Stance-Control Knee–Ankle–Foot Orthoses for People With Knee Instability: Recommendation

Final Recommendation

- Ontario Health, based on guidance from the Ontario Health Technology Advisory Committee, recommends publicly funding mechanical stance-control knee–ankle–foot orthoses for people with knee instability

Rationale for the Recommendation

The Ontario Health Technology Advisory Committee has reviewed the findings of the health technology assessment[1] and agreed there is uncertainty about whether stance-control knee-ankle-foot orthoses (SCKAFOs) improve walking ability, energy consumption, or activities of daily living compared with locked knee–ankle–foot orthoses (locked KAFOs), the devices currently publicly funded in Ontario. However, in making their recommendation, the committee acknowledged that SCKAFOs represent an additional device option to a locked KAFO and not a replacement for it, and that higher quality evidence for SCKAFOs is unlikely to be published. The committee also recognized that unlike a locked KAFO, SCKAFO devices offer the ability to retain a more typical gait, which may be helpful to some people with knee instability, depending on their condition. In considering the different types of SCKAFO devices, the committee reflected upon the results of the budget impact analysis for the mechanical, electronic, and microprocessor SCKAFO devices. The committee acknowledged that the estimated budget impact for the mechanical SCKAFO devices was lower compared with the electronic and microprocessor SCKAFOs and, therefore, is the preferred choice to publicly fund. The committee acknowledged that choosing the mechanical SCKAFO devices for public funding aligned with the types of SCKAFOs funded in other national and international jurisdictions.

The committee considered the lived experience of people using a locked KAFO who expressed that they valued a device that provided a more typical gait. Patients also expressed that switching from a locked KAFO device to a SCKAFO device was difficult once they had invested the training time to use the locked KAFO. Because of this, there was preference for SCKAFO devices to be publicly funded so that they could be an option when trialing a mobility device early in the course of care.

Public Comment: May 7 to 28, 2021

Decision Determinants for Stance-Control Knee–Ankle–Foot Orthoses for People With Knee Instability

Decision Criteria	Subcriteria	Decision Determinants Considerations
Overall clinical benefit How likely is the health technology/intervention to result in high, moderate, or low overall benefit?	**Effectiveness** How effective is the health technology/intervention likely to be (taking into account any variability)?	We are uncertain if SCKAFOs improve walking ability, energy consumption, or activities of daily living (GRADE: Very low) compared with LKAFOs.
	Safety How safe is the health technology/intervention likely to be?	One narrative summary of data stated that "some participants felt SCKAFOs were helpful in safeguarding against falls and providing stability." However, through patient engagement, people had a greater concern for falls when learning to use SCKAFO if they were already familiar with LKAFO.
	Burden of illness What is the likely size of the burden of illness pertaining to this health technology/ intervention?	In Canada, the crude prevalence in 2010/11 of motor neuron disease for persons aged 0–17, 18–64, and ≤ 65 was 0.029, 0.052, and 0.254 per 1,000 persons, respectively. In the same time period, approximately 319,000 people were suffering from the effects of stroke and 118,000 people were living with spinal cord injury.
	Need How large is the need for this health technology/intervention?	The Ministry of Health approved 429 publicly funded locked KAFOs in 2018/19. It is difficult to provide precise estimates on the population size of people in Ontario with knee instability who would benefit from a SCKAFO because knee instability is associated with many health conditions and causes.

Decision Criteria	Subcriteria	Decision Determinants Considerations
Patient preferences and values How likely is adoption of the health technology/ intervention to be congruent with patient preferences and values and with ethical or legal standards?	**Patient preferences and values** Do patients have specific preferences, values, or needs related to the health condition, health technology/intervention, or life impact that are relevant to this assessment? (Note: The preferences and values of family members and informal caregivers are to be considered as appropriate.)	Patients expressed preference for a mobility device that provided a typical gate, stability, and comfort. While many adapted to the locked KAFO, they would have preferred a device that provided a more typical gait if they were able to start with such a device. But switching from a locked KAFO to a SCKAFO may be difficult.
	Autonomy, privacy, confidentiality, and/or other relevant ethical principles as applicable Are there concerns regarding accepted ethical or legal standards related to patient autonomy, privacy, confidentiality, or other ethical principles that are relevant to this assessment? (Note: The preferences and values of the public are to be considered as appropriate.)	There are no concerns regarding autonomy, privacy, confidentiality, or other relevant ethical principle. When deciding on a particular orthosis, the decision-making considers the patient's preferences, physical assessment, and financial means.
Equity and patient care How could the health technology/ intervention affect equity of access and coordination of patient care?	**Equity of access or outcomes** Are there disadvantaged populations or populations in need whose access to care or health outcomes might be improved or worsened that are relevant to this assessment?	Access to either a locked KAFO or SCKAFO may be impacted by access to a referring primary care provider/ specialist, access to orthotist and physiotherapist, ability to maintain the device, or support to take the device on and off, either independently or with the help of a caregiver (depending on the level of impairment of the patient).
	Patient care Are there challenges in the coordination of care for patients or other system-level aspects of patient care (e.g., timeliness of care, care setting) that might be improved or worsened that are relevant to this assessment?	Many appointments are necessary to assess a patient's function and ensure proper fit of the device. Training, including physiotherapy, is also needed for a patient to be successful. If a patient lives in a rural location, barriers can include the cost transportation (possibly including specialized transport), travel time, and loss of work time for themselves and/or a caregiver.

Decision Criteria	Subcriteria	Decision Determinants Considerations
Cost-effectiveness How efficient is the health technology/ intervention likely to be?	**Economic evaluation** How efficient is the health technology/intervention likely to be?	We did not identify any published cost-effectiveness analyses that were directly applicable to our research question. Further, we did not conduct a primary economic evaluation because of limited and very low quality comparative clinical evidence that could be used to inform a cost-effectiveness or cost–utility analysis. Therefore, the cost-effectiveness of SCKAFO in Ontario is unknown.
Feasibility of adoption into health system How feasible is it to adopt the health technology/ intervention into the Ontario health care system?	**Economic feasibility** How economically feasible is the health technology/intervention?	The cost of a mechanical SCKAFO is approximately $10,784 (compared with the costs of electronic and microprocessor SCKAFOs of about $25,728 and $99,296, respectively). Costs related to locked KAFOs may decrease over time as the uptake for SCKAFO increases. We estimated that the annual budget impact of publicly funding a mechanical SCKAFO in Ontario over the next 5 years will range from an additional $ 0.50 million in year 1 (30% uptake) to $0.83 in year 5 (50% uptake) based on an assumption of 429 orthotic devices approved per year. The total budget impact is $3.34 million over 5 years.
	Organizational feasibility How organizationally feasible is it to implement the health technology/intervention?	Implementation of SCKAFO devices may be feasible. While SCKAFO is more expensive than a locked KAFO, the estimated volume is small based on the annual publicly funded volume of the locked KAFOs (429 in 2018/19).

Abbreviations: KAFO, knee–ankle–foot orthosis; LKAFO, locked KAFO; SCKAFO, stance-control KAFO.

Reference

(1) Ontario Health. Stance-control knee–ankle–foot orthoses for people with knee instability: a health technology assessment. Ont Health Technol Assess Ser [Internet]. 2021 Aug;21(11):1–96. Available from: https://www.hqontario.ca/evidence-to-improve-care/health-technology-assessment/reviews-and-recommendations/stance-control-knee-ankle-foot-orthoses-for-people-with-knee-instability

Disclaimer

About Ontario Health

About the Ontario Health Technology Advisory Committee

How to Obtain Recommendation Reports

Ontario Health
130 Bloor Street West, 10th Floor
Toronto, Ontario
M5S 1N5
Tel: 416-323-6868
Toll Free: 1-866-623-6868
Fax: 416-323-9261
Email: oh-hqo_hta@ontariohealth.ca
www.hqontario.ca

ISBN 978-1-4868-5430-1 (PDF)

Citation

Ontario Health. Stance-control knee–ankle–foot orthoses for people with knee instability: recommendation [Internet]. Toronto (ON): Queen's Printer for Ontario; 2021 August. 5 pp. Available from: https://www.hqontario.ca/evidence-to-improve-care/health-technology-assessment/reviews-and-recommendations/stance-control-knee-ankle-foot-orthoses-for-people-with-knee-instability