRG
- Funded by WHSSC (WG) and Commercial Testing

Procurement Support

Services

- Provision of technical advice
  - standards selection & application
  - test selection
  - assessment of data submissions
- Product testing
  - to standards
  - to clinicians requirements
    - e.g., drug storage in syringes
  - test method development
    - e.g., British Standard for bandages
- Defect & Incident Investigation

A typical contract

- Planning
  - 12+ months before contract starts
  - Relevant products for SMTL input
- Test programme
  - Which standards
  - Which tests
- Samples -> SMTL
- Product testing
- QA for audit
- Issue report to Procurement
- Post contract monitoring

TEST REPORTS

Glove powder

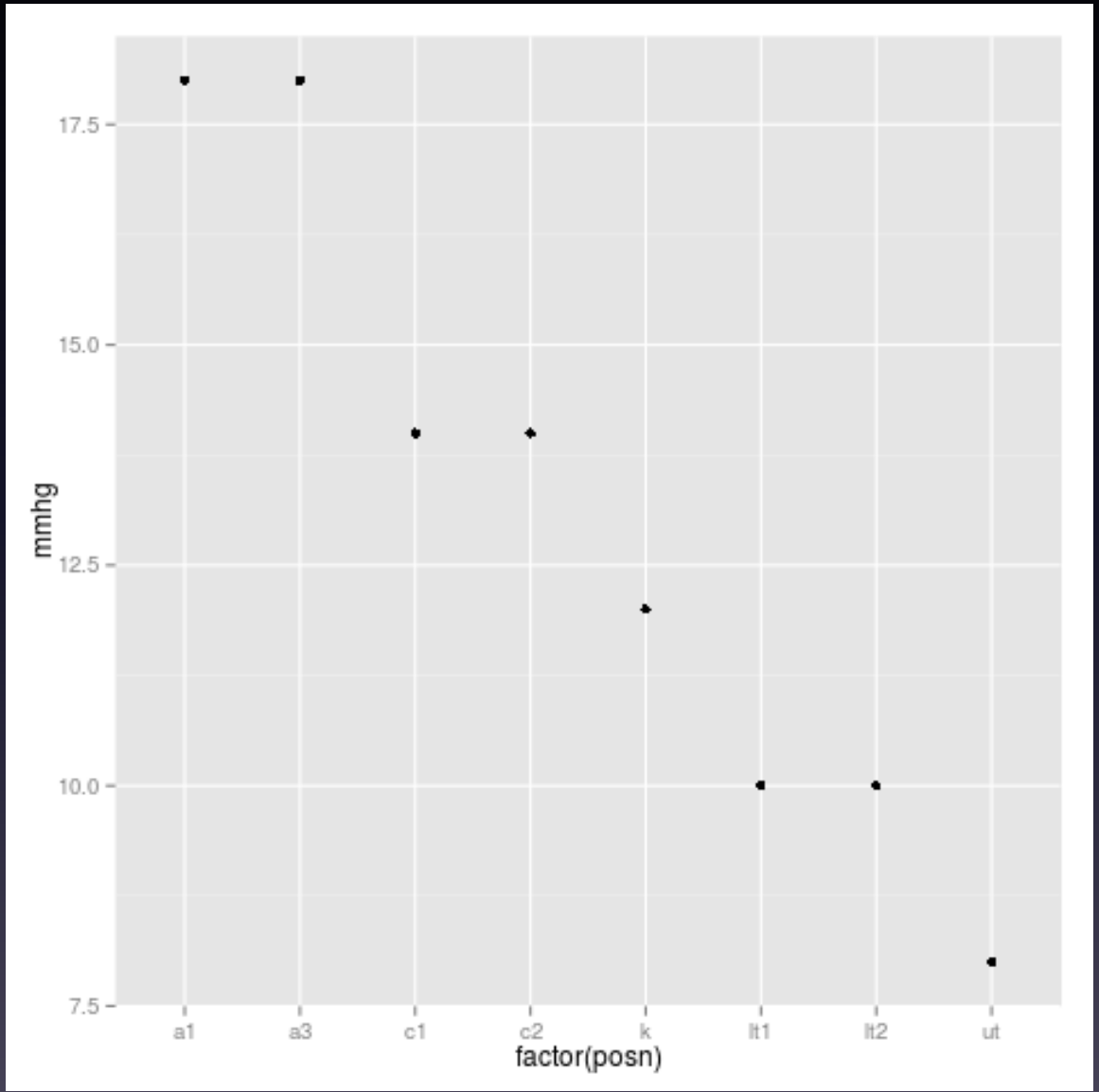
Manufacturer	Mass mg/glove	Pass/ Fail
A	0.32	PASS
B	0.02	PASS
C	0.04	PASS
D	7.34	FAIL
E	0.56	PASS
F	0.16	PASS
G	0.16	PASS

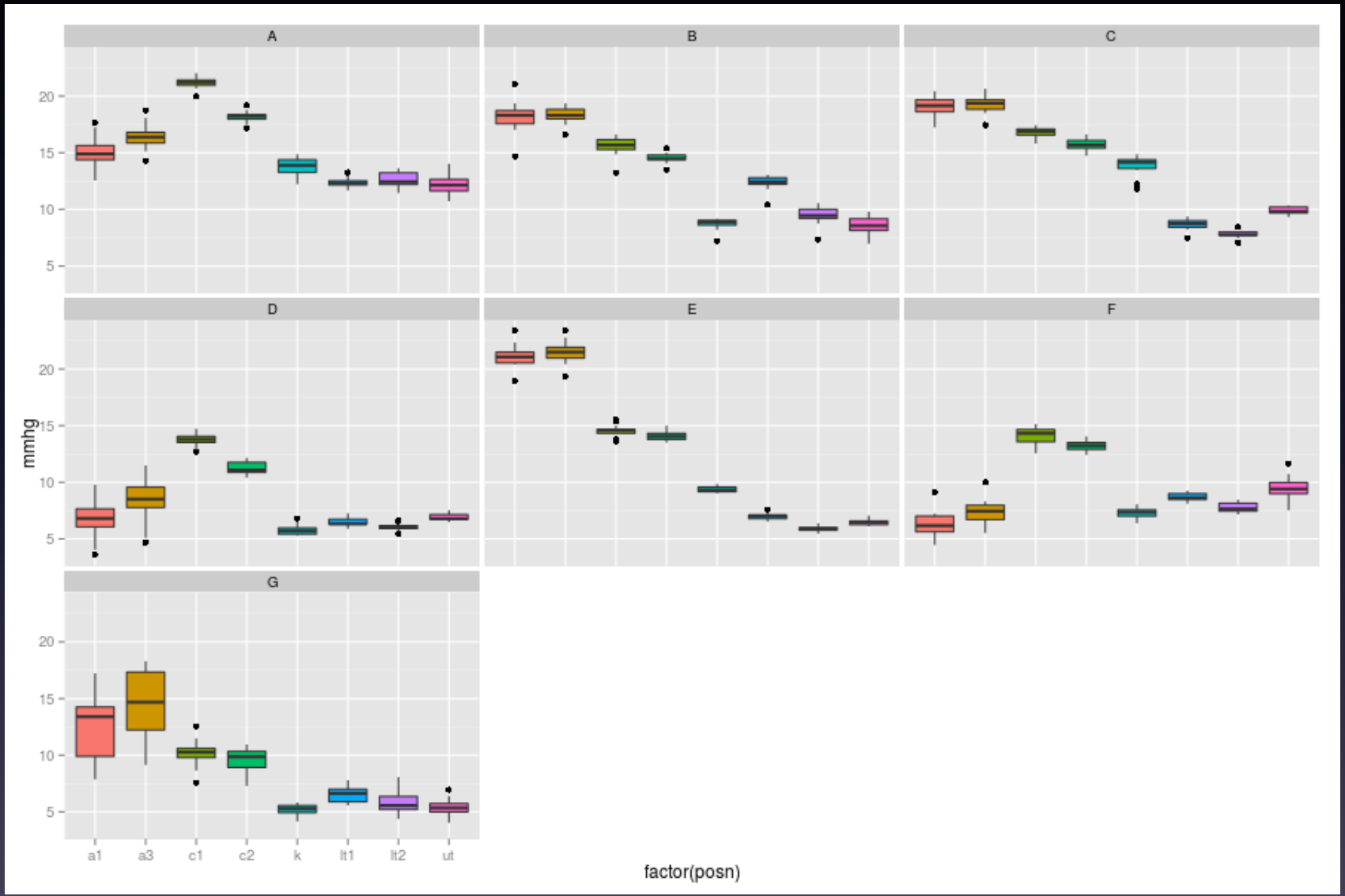
Table 1:Powder Free Latex Results 2011

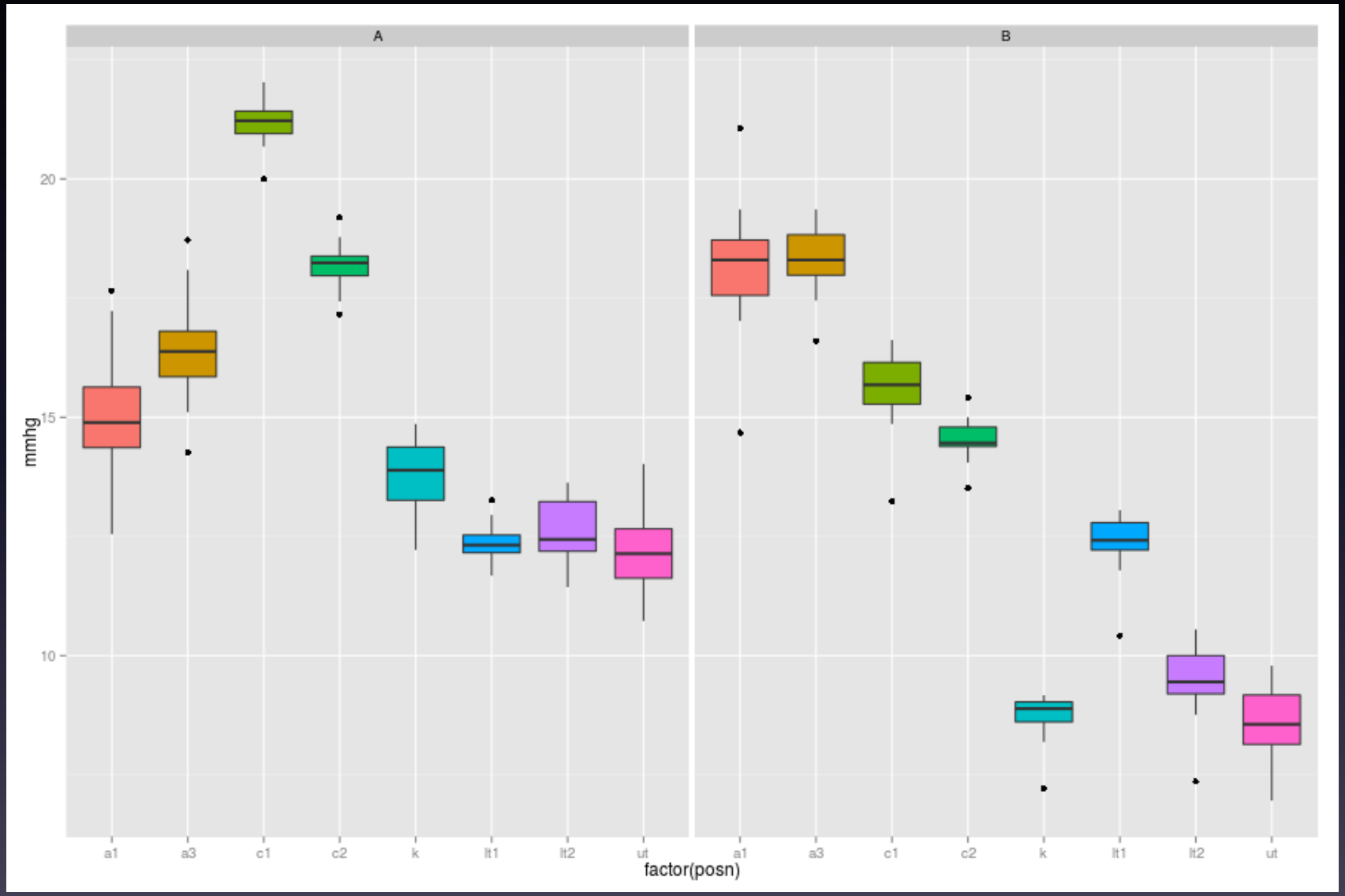
- EN 455-3 - Limit of 2mg/glove

AE Stockings

Siegel Profile




A
B
C
D
E
F
G
mmhg
20
15
10
5
a1
a3
c1
c2
k
lt1
lt2
ut
factor(posn)


A
B
mmhg
20
15
10
a1
a3
c1
c2
k
lt1
lt2
ut
factor(posn)

Tonsillectomy

Background

- 2000/2001- SEAC advice:
  - Tonsil/Adenoid surgery - performed with single-use instruments
- Immediate clinical problems
  - post op bleeds - 1.6% (pre 2001) to 4.4% (during 2001)
  - instrument malfunction - 20% operations
- WAG steering group
  - SMTL, WHS, Alun Tomkinson (ENT, UHW)
  - Paper audit
  - Lab testing
  - Benchtop analysis
    - Compared reusables with single use devices
  - Suppliers audited

Results

- Significant instrument design issues
  - One design on the 4th revision
- Systematic QA problems
  - One supplier had 15% defective instrument rate
  - relied on 100% inspection to weed out poor quality
- Only one acceptable supplier
- Bleed rates returned to pre-2001 (1.5%)
- Surveillance funded through an ‘on-cost’

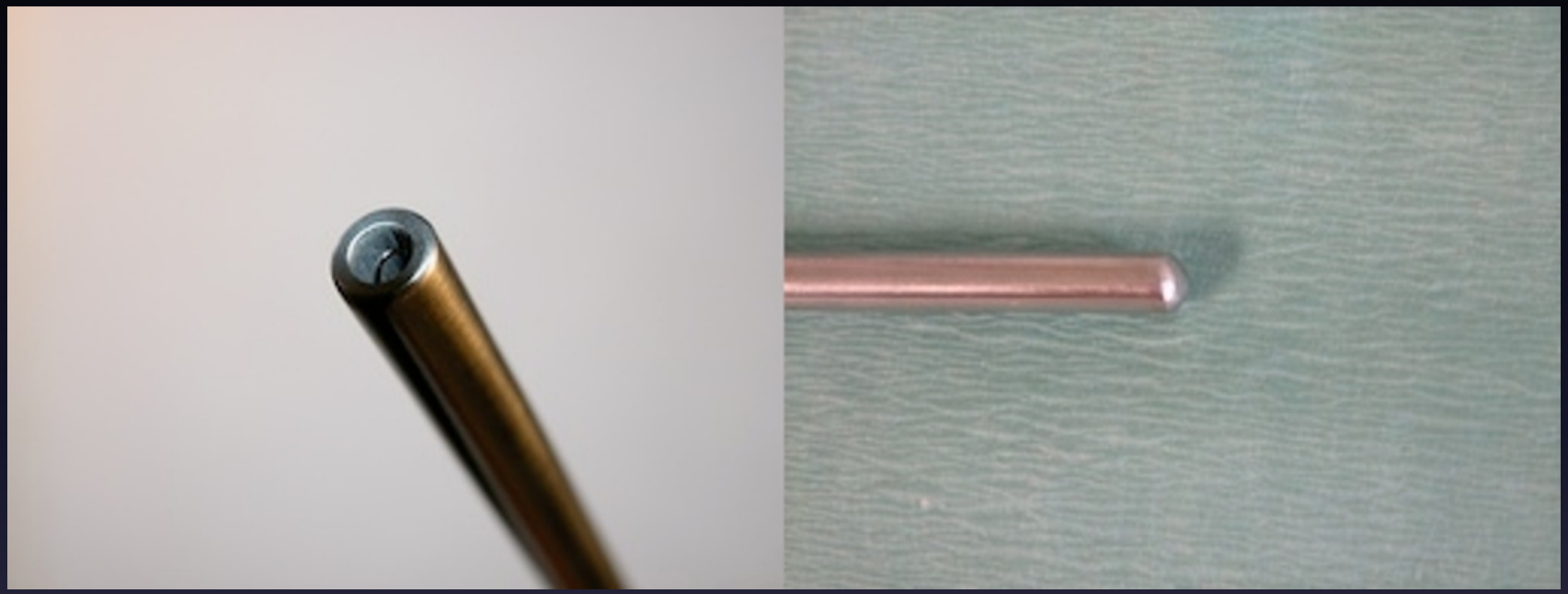


Figure 1:Draffin Rod

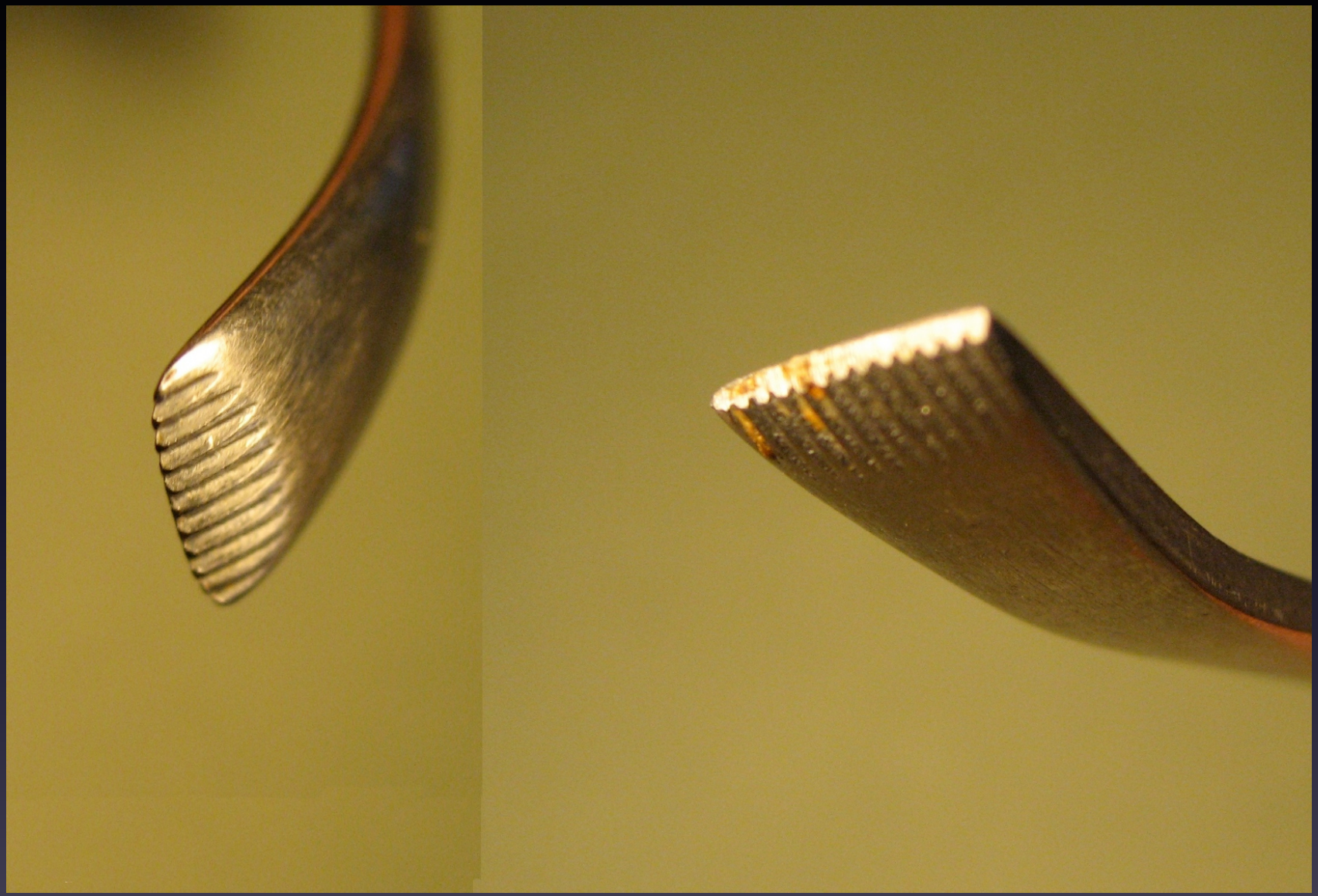


Figure 2:Gwynne Evans Dissector

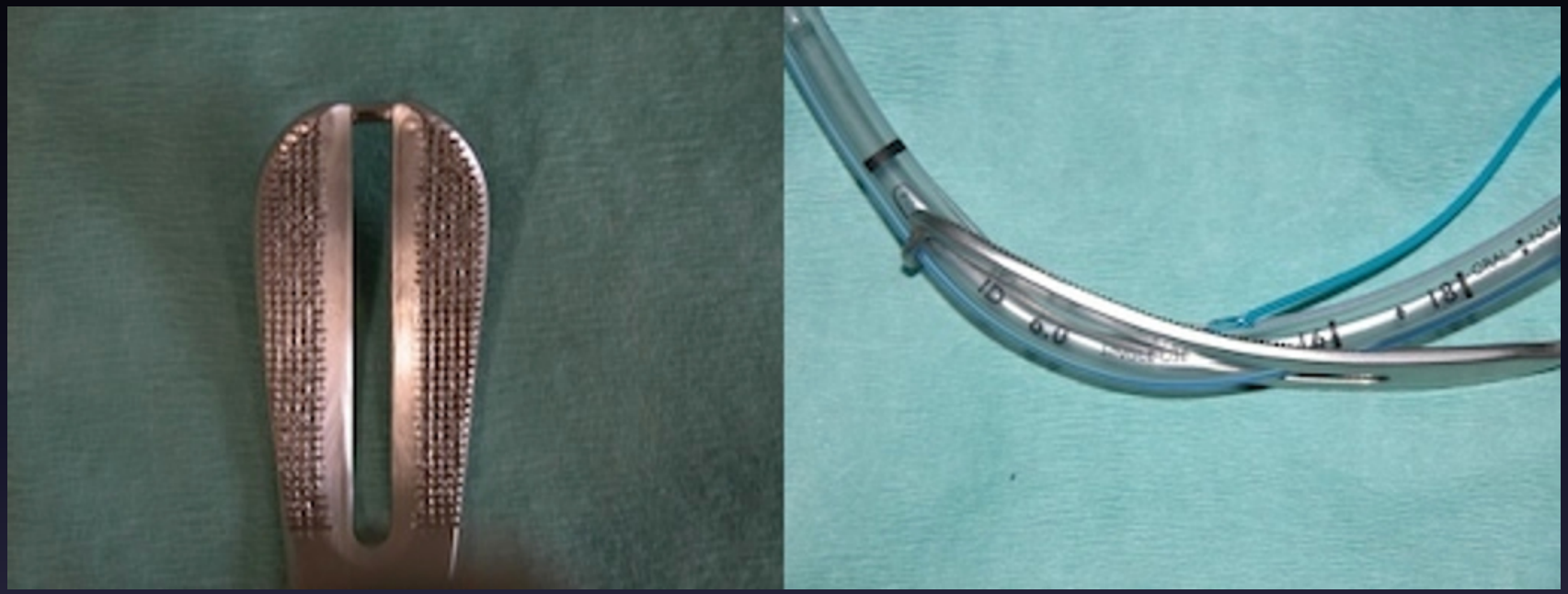


Figure 3:Tongue Plate

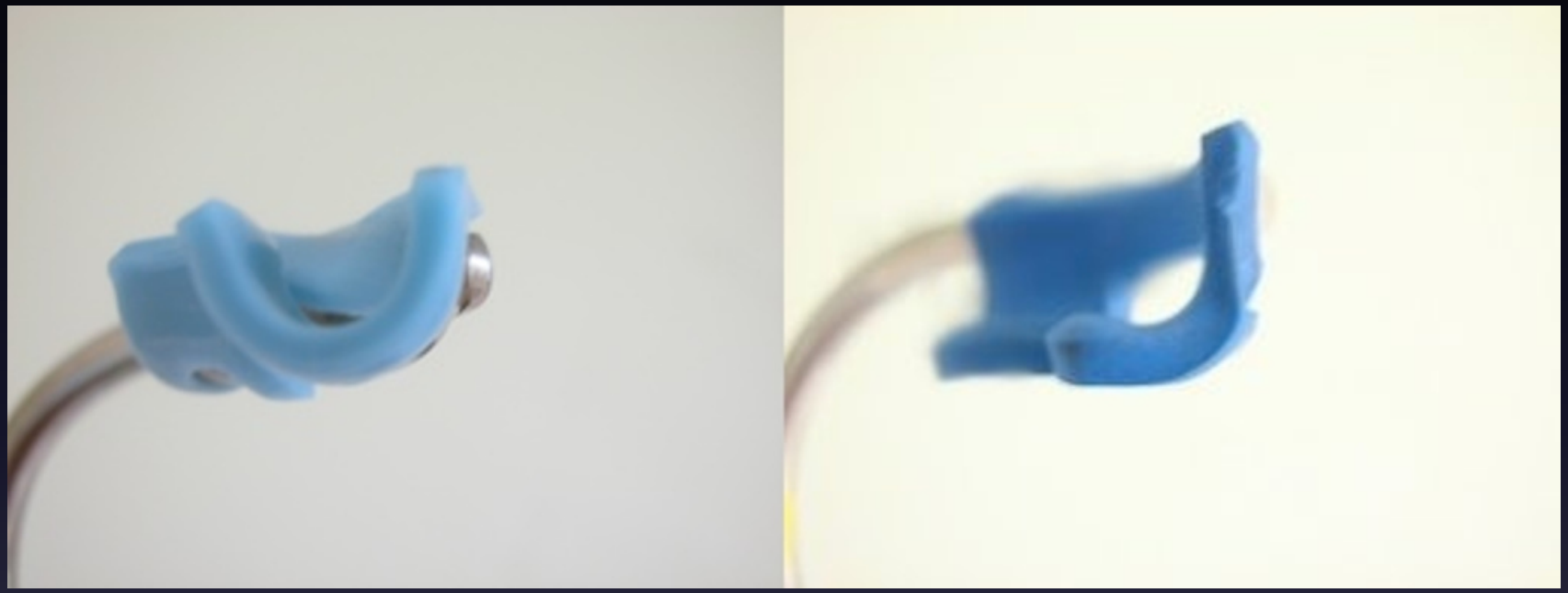


Figure 4:Tooth Guard

Clinical Incidents

- Draffin rods slip
- Mouth gag disengages off teeth
- Gag comes out of mouth
- . . . taking the tongue plate out
- . . . dragging the ET tube out of the patient

Data assessments

Test Report submissions

- If no SMTL testing required or possible
  - Independent data may be requested
    - Evidence that devices meet minimum quality threshold
  - Expect data from certified labs
  - Usually require 17025 accreditation
  - Independent data is preferred
- **Internal non-accredited is not usually acceptable**

Certification

- ISO 13485
  - Pretty much mandatory for any potential medical device supplier
- MDD certification
- ISO 17025
  - For test lab reports

Submission Problems & Issues

Competence

- Post contract monitoring glove contract 2007
- Gloves failed FAB (just over 6N - limit was >=9N)
- Other batches from stores failed
- UK supplier disputed results
  - Chinese test reports were reporting >12N
- Observed testing at SMTL
- Visited Chinese manufacturer
  - Were using a 6mm cutting die instead of 3mm
  - therefore all results were effectively doubled (wrongly!)

Cherry Picking

“On balance, I’ll go through the data we have and pick out some prime reports that will give things a bit of extra ‘zing’.”

Fraud . . .

- Drawings submitted for surgical instruments
- Not possible to actually make instruments to the drawings

2002-2003 Drawing

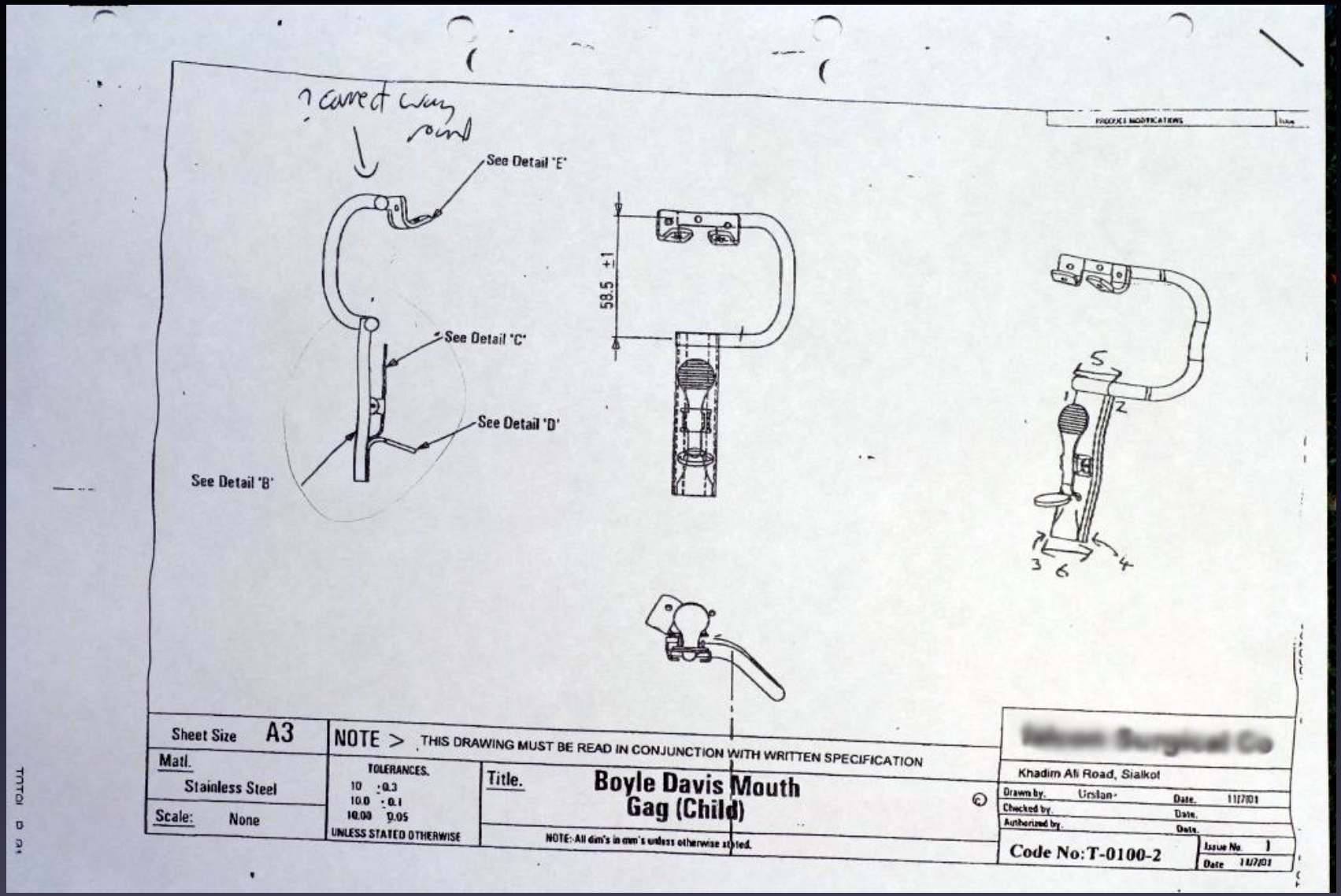


Figure 5:Boyle Davis Gag

2003-2004 Drawing

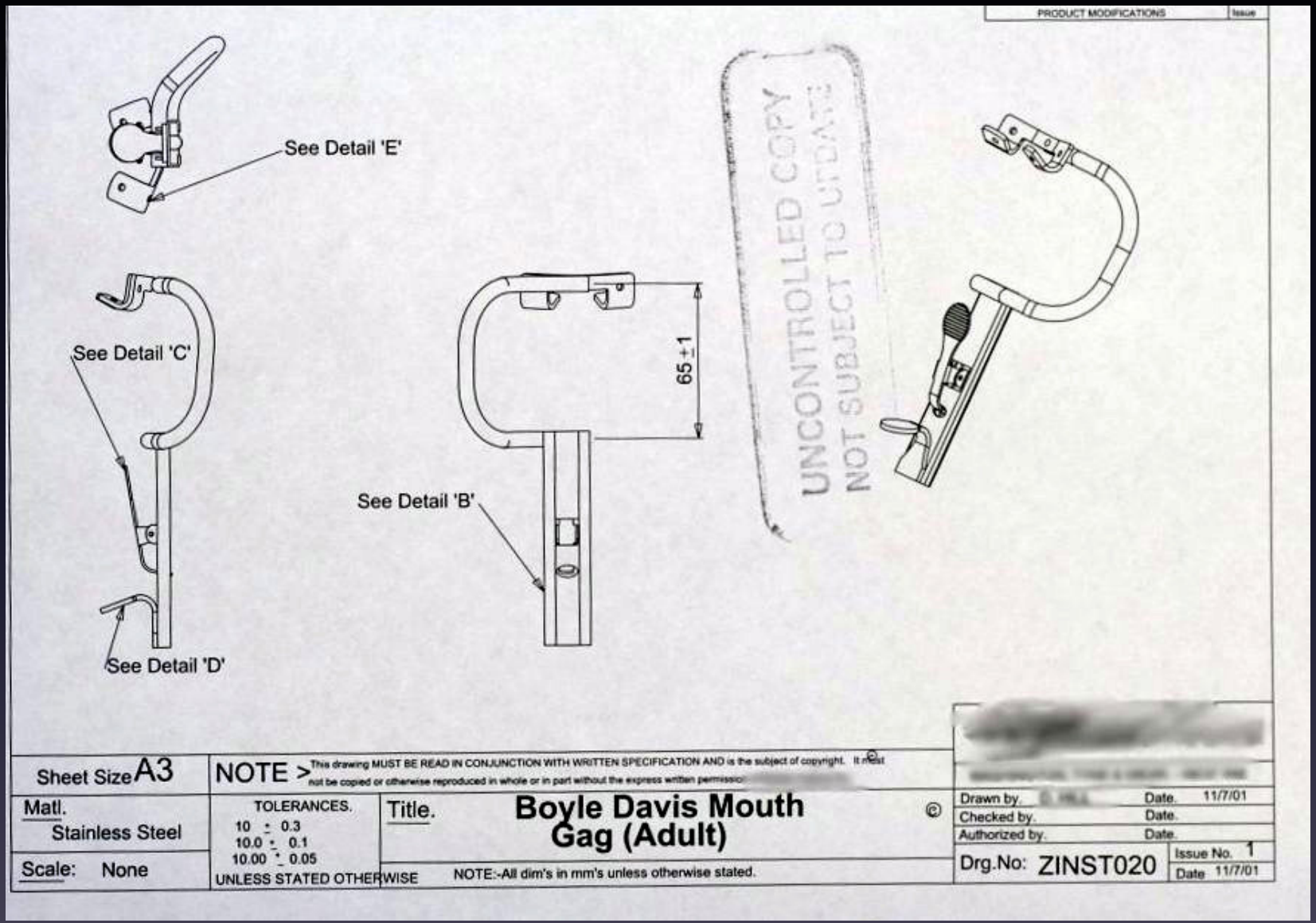
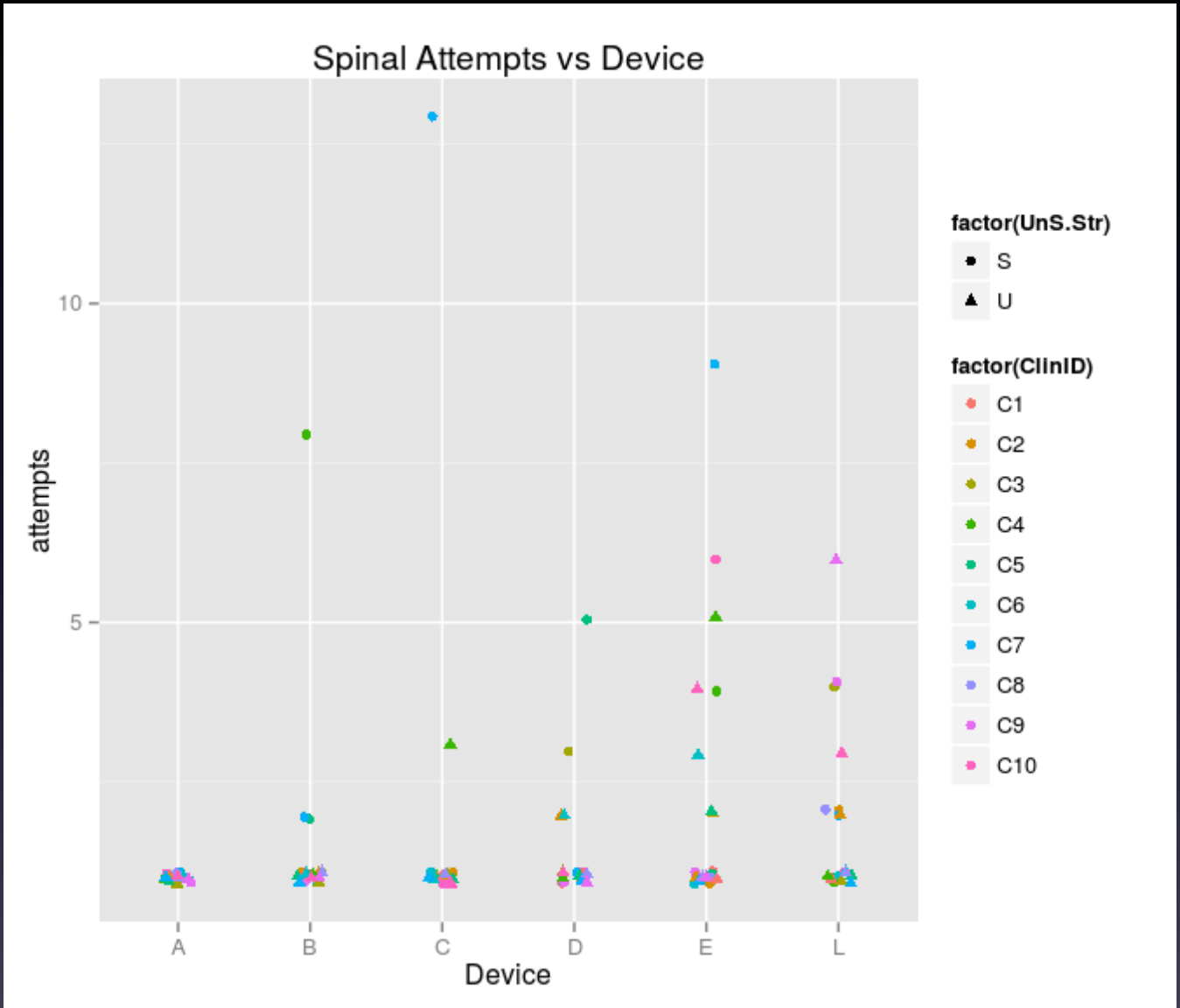


Figure 6:Boyle Davis Gag

Human Factors Testing

Non-Luer Devices

- Wayne Jowett died from intrathecal vincristine 2001
- Toft report - non-luer devices would prevent wrong route injections
- Around 50% English NHS using proprietary solution
- ISO standard under development
- Scotland, Ireland, Wales all presently waiting for ISO
- Wales developing Human Factors capability
- Testing ISO design over the Summer
- Likely to use more frequently in future


Spinal Attempts vs Device
attempts
10
5
A
B
C
D
E
L
Device
factor(UnS.Str)
S
U
factor(ClinID)
C1
C2
C3
C4
C5
C6
C7
C8
C9
C10

Conclusion

SMTL help NHS Wales with

- Evidence based procurement
- Standards compliance
- Patient safety
- Compliant contracting
- Clinician confidence
- Level playing field for manufacturers

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