

CADTH Horizon Scan

ClotChip Portable Blood Clotting Sensor

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Key Messages

- Horizon Scan reports provide brief summaries of information regarding new and emerging health technologies; Health Technology Update reports typically focus on a single device or intervention. This Horizon Scan summarizes the available information regarding an emerging technology, ClotChip, for the identification of blood clotting defects.
- ClotChip is intended for use at the point of care and uses novel, low-cost technology to perform a rapid assessment of the blood's clotting ability.
- Early evidence has demonstrated the feasibility and utility of ClotChip, which could benefit patients with a variety of bleeding disorders and could potentially save time for health care professionals.

ClotChip Aims to Bring Rapid Assessment of Blood Clotting to the Point of Care

Rapid and accessible assessment of a patient's clotting ability can be critical to ensuring that effective and life-saving treatment is available – particularly for patients living with a bleeding disorder, as well as those who have experienced trauma.¹ Among the many point-of-care (PoC) health technologies that are becoming available in a variety of settings, ClotChip is a portable device designed to rapidly assess the blood's ability to clot.²

How It Works

ClotChip is a PoC device that measures the clotting characteristics of a patient's blood – often at the bedside – and can quickly identify patients who are at risk of either excessive bleeding or clotting, which can hasten life-saving treatment.¹ The ClotChip device requires a small amount of whole blood,³ which can be collected quickly and with the ease of a finger stick (which is similar to the method used for collecting blood with a glucometer).⁴

ClotChip uses dielectric spectroscopy (DS) to analyze the clotting characteristics of the blood.⁵ DS is an analytical method that is used in a variety of contexts, and relies on electrical frequencies to identify the composition, structure, and behaviour of nanomaterials.⁶ When assessing the clotting properties of blood, DS is more specifically known as dielectric coagulometry, and is unique in its ability to characterize both the clotting time and platelet function of the blood.⁵ This measurement of both thrombin formation and platelet activation in a portable, PoC-enabled device is a feature of the ClotChip technology.³ The developers of ClotChip also highlight that the device is designed to assess the clotting properties of the blood as opposed to identifying the cause of a clotting defect, and that no reagents are required to operate the technology, setting it apart from some other coagulation sensors.^{3,4,7}

Who Might Benefit?

Recent estimates indicate that there are approximately 300,000 people in Canada with a bleeding disorder (which can cause excessive bleeding).⁸ In addition, incidents of trauma and deaths from clotting defects number in the thousands each year in Canada,^{9,10} representing a large number of people who might benefit from more accessible and/or timely testing for blood clotting.

The portability of ClotChip and its availability at the PoC reduces the time associated with producing a test result by eliminating the need to send samples to a laboratory and ensuring that health care decisions can be made quickly.^{11,12} In addition to the reduced turnaround time for a test result, the very small amount of blood required from a patient is also suggested to be a beneficial feature of the device – particularly in emergency and neonatal care settings.¹³ Furthermore, the technology is described as requiring no special expertise or training to operate the device, making it usable by patients, caregivers, and clinicians alike.⁷

The benefits of ClotChip for assessing and/or monitoring the blood's ability to clot may extend to patients in acute and/or trauma care settings,^{5,14} and cardiac surgical settings,¹⁵ as well as those with established clotting disorders.^{12,13} In addition, patients who are receiving anticoagulant therapy – such as direct oral anticoagulants (DOACs) – may also benefit from the availability of a PoC device such as ClotChip (i.e., in acute care and emergency surgery settings), as a rapid and accurate assessment of the effects of DOAC therapy on the blood's ability to clot can support safe and effective treatment decisions.¹⁶

Availability in Canada

Health Canada currently lists no information regarding the availability or use of ClotChip in a Canadian context (including any trials or studies).¹⁷

The technology was designated by the FDA in the US as a breakthrough device in early 2020,¹ and remains under investigation in clinical trials while awaiting FDA clearance.⁷ The commercial launch of ClotChip has been projected for late 2022.⁷

What Does It Cost?

While no detailed cost information was identified for the ClotChip device, it has been described as low-cost in several published sources.^{3,5,18} Two of these sources indicate that the disposable chip used in the technology comes at a material cost of less than \$1 per unit (though the currency used in this description is not specified).^{3,18}

In addition to the cost of the device, as well as its use and maintenance over time, health care organizations and facilities that consider investing in a device like ClotChip should weigh its potential impact on current systems in place for coagulation testing, including care protocols, implications for health care workers (e.g., training), quality control, robust documentation, and data security.¹¹ While no information specific to the cost of implementing the ClotChip

was identified, it is described as easy to use, requiring no special training. This feature of the device could make implementation costs for health care facilities lower than would be necessary if in-depth staff training were necessary. In addition, resources and costs may be freed up for hospital-based and other laboratory services.

Current Practice

Current tests for monitoring blood clotting can be time-consuming or may not be readily available,¹⁹ with test turnaround times potentially taking hours,²⁰ as compared to minutes for a PoC test. Conventional blood clotting tests are usually available in hospital only, and require the services of a central laboratory for processing, making rapid identification of clotting defects in non-hospital settings (e.g., community health care or field settings) difficult to access.⁵ The time delay associated with these conventional methods can be a barrier to identifying patients who may require immediate treatment for uncontrolled bleeding or excessive clotting.⁵

What Is the Evidence?

Evidence for ClotChip remains early in its development, mostly limited to pilot and feasibility studies with small sample sizes, ranging from 12 to 104 study participants.^{3,16,21-23} Earliest investigations of the technology relied on ex vivo assessments,³ with later studies using controlled methods and whole blood from study participants.⁵

Evidence to date has demonstrated the feasibility of ClotChip in the assessment of coagulation and clinical risk of bleeding, as well as monitoring of coagulation factor replacement therapy, for patients with hemophilia (both with and without inhibitors, as well as for those receiving emicizumab).^{18,19,21,22} Additional investigations have demonstrated the feasibility of ClotChip for identifying coagulation defects across a variety of clotting disorders, such as hemophilia and von Willebrand disease.^{3,23,24} Further investigation has focused on the utility of ClotChip for monitoring DOAC therapy, demonstrating its sensitivity to detect the anticoagulant effects of these drugs.¹⁶ While the accuracy of the ClotChip device has been compared against conventional technologies (including rotational thromboelastometry and thrombin generation assays) and produced comparable results,^{19,21,22} no evidence was found that compared ClotChip to another PoC device.

Since then, additional work has been initiated to assess the utility of ClotChip for patients with traumatic injuries¹⁴ as a presurgical screening tool, and for patients who may be at risk from COVID-19 clotting defects.⁷ The ability to rapidly detect clotting abnormalities has become increasingly important in recent years due to COVID-related complications that affect coagulation.^{2,25}

Safety

While no data detailing the safety of ClotChip were identified, some sources describe relevant considerations for patient safety when using PoC coagulation tests.^{11,26} The small amount of blood required may benefit patient safety by reducing the risk of biohazardous contamination and/or the potential for mishandling of samples that may be associated with transportation from the point of collection to the site of analysis.¹¹

One concern raised regarding PoC sensors is the potential for inconsistent or compromised documentation (i.e., whereas samples analyzed in a laboratory are generally entered systematically into institutional health care records, results from a PoC device may require manual data entry, which can introduce the risk of error).¹¹ Of note, ClotChip devices can be Wi-Fi and Bluetooth enabled,¹ which are useful features that may support integration within existing health care facility documentation systems, and could help minimize the potential for documentation errors or oversights.

Related Developments

Other PoC devices have also been developed to assess blood clotting using a variety of technologies, including electrical transduction,²⁷ impedance platelet aggregometry,²⁸ surface acoustic wave,²⁹ and aptamer-based technologies.³⁰

Some limitations of other PoC devices, as described by ClotChip developers, include variable accuracy in their assessments of coagulation and limitations in their characterization of platelet function.^{3,5} Some of these other PoC devices are specifically designed for assessing patients who are taking warfarin anticoagulant treatment; so, may not be useful to a broader population at risk for uncontrolled bleeding.⁵

The developers of ClotChip are also working toward expanded uses of the technology, including a similar device under development called TraumaChek.^{31,32} TraumaChek is described as a next-generation technology designed specifically for the assessment of coagulopathy in trauma settings.^{31,32} Proposed applications of this emerging technology have been described as including military field operations, as well as rural and remote health care settings, where the rapid detection of uncontrolled bleeding from trauma is essential for supporting the ability of health care providers to save lives.³¹⁻³³ Of note, the developers of TraumaChek are partnering with other experts in the treatment of trauma-induced hemorrhaging to develop innovative approaches for rapidly detecting and treating uncontrolled bleeding at the PoC.³¹

Looking Ahead

Additional investigation has been proposed to examine the potential utility of ClotChip for the individualized care of people living with hemophilia A, such as the development of tailored prophylactic factor replacement therapies.²² In addition, ClotChip has been proposed and investigated as an intervention for measuring hypercoagulation in patients with conditions

such as deep vein thrombosis, or infectious diseases that can cause dangerous clotting defects, such as sepsis and COVID-19.^{23,34} These and related developments in PoC technology have the potential to improve care and care pathways for patients with bleeding disorders, and could introduce efficiencies and resource savings for health care facilities and systems.

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