

Improving The Shelf Life Of Oxygen Concentrators

Last Updated: 08 July 2021

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Abbreviations:

LMIC - Low to Middle Income Country

LRS - Low Resource Setting

PSA - Pressure Swing Adsorption

VP SA - Vacuum Pressure Swing Adsorption

VSA - Vacuum Swing Adsorption

1. Introduction

This document is a summary of the 'Shelf Life Workshop' conducted by the *Oxygen CoLab* via webinar on the 22nd of April, 2021. The workshop sought to explore the challenges and potential solutions to improving the shelf life of oxygen concentrators when in storage. The Oxygen CoLab is a global network that enables, supports and connects those working to design oxygen concentrators that are fit for low and middle-income countries (LMICs) and low resource settings (LRS) around the world.

2. The Shelf Life Challenge

2.1 What is Shelf Life?

The shelf life of an oxygen concentrator is the length of time that a new, unopened concentrator can be stored before you need to be concerned about whether it is fit for use. After this period of time the sieve beds would likely have degraded to a point where - when you switch on the oxygen concentrator - it would not operate to the levels of flow and concentration to meet the required standards.

The shelf life of an oxygen concentrator is important because it is not uncommon for devices to sit unused for considerable periods of time. For example, they might be stored in warehouses and spend considerable periods of time in transportation. There have been numerous cases of oxygen concentrators being stored and then a significant number not functioning when taken out of storage. Furthermore, even when they arrive in clinics it has been noted that they can spend a considerable amount of time in storage in between patients, which although not strictly a 'shelf life' issue, is an issue which shares the same root cause: deterioration of the sieve bed caused by exposure to moisture.

2.2 Why do Oxygen Concentrators have a Shelf Life?

Pressure swing adsorption (PSA) works by using a material known as an adsorbent, which preferentially attracts nitrogen molecules compared to oxygen. Adsorption is the accumulation of molecules at the surface of the zeolite. This occurs because of an attraction between adsorbate (e.g. nitrogen and oxygen) molecules and the porous adsorbent surface (as described above).

Adsorbents are crystalline porous structures with a large surface area per unit mass. At a given pressure and temperature, different molecules interact with the surface differently and some will adsorb preferentially onto the micro porous surface over others. The challenge is that typical zeolites used in oxygen concentrators preferentially adsorb polar molecules, such as water, which has a strong polar van der Waals force and therefore will preferentially attach to the surface of the zeolite and reduce its capacity to adsorb nitrogen.

There are two main types of adsorption: physical adsorption and chemical adsorption. Physical adsorption can be more than a single layer and is easily reversible. On the other

hand, chemical adsorption involves the formation of bonds between the adsorbate and adsorbent surface. It can only form a single molecular layer on the surface and is not easily reversible. When water comes into contact with zeolite it can form a physical electrochemical bond and effectively block the pores, reducing the capacity of the zeolite material. When the bond is 'chemical' adsorption, it is hard to regenerate. Over time the interaction of CO₂ and water with a zeolite can lead to irreversible chemical adsorption throughout the bed, after which the zeolite cannot be regenerated. This contamination is the cause of the gradual long term degradation of sieve beds.

During operation, when the concentrator is in cycling, there is a small purge from the column generating a very dry low dew point 'light' gas, which passes through the regenerating column and facilitates the desorption of nitrogen and moisture from the zeolite. This is what enables effective regeneration. Regularly running the concentrator therefore significantly prolongs sieve bed life.

3. The Journey of an Oxygen Concentrator

An oxygen concentrator begins life typically under well managed environmental conditions where zeolite columns are rapidly packed in humidity and temperature controlled environments. At this stage, the importance of quality management, including, for example, leak testing the concentrators before they leave the factory, is an important factor in ensuring a long shelf life. Without strong quality management systems in place, the overall reliability of oxygen concentrators has been shown to suffer.

After being fabricated and tested, oxygen concentrators are either shipped or travel by air to their destination. Shipping containers, in which goods are transported, do not generally have controlled environments. For other goods transported in containers in other industries, it is known that it is not uncommon for 10% of overall products to be damaged en route. Concentrators can be in shipping containers at least 45 days, often over 60 days.

When concentrators are transported by air, travel times are of course much shorter. At 35,000ft temperatures *outside* an aircraft can fall as low as -50C, however, although cargo hold temperatures are not tightly controlled, they are generally kept above freezing (typically 5-15 C). It is important to bear these variations in temperatures in mind (as compared to the temperature at which the sieve beds are filled), when designing the likely air volume changes in the columns during transport due to the effects of temperature swing adsorption occurring in the columns.

After transportation, concentrators are often then warehoused for a period of time before distribution. This might be at the supplier or procurement agency. This can be between 1 week to 12 months, but typically will be around 2 months before units are used. Some warehouses will have environmental control, but it should be assumed that the majority will not.

When concentrators arrive at their place of use, it is not uncommon for them to sit idle for periods of time in between patient use - between one week to many months, depending on whether the system is being used as a primary oxygen supply or as a backup system. Some can sit idle for considerable periods waiting for spare parts. The use case significantly affects how long it will sit in storage. It is during these idle periods when the zeolite deteriorates. Although user behaviour and usage of the concentrator is not in the strict definition of shelf life, it is an essential factor to consider in the design of a concentrator as it may lead to an oxygen system being unable to deliver when it is required, which can have potentially critical health impacts.

4. Typical Shelf Life Challenges

Exposure of the sieve bed is one of the primary causes of reduced shelf life. This can occur with rotary valve systems that do not close off the sieve bed to the atmosphere when they are switched off, which is not uncommon practice in many existing off the shelf concentrators. It can also occur due to leaks in the system, and vapour diffusion through plastic components and the use of flexible silicone tubing - which has free volumes that permit gas diffusion.

Many issues with moisture diffusing into the sieve bed and causing degradation occur while they are in use in clinical settings. This often occurs due to a problem that has been undiagnosed, such as a leak or faulty valve. For example, there are reported cases of one way valves failing leading to moisture being sucked back into sieve beds from a humidifier, leading to irreversible degradation. Although these are not shelf life issues, they come back to the same root cause - of moisture and CO₂ degrading the sieve bed and rendering it unusable.

5. Solutions to the Shelf Life Challenge

5.1 Improving Resilience at the Clinic: Storability

When sieve beds fail it is easy to think that the problem can be solved by simply replacing them with new ones. However, sieve bed failure is often symptomatic of something else wrong with the oxygen concentrator. Therefore it is essential to seek to understand the reason for the failure before replacing the sieve bed, especially if this happens sooner than you would expect. For instance, it is important to check if there was a valve failure, a leak in the system or some other issue. There are ways in which the storability of a concentrator, however, can be extended and the concentrator made more resilient.

5.2 Improving Resilience Through Good Design

The shelf life of a concentrator can be extended by good design. For example, the following principles were suggested during the workshop:

Sealable Valves	Ensuring the valves to the sieve beds close when the system is not in use, sealing the columns from direct contact with the atmosphere.
Quality Control	Quality control is absolutely critical in the manufacturing process, e.g. ensuring there are no leaks in the product by testing every concentrator before it leaves the factory. Potentially an automatic system could be developed to facilitate this procedure. N.B. this is even more important with a vacuum swing adsorption system, where a leak would lead to moisture being drawn into the bed.
Minimizing Use of Silicone and Plastic	Minimising the use of silicone tube and plastic parts in the design, which, in many existing commercial concentrators, provide a surface for vapour diffusion into the columns.
Sealed Packaging	Sealing the whole of the concentrator in a membrane wrapper to keep it free from vapour diffusion before first use. Individual spare sieve beds can also be wrapped before transportation.
Pre-pressurization of Columns with Dry Air	Pressuring the columns with dry air at manufacture - to be released on first use. Being able to do this in practice depends on the valve design.

Perhaps one of the bigger challenges is how to ensure that a concentrator continues to work effectively after its first use. This is especially important when it has been purchased as a back up and might sit for a number of weeks or months in storage, likely in an uncontrolled environment.

In the next section we summarise some of the ideas which have emerged as suggestions to improve a concentrator's resilience through 'over engineering' the components to make the system much more robust and repairable, while keeping a close eye on quality during manufacture. Aspects to consider include:

High Quality Valves and Tubing	Using high quality check valves and metal tubing with compression fittings rather than plastic or silicone tubing will extend the life of the concentrator.
Sealable Valves	Designing the system to have valves that shut off the sieve beds and ensure they are sealed when the system is not being used or is in storage. Commonly used 4 way and 3 way valves, for example, leave an open pathway to the atmosphere. Solving this challenge of sealing the beds has been shown to impact the long term dependability of oxygen concentrators in challenging environments. Furthermore, it is important for valves to fail closed, so that if power goes down unexpectedly, then the sieve beds are sealed.

Replaceable Sieve Beds	Designing sieve beds to be easily replaceable/easy to refill and potentially providing simple ways to regenerate zeolite and/or the beds so this can be done in country rather than having to send them internationally to have the beds regenerated.
Balanced Beds	Ensuring that the beds are balanced in terms of oxygen and nitrogen generation before leaving the factory. This can be done by carrying out waste gas profiles. If the beds are out of balance, and one bed is doing more work than the other, the moisture zone can move up higher in one of the beds causing deterioration.
Balancing Bed Size and Energy Consumption	Maintaining a balance between bed size and energy consumption is important - a larger bed requires greater flow rates and has, consequently, a higher energy requirement but is more stable and has a longer life, whereas smaller beds with high lithium exchange are easier to contaminate, but lead to a lower energy consumption.
Guard Beds	Having a guard bed of Alumina-Silica gel and NaX before the lithium-X, remembering that it is also important to protect against contamination with CO ₂ , which can also bond to the zeolite sieve. The protective layer could be in a separate cartridge that fits inside the bed and that can be more easily replaced.
Packaging of Replacement Sieve Beds	Storing replacement sieves bed in moisture barrier membrane packing, so that even if it is packaged for an extended period (e.g. 5 years), then users can be sure they will function well.
Super Hydro-phobic Membranes + PSA	Using super hydro-phobic membranes combined with PSA to remove the moisture before the sieve bed. These are commercially used in dehumidification applications and could potentially be hybridised with PSA.
Automatic Tuning of System	Finding ways to automatically tune the system timing to control the moisture front location in sieve beds, this could potentially be used to control the sieve beds.
Modifying Zeolite	Modifying the zeolite e.g. coating in hydrophobic coating in order to protect the zeolite.
Bed Regeneration Devices	Developing a device to regenerate beds that could be used to regenerate relatively new beds that have been in storage for a bit too long. Such a device used to be manufactured by Foothills Medical in Colorado, and used to rejuvenate beds. This was popular for a while until the cost of beds came down to make it not worth it in the USA. There is potential for a device of this type as it reduces the dependence on supply chains for spare parts in the Global South. It is essential to consider the context where this would be used in and how appropriate this would be.

5.3 Improving Resilience Through User Behaviour

How a end-user uses the product and maintains it has an important impact on an oxygen concentrators life. There are things that can be done to improve the longevity of the system and how the user interacts with the system. For example, it has been shown that simply running the concentrator for about 2 hours every 3 months keeps the degradation quite low and significantly prolongs the life of the sieve bed. The challenge is how to either automate this or better encourage good user behaviour. System features that should be considered to improve concentrator resilience include:

Regular Leak Testing	Regular leak testing of the concentrator - perhaps as regular servicing or maybe built in and automatic.
Indicator System To Prompt Regular Use of the Concentrator	Design some sort of indicator system to feedback to users when the concentrator has not been run for an extended period. E.g. this might be a indicator light, or a text message to the user to encourage them to run the system for a period of time.
Monitoring of Sieve Beds	Finding cost effective ways to monitor the status of a bed in-situ and feedback to users when a replacement is going to be required imminently.
Standardized Diagnostic System	Development of a standardised diagnostic system, similar to that used with cars, to support diagnosing problems with the concentrator.
Plug and Play Prepacked Sieve Beds	Plug and play pre-packed sieve beds to make it simple for users to carry out changes themselves.
Simplifying Maintenance	Making it easier to maintain and replace parts including tubes and valves.

6. Conclusion

Improving the shelf life of oxygen concentrators is of vital importance to ensure that these devices are able to function as intended when they arrive at their destination and are put into operational use. To solve the shelf life challenge, solutions must be found that take into account the whole journey of a concentrator: design & manufacture; packaging; quality control at the factory; transport; storage; user behaviour; and maintenance and repair.