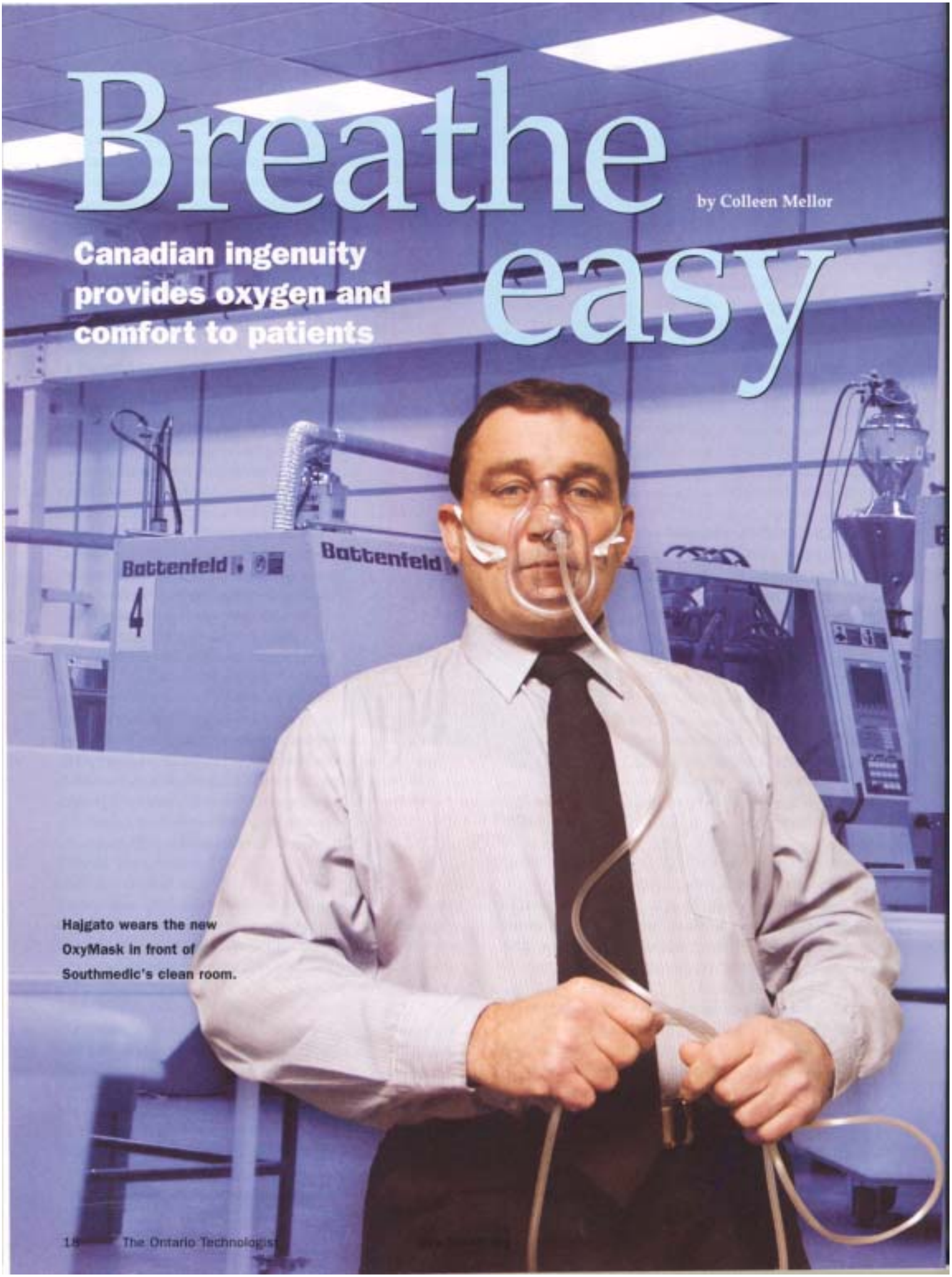
Breathe easy

by Colleen Mellor

Canadian ingenuity provides oxygen and comfort to patients



Hajgato wears the new OxyMask in front of Southmedic's clean room.

Certified engineering technologist Julius Hajgato joined a medical technology company to co-ordinate its expansion, but he ended up playing a major role in developing a revolutionary oxygen device. The Barrie, Ontario company has combined business, technology and innovative thinking to help people who need oxygen get it safely and comfortably. Southmedic, specializing in respiratory and anesthetic products, asked doctors what device needs changing the most.

"The answer was always the face mask," says CEO and president Lee McDonald. As a result, Southmedic developed a unique oxygen system and launched it late last year.

"It's awesome," says McDonald. "It's changing a paradigm that's gone unchanged for years — we've been using a closed oxygen system for years when we didn't have to."

Southmedic started the development process by improving the comfort of the mask, but heard, "it's still a mask." When McDonald watched the company's receptionist walking around with a headset on, the idea of the open oxygen technology took hold.

The team came up with the OxyArm, a device that works like a telephone headset with the oxygen flowing into the patient's mouth through an innovative diffuser mushroom assembly positioned in front of the mouth and nose.

The open oxygen system is a significant advancement in medical technology because it allows patients to speak, drink through a straw and use a nasal gastric tube. Many patients, who may suffer from claustrophobia or don't tolerate the traditional oxygen mask, take it off. The open system is lighter, more comfortable and allows the patient to also breathe ambient oxygen.

Julius Hajgato, C.E.T., is manager of Southmedic's research and development program. He has worked extensively on the research, development and testing of this technology, says McDonald.

Hajgato, a Sheridan College graduate in mechanical engineering technology, joined Southmedic as project manager for the plant's expansion from 30,000 to 60,000 square feet. He got involved in the OxyArm development because he has a background in flow dynamics and analysis.

"I'm excited with the product line because I embrace the idea that what is being done will improve a person's quality of life," says Hajgato. "I've worn an oxygen mask and it's not comfortable if you have to wear one for a length of time. I've also seen the effects of nasal cannula on seniors, burn marks that they get from chafing and dried out mucus membranes, so the fact that we're developing a product that will make their lives more comfortable is a bonus."

The key to the OxyArm family is the pin/diffuser technology that allows the patient to receive the appropriate oxygen flow.

Southmedic designed the pin/diffuser by hand and Hajgato spent a lot of time studying it, testing it, verifying its validity and comparing rate of flows to a standard mask. The company also did flow simulations using the University of Western Ontario wind tunnel computers. "We went through a year of trials to get the critical dimensions for the diffuser, pin and all structural components," says Hajgato.

The evolution of the mask

While the OxyArm is very popular for a cognitive person who sits up and is mobile, it doesn't work as well for patients lying down in bed.

So with the OxyArm serving the long-term care market, the Southmedic team went back to the drawing board to capture the hospital market, says McDonald. The result —the OxyMask and OxyChin, two devices that use the same pin/diffuser technology as the OxyArm, but with different holders to make it suitable for the hospital setting.

The OxyChin is for patients having surgery around the mouth or eye area where a mask would get in the way. Surgeons typically cut the mask. The

OxyArm, a device that works like a telephone headset.

Photography: Don Gosling

OxyChin, built to suit that type of surgery, is basically a holder for the diffuser and mushroom that fits snugly on the patient's jaw. Part of the development of this product was to send it out to surgeons asking for feedback, then incorporating the feedback into the design.

The company distributes O_2 and CO_2 versions of the OxyMask and OxyChin. The mask is much lighter and more comfortable than a conventional mask because it has two large holes cut on either side of the face and one cut below the nose. This eliminates CO_2 rebreathing. Patients may feel less claustrophobic, and with the O_2/CO_2 model, hospital personnel can monitor rate and trend of breathing.

The CO_2 monitoring function is totally unique and Hajgato's team developed a different kind of pin for it. The design of the holes allows different flow rates around the outside of the cone, yet creates a vacuum in the pin's center to allow for CO_2 sampling with a monitor, strictly applying flow dynamics.

When using traditional masks, nurses must add a diffuser device specific to the flow and concentration of oxygen and change it as patient's requirement change. With Southmedic's device, all that's needed is to adjust the oxygen tank settings.

To develop the mask, Hajgato used sensors to test and measure where the CO_2 built up. Machinist John Gibbons (also the company's plant maintenance manager) machined different configurations of the pin on the way to prototyping a design. Hajgato tested the variations and adjusted the slope and angles to improve the ability to measure CO_2 and also to supply the required oxygen concentration levels. Testing included computer simulations at the University of Western Ontario wind tunnel facility.

Once dimensions were confirmed, the team made a model of the mask out of modeling clay, sent it to be digitized, then modified it on the screen and went to rapid prototyping.

After more computer work including composing a skeletal drawing and tweaking the surface features, Southmedic manufactured a mould for it and began manufacturing it.

Once the research and development phase has a prototype, the designers in the engineering office design the tool or mould using SolidWorks, a 3-D solid modeling software. This stage may require modifications in order to ensure the company can mass-produce the product. The finished design goes to the tool shop where the tool and die makers convert the design into a CNC program, and configure the equipment to produce it. When the prototypes and tooling are complete, the product goes to the manufacturing stage.

Southmedic employs about 80 people and produces more than 100 medical parts for client companies plus its own

Respiratory medical studies

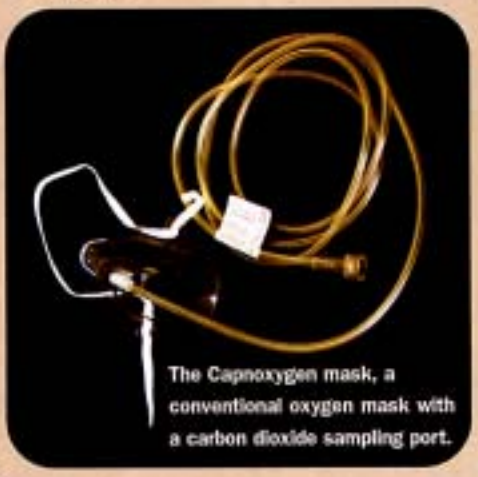
A recent study shows that both the OxyArm and Capnoxygen mask provide clinically useful capnographic monitoring capability in volunteers. Capnography is a graphic display of instantaneous CO_2 concentration versus time or expired volume during a respiratory cycle.

James Paul, BSc, MD, MSc, FRCPC, Elizabeth Ling, BSc, MD, MSc, FRCPC, from the Department of Anesthesia at McMaster University in Hamilton, Julius Hajgato, C.E.T., and Lee McDonald, RN, of Southmedic Inc. in Barrie conducted the study.

The purpose was to compare the capnography monitoring performance of the OxyArm with the Capnoxygen mask, a conventional oxygen mask with a carbon dioxide sampling port.

Eleven healthy volunteer adult subjects underwent capnographic monitoring (in a non-randomized, un-blinded crossover study) at baseline and while receiving oxygen at seven different flow rates, applied first with the mask and then with the OxyArm.

Both the OA and CM produced acceptable capnographs with consistent waveforms. The measured end-tidal (ET) CO_2 was equivalent for the two devices at all seven oxygen flow rates. On average, the $ETCO_2$ measured with the OA was about 2 mmHg greater than that of the CM.



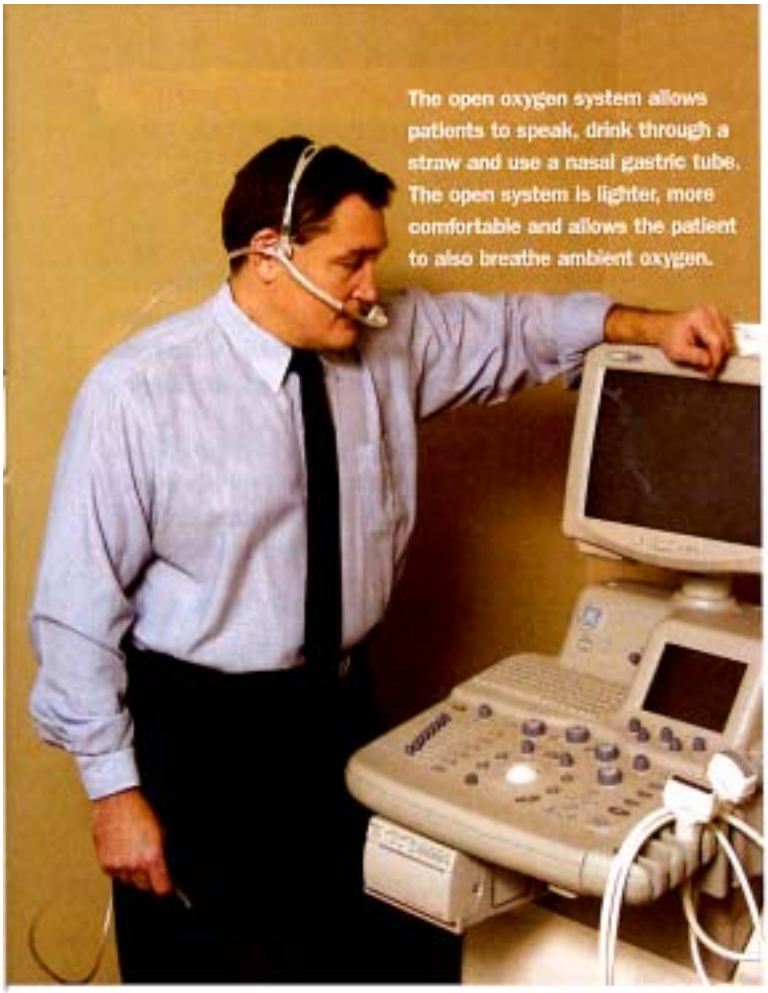
The Capnoxygen mask, a conventional oxygen mask with a carbon dioxide sampling port.

Regression analysis showed an inverse relationship between oxygen therapy flow rate and measured $ETCO_2$ whereby the measured value of CO_2 decreased as the oxygen flow rate was increased ($P < 0.001$). Both the CM and OA produced consistent measurements of $ETCO_2$ as illustrated by their reliability coefficients, 0.95 and 0.86 respectively. The biggest source of variation in measured CO_2 for both devices was different subjects.

This study suggests that the OA and CM could prove useful for respiratory monitoring and oxygen delivery in spontaneously breathing volunteers. The authors conclude that the OA is an alternative to the conventional methods of oxygen delivery and CO_2 sampling in patients.

Other studies commissioned by Southmedic include a description of the OxyArm development and performance as well as comparison of the OxyArm and standard nasal cannulae in chronic obstructive pulmonary disease patients, both published in the *Canadian Journal of Anesthesia*.

For more information, visit the Web site at www.OxyArm.com.



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proprietary products at the plant. The company also distributes manufactured surgical instruments on behalf of other manufacturers.

On the plant side, another OACETT member, David Squires, C.E.T., is the director of manufacturing and oversees some of the engineering design, specifically for other manufacturers. He graduated from Georgian College in Barrie in mechanical engineering technology.

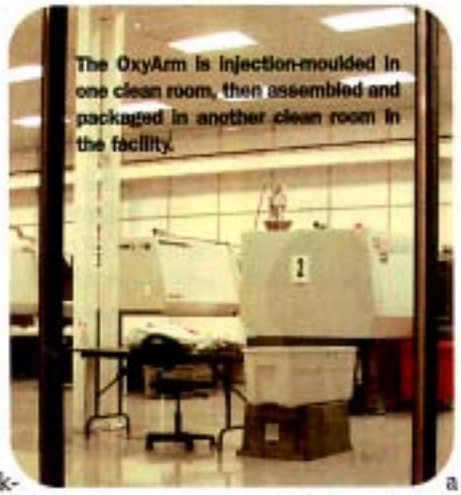
"We bill ourselves as a one-stop shop," says Squires who oversees project managers working on these types of products. "We'll take a conceptual design from doctors or entrepreneurs and the design team will develop a 3-D concept."

The designers use Pro Engineer and SolidWorks.

The next steps are to design the full part, the mould, then produce the mould and the parts. In some cases, Southmedic will take the product from concept to packaging, says Squires.

Gibbons has done one-off prototype stainless steel surgical instruments for surgeons who may have an idea for a unique instrument. He will make a prototype by hand, then revise the design based on feedback from the surgeon. For example, Southmedic designed and manufactured an aortic punch that cuts a little circle out of aorta during heart bypass surgery.

The company's class 10,000 to 100,000 injection moulding room contains state-of-the-art closed loop moulding machines and allows Southmedic to take products from the moulding of parts though assembly operations and into final consumer packaging under one roof. For example, the OxyArm is injection-moulded in this clean room, then assembled and packaged in another clean room at the facility.



The OxyArm is injection-moulded in one clean room, then assembled and packaged in another clean room in the facility.

One of the challenges of working with plastics is the variation in the shrinkage rate of the different resins, says Squires.

The key is a good tool designer who can help meet the challenges in mouldability.

"We have good mould designers and makers who have the experience to make a successful tool without too many tries," he says.

Another challenge is that Southmedic's moulds must last millions of cycles so it's crucial to know where to have hardened steel to ensure reliability and avoid malfunctions, says Squires.

As the OxyArm product line flourishes, Southmedic continues research and development on other medical devices.

"We're becoming known as leaders in the respiratory field," says Hajgato, noting that the company holds numerous patents on products such as the OxyArm and the new OxyMask.

Recent nursing focus groups generated ideas for new products including a sterilization tray and a tape dispenser/carousel unit for the medical field.

Two crucial parts of research and development are a cost analysis to see if a device is manufacturable at an appropriate cost and product verification and testing. This can include medical studies and focus groups.

The company follows a set procedure with each new product idea: the team meets and everyone provides their input. "Then we design the product and assess it again, before we devote the resources to it," says Hajgato.

"We're doing something unique that will make a difference to the health and comfort of people, whether in an acute or chronic care setting," says Hajgato. "They will get the supplementary oxygen they require safely. People with COPD, or who are chronic hypoxic, will be more mobile, so that it will have a positive impact on their quality of life."