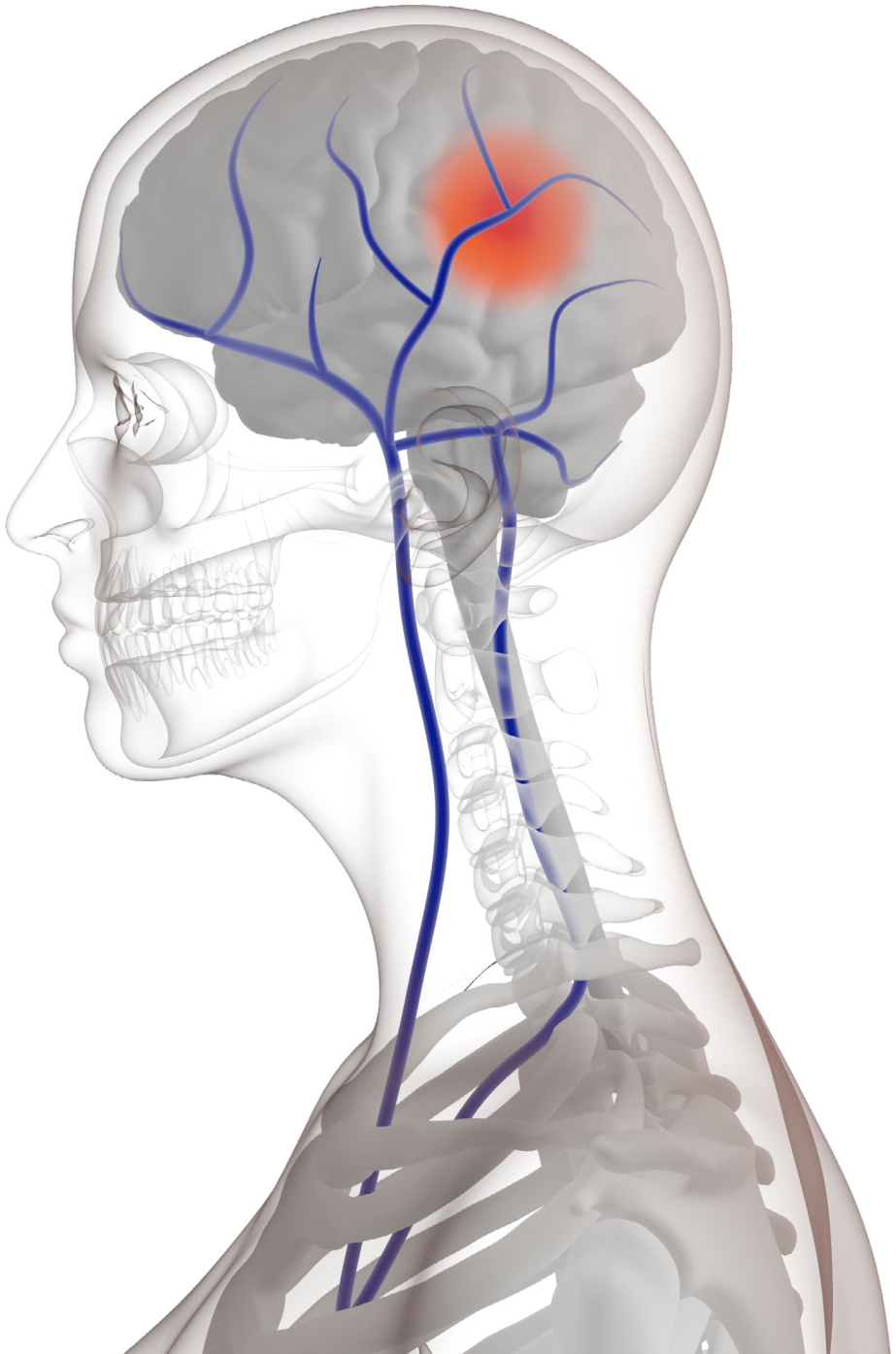
geko™
circulation support

The Royal Stoke University Hospital Impact Story

Acute Stroke Venous Thromboembolism (VTE) Prevention



Project led by:
Dr. Indira Natarajan. Consultant Stroke Physician, Clinical Director Neurosciences, The Royal Stoke University Hospital.

Impact story narrated by:
Jodie Williams. Clinical Nurse Specialist for the Stroke Prevention Team, The Royal Stoke University Hospital.

G&N

www.gekodevices.com

Background

NICE Guidance recommends intermittent pneumatic compression (IPC) as the primary VTE prophylaxis intervention, immediately post stroke, and does not recommend anti-coagulation due to bleed risk.

Case study - In summary

When we were first introduced to the geko™ device we were aligned, and still are, to UK NICE Guidance (CG92) which specifies, following risk assessment, the use of IPC with low or no use of drugs (LMWH) immediately post stroke.

The manufacturer of the geko™ device discussed with us the CLOTS3 study findings – which reports >30% non-compliance to IPC, and an 8.7% VTE risk if a patient has no VTE prophylaxis prescribed.

We were aware we had an unmet need, but were unclear on the precise level of our IPC non-compliance, and were sceptical that it might be as high as the CLOTS3 >30% findings.

We were, though, open to exploring our unmet need, to determine geko™ as an alternative anti-stasis intervention as part of the care pathway.

This led to a formal audit of clinical practice which allowed us to quantify IPC patient compliance, as part of a pilot, 1,000 patient observational study - geko™ vs IPC, measuring VTE events at 90 days post-stroke.

- The pilot study reported a 29.5% contraindication or intolerance to IPC in the patient group requiring mechanical prophylaxis. Much higher than we had anticipated and almost equal to the CLOTS3 findings.
- Key to our 29.5% unmet need finding was the close attention our team paid (a requirement of the audit) to ensuring the correct fitting of IPC and to conduct regular checks (on both devices) throughout wear time. The audit, in effect, exposed prior IPC fitting challenges.
- Importantly, these highly precise real-world findings reported a zero VTE incidence in patients prescribed the geko™ device alone, compared to a 2.4% VTE incidence in patients prescribed IPC alone.
- These collective results have since driven change to our clinical practice - and subsequently across other NHS stroke units.
- Our standard of care, which now incorporates the geko™ device, allows us to offer 100% VTE prophylaxis – providing an option to the 29.5% of patients contraindicated or intolerant to IPC, who previously would have had no other intervention available to them. Plus the certain knowledge we are now fitting IPC correctly, where previously this had proven a challenge.
- The audit has continued. The data set now stands at 2,000 patients and is being written-up for publication.

About the geko™ device

The size of a small wrist-watch, the geko™ device is a battery powered, disposable, neuromuscular electro-stimulation therapy that is applied non-invasively to the skin over the common peroneal nerve at the side of the knee. It gently stimulates the nerve, once every second, activating the calf and foot muscle pumps resulting in increased blood flow in the deep veins of the calf, at rate equal to 60% of walking without the patient having to move.

The questions Firstkind (the manufacturer) asked us at the start of the process:

Have you ever considered how many acute stroke patients are:

- Contraindicated to early administration of anticoagulants (e.g. bleed risk)?
- Contraindicated to IPC (e.g. vascular diseases)?

How do you manage VTE risk in either of these circumstances?

Probing deeper they asked:

Q1. What prophylaxis do you prescribe your patients immediately post-stroke? (What is the standard of care)?

Anti-coagulant drug	Aspirin	Compression (IPC)	Other
If drug (go to Q2/3)		If compress (go to Q4-6)	(What?)

Q2. What percentage of patients at risk of VTE (following risk assessment) are unable to be prescribed drug prophylaxis?

- Upon initial risk assessment?
- Upon updated risk assessment i.e. at 14 days or when the patient becomes mobile?
- Upon changes to circumstances?

Q3. Of those unable to be prescribed drug prophylaxis – what alternative prophylaxis are they prescribed?

Q4. If IPC – what percentage of these patients are typically contraindicated or become intolerant to IPC?

When we answered low – the CLOTS3 study was discussed (the >30% unmet need finding).

Q5. Of those unable to be prescribed IPC – what prophylaxis are these patients given?

Other (What?)	Nothing (go to Q6)	If nothing – again we discussed CLOTS3 findings (8.7% VTE risk When given no prophylaxis)

Q6. Of those able to be prescribed IPC – what is the average duration of wear time?

Here we discussed the number of patients who later become intolerant to IPC?

Q7. What is the stroke unit's VTE incidence rate (at 90 days)?

- For IPC?
- For drug?

Q8. What is the readmission rate, due to bleeding, caused by the early use of drugs?

For both Q7 & Q8, we were also asked Q9:

Q9. Do you have root cause analysis data?

All the above questions peaked our interest in the geko™ device and we were initially offered product to evaluate ease-of-fitting and patient tolerance. The observational study flowed from there.

Stakeholders engaged and obstacles overcome:

Any pilot study involving patients involves a huge amount of staff effort, time and investment, not least for the initial stages in securing buy-in from a Trust.

The close collaboration and support of key stakeholders, included governance, the pharmacy and procurement and most importantly, patients, to enable our pilot observational study to proceed.

Pre-study, we first contacted our Trust Directorate of Governance for Neurosciences to inform them of our wish to commence the pilot study and to make a solid case for pursuing it.

In a step wise approach, we then also sought the permission of the VTE Steering Group and Divisional Governance. They were each sold on the potential >30 % unmet need patient cohort; and remained on hand to approve each stage of the study, including the proposed inclusion/exclusion criteria and the process for patient recruitment, monitoring and follow-up. A main challenge, in gaining buy-in, was mostly the time delay in adding the study to the agendas of scheduled meetings.

But it was thanks to the collective effort of our stroke unit team – their hard work and passion to keep things rolling. This ensured the study proposal was properly devised; enabling Governance to grant their permission and their support for the research ongoing.

Given our team were exploring the use of geko™ as a prescribed device, we also had to inform the Royal Stoke University Hospital pharmacy in order for geko™ to be added the drug chart (DC), alongside the other standard care therapies listed for VTE prevention. This was critical to implementing the study, and was made complex in that the pharmacy were first required to exhaust the existing stock of paper DCs before ordering a reprint, with the geko™ device added. This took several months – a long delay!

It was also vital to have a database in place to enable the team to track and carefully monitor the patients selected to participate. We devised our own database in Excel. It was easy to set-up and maintain and incorporated all that we needed to collect the data.

With an initial goal to include 1,000 patients, it took approximately one year to collect data from each patient. It was methodical, detailed work.

A study of this scale meant the unit needed additional staffing support and device user training, as well as the commitment and buy-in of the entire team, who offered their time to make the pilot study a success.

Working with the manufacturer (Firstkind/Sky Medical Technology), a geko™ device user training programme was put in place to get staff familiar with fitting the device. The geko™ user training programme is RCN accredited, and extremely comprehensive. It also provides CPD points if staff can demonstrate applying what they have learnt when back on the ward.

Additional staff were also enlisted to ensure regular daily checks were carried out with each patient to ensure correct device fitting and compliance, and participant patients received regular follow-ups once they had left the unit.

Having qualified the level of our unmet need and established the geko™ device as an alternative mechanical anti-stasis intervention; and having overcome initial apprehensions regarding a potential modification to clinical practice, there was a collective motivation to embrace the new clinical practice. Incorporating the geko™ device now means all our unmet need patients can now receive VTE prophylaxis where previously no intervention was available. Introducing any change requires leadership, energy and collaboration. In our case, the close collaboration and support of key stakeholders, including Governance, the pharmacy and nursing staff and most importantly, patients, has enabled us to embrace innovation for VTE prevention. It was by no means an easy undertaking, and took considerable investment of staff time, effort and dedication.

Jodie Williams

For acute stroke patients unable to be prescribed IPC (intermittent pneumatic compression) there is a very real danger of serious, sometimes fatal, blood clotting. We therefore welcomed the opportunity to quantify the level of our unmet need and to examine the role of the innovative geko™ device as an alternative mechanical intervention. Now in routine use, our findings show the geko™ device is safe and well-tolerated and can be used to protect high-risk acute stroke patients, who otherwise would have no Venous Thromboembolism (VTE) prophylaxis available to them.

Comment from Firstkind - the manufacturer:

The benefit of the Royal Stoke Hospital patient data set is that it has influenced wider NHS stroke units to consider and then more rapidly adopt the geko™ device, without the need to conduct the same pilot observational study, which measured IPC vs. geko™ compliance and VTE incidence outcomes. They can simply choose to measure IPC compliance in order to determine the level of unmet need in their unit, and in order to then make the case for purchase within their Trust.

Luton & Dunstable University Hospital are a good example of this. They considered the same questions that were posed to the Royal Stoke Hospital (listed above) and then embarked on a much smaller clinical audit to measure and report their IPC compliance.

Dr Lakshmanan Sekaran, Consultant Stroke Physician and Clinical Director at the Luton & Dunstable University Hospital, said:

> *"When treating acute stroke patients, VTE is a very real and present threat to their recovery. The Royal Stoke real-world data, which led us to consider the geko™ device, reinforced that while current methods (IPC) are effective for most patients, a small but significant number are unable to tolerate IPC therapy, leaving them at greater risk of blood clotting."*

> *"Recognising the need to provide effective prophylaxis to this patient group, we embraced the opportunity to examine our unmet need and determine the effectiveness of the geko™ device. The device is now in routine use across our stroke unit, when IPC cannot be prescribed, and ensures that all patients can now receive post-stroke VTE prevention."*

Adoption of the device by the Luton & Dunstable University Hospital acute stroke unit aligns the team to NICE Guidance (MTG19), which supports use of the geko™ device for people who have a high risk of VTE and for whom pharmacological or other mechanical methods of VTE prevention are impractical or contraindicated.

To read the Royal Stoke and Luton & Dunstable impact stories in greater detail, simply click this link to BOB.health – sign-up takes seconds and is completely free for NHS and social care staff.

firstkind
living science

G&N

Griffiths and Nielsen Ltd
Stane Street
Slinfold
Horsham
West Sussex
RH13 0GN

T. +44 (0) 1403 799 190
W. www.gekodevices.com

MSTK0603