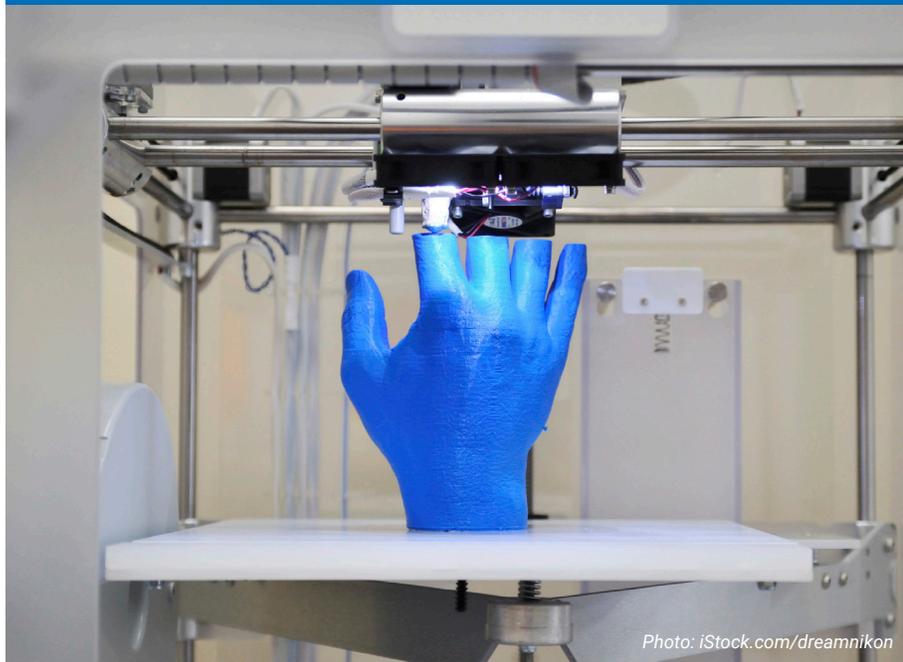


Health Technology Update

CADTH

A newsletter on new and emerging health care technologies in Canada

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Informing Decision-Makers About Emerging Medical Device Technologies

This issue of *Health Technology Update* features brief summaries of the evidence on a broad range of medical device technologies – from mobile health apps to exoskeletons. These technologies were identified through CADTH's Horizon Scanning service as topics likely to be of interest to health care decision-makers in Canada.

We hope you find this newsletter interesting and informative. Your comments and suggestions of topics for future issues are always welcome.

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FEEDBACK

Have you heard of a new health technology you think will have an impact on health care in Canada?

Please let us know!

Email: HorizonScanning@cadth.ca.

About This Document: *Health Technology Update* is a source of information for those involved in planning and providing health care in Canada. The information contained in this newsletter is based on a limited literature review and should not be construed as a recommendation for or against the use of a particular health technology. Readers should also be aware that a lack of good quality evidence to support effectiveness does not necessarily mean a lack of effectiveness, particularly in the case of new and emerging technologies.

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New Devices to Prevent Positional Obstructive Sleep Apnea

Obstructive sleep apnea (OSA) is a respiratory disorder that occurs when a person's breathing stops (apnea) or is restricted (hypopnea) periodically while they sleep.¹ People with untreated OSA, particularly severe OSA, often feel excessively sleepy during the day and are at increased risk for conditions such as cardiovascular disease, depression, and diabetes.¹ They are also at a higher risk for motor vehicle collisions and workplace accidents because of daytime sleepiness.¹

Many patients with OSA stop breathing more frequently when sleeping on their backs. This is known as positional OSA.² New devices that use small sensors and vibrations to discourage back-sleeping are now available.³⁻⁵ These devices may be a treatment option for positional OSA patients who cannot or do not wish to use standard treatments such as continuous positive airway pressure (CPAP).

HOW IT WORKS

In Canada, positional therapy is a recommended treatment option for positional OSA.⁶ Positional therapy often uses simple devices, such as a tennis ball or a foam wedge placed between the shoulder blades, to prevent a person from moving onto the back while sleeping.² However, these devices are often uncomfortable — which affects long-term use.² New, smaller devices that use small sensors to detect sleeping positions and vibrate to discourage back-sleeping are now available.

WHO MIGHT BENEFIT?

More than 3% of Canadian adults (850,000 people) reported being diagnosed with OSA, and an additional 26% reported symptoms associated with a high risk of having OSA.¹ The prevalence of OSA is higher in adults over the age of 45 (5%), and it affects nearly twice as many men as woman.¹ More than half of all individuals with OSA may have positional OSA.²

AVAILABILITY IN CANADA

Several new positional therapy devices are currently available. One device, the Night Shift⁷ (Advanced Brain Monitoring, Inc., Carlsbad, California, US) is licensed by Health Canada as a Class II medical device and is also available in the US.⁸

Other, similar devices include:

- BuzzPOD⁹ (Gorman ProMed Pty Ltd., Victoria, Australia), available through mail order (Michael Gorman, Gorman ProMed Pty Ltd., Victoria, Australia: personal communication, 2015 Nov 25) but not licensed for sale in Canada.
- The Sleep Position Trainer (SPT)¹⁰ (NightBalance BV, Delft, The Netherlands), available in Europe with plans for Canadian distribution (Arjan van der Star, NightBalance BV, Delft, The Netherlands: personal communication, 2016 Mar 8).

WHAT DOES IT COST?

Positional therapy may be a less expensive option for treating positional OSA than CPAP (average cost US\$850¹¹) or other methods.¹² For example, the Night Shift sells for US\$349¹³ and the SPT is available for €600 to €700 (US\$680 to \$790) (Arjan van der Star: personal communication, 2016 Mar 8).

CURRENT AND ALTERNATIVE PRACTICES

The apnea/hypopnea index (AHI), which reflects the total number of apnea and hypopnea events per hour of sleep, is commonly used to describe OSA severity:



Photo: iStock.com/chameleonseye

- **Mild** — OSA has an AHI of 5 to 15 events per hour
- **Moderate** — OSA has an AHI of 15 to 30 events per hour
- **Severe** — OSA has an AHI of more than 30 events per hour.⁶

The treatment goal for OSA is to reduce the AHI and alleviate other symptoms.⁶ In Canada, CPAP — a flow of pressurized air to prevent the airway from closing¹ — is the primary treatment for patients with OSA.⁶ Other treatments may be considered depending on the type and severity of OSA and patient preference, and the response to CPAP.⁶ These include weight loss, oral appliances (devices that change the position of the jaw to keep the airway open¹) and upper airway surgery.⁶

Many patients, particularly those with mild symptoms, do not use their CPAP devices enough to benefit from treatment.¹⁴ Side effects such as dry mouth and skin irritation contribute to low use, and only 39% of patients continue to use CPAP at 12 months.¹⁴ Compliance is also an issue with other OSA treatments, including positional therapy.²

WHAT IS THE EVIDENCE?

Individuals with positional OSA are usually described as those having an AHI at least twice as high when sleeping on their backs than when sleeping on their sides.¹⁵ However, this is not a consensus definition, making comparisons across studies difficult.^{2,15}

Positional Therapy Compared with CPAP

A 2014 meta-analysis compared the efficacy of positional therapy with CPAP, based on the results of three small randomized crossover trials.¹⁶ The review found that CPAP was superior to positional therapy for reducing the AHI in patients with positional OSA.¹⁶ However, the difference in AHI between CPAP and positional therapy was less in patients with mild positional OSA than in those with more severe positional OSA.¹⁶

The Sleep Position Trainer

The SPT is a small device held in place on the chest by a strap and pouch.⁵ Sensors inside detect the sleeping position.⁵ When back-sleeping occurs, the device vibrates with increasing intensity and a variable pattern until the patient changes position.⁵

A 2015 randomized controlled trial comparing the SPT with tennis ball positional therapy in 55 patients found the device to be as effective as tennis ball positional therapy for reducing the AHI and improving patient-reported symptoms of sleepiness in patients over one month.¹⁷ Other small studies found that the SPT reduces the time spent sleeping on the back, daytime sleepiness, and AHI.^{5,18}

Night Shift

The Night Shift is a small device placed on the back of the neck and attached by straps using a magnetic clasp.⁴ The Night Shift detects sleeping positions and provides a gradually increasing vibration to discourage back-sleeping.⁴

A 2014 prospective study of 31 patients found that the Night Shift reduced the AHI in 73% of patients after one month of treatment.⁴ No reduction in daytime sleepiness was found.⁴

BuzzPOD

The BuzzPOD is a small device that attaches to the chest with a strap and uses sensors and vibrations to detect and discourage back-sleeping.³

A 2011 randomized crossover study of 15 patients found that the BuzzPOD reduced AHI by 45% over the course of a week.³ Daytime sleepiness was not assessed.³

TREATMENT COMPLIANCE

Long-term compliance affects the success of positional therapy.^{2,19} Compliance with tennis ball positional therapy is reported to be good in the first weeks of use but drops to 35% after 13 months.¹⁹ Sensors in new positional therapy devices can objectively track device use.³⁻⁵

The longest study of new positional therapy devices found the SPT was used by almost 65% of 106 patients after six months.²⁰ Month-long compliance for the Night Shift was found to be 96%.⁴

Whereas the evidence suggests that new positional therapy devices may be effective at reducing the AHI, it is unclear whether or not patient-reported outcomes — such as daytime sleepiness — are improved.

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Keeogo: A Powered Assistive Walking Device

Originally developed for military purposes from the field of human augmentation, Keeogo is a new assistive device that has been adapted for home and community use.² Whereas the military purpose was to improve a soldier's endurance, Keeogo may also improve the mobility of individuals who have difficulty walking.

HOW IT WORKS

Keeogo (B-TEMIA Inc., Quebec City) is a motorized, assistive walking orthosis — a robotic, external brace, sometimes called an exoskeleton. It resembles a pair of leg braces that extend from just above the hips to below the knees. The device reinforces the knee to make standing, walking, and climbing stairs easier. Sensors at the hip and knee detect the user's intended movement, and settings are adjusted to complement the individual's body strength.³

The Keeogo is intended for people who can walk, but who have lower limb muscle weakness because of conditions such as osteoarthritis, multiple sclerosis (MS), Parkinson disease, stroke, and partial spinal cord injury.³ (It is not intended for individuals with spinal cord injuries causing complete paralysis.)³

“This is rapidly emerging technology, and it has the potential to become the next big disruptive technology...”

— Dr. Chris McGibbon, University of New Brunswick, Centre for Research in Dermoskeletics¹

AVAILABILITY IN CANADA

Keeogo is available for sale or rental in Canada.³ Health Canada considers it a Class I medical device, meaning that the manufacturer only needs a Medical Device Establishment License — which B-TEMIA has received — to market the device.⁴

The Keeogo website lists four Canadian distributors for the device: two in Quebec and two in Ontario.³ As of March 2016, more than 20 units were in use by individuals and rehabilitation clinics in Ontario, Quebec, and New Brunswick (personal communication: Paule De Blois, B-TEMIA, Quebec City; 11 Apr 2016).

B-TEMIA plans to apply for 510(k) US FDA clearance soon.⁵

WHAT DOES IT COST?

Keeogo costs C\$40,000 to purchase or C\$1,000 per month to rent (personal communication: Paule De Blois, B-TEMIA, Quebec City; 4 Apr 2016).

WHAT IS THE EVIDENCE?

The manufacturer notes that, “The benefits of Keeogo are currently under investigation and have not yet been clinically proven.”³

A conference presentation of a pilot study of three patients with MS found two participants had an improved gait and one participant was able to walk 57 metres further while using a prototype Keeogo device.⁶ Participants reported they would use the technology for daily activities such as grocery shopping, and would have liked to test the device at home.⁶

A multi-centre trial to assess the clinical effectiveness and safety of Keeogo for home use — rather than for rehabilitation — is currently underway, under the direction of the University of New Brunswick, Centre for Research in Dermoskeletics.⁵



The Keeogo. Reproduced with permission from B-TEMIA.

SAFETY

Patients with spinal cord injuries reported safety and costs as their key concerns with using exoskeleton devices.^{7,8}

Published information on adverse events or safety outcomes in people who have used the Keeogo is currently unavailable. This lack of published information does not mean that there are not any potential safety concerns, only that knowledge regarding safety is lacking. Information from the University of New Brunswick trial will provide a better understanding of the safety of the device.⁵

Fitting, training, and usability

The Keeogo must be fitted and programmed for each individual and requires training to use. Patients attend an initial 90-minute fitting by a specialist, followed by two weekly appointments and monthly or as-needed follow-up thereafter (personal communication: Paule De Blois, B-TEMIA, Quebec City; 11 Apr 2016).

Equitable access

The cost of exoskeleton devices has been identified as a barrier to use by patients and may lead to inequitable access to the technology.^{8,9}

Assessing exoskeleton technologies

Ways to assess and compare these devices will be important as more exoskeleton-type devices become available. Researchers at the Icahn School of Medicine at Mount Sinai have proposed a Framework of Usability for

Robotic Exoskeletal Orthoses (FUREO) for the assessment of exoskeletons.¹⁰ This framework incorporates the perspectives of all stakeholders, including patients, clinicians, caregivers, and policy-makers.¹⁰ The six main “modules” – and accompanying metrics and measurements – of FUREO are:

- **Functional applications** (e.g., exercise, or at-home or community mobility)
- **Personal factors** (e.g., body weight, height, device fit, type of injury)
- **Device factors** (e.g., device weight, battery life, noise, and customizability)
- **External factors** (e.g., regulatory approval, cost, and insurance coverage)
- **Activities** (e.g., training or assistance needed, time and effort needed to put the exoskeleton on and take it off)
- **Health outcomes** (e.g., cardiovascular fitness, sleep, pain relief, bowel function, bone density, or psychological benefits; and potential risks – e.g., for falls.)¹⁰

RELATED DEVELOPMENTS

Other assistive walking devices intended for individuals with lower limb weakness include the Stride Management Assist (Honda),¹¹ the Axo-Suit (Aalborg University),¹² the Kickstart (Cadence Biomedical),¹³ and the Levitation knee brace (Spring Loaded Technology).¹⁴ The Kickstart and Levitation devices are passive or unpowered; rather than a battery, they rely on mechanics and power from the user’s muscles.¹⁵

Several exoskeleton systems are also available for rehabilitation or for personal use by individuals following a stroke or spinal cord injury.^{7,16} These include the ReWalk (ReWalk Robotics), REX (Rex Bionics), Ekso (Ekso Bionics), and the Indego (Parker Hannifin).^{17,18}

LOOKING AHEAD

In addition to improved mobility, exoskeletons may prove to be useful in falls prevention for the elderly.¹⁹

Exoskeleton use is likely to expand for patients with many different conditions that affect mobility. A 2015 report forecasts that the market for these devices (including both health and military uses) will expand by more than 72% from 2014 to 2019.⁹

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Is Mobile Health Transforming Health Care?

Mobile health applications (apps) and the mobile devices they run on – collectively referred to as “mHealth” – are used to encourage healthy behaviours and deliver health care interventions.¹ In the past, people mainly relied on doctors for health advice, but today at least 70% of Canadians with home Internet use mHealth to find health and medical information on their own.² The public’s desire to control their own health outcomes, coupled with lessening concerns about personal privacy,² are helping to drive the popularity of mHealth.¹ But will it transform health care?



Photo: iStock.com/Lesia_G

HOW IT WORKS

It is predicted that, by 2018, half of the more than 3.4 billion mobile phone and tablet users will have downloaded mHealth apps to their devices.³ Of the nearly three billion apps downloaded from the Apple app store in December 2013, the most popular were for weight loss and exercise.⁴ From smoking cessation to blood glucose tracking, there are apps for a wide range of health goals and conditions.

Expanding Reach

Because mHealth can relay data between a central point and a remote location, it can be used to engage, inform, and monitor patients. Therefore, it has the potential to improve health care accessibility and equity⁵ by bringing health services to populations that are typically hard to reach – such as those living in rural and remote areas, elderly people, and the mobility-impaired.⁴

Providing Innovative Health Solutions

Health care systems and providers are using mHealth in various ways. The Australian government’s My Child’s eHealth Record app allows parents to keep track of their children’s immunizations and other health information on their mobile phones.⁴ In Canada, patients with dementia who are prone to wandering can be tracked by their caregivers via a Global Positioning System, or GPS, embedded in the patients’ shoes.⁵

Targeting Disease Reduction Strategies

mHealth can be used for targeted interventions related to disease prevention.² A joint initiative by the World Health Organization and the International Telecommunications Union – Be He@lthy, Be Mobile – is using mobile phones to deliver disease prevention messaging to the public to improve the health outcomes of the participating, mostly less-developed, countries.⁶

HOW IS mHEALTH REGULATED?

The effectiveness of mHealth apps can be compromised by the quality of the evidence they are based on. Health care systems play a role in safeguarding the public against apps that can do more harm than good.¹ In Canada, mHealth apps considered to be in a higher-risk category – for example, those for diagnosing or

treating a medical condition – must be licensed by Health Canada before they can be marketed.⁷ Similarly, the US FDA regulates mHealth apps that could carry a high risk to users if they fail to work as intended.³ Regulatory systems in developed countries such as these can serve as models for less-developed countries where, despite the rapidly increasing use of mHealth, regulation is lacking.

WHAT ARE THE LIMITATIONS?

Some people are reluctant to adopt mHealth, preferring in-person contact with a health professional; and the cost of the devices is still a barrier for some.¹ Because 60% of Canadians older than 15 years of age lack an adequate level of health literacy² – the ability to understand health information, apply it, and make good health decisions – even mHealth adopters

UK Review on Mobile Health Interventions that Promote Behavioural Change

A 2015 report from the UK Horizon Scanning Research & Intelligence Centre (HSRIC) reviews the health, societal, and technological drivers of mHealth.¹ The report discusses the potential applications of mHealth across many areas of health care, and highlights yet-to-be-resolved issues – including who will be responsible for regulation and quality assurance of mHealth applications. Over 90 mHealth technologies are described, including wearables, non-wearables, training, and platform-based interventions.

The report, *New and emerging mobile health interventions that promote behavioural change*, is available from the HSRIC website hsric.nihr.ac.uk.



will not necessarily benefit from it.¹ To address some of these barriers, health care providers may need to play an enhanced role, helping patients use mHealth apps and selecting apps based on patient aptitude.¹ A framework for assessing the quality of mHealth apps being developed by the National Institute of Health and Clinical Excellence (NICE) in the UK may soon offer some guidance in this area.⁸

IS mHEALTH HERE TO STAY?

There is not yet enough evidence to know if mHealth is truly having a positive impact on health; however, hundreds of efficacy studies are currently being conducted worldwide.⁶ In the meantime, the potential of mHealth to make health care delivery more efficient and equitable suggests it will be with us for some time. And if it is shown to improve health outcomes, it will likely transform health care.

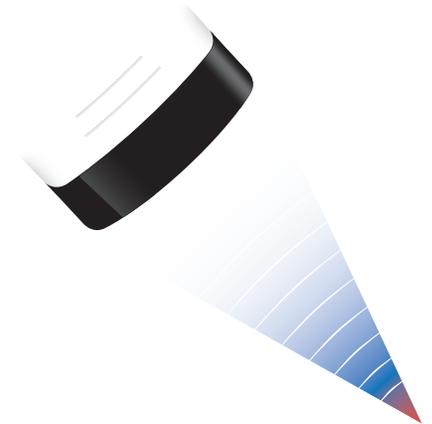
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High-Intensity Focused Ultrasound (HIFU) for the Treatment of Benign Thyroid Nodules

Some medical technologies take longer than anticipated to enter clinical practice. This is the case with high-intensity focused ultrasound (HIFU) for the treatment of benign (non-cancerous) thyroid nodules — a technology first reviewed by CADTH in 2007.¹ Although some Canadian centres use HIFU for conditions such as prostate cancer and uterine fibroids, it is still not used for treating thyroid disease. However, HIFU treatment for thyroid nodules is now available in Europe and Asia, and more trials are starting in the US this year — prompting an updated look at this technology.²



HOW IT WORKS

HIFU is sometimes referred to as focused ultrasound surgery or echotherapy.^{3,4} It is a minimally invasive procedure that uses ultrasound to provide both image guidance and treatment, delivering a high, focused dose of “heat energy” to destroy tissue, while sparing adjacent tissue.⁵

WHO MIGHT BENEFIT?

Thyroid nodules are single or multiple growths on the thyroid — a butterfly-shaped gland in the neck that regulates growth and metabolism. Thyroid cancer is relatively rare (only an estimated 5% of nodules are cancerous)⁶ and most nodules are benign and do not affect the function of the thyroid gland. However, benign nodules that release hormones, and those that continue to grow and affect breathing or swallowing, may require treatment.⁷

Thyroid nodules are common in adults — particularly in women and in the elderly.^{6,8} An estimated 5% to 10% of people have nodules that can be felt during physical examination, while even more have smaller nodules that can be detected by ultrasound.^{6,9}

AVAILABILITY IN CANADA

The EchoPulse high-intensity focused ultrasound system (Theraclion, France) is not yet licensed by Health Canada. EchoPulse has CE marking that allows marketing in the European Union.¹⁰ At least 16 sites in the United Kingdom, Europe, and Asia currently offer EchoPulse HIFU.⁴

WHAT DOES IT COST?

In a recent interview, the CEO of Theraclion mentioned the price of the EchoPulse HIFU system as being €300,000 (approximately C\$441,000).²

CURRENT AND ALTERNATIVE PRACTICES

Benign thyroid nodules that cause symptoms are usually removed with surgery or shrunk using radioactive iodine.^{6,11} Adverse events associated with these treatments include: nerve damage, infection, and the risks associated with general anesthesia for surgery.^{7,11-13} Thyroid function may also be affected, resulting in the need for lifelong thyroid hormone replacement therapy.¹² In addition to HIFU, other less invasive treatments — such as radiofrequency ablation, microwave ablation, and ethanol sclerotherapy — are under investigation.¹¹

WHAT IS THE EVIDENCE?

A literature search conducted for a 2014 Cochrane review of minimally invasive therapies for benign thyroid nodules did not find any randomized controlled trials of HIFU.⁸

Clinical effectiveness

Results from three, small, non-randomized studies in European centres found average nodule reduction at three to six months post-HIFU, ranging from 30% to 49%.^{11,12,14} Another study using an earlier version of

the EchoPulse found nodule reduction ranging from 2% to 80% in about half of the 25 patients.¹⁵

Investigators in one study noted that some nodules continued to decrease in volume during the follow-up period.¹² Treatment time was approximately one hour.¹⁴

Safety

No serious adverse events have been reported in studies of HIFU to treat benign thyroid nodules.^{11,12,14,15} Minor adverse events include: mild skin burns, swelling, bruising, and skin irritation.^{7,12,14}

Two studies reported that thyroid function was maintained after HIFU treatment.^{7,11}

ISSUES TO CONSIDER

As most benign thyroid nodules do not require treatment, only a small number of patients might benefit from this therapy.

Most of the available evidence on HIFU is in treating smaller nodules (less than 10 mL in size) — usually in a single treatment session. Some studies report the treatment is less successful in ablating deeper nodules.^{11,14,16} The type of thyroid nodule tissue does not appear to affect treatment success,^{7,14} although one study noted that nodules with more blood vessels did not respond as well to treatment.¹²

Technical issues include the relatively long duration (approximately one hour) of the

treatment procedure^{7,12,14} and the need for multiple treatments for larger nodules.¹¹ A recent company press release describes new technology that has reduced the procedure time in HIFU treatment of patients with breast fibroids.¹⁷

Patient preferences for less invasive treatment procedures with better cosmetic results (“scarless surgery”) may influence the uptake and diffusion of HIFU.¹⁸

WHAT ELSE IS HAPPENING?

HIFU is under investigation for the treatment of other thyroid and neck disorders, including thyroid cancer and hyperparathyroidism; other types of cancer; and movement disorders, such as Parkinson disease.^{3,5,11,18,19}

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Focus On: 3-D Printing

Three-dimensional (3-D) printing is the process of creating physical objects out of plastic, metal, and even tissues by building the objects, layer by layer, using files designed on a computer and sent to a specialized printer.^{1,2} Also called additive manufacturing or rapid prototyping, 3-D printing has been used for many years in aerospace and manufacturing industries. Recent advances that have reduced the cost and time required for printing have made 3-D printing a new tool for health care.^{2,3}

Most 3-D printing follow similar steps in producing a final product:

- An image or set of images is acquired.
- The area of interest is selected.
- A 3-D model — a mesh or scaffold — is designed using a computer program.
- The 3-D model file is sent to a printer.
- The final object undergoes post-production processing to make it suitable for use.¹

Objects can be printed using various techniques, depending on the intended use of the object or the material used.² For example, selective laser sintering can be used to build objects out of metal or ceramic by melting or fusing layers of powder with a laser;^{1,2} fused deposition modelling builds objects from molten, extruded plastics;⁴ whereas inkjet printers — working at much lower temperatures — can build objects using biological materials.^{1,2}



3-D printed kidney showing a renal tumour (purple), renal vein (blue), and renal artery (red). Reproduced with permission from Dr. Shuji Isotani, MD, PhD, Department of Urology, Teikyo University School of Medicine, Tokyo, Japan.

HOW IS 3-D PRINTING BEING USED IN HEALTH CARE?

As the availability and affordability of 3-D printing has increased, so has the evidence on its use in health care. Most of the literature on 3-D printing applications in health care falls into one of the following areas.

Surgical planning

3-D printing gives surgeons the ability to visualize, plan, and practice procedures before the actual surgery.^{1,3,5,6} 3-D models have been printed to help select appropriate devices for abdominal aneurysms,¹ visualize the internal structure of organs for living donor transplants,¹ or more clearly show areas of disease when simulating tumour removal from a kidney.⁷ In Saskatchewan, clinicians have printed models of patient's brains using their imaging scans.⁸

Education and training

3-D printing is now used in clinician education and training.^{1,3,5,6,9} It offers trainees the opportunity to interact with models — examine, feel, dissect — without the time or safety constraints of working with a real patient.^{5,6,9}

Tissue engineering

One of the more exciting applications of 3-D printing is the ability to create different types of human tissue.¹⁰⁻¹² While this is still limited by the available technology,¹⁰ there have been successes in creating less complex structures, such as cartilage,¹³ skin used for skin grafts,¹³ and heart valves.¹¹

Other applications

Custom implants and prostheses

Combining medical imaging techniques with 3-D printing has allowed clinicians to create and refine implantable and prosthetic devices, such as endotracheal splints,¹⁴ mandibular scaffolds that allow bone to regrow,¹⁵ prosthetic noses,⁵ dental implants with antimicrobial properties,¹⁶ and low-cost artificial arms.¹⁷ In Toronto, custom finger splints have been printed using fused deposition modelling technology.⁴

Medications

3-D printing is also involved in the delivery of medications on the smallest of scales.² The first 3-D printed medication — to treat epilepsy — was approved by the FDA in 2015.¹⁸ Building pills layer by layer enables more precise control over the dosage of medication, which is particularly important with difficult-to-manage conditions such as epilepsy.¹⁸ The other benefit of the 3-D printing process is that a pill made up of layers allows for a more porous structure that dissolves rapidly, something that may be a benefit if a medication is difficult to swallow.¹⁸

“3-D printing may also raise ethical issues regarding ownership, privacy, and consent when using tissue or images from individual patients.”

On-demand tools

Moving away from medications and implants, 3-D printing is also being used to build customized instruments for surgical procedures.^{5,6} An example of these applications is the use of medical images to print custom tool guides to allow for precise drilling during surgery.⁵ Fused deposition modelling printing has also been used to build and test the suitability of surgical instruments.¹⁹

CURRENT AVAILABILITY AND REGULATION

In Canada, medical devices are regulated by Health Canada based on the claims made about the devices, not whether the devices were made using 3-D printing. While there are companies in Canada using 3-D printing to produce health care products, there is concern that industry and government are not moving quickly enough to provide tools and support to encourage their widespread use.²⁰

The process of creating customized, on-demand, or patient-specific materials through 3-D printing can potentially disrupt the normal processes designed to ensure products are safe and effective.^{5,13,14,21,22} Draft guidance from the FDA was released in May 2016 to help address and clarify these concerns.²³

Some of the benefits of the printing process, such as the porous structures to encourage tissue growth, create challenges for sterilizing materials, and the type of material used affects the sterilization method.^{4,22} In some cases, clinicians and manufacturers are seeking regulatory exemptions on a case-by-case basis to have customized devices approved.¹³

3-D printing also raises unique concerns related to intellectual property and ownership.^{2,21,22} Printing an object is more than just capturing an image and sending it to a printer — it requires software to interpret images and design the final product.²² In the US, the FDA has questioned who controls or owns the design process: the software vendor, the end-user, or the company who made the printer?²² Another grey area is if hospitals doing their own printing should be considered as manufacturers, further complicating regulation.²²

ETHICAL ISSUES

3-D printing may also raise ethical issues regarding ownership, privacy, and consent when using tissue or images from individual patients.²¹

The ease with which design software and files can be copied and shared may deter manufacturers from becoming involved in 3-D printing and stifle the innovation needed to advance the technology.²² However, these concerns are as yet untested, and there is some indication that a culture of sharing intellectual property may even help develop the industry.²

In remote communities, local printing may help reduce dependence on external suppliers, shipping costs, and on-site storage.⁴ Additionally, potential cost savings associated with 3-D printing may help humanitarian efforts provide low-cost devices, such as prosthetic hands or stethoscopes, to areas in need.^{17,24}

SAFETY

Some researchers have raised concerns about toxicity when printing 3-D objects, in part because of the processes involved in printing — which often involve the heating of plastics or resins — and the materials used for printing.²⁴ As 3-D printing moves out of traditional manufacturing facilities, such as factories, and into hospitals and homes, strategies for safely printing, handling, and disposing 3-D printed materials will be needed.²⁴



Photo: iStock.com/Suljo

HOW MUCH DOES IT COST?

As with most technologies, the cost of 3-D printers is dropping.^{1,5,21} Upfront costs for commercial-grade equipment and software may be in the tens of thousands of dollars for devices capable of printing health care grade materials at appropriate resolutions;⁵ however, researchers in Toronto have printed skin grafts in a proof-of-concept project on a machine that cost about \$1,000,¹³ and fused deposition modelling printers cost between \$300 and \$3,000.⁴ Ongoing printing costs must also be considered, but, in many cases, models can be printed inexpensively, ranging from under a dollar to under \$1,000 depending on their size and complexity.⁵ Model hearts used for a recent training course at SickKids — the Hospital for Sick Children — in Toronto were printed at \$2,000 per heart.²⁵ 3-D printing also

compares favourably to other technologies, like computer simulation, and could be less expensive.⁵ A limited potential for in-house use may encourage some institutions to outsource 3-D printing, but this will likely result in increased costs per model.⁵

LIMITATIONS OF CURRENT TECHNOLOGY

Widespread use of 3-D printing in health care faces a number of limitations. Both the temperature required to print (currently too high for many printers) and the ability to print materials on a small enough scale (currently too small for many printers) make printing complex tissues a challenge.^{6,14}

Production time is currently a constraint, but as 3-D technology has improved so have printing times, with some printers capable of producing objects in minutes instead of hours.⁵ However, the time required for printing may still be too long to rely on 3-D printing in emergency situations.⁵

LOOKING AHEAD

Much of the excitement surrounding 3-D printing lies in its potential to print replacement organs and other complex tissues, with the goal of eliminating the need for organ donors and anti-rejection drugs.^{12,26} While still years away, every day there are more examples of viable cell structures, small organs, and the ability to print objects that can adapt and change their structures — illustrating how quickly this technology is evolving.²⁷⁻³⁰

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