

NHS Wales Lymphoedema Compression Garments Contract Testing

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THE QUEEN'S AWARDS
FOR ENTERPRISE
2001



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WALES
GIG
CYMRU

Disclosure Information

All-Ireland Lymphoedema Conference 2019
Dr Gavin Hughes

I have no relevant personal financial relationships to disclose.



- Who are SMTL, and what do we do?
- Why test medical devices?
- Experience of testing compression garments and share our information demonstrating that there are potential problems with quality of lymphoedema garments
 - Testing for working groups
 - Contract test results
 - Adverse incidents

SMTL

- Established in late 1970's as a pharmaceutical QA laboratory
- Part of the Welsh NHS hosted by NHS Wales Shared Services Partnership (NWSSP) Health Board.
- Provide testing and technical services on medical devices to the Welsh NHS, Industry and the UK Health Service.
- 25 members of staff including pharmacists, chemists, microbiologists, HTRs...
- UKAS accredited to ISO 17025 International Standard Testing Laboratories
 - Audits, Intra & Inter-Laboratory programmes, UoM budgets
 - Independent, robust & traceable datasets
- Mixed Economy
 - Commercial Income
 - Medical device companies, Government agencies, Coroners, Police forces, Legal representatives
 - Welsh Government Funding
 - Testing and technical input on NHS working groups – NHS Wales Procurement
 - Medical Device Adverse Incident Reporting (400+ per year) – Welsh Government Guidance NHS

Lymphoedema Contract – 2013 – Medical Devices

- 2011 - Welsh government funding to implement the Strategy for Lymphoedema in Wales.
- National Compression Garment Contract and Formulary for 1° & 2° care
- 2013 - Initial working group led by clinicians
 - *“Why do we need to test compression garments?”*
 - Class 1 medical devices - self certification ; no third party involvement
 - Often suppliers do not have data to support claims
 - i. no data
 - ii. borrowed data (fraudulent test reports)
 - iii. old data (>10 years)
 - iv. manufactured to a standard does not mean that the device complies with the standard

Lymphoedema Procurement Contract - 2013

- CE marking alone not robust enough to identify safety and functional issues
 - Surgical tonsillectomy instruments ¹
 - Misclassification of instruments
 - Fraudulent technical drawings
 - Wrong cutting angles of currettes
 - PIP breast implants ²
 - Metal-Metal joint implants ³
- Previous experience with similar compression garments
 - Anti-embolism hosiery

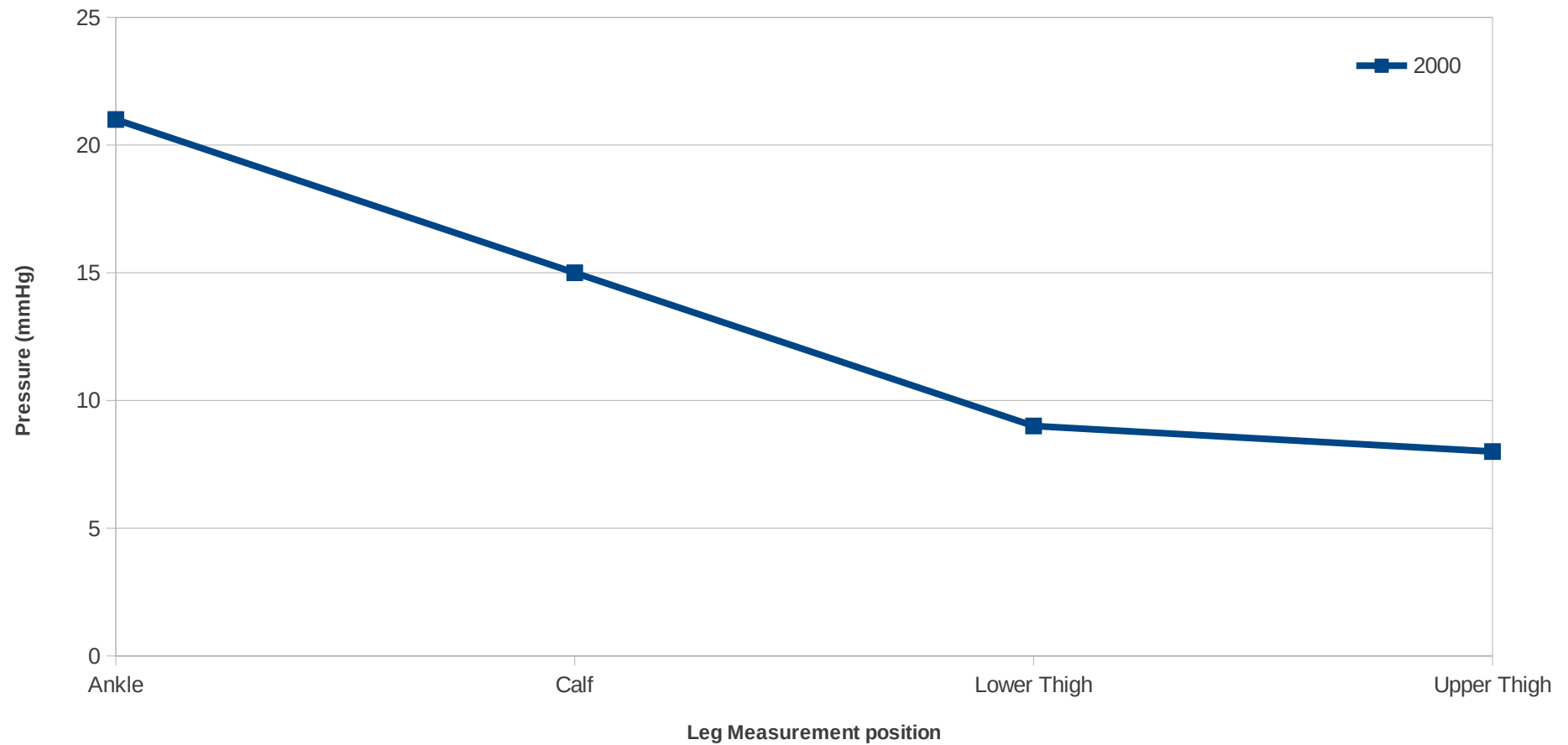
1. Tomkinson A, et al. *Clin Otolaryngol.* 2005 Apr;30(2):135-42. A laboratory and clinical evaluation of single-use instruments for tonsil and adenoid surgery

2. Department of Health, *Poly Implant Prothese (PIP) Breast Implants: Final Report of the Working Group*
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/214975/dh_134657.pdf

3. MHRA, MDA/2012/036. <https://assets.publishing.service.gov.uk/media/5485abf6ed915d4c10000273/con155767.pdf>

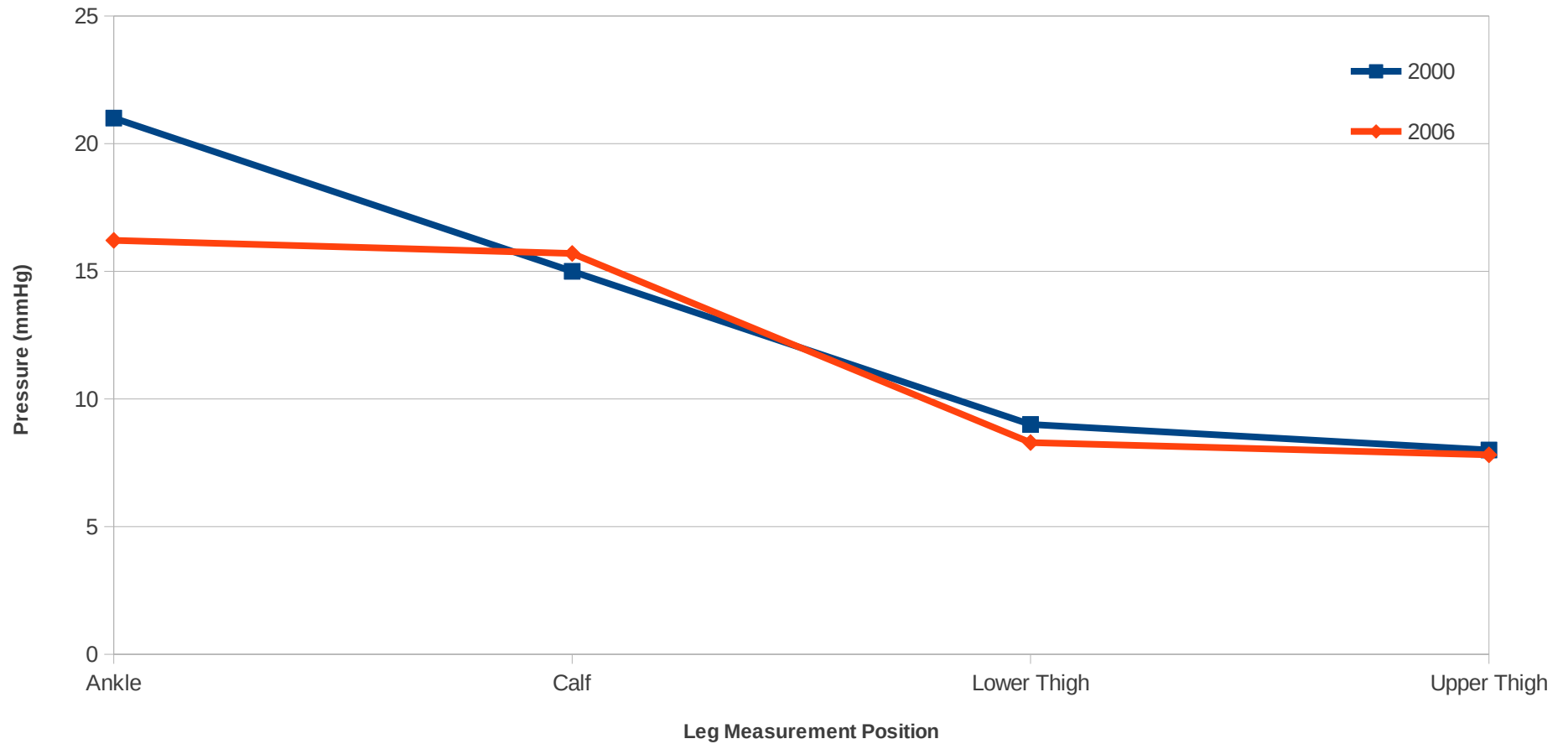
Lymphoedema Procurement Contract - 2013

AWC – Anti-Embolism Hosiery 2000 – Sigel Profile (18, 14, 10, 8mmHg)



Lymphoedema Procurement Contract - 2013

AWC – Anti-Embolic Hosiery 2006/07 - lower ankle pressure



Lymphoedema Procurement Contract - 2013

AWC – Anti-Embolic Hosiery 2010/11 – negative gradient



Lymphoedema Procurement Contract - 2013

- **Initial User/Clinician Queries**

- Garment consistency – difference in pressures between different colours
 - i. Difference in garment lengths/pressures within packaging
 - clinicians reporting differences of 5-10cm between left and right leg garments



Lymphoedema Procurement Contract - 2013

- **Initial User/Clinician Queries**

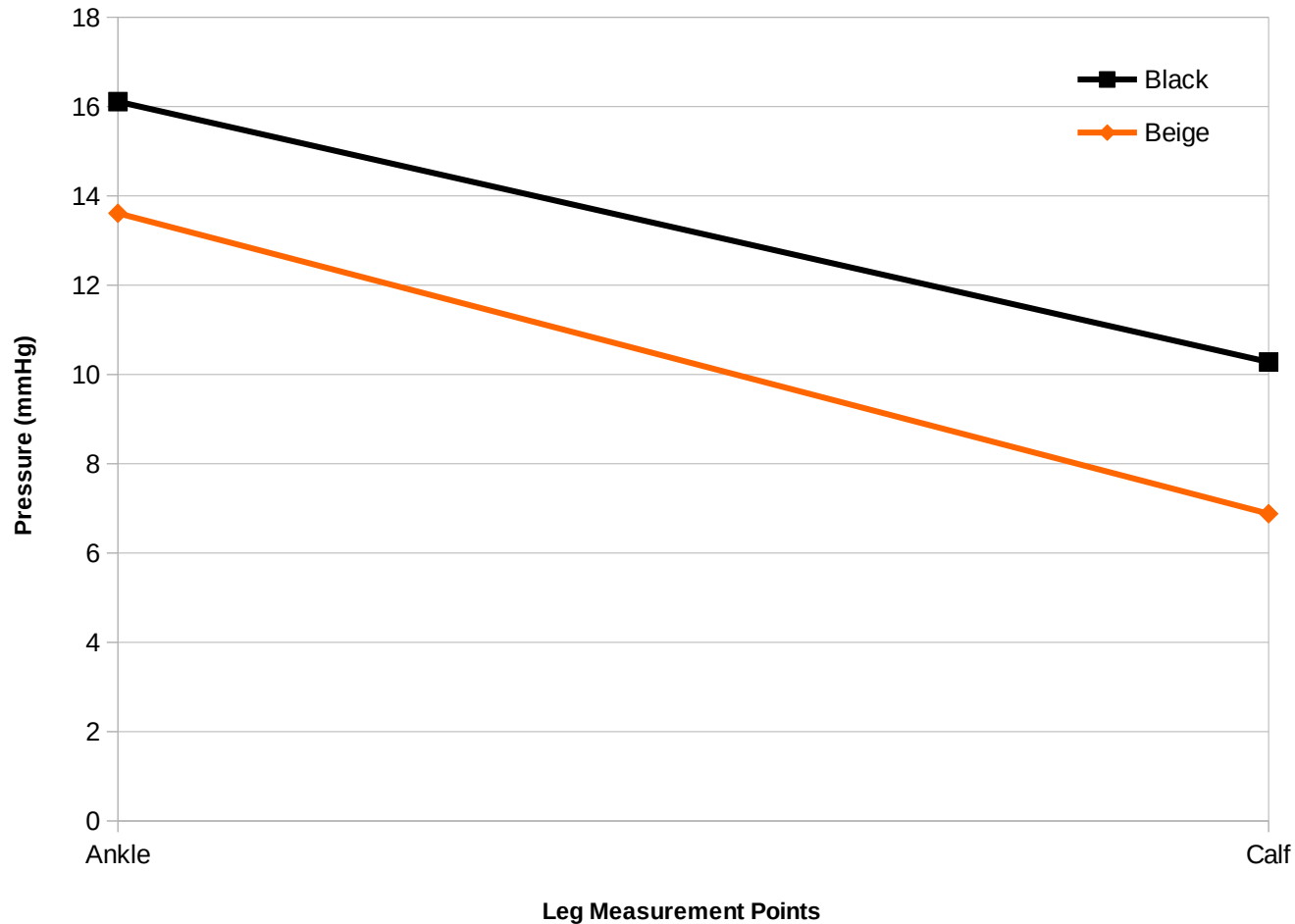
- **Garment consistency – difference in pressures between different colours**
 - i. Difference in garment lengths/pressures within packaging
 - ii. **Difference in garment lengths/pressures between colours (Black vs Beige)**

Haddenham Pertex Leicht CCL 1 same size garment



Lymphoedema Procurement Contract - 2013

Beige vs Black – Haddenham Pertex Leicht CCL 1 same size garment



CLASS 1	Ankle (mmHg)	Calf (mmHg)
Black	16.11	10.28
Beige	13.61	6.88

Lymphoedema Procurement Contract - 2013

- Initial User/Clinician Queries

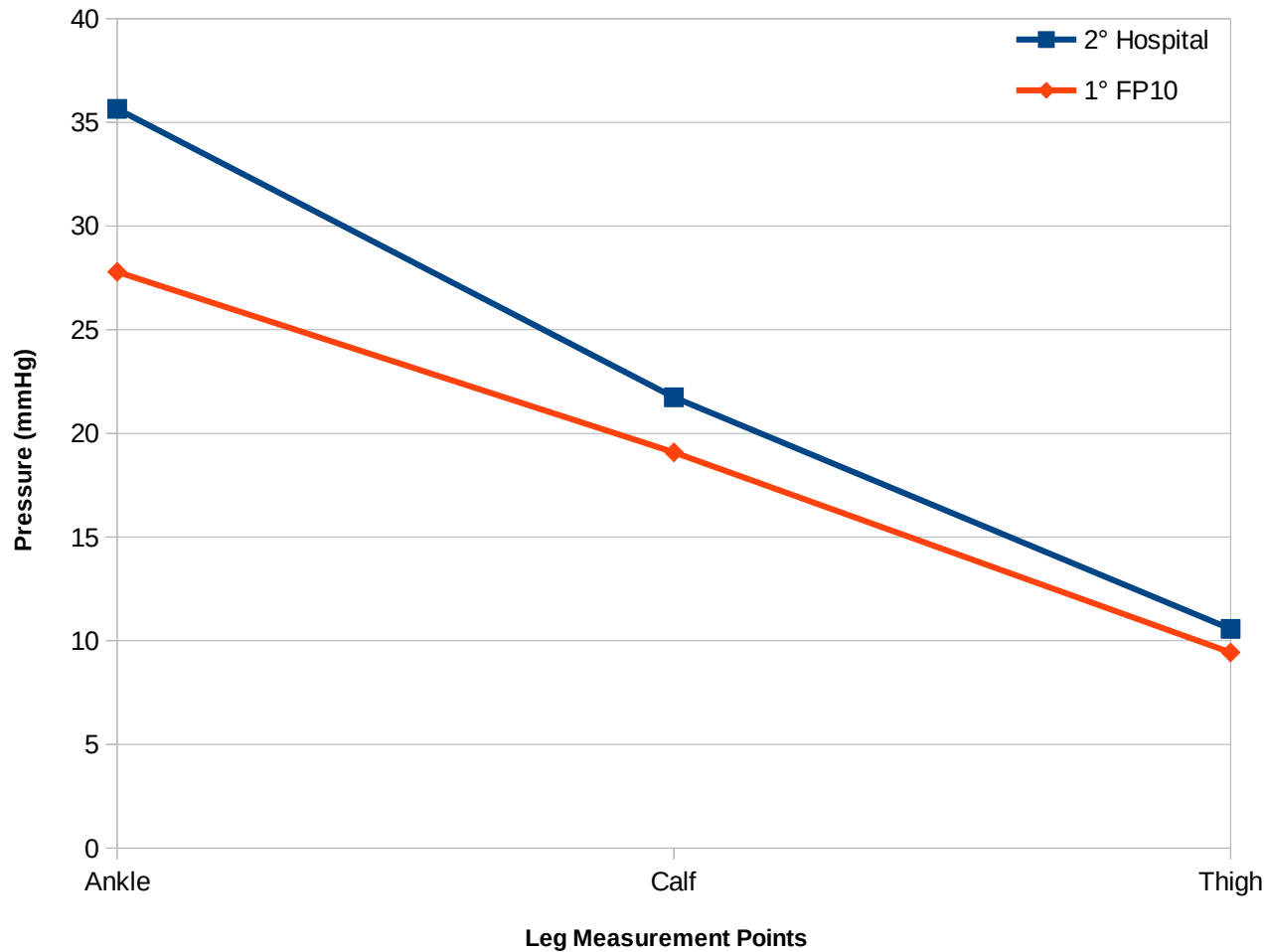
- Garment consistency – difference in pressures between different colours
 - i. Difference in garment lengths/pressures within packaging
 - ii. Difference in garment lengths/pressures between colours

- Post Meeting User/Clinician Queries

- i. Difference in garment pressures between 1° (prescription) and 2° (hospital) sources.

Lymphoedema Procurement Contract - 2013

1° (WP10 Prescription) vs 2° (Hospital) sourced garments – Medi UK Mediven Plus



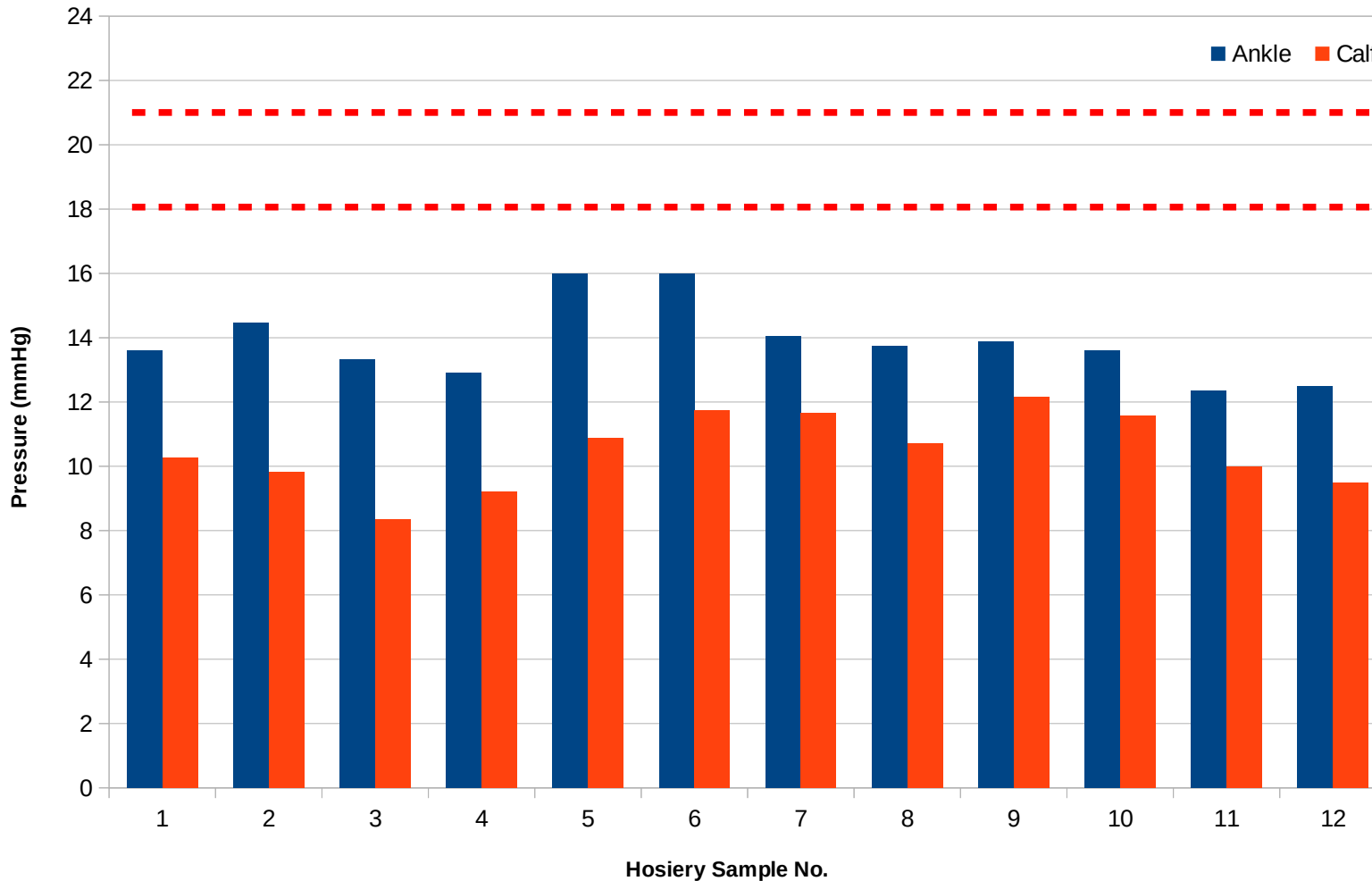
	Ankle	Calf	Thigh
2°	35.7	21.7	10.6
1°	27.8	19.1	9.4

Lymphoedema Procurement Contract - 2013

- Post Meeting User/Clinician Queries
 - i. Difference in garment pressures between 1° (prescription) and 2° (hospital) sources.
 - ii. For reassurance request to assess pressures of high usage lower limb garments
 - ✓ Patients like the garments
 - ✓ Easy to don
 - ✓ Good patient compliance
 - ✗ Easy to don - *although clinicians often choose 1-2 smaller than optimum*
 - ✗ Uncontrolled oedema?

Lymphoedema Procurement Contract - 2013

Haddenham Pertex Light RAL CCL 1 garments (18-21mmHg)



mean	13.87 mmHg
lowest	12.35 mmHg
highest	16.00 mmHg

NHS Wales Procurement Contracts

- Phased process driven by clinicians
 - (1) Working groups drafting specifications – clinician led
 - (2) Supplier days to meet tendering companies and explain process
 - (3) Bench-top assessment
 - Packaging, seams, stitching, welt, donning (patients) etc...
 - (4) Laboratory testing – functionality, safety, equivalence
 - Pre-contract Testing – Ensure that devices meet our stated specification
 - (5) Clinical assessments
 - (6) Contract Award
 - Archive samples when contract starts – LOCKED DESIGN
 - Contract Monitoring – Ensure that devices do not change during the course of the contract
 - Address concerns with suppliers/MHRA at earliest opportunity.

All-Wales Lymphoedema Contract - Jan 2014

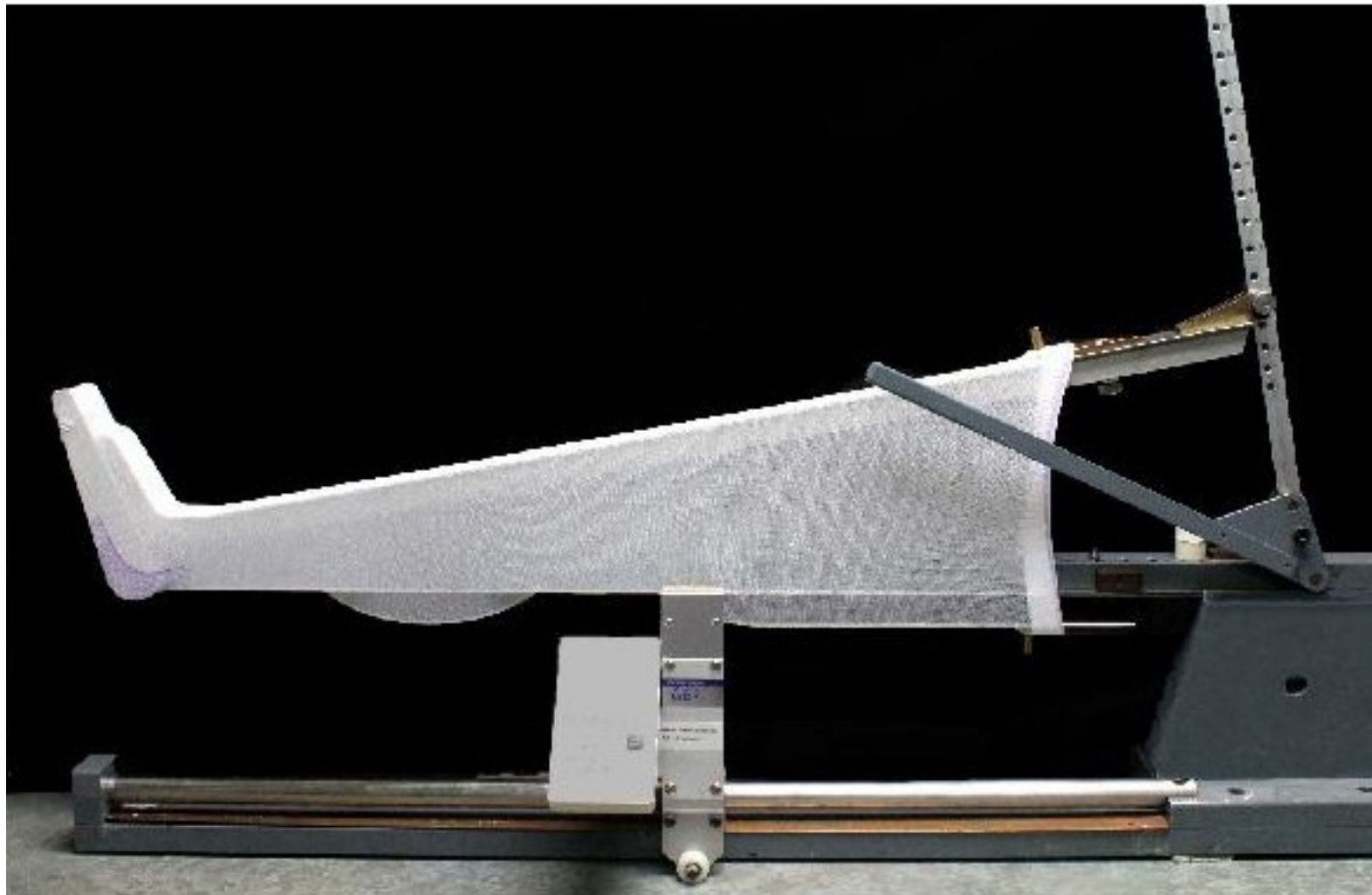
- 100's of contract lines.
- Snap shot of quality of 11 main high volume contract lines:
 - 8 lower limb garments covering:
 - Circular and flat knit
 - Below knee and thigh length
 - Off the shelf and Made to measure
 - Pressure classes 1,2 & 3
 - 3 upper limb garments covering:
 - Circular and flat knit
 - Off the shelf and Made to measure
 - Pressure classes 1 & 2
- Surrogate lymphoedema patient limb based on average patient size:
 - Patient limb sizes provided to companies
 - Companies supply product to fit the patient limb

All-Wales Lymphoedema Contract - Jan 2014

- Defined graduated pressure requirements based on RAL pressure classes:
 - Lower Limb
 - Class I – 18-21mmHg
 - Class II – 23-32mmHg
 - Class III – 34-46mmHg
 - Upper Limb
 - Circular Knit Class I – 14-21mmHg
 - Flat Knit Class I – 18-21mmHg
 - Class II – 23-32mmHg
- Failures
 - Mean compression pressures fell outside of the limits listed above (plus uncertainty of measurement of test method 13%)
 - Compression garments exhibit a negative gradient.

Lymphoedema Procurement Contract - 2014

HATRA Hosiery Tester – British Standard (*BS 6612* superseded by *BS 661210*)



Lymphoedema Procurement Contract - 2014

Results = Lower limb 78% compliance

Category	Pressure Class	Pass / Samples	Comments
Thigh, circular knit, light sheer	18 – 21	5 / 5	
	23 – 32	5 / 5	
Thigh, circular knit, firmer denser	23 – 32	3 / 3	
	34 – 46	2 / 3	1 < ankle pressure (<i>Sigvaris Traditional</i>)
Knee, flat knit	18 – 21	0 / 1	< ankle pressure (15mmHg <i>Haddenham Goldpunkt</i>)
	23 – 32	0 / 1	< ankle pressure (18.6mmHg <i>Haddenham Goldpunkt</i>)
	34 – 46	0 / 1	< ankle pressure (22.2mmHg <i>Haddenham Goldpunkt</i>)
Thigh, flat knit, M2M	23 – 32	3 / 4	1 -ve gradient <i>Haddenham Goldpunkt</i>
		18 / 23 = 78%	

Lymphoedema Procurement Contract - 2014

Results = Upper limb 50% compliance

Category	Pressure Class	Pass / Samples	Comments
Arm sleeve, circular knit	14 – 21	0 / 2	> wrist pressure (27.4 mmHg <i>Medi Harmony</i>) 1 -ve gradient (Sigvaris Advance)
	23 – 32	1 / 2	> wrist pressure (42.7 mmHg <i>Medi Harmony</i>)
Arm sleeve, flat knit , M2M	23 – 32	3 / 4	1 -ve gradient (BSN Elvarex)
		4 / 8 = 50%	

- Overall 71% compliance rate
- Requirement to re-tender for a number of contract lines

Lymphoedema Contract – Re-Tender 2014

Results = Lower limb 81% compliance

Category	Pressure Class	Pass / Samples	Comments
Thigh, circular knit, firmer denser	23 – 32	4 / 4	
	34 – 46	2 / 3	1 < ankle pressure (<i>Juzo Dynamic</i>)
Knee, flat knit	18 – 21	1 / 1	
	23 – 32	2 / 2	
	34 – 46	2 / 2	
Thigh, flat knit, M2M	23 – 32	2 / 4	1 -ve gradient (<i>Haddenham Goldpunkt</i>) 1 < ankle pressure (<i>Juzo Expert</i>)
		13 / 16 = 81%	

Lymphoedema Contract – Re-Tender 2014

Results = Upper limb 86% compliance

Category	Pressure Class	Pass / Samples	Comments
Arm sleeve, circular knit	14 – 21	2 / 3	-ve gradient - Sigvaris Advance
	23 – 32	3 / 3	
Arm sleeve, flat knit , M2M	23 – 32	1 / 1	
		6 / 7 = 86%	

- Overall 83% compliance rate
- We could tender for all of the categories tested

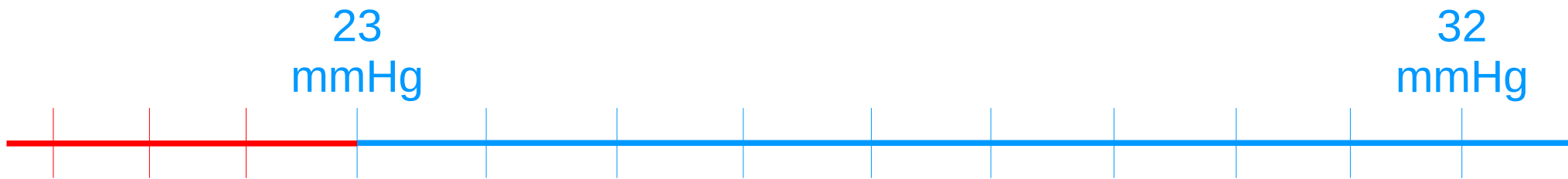
2014 Lymphoedema Contracts Summary

- i. A number of garments exert negative gradients which may cause patient harm
- ii. Only 75% of compression garments comply with pressure claims
- iii. Experienced problems with Made to Measure garments
 - i. Poorly sized
 - ii. Low pressures
- iv. Exerted pressures are usually at the lower end of the claimed pressure range.

Lymphoedema Procurement Contract - 2014

Results Lower limb Class 2

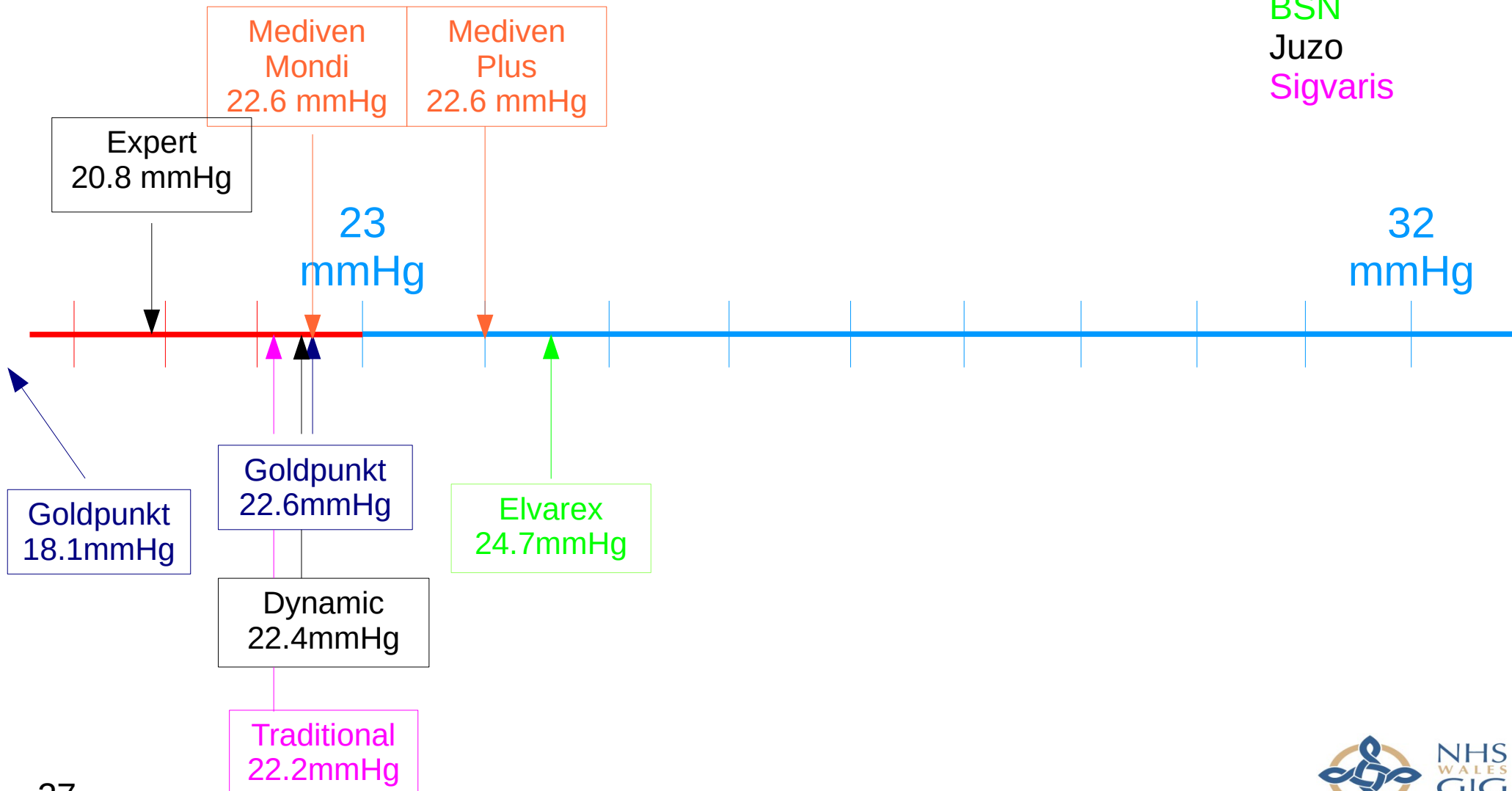
Medi UK
Haddenham
BSN
Juzo
Sigvaris



Lymphoedema Procurement Contract - 2014

Results Lower limb Class 2

Medi UK
 Haddenham
 BSN
 Juzo
 Sigvaris



All-Wales Lymphoedema Contract - 2018

- New 4 year new contract ; Similar process to 2014 contract
- SMTL testing of 10 contract lines
 - Issues identified during 2014 contract period
 - High volume contract lines
- Surrogate lymphoedema patient limb based on average patient size.
- Defined graduated pressure requirements with 20% tolerance from the mid-point of the pressure range e.g.
 - Class 1 limits = 15.6 – 23.4mmHg
 - Class 2 limits = 22.0 – 33.0mmHg
 - Class 3 limits = 32.0 – 48.0mmHg

(Takes into account uncertainty of measurement and manufacturing variability)
- Externally cross reference SMTL test results.
 - Sample sent to Hohenstein Institute for RAL compliance testing.

Lymphoedema Procurement Contract - 2018

Results = Overall 58% compliance

Lower limb

Category	Pressure Class	Pass / Samples
Circular Knit	18 – 21	7 / 9
	23 – 32	8 / 12
Flat Knit	18 – 21	0 / 1
	23 – 32	1 / 5 *
	34 – 46	1 / 1

Upper limb

Product	Pressure Class	Pass / Samples
Circular Knit	23 – 32	2 / 4
Flat Knit	23 – 32	0 / 1

Test requirements and test reports published on - www.medidex.com

Lymphoedema Procurement Contract - 2018

- * Made to measure garments submitted for 2018 contract



Lymphoedema Procurement Contract - 2018

* Made to Measure Lower Limb Below Knee Class 1 Flat Knit

Garment	Mean Ankle (mmHg)	Mean Calf (mmHg)	Pass / Fail (15.6 – 23.4 mmHg)	Comments
Sigvaris Optiform Hold	9.8	9.0	Fail	< Ankle pressures
Haddenham Goldpunkt	26.0	20.1	Fail	> Ankle pressures
BSN Jobst Elvarex	21.0	14.4	Pass	-
Mediven Mondri	13.8	9.5	Fail	< Ankle pressures

Lymphoedema Procurement Contract - 2018

Hohenstein HOSY RAL testing (2 garments tested)

Garment	RAL Compliance	Comments
* Sigvaris Optiform Hold (Class 1)	Fail	Ankle pressure failure
* Haddenham Goldpunkt (Class 1)	Fail	Ankle pressure failure
* BSN Jobst Elvarex (Class 1)	Fail	Ankle pressure failure
* Mediven Mondri (Class 1)	Fail	Ankle pressure failure
Mediven Legance (Class 1)	Fail	Ankle pressure failure
BSN Jobst Ultrasheer (Class 1)	Fail	Ankle pressure failure and B1 ratio
BSN Jobst Opaque (Class 2)	Pass	
Juzo Dynamic (Class 2)	Pass	
Mediven Harmony (Class 2)	Pass	
BSN Jobst Bella Lite (Class 2)	Fail	Wrist pressure failure
Mediven Esprit (Class 2)	Pass	

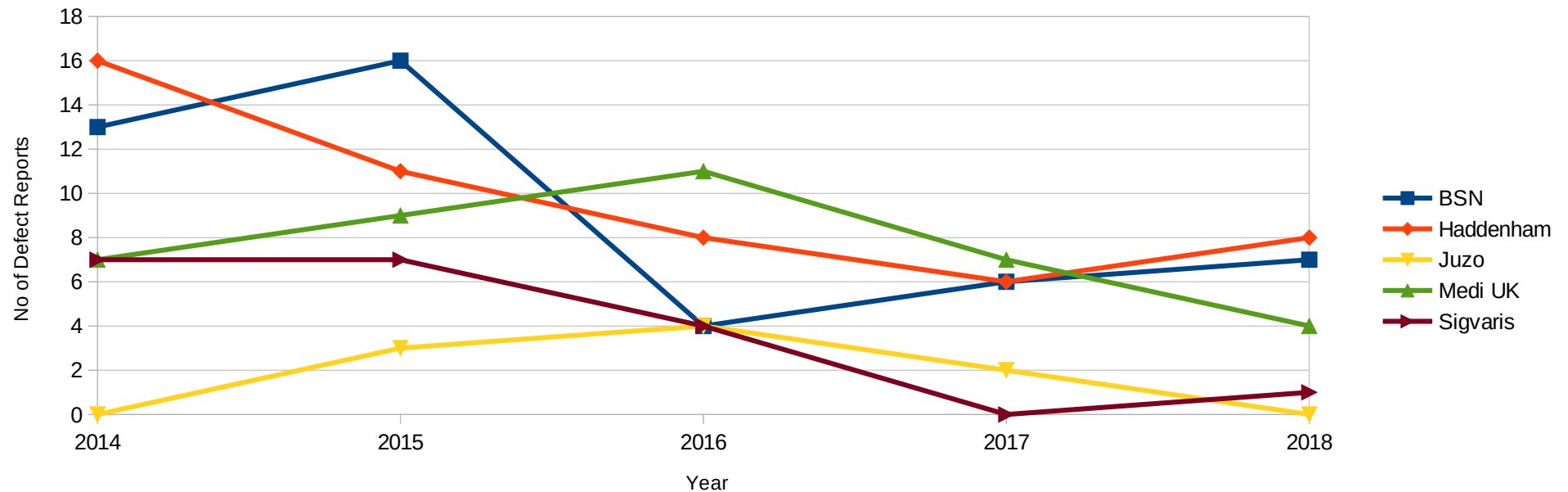
Reporting Adverse Incidents - Lymphoedema Garments

- **Independently** assess the device to confirm the adverse incident.
- Make sure that the company undertakes the appropriate corrective action if there is an issue with the medical device.
- Record and trend adverse incidents.
- Take this information through to future procurement contracts.

- 161 reported adverse incidents with lymphoedema compression garments since Jan 2013.
 - 1331 reports received over this period
 - 12% of all NHS Wales medical device incidents

Reporting Adverse Incidents - Lymphoedema Garments

Manufacturer	2014	2015	2016	2017	2018	TOTAL
BSN	13	16	4	6	7	46
Haddenham	16	11	8	6	8	49
Juzo	0	3	4	2	0	9
Medi UK	7	9	11	7	4	38
Sigvaris	7	7	4	0	1	19
TOTAL	43 (12%)	36 (16%)	31 (12%)	21 (9%)	20 (8%)	161 (12%)



Reporting Adverse Incidents - Lymphoedema Garments

- Investigations have also identified training requirements / not necessarily garment anomalies.
- Not necessarily the companies with the highest number of adverse incident reports, but rather how the problem is investigated.

GOOD EXAMPLE REPLY

“I have referred the stockings to the manufacturing facility. They have concluded their own investigation and they advise that, in this case, the tear at the grip top is a manufacturing error.”

“They acknowledge that this should not have passed their quality control checks and they have installed additional control measures to avoid these problems in the future”

“I am not clear if in this instance replacement garments have already been provided, but if such are required we would be happy to provide them free of charge”

Reporting Adverse Incidents - Lymphoedema Garments

BAD EXAMPLE REPLY

“Sadly on checking the garment, it was found to have been produced in week 3, 2014 and is therefore too old to be assessed under our 6 month guarantee period.”

“I therefore return the garment to you”

- **6 month guarantee but from what date?**
 - Date of manufacturer **not** date of donning
 - Made 2 measure and 'off the shelf' garments
 - These do not match our contract Ts & Cs

Lessons Learnt

- Clinicians in general did not objectively assess the garments they don.
 - Clinicians should trust own and patients assumptions.
 - Will question patients compliance but not the garment pressures.
- Devices on the market that exert negative gradients that have the potential to cause patient injury.
- Compliance and performance issues with some RAL accredited companies.
- Don't assume the pressures exerted on the patient are the same as claimed on packaging.
 - Pressures exerted are likely to be at the lower end of the pressure range
 - Question the companies
 - Ask for independent evidence of claims

Acknowledgements

Mel Thomas, Karen Morgan and the other lymphoedema clinicians in Wales

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