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# Material and Technology: Back to the Future for the Choice of Interface for Non-Invasive Ventilation – A Concise Review

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**Keywords**
Non-invasive ventilation · Interfaces · Respiratory failure · Home ventilation

**Abstract**
Non-invasive ventilation (NIV) has dramatically changed the treatment of both acute and chronic respiratory failure in the last 2 decades. The success of NIV is correlated to the application of the "best ingredients" of a patient's "tailored recipe," including the appropriate choice of the selected candidate, the ventilator setting, the interface, the expertise of the team, and the education of the caregiver.
The choice of the interface is crucial for the success of NIV. Type (oral, nasal, nasal pillows, oronasal, hybrid mask, helmet), size, design, material and headgears may affect the patient's comfort with respect to many aspects, such as air leaks, claustrophobia, skin erythema, eye irritation, skin breakdown, and facial deformity in children. Companies are paying great attention to mask development, in terms of shape, materials, comfort, and leak reduction. Although the continuous development of new products has increased the availability of interfaces and the chance to meet different requirements, in patients necessitating several daily hours of NIV, both in acute and in chronic home setting, the rotational use of different interfaces may remain an excellent strategy to decrease the risk of skin breakdown and to improve patient's tolerance. The aim of the present review was to give the readers a background on mask technology and materials in order to enhance their "knowledge" in making the right choice for the interface to apply during NIV in the different clinical scenarios.


## Introduction

Non-invasive ventilation (NIV) is referred to a ventilatory technique that provides positive pressure-related support to the patient by means of a "non-invasive" interface without the need of an artificial airway, such as endotracheal tube or a tracheostomic cannula [1]. Specifically, NIV delivers pressurized gas to the airways into 2 distinct modes, namely, non-invasive continuous positive airway pressure (nCPAP) and non-invasive pressure positive ventilation (nPPV). While during CPAP, the pressure applied to the respiratory system (Paw) is generated only by the respiratory muscles and thus all the work

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of breathing is done by the patient, during nPPV, Paw can be generated either by the ventilator alone (controlled modes) or both by the respiratory muscles and the ventilator (assisted modes). The main advantage of NIV is to avoid invasive ventilation and its related complications (i.e., airways damage, ventilator-associated pneumonia, ventilator-induced lung injury, and weaning difficulties) [1–6].

With the limit that nPPV is now questioned for the treatment of acute "de novo" hypoxemic patients [5], it has dramatically changed the treatment of both acute and chronic respiratory failure in the last 2 decades [3, 4, 6–16]. The use of NIV has also been largely applied in the treatment of stable chronic hypercapnic respiratory failure as well as in the treatment patients with obstructive sleep apnoea and central sleep disorders [17–23]. The success of NIV is correlated to the application of the "best ingredients" of a patient's "tailored recipe," including the appropriate choice of the selected candidate, the ventilator setting, the interface, the expertise of the team, and the education of the caregiver [1, 3, 24, 26–28]. As a consequence, the choice of interface has been recognized to be a major determinant of NIV success, mainly because the interface strongly influences patient's comfort and other important correlated aspects [23–25], such as air leaks, claustrophobia, facial skin damage, eyes irritation, and abdomen distension [29–36]. Concerning the air leak issue, the distinction between nCPAP and nPPV is very important because even if the same interface may be used during both modalities, the likelihood of unintentional air leaks [26], the type of exhalation system, the amount of skin breakdown, and the degree of patient's tolerance may be deeply different. Although in the acute setting, comfort seems to be less important than the efficacy of the treatment, mask fit and care are needed to prevent interface-related complications as in patient candidates for long-term domiciliary NIV [20–23, 37]. Furthermore, a poorly fitting interface generating excessive air leaks that are not compensated by the ventilator may decrease the clinical effectiveness of nPPV and induce air leaks patient-ventilatory dyssynchrony (through loss of triggering sensitivity or auto-triggering or hindering achievement of the inspiration-termination criterion in pressure support mode). This may result in less subjective comfort and less effectiveness of nPPV in unloading respiratory muscles causing daytime hypercapnia [38–40], as well as inducing sleep fragmentation [41, 42] until delirium [43, 45]. Conversely, the strategy of keeping the interface strongly tightened around the face/nose of the patient in order to decrease air leaks as much as possible is a cause of discomfort and nPPV failure. Furthermore, if the pressure applied between the interface and the skin exceeds the capillary pressure, skin breakdown may occur for ischaemic reasons and nPPV has to be interrupted for the huge burden of pain and intolerance [43, 46]. In the paediatric setting, the choice of the interface for NIV is determined by the patient's age and the underlying disease. Discomfort and leaks [47, 48] are the main reason for mask change [49, 50]. A review based on a MEDLINE search [30] found that in studies in which NIV was applied to treat acute respiratory failure (ARF) in an adult population, an oronasal mask was used in 70% of the cases, while a nasal mask was chosen in the remaining 30% of the cases. These data were confirmed by a recent web-based survey involving about 300 European intensive care units and respiratory high-dependency units performed by Crimi et al. [51] who found that oronasal masks are the first-choice interfaces used to treat ARF, followed by nasal masks, face masks, and helmets. The authors also found that main reasons for mask choice were nurse's preference and/or respiratory therapists' confidence, patient's comfort, minimization of air leaks, and interface-related complications. In the home care setting, Meslier et al. [52] found that only about half of the patients classified their interface fit as "good" or "very good." Interface rotational strategy and use of different interface during the day and the night are likely to improve patient adherence to both acutely and chronically delivered ventilator treatment especially for high demanding patients [3]. If rotation of interfaces, accurate re-setting of ventilator and psychological support are not effective, analogosedation may be part of the strategy aimed at improving patient's tolerance in selected cases at a risk of nPPV failure. The goal of analogosedation is to achieve a good control of anxiety, agitation, and discomfort induced by nPPV without causing significant respiratory drive depression [3, 43, 45]. In consideration of the low or absent impact on respiratory drive of, respectively, low doses of remifentanil and dexmedetomidine, these drugs may be preferred to other sedatives, such as benzodiazepines and propofol, for a safe sedation of poorly tolerant patient during nPPV in expert and monitored environment (Fig. 1) [44, 45].

Although the availability of interfaces has greatly increased in the recent years and new products are continuously coming in the hands of physicians and respiratory therapists, the ''ideal interface,'' which turns out to be the "best solution" for all patients in all situations, does not exist and will likely never exist [53]. Some promising proposed sophisticated technological solutions to reduce in-

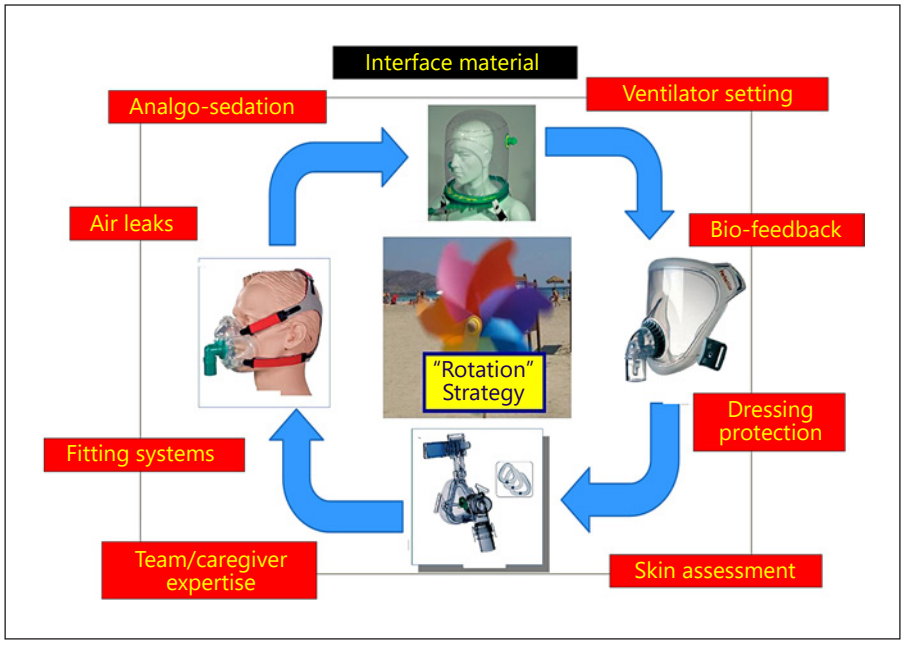


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**Fig. 1.** Interface-correlated factors conditioning patient's comfort during NIV. NIV, non-invasive ventilation.

terface-induced pressure ulcers have been developed. Nevertheless, technologies as pressure sensing visual feedback systems, 3-dimensional colour scan-based fitting assessment, and design of personalized fitting device between the face and the NIV mask [53, 54], objective measurement of pressure on the skin of nasal bridge during mask fitting [55] does not seem to have an easy application yet in the clinical practice [56]. Furthermore, humidification delivered by a heated humidifier [57] during NIV may potentially increase the risk of facial skin pressure ulcers as evidenced by the disrupting effect on barrier function of the underlying skin and associated trends in inflammatory response [58, 59].

However, mask technology and overall mask material have changed over the time helping physicians, nurses, and respiratory therapists to improve NIV patient's acceptance and to minimize air leaks both in acute and home care setting. The aim of the present review is to give the readers a background on mask technology and materials in order to enhance their "knowledge" in making the right choice for the interface to apply during NIV in the different clinical scenarios.

## Mask Classification and Materials

NIV interfaces can be classified as shown in Table 1. Masks can be further divided into "ready to use" or "made to measure" (also named "custom made") [34, 36]. Tsuboi et al. [33] demonstrated that nasal intermittent positive pressure ventilation delivered with custom-fabricated nasal mask was more effective than nasal intermittent positive pressure ventilation applied with a commercially available mask due to the smaller dead space and the less amount of leaks. Custom-made interfaces were also associated with less skin breakdown [54, 60–62] as compared to commercial "ready-to-use" masks [50]. Custom masks have been employed for a long time, but now their use is limited almost exclusively to the paediatric setting [49]. Interestingly, Fauroux et al. [50] found that the incidence rate of global facial flattening (68%) was not dependent on the type of mask in paediatric patients, presumably because both commercial and custom-made masks exert pressure on the same anatomical area. The authors also observed a significant correlation between the global facial flattening and the underlying disease, with an increased risk of developing facial side effects in

**Table 1.** Classification of NIV interfaces

| |
|---|
| Oral: a mouthpiece held between the patient's lips |
| Nasal pillows (or nasal slings): applied externally to the nares |
| Nasal mask: covers the whole nose |
| Oronasal mask: covers both the nose and the mouth |
| Total-face mask: covers mouth, nose and eyes |
| Helmet: covers all the head and the neck |

NIV, non-invasive ventilation.

**Table 2.** Ideal characteristics of the interface for NIV

| |
|---|
| Leak-free |
| Good seal and stability |
| Non-traumatic |
| Light-weight |
| Low dead space |
| Long-lasting and nondeformable |
| Range of sizes |
| Made of nonallergenic and latex-free material |
| Low resistance to airflow |
| Easy to secure |
| Easy to clean |
| Least possible noise from the "vent system" |
| Low cost |
| Transparent[a] |
| Quickly removable[a] |
| Anti-asphyxia valve[a] |

NIV, non-invasive ventilation. [a] Desirable characteristics for oronasal mask.

obstructive sleep apnoea and neuromuscular patients as compared to those with cystic fibrosis. This finding might be explained by that fact that the former were younger and required a longer daily and cumulative use of NIV than the latter [50].

Interfaces for NIV are available in various sizes both for adult and paediatric population [63], and the right choice of the type and size is very important to obtain the greatest patient's comfort, to avoid excessive air leaks and, possibly, to achieve the best clinical results. The majority of the interfaces are available in "vented" or "non-vented" configuration to allow the application of NIV by means of, respectively, a "vented single circuit" or "non-vented single- or double-limb circuit" [37, 53, 64–67]. In the Table 2, the "ingredients" required by an "ideal interface" are reported.

*Oral Interfaces*

There are 3 types of oral interfaces: flexible standard narrow mouthpiece, held in place by the patient with teeth and lips, mouthpiece simply put over the mouth, and custom-moulded bite-plates (Fig. 2–4). Even if rarely applied in the acute setting, this kind of interfaces finds a useful application in patients ventilated all round the clock (i.e., neuromuscular diseases, cystic fibrosis, and COPD) [68–73]. In this category of patients with high degree of ventilatory dependency (>16 h a day), Bach et al. [68] reported the successful sequential use of mouthpiece during the daytime and a nasal mask overnight.

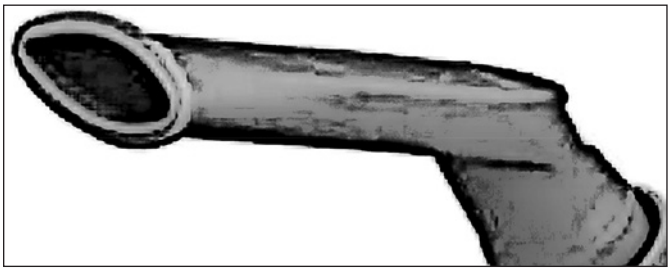

**Fig. 2.** Angled mouthpiece, kept in place by lips and teeth.

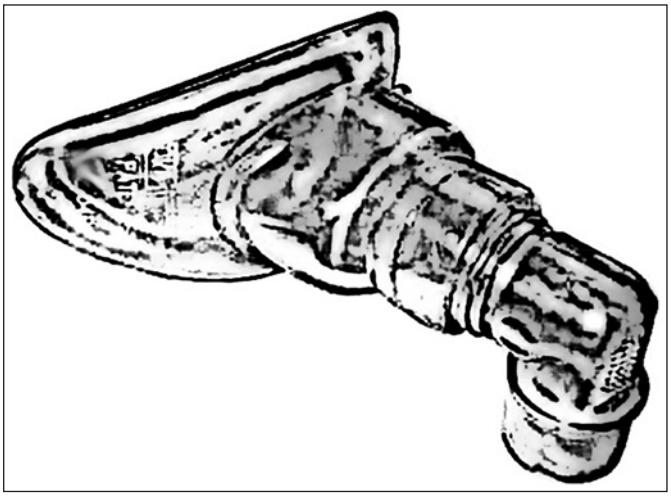

**Fig. 3.** Oral mouthpiece.

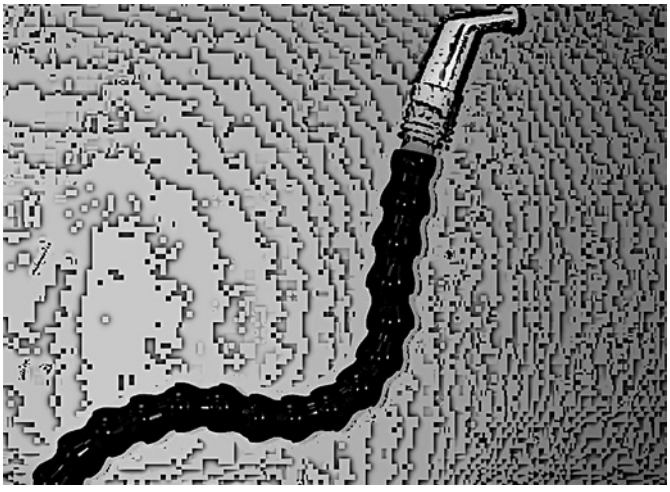

**Fig. 4.** Flexible mouthpiece.

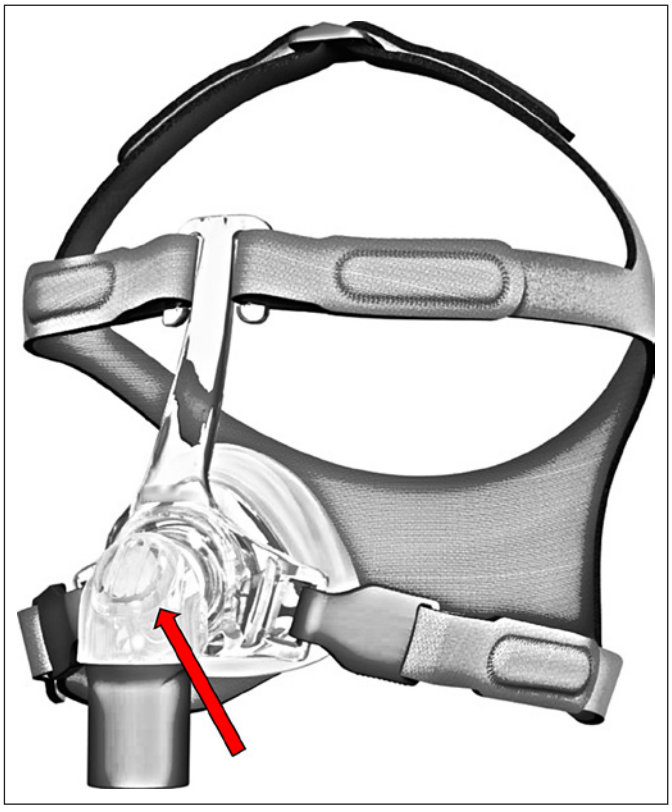

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**Fig. 5.** Vented nasal mask. The arrow indicates the intentional leak port.

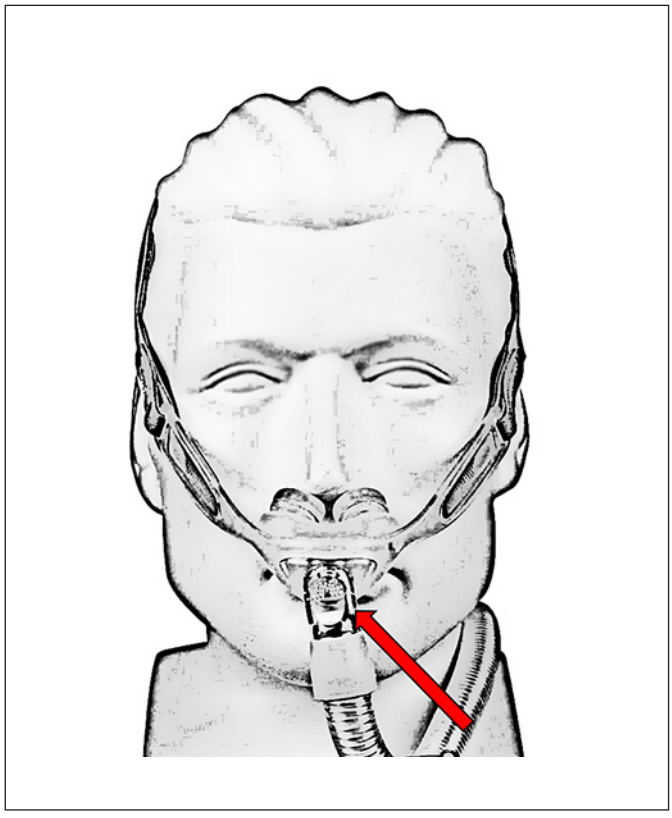

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**Fig. 6.** Nasal pillows. The arrow indicates the intentional leak port.

Similarly, Touissant et al. [72] found that daytime mouthpiece ventilation is safe, prolongs survival, and stabilizes vital capacity in Duchenne muscular dystrophy patients, which were already on nasal nocturnal home nPPV. This interface is recommended with a self-supporting harness [68].

Furthermore, the efficacy of mouthpiece in reducing respiratory effort in acute patients needing nasal nPPV, has been demonstrated by a physiologic study [74]. In COPD exacerbations with mild to moderate acidosis, clinical efficacy was similar in both the modes while patient's comfort turn out to be better with mouthpiece ventilation [75]. Conversely, the likelihood of air leaks and patient-ventilator asynchronies was found higher with mouthpiece with respect to oronasal and total-face ventilation [74]. Drawbacks of a mouthpiece are: gag reflex, salivation, vomiting eliciting, gastric distension and eventually pulmonary aspiration, as well as orthodontic deformities. Since mouthpiece NIV is "an open circuit" ventilation, air leaks with continuous alarm's activation may be a severe drawback. Modification of pressure alarms, use of volume cycled modality, and choice of ventilators with a dedicated mouthpiece ventilator mode could overcome these disadvantages [76, 77]. Furthermore, the large choice in types and sizes of mouthpiece may improve patient's comfort and adherence to nPPV [68].

*Nasal Masks and Pillows*

Several studies demonstrated the large applicability and usefulness of nasal masks in patients on long-term home ventilation. Nasal masks (Fig. 5) have been used with success also to deliver nPPV in both hypercapnic [6, 7, 9, 18, 78–83] and hypoxemic ARF [81, 84–92].

With the nasal mask, there is less interference with speech and eating, less danger in terms of vomiting, no risk of asphyxia in case of ventilator malfunction, and less likelihood of gastric distension. It also allows cough and expectoration, while claustrophobia is uncommon. On the other side, there are some "relative" contraindications like edentulism that increase air leak from the mouth and/or open-mouthed sleeping patients, and other "absolute" contraindications like inability to breathe through the

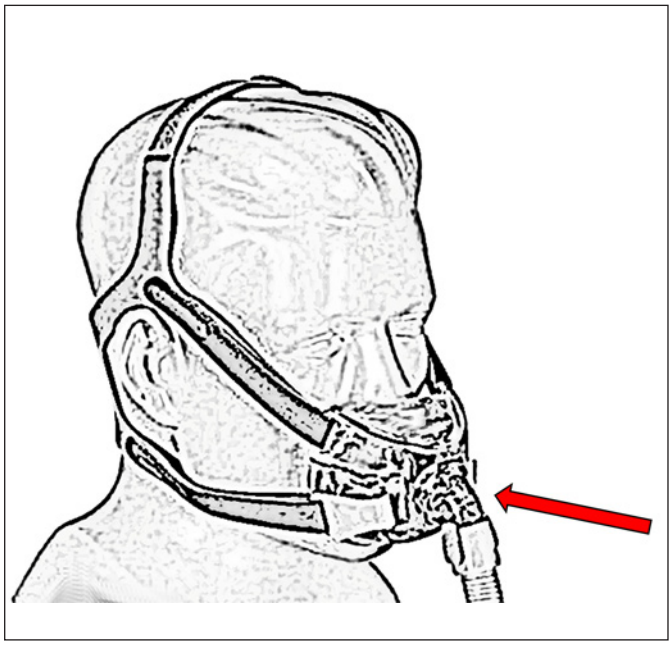


**Fig. 7.** Hybrid vented oronasal mask. The arrow indicates the intentional leak port.

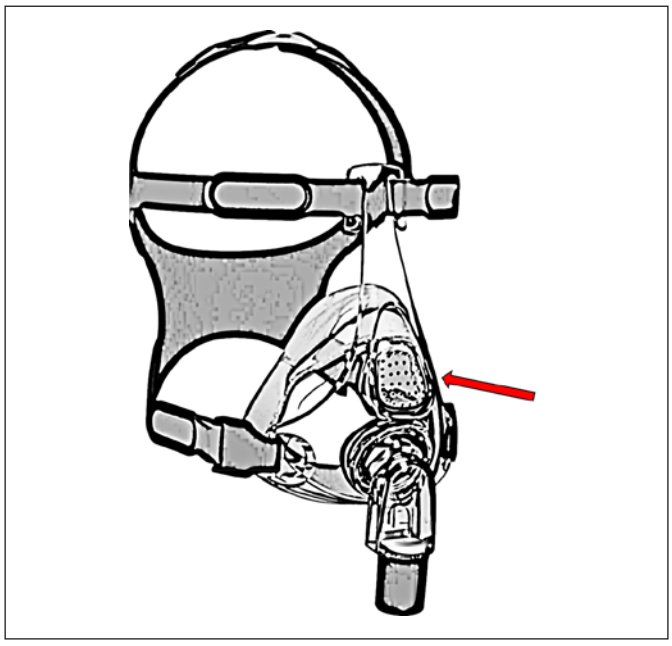


**Fig. 8.** Vented oronasal mask. The arrow indicates the intentional leak port.

nose, oral breathing, and surgery of the soft palate. A "rotational strategy" based on the alternative use of oronasal and nasal mask may be helpful to improve patient's tolerance to nPPV, minimize skin damage, and increase the hours of ventilation a day. Because it is generally well tolerated, patients with less severe ARF could use a nasal mask first switching to the oral one as a second choice [37, 93].

Recently, a nasal mask covering a minimal surface around the outer wall of the nostrils has been developed. As nasal pillows (Fig. 6), they apply a minimal pressure externally to the nostril, skip the nasal bridge and eliminate the occurrence of claustrophobia and skin breakdown. Even though there are also some "vented" paediatric nasal mask, the "scenario" of the available masks for children is still very scanty [63, 94–99].

Internal nostril masks, often called nasal plugs or nasal pillows were provided by few manufacturers until few years ago. More recently, the availability of these nasal interfaces has been increased in the market. They consist of soft plastic plugs inserted into the nostrils. The pressure applied during inspiration allows to almost seal the wall of the pillows against the inner surface of the nasal vestibule. Nasal pillows are held in place with specifically designed headgears. The nasal pillows can be as effective as oronasal masks in improving gas exchange but are usually less tolerated than full nasal masks. In comparison with the latter interface, nasal pillows have the advantage of "skipping" the nasal bridge. As a matter of the fact, they can be used to let the skin heal from the damage induced by prolonged nasal or face mask ventilation [33, 53].

*Oronasal and Total-Face Masks*

As compared to nasal masks, these interfaces give the potential advantage of generating less air leaks and of maintaining more stable mean airway pressure. In addition, in the acute setting less patient's cooperation is required from the patients. For these reasons, both oronasal and full-face masks (Fig. 7–12) are preferred to nasal interfaces during the acute phase of respiratory failure, when the patients are intensively dyspnoeic and, generally, opened-mouth breathers. However, they are also used in the home care setting in case of air leaks from the mouth [33, 37, 53].

Contraindications for the use of the oronasal or full-face mask are tetraparetic patients with severe disability in arms movements, as well as vomiting or claustrophobia [37, 53]. The total-face mask that covers mouth, nose, and eyes was first designed by Criner et al. [34] who found that nPPV delivered via this new interface ensures a good subjective comfort and improves gas exchange in selected patients who were intolerant to more conventional masks.

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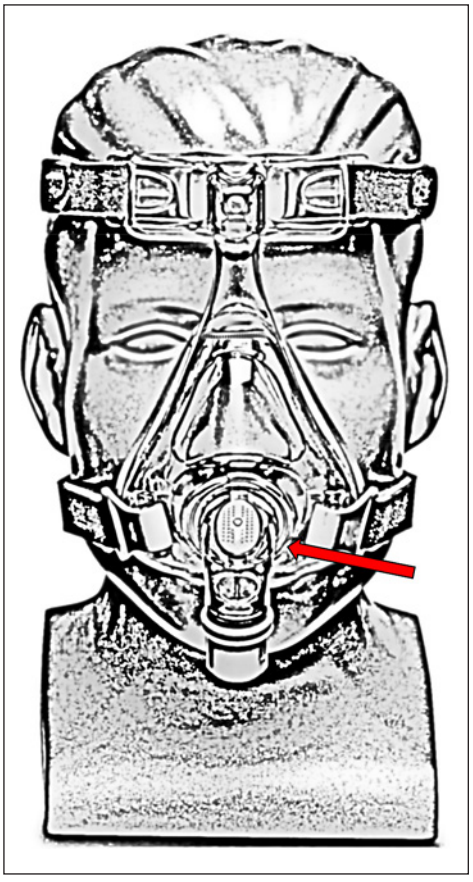

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**Fig. 9.** Vented oronasal mask. The arrow indicates the intentional leak port.
**Fig. 10.** Non-vented oronasal mask.

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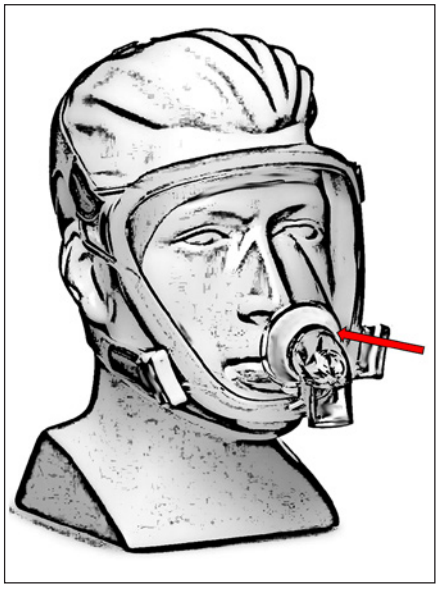

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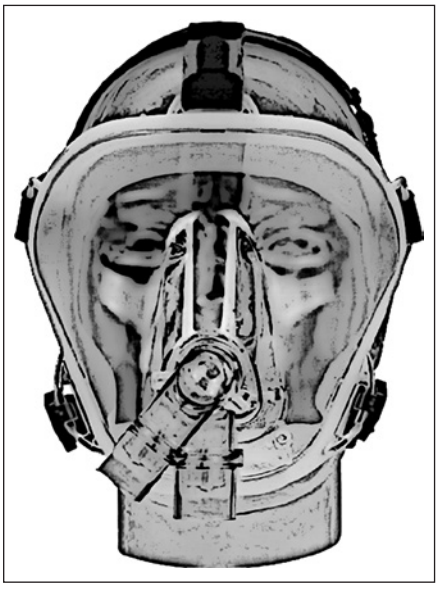

**Fig. 11.** Vented total-face mask. The arrow indicates the intentional leak port.
**Fig. 12.** Non-vented total-face mask with an inlet and an outlet port.

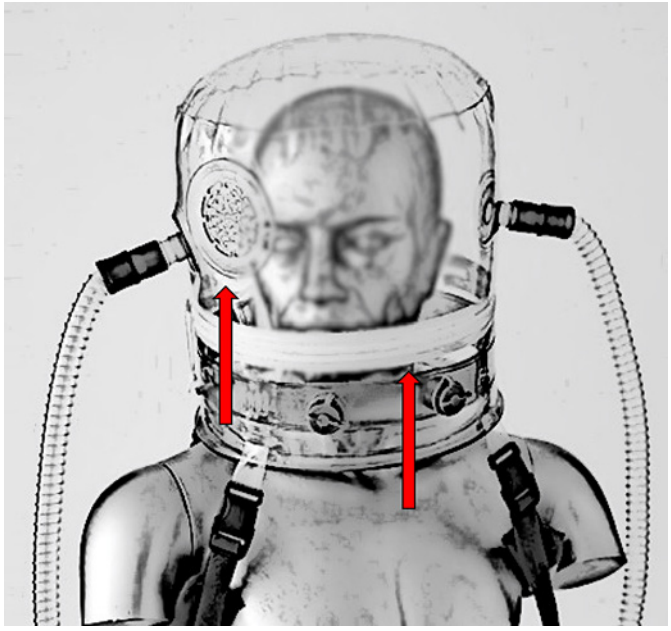

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**Fig. 13.** nPPV helmet with "zip" closure. The arrows indicate a safety (anti-suffocation) valve on the left and the zip closure on the right. nPPV, non-invasive pressure positive ventilation.

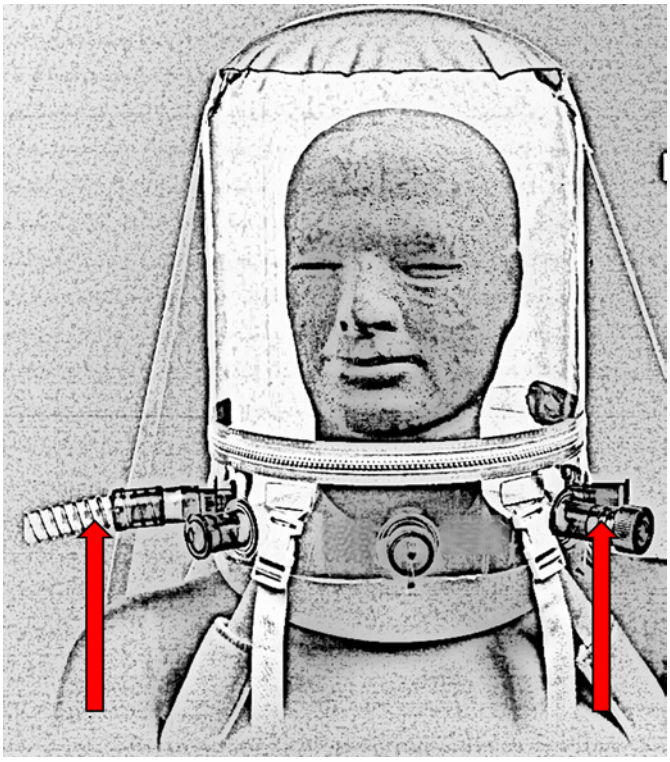

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**Fig. 14.** CPAP Helmet. The arrows indicate the inlet on the left and the mechanical PEEP valve on the right. PEEP, positive end-expiratory pressure.

Total-face mask is likely to be useful in patients with high skin susceptibility to pressure lesions needing long-term nPPV in the acute and home care setting. The application of the total-face mask whose pressure points are distributed on a larger surface all over patient's face may potentially reduce skin injuries. In patients with hypercapnic ARF, for whom escalation to intubation is deemed inappropriate, switching to a total-face mask can be proposed as a last resort therapy when face mask-delivered nPPV has already failed to reverse ARF. This strategy is particularly indicated in patients undergoing prolonged periods of continuous nPPV [100]. However, there is no clear evidence yet on the real advantage in terms of effectiveness and compliance of this interface as compared to other conventional oronasal masks as well as to nasal mask [101–104].

Both oronasal and total-face masks are associated with the risk of developing or worsening upper airways obstruction due to the backward jaw displacement. In turn, this drawback may lead to inefficient control of nocturnal hypoventilation, especially in patients with unrecognized OSA [105]. This side effect is likely to have detrimental effects also in the setting of chronic and ARF in patients at risk of unrecognized OSA (i.e., hypercapnic encephalopathy and anatomic conditions leading to upper airway narrowing).

Opposed to oronasal interfaces, nasal mask is more effective at maintaining open the upper airway in the retropalatal space within a wide range of applied CPAP. Accordingly, the use of oronasal mask is associated with higher CPAP level compared to a nasal mask use, particularly in patients on very high CPAP levels (≥15 cm $H_2O$) [106]. A combination of an oral and nasal pillow mask has also been introduced in the market (Fig. 7). This hybrid mask consists of a mouth non-inflatable cushion coupled with 2 nasal pillows or a small slot that includes just the nostrils. It has the advantage of skipping the nose, avoiding pressure points on the nasal bridge. Differently from nasal pillows, the hybrid mask is more efficient in terms of less leakage than the nasal pillows when high pressures are applied during nPPV.

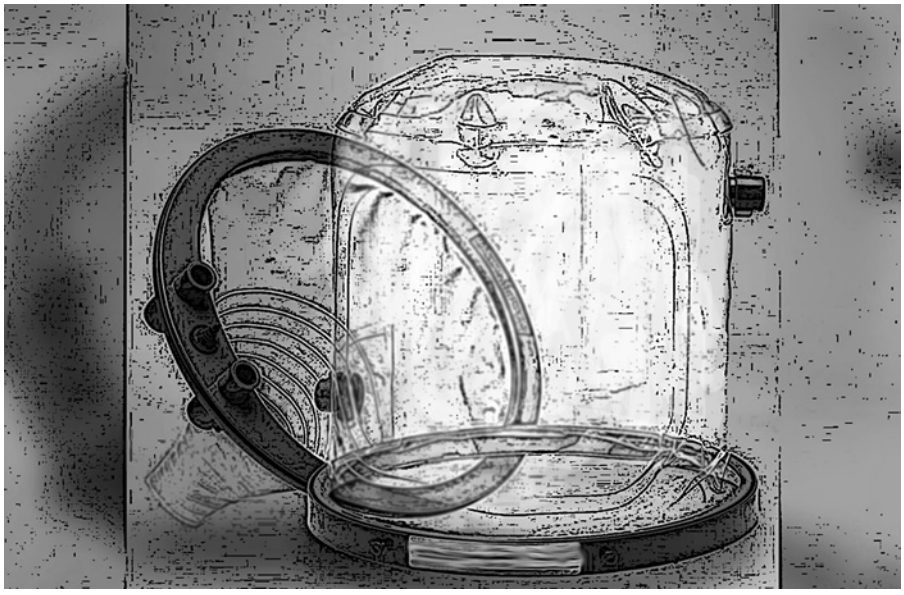

**Fig. 15.** CPAP helmet in its original components unassembled.

*Helmets*

With the aim of improving patient adherence to prolonged nPPV treatment and overcoming side effects, new interfaces have been introduced. The helmet (Fig. 13–16) is an interface that can increase comfort, reduce skin breakdown, minimize gastric distension, and eye irritation, with a higher increase of success rate during NIV compared to the face mask [107–110]. The helmet is a transparent latex-free polyvinyl chloride hood; in its standard configuration, it is joined by a rigid plastic ring to a soft collar and fixed by 2 padded armpits braces with 4 hooks (2 in the front and 2 in the back of the plastic ring).

However, the helmet also has specific drawbacks related to the high volume and compliance causing a greater dead space compared to the face mask [109]. Furthermore, the dissipation of inspiratory pressure to inflate the helmet may increase the delay between inspiratory effort and ventilator assistance causing patient's ventilator asynchrony and less efficient inspiratory muscle discharge compared to a face mask. Handling of the ventilator setting might be useful to minimize these drawbacks [111–116]. New neurally triggered modes have been demonstrated to improve patient's comfort and patient-ventilator synchrony during both helmet [117, 118] and mask nPPV [119] as compared to conventional pneumatically triggered modes of ventilation.

The armpit braces that hold the helmet in place can also cause discomfort to the patients and skin lesions that lead to nPPV intolerance and nPPV failure. The best suggested approach to anchor the helmet during CPAP is to apply the counterweights system in alternative to armpit straps; this choice minimizes the risks of pressure sores and pain during this treatment [120]. Helmet-induced noise levels could be also a potential cause of patient discomfort [121].

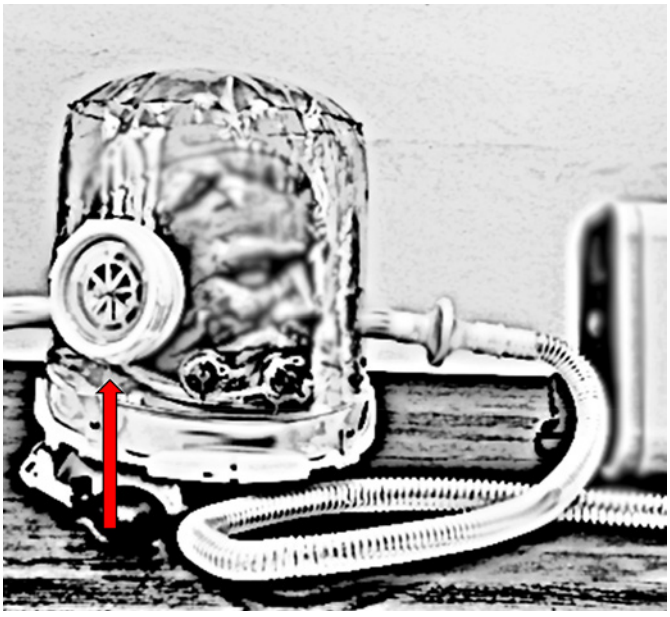

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**Fig. 16.** nPPV helmet without armpit braces. The arrow indicates the safety (anti-suffocation) valve. nPPV, non-invasive pressure positive ventilation.

Finally, helmet for its intrinsic mechanical properties did not allow so far to measure tidal volume. Recently, a new configuration of a turbine-driven ventilator with dedicated software allowed its measurement both in nCPAP and nPPV [122–124].

To reduce these side effects, a new helmet (Fig. 16) has been developed. An opening ring placed under an inflatable cushion secures the helmet without the need for the armpits brace. With the new helmet, the pressure swings are reduced to a large extent. A bench study that compared standard helmet vs new helmet suggested a better performance of the latter in terms of trigger performance, patient-ventilator synchrony, and pressurization speed [125]. Recently, a new device combining the helmet with the nasal high flow cannula has been described with the potential advantage to couple the helmet CPAP with the physiological benefits of high flow through nasal cannula (i.e., heated humification and nasopharyngeal dead space washout) [126, 127].

*Materials and Design*

There are masks manufactured from a single piece made by 1 or more materials. Most of the available masks consist of 2 or more parts: a cushion typically of soft material (like polyvinyl chloride, polypropylene, silicon, silicon elastomer, or hydrogel) which is in contact with patient's face and frame of stiff material (like polyvinyl chloride, polycarbonate, or thermoplastic). The 2 parts may be hooked together in the so-called "modular masks" or simply glued. Some mask package comes with different cushion sizes making the operator free to choose the best one which better fits with the patient's face contour or nose shape. In some masks, the face-seal cushion is replaceable, so the frame can be used longer and costs are reduced.

The cushion can be transparent non-inflatable, transparent inflatable, made of hydrogel, full foam, or silicon [37]. Silicon is a biocompatible material used in medical appliances and, in the majority of the cases, largely used to build the interfaces because true allergic reactions are extremely rare. In fact, skin irritation, pressure sores, and blisters are more commonly caused by other associated factors rather than the silicone material itself. Hydrogel masks may allow softer support and are an important alternative for those patients who are allergic to silicon.

Over the years, many companies developed new cushion designs to improve patient's comfort. Consequently, headgear needs only small adjustments to achieve the best fitting. New technologies allow mask cushion to be made by 2 silicon membrane. An inner one is contained in thinner outer membrane (so called dual wall technology) providing a possible greater seal in order to maximize patient's comfort. The mechanism of function is linked to the air coming from the ventilator blower. Air blows from the flow generator through the mask inflating the thin outer layer membrane of the mask cushion; as it inflates the membrane rests slightly against the patient's face. The inflated membrane adjusts itself during the patient's movement and remains in contact with the face, maintaining an effective seal. The main benefits of the dual wall technology are reduced pressure on the face, lowered risk of over-tightening the headgear, and decreased mask leaks. A mask seal which self-inflates around the nares in a "hover-like-way" has also been proposed for nasal pillows. As mentioned above, companies are also proposing "modular solutions" to create real "platform" with many different solutions on the same frame. Polycarbonate and polyamide polypropylene still remain the worldwide material used to manufacture the masks frame. Thermoplastic polyester elastomer is usually employed for the swivel connectors.

All manufacturers of medical devices are subject to strict regulation. One of the requirements in this regard is to demonstrate an appropriate level of biocompatibility for every material to which a patient is exposed. There are a number of innovations that the main companies manufacturing interfaces have delivered on the market of the mask portfolio over the past 15 years:

- Material innovations: liquid silicone rubber advancements (e.g., self-bonding formulations), gel advancements, and polycarbonate alternatives (e.g., nylons and polypropylene).
- Manufacturing innovations: some of the largest advancements in manufacturing technologies over the last decade have been in the efficiencies and accuracies of modern day equipment and processes: from the increased sensitivity of machining the tolerances of modern 3 and 5 axis computer numerical control milling machines to highly accurate hybrid and fully electric injection moulding machines. However, to paint a clearer picture of advances in mask design and manufacturing technologies, mention should also extend further back into the development process where tools now widely used were not economically or technically feasible before: over-moulding, multi-shot liquid silicon rubber, vertical moulding, rapid prototyping technologies (e.g., 3D printing). Where 3D scanners were once a thing of science fiction, they are now science fact. They are also now a common tool in a masks original equipment manufacturer (OEM) workshop. They

can be used as a development tool for scanning facial data of patients or digitizing preliminary prototypes for developing into a fully resolved and optimized breathing mask. Contextually, 3D printers have also developed rapidly in the last decade. However they are not yet largely utilized in manufacturing of high volume finished product. Most of the mask's manufacturing is still largely dominated by the injection moulding machines and processes which create a complex geometry of the components and ultra-thin silicone membranes. Manufacturing this type of product demands a high level of accuracy in terms of machining tolerances in the creation of injection moulding tools. This extends to a high level of sensitivity in the processing parameters of liquid injection moulding (LIM) and the associated dosing units. Without this high level of control, modern breathing masks could simply either not be created or would result in unacceptable and/or uneconomic defect rates. In the last years, some company have been able to design and consistently manufacture product with complex silicone seals as thin as 120 micron. This results in soft, compliant, and exceptionally comfortable masks for the patient. This is testament to the ability of manufacturing equipment to build products with such tight tolerances. In order to control and monitor these types of tolerances and specifications, measurement technology has also developed to a point where it is able to be used to rapidly provide accurate critical dimensional data. Other advancements of mention include automation and vision systems, which are capable of detecting variances in product from predetermined specifications, allowing greater and more consistent control of product and processes. So, from robotic de-moulding to automated testing, all these developments in the manufacturing of masks are in place to ensure that the product that reaches the end user is safe and of the utmost quality.

- Design innovations: modular designs, masks with no forehead arms, pillows masks, weight and noise reduction, improve ease of use, and aesthetics. Concerning this issue, masks are now also designed to wear glasses, while patients are doing their nPPV therapy and improve acceptance of the masks thanks to its aesthetic. Some company now offer the possibility to have the same model reusable or disposable. Disposable means a single-patient mask, which is especially developed for single-patient use in hospital environments custom-made masks may be composed of a thermoformable plastic frame [50] with an interior coverage of either self-sticking foam or a protection and comfort gel [49, 50]. The masks are usually modelled on plaster phantoms corresponding to the age and the physiognomy of the patient [128]. Custom mask can be then adjusted by thermoforming the plastic frame to obtain the best comfort with minimal leaks [49]. Finally, a plastic tube (usually of an inner diameter 22 mm) is glued onto the mask by an auto-polymerizable resin and then connected to the ventilator. According to the single circuit configuration (vented vs. non-vented) of the ventilator, the mask can be provided with a "vented system or with an "expiratory valve." Differently, it can be connected to a double respiratory circuit with those ventilators which are provided by an inspiratory line separately from the expiratory line. Custom-made masks are usually kept in place by means of an industrial headgear or a custom-made gear [49, 50].

### Headgear and Accessories

An "ideal" securing system should be stable (to avoid interface movements or dislocation), easy to put on or remove, non-traumatic, light and soft, made of breathable material, and available in various sizes. It should also be re-washable, for home care or disposable, for hospital use [34].

Commercially, headgears are made by materials that may be different among the manufacturers. The materials can be a foam layer made of polyurethane and Nylon/Lycra. Some headgears are made by more different materials as elastomer layer (polyurethane loop material), Nylon/Lycra underside fabric (Nylon/Lycra Fastener Tabs), Polyamide Cloth Label (Rayon acetate satin). Some companies have headgears consisting of a 3 layers breathable and elastic composite; a polyurethane foam layer is built in between 2 different Nylon and Lycra fabrics. One side (the outer and fluffier side) has an un-broken loop (UBL) knit fabric, or UBL loops, so that the Velcro hook tabs can attach to it, and the other side has a silky smooth finish as it rests on the patients skin. For *her version*, some companies provide cushions with headgear size and colour code for the increase number of women receiving nPPV therapy. To improve stability, some masks have been equipped with an innovative non-slip headgear and are available with either a fabric soft frame or with a gel frame. Some headgears are labelled as "active" because a connector moves when the patient changes his/her position to help in keeping a good mask seal throughout the night.

All the head straps equipping home care oronasal or total full-face mask have a quick-release headgear feature

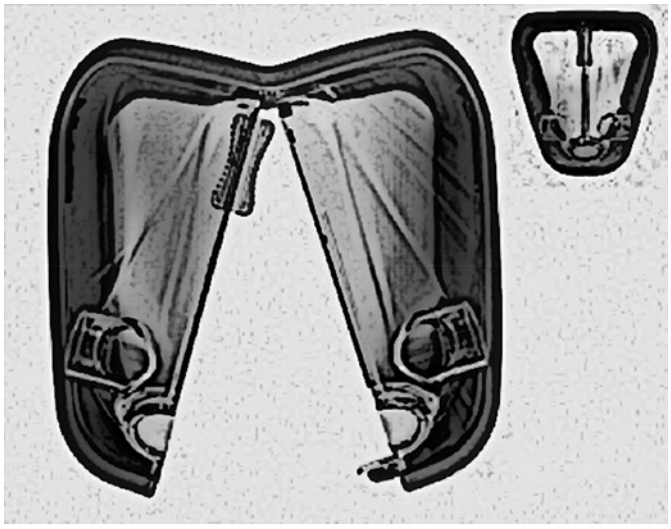

**Fig. 17.** Full-face mask for endoscopic procedures.

allowing the patient to slides off it with 1 hand. Chin restraint straps made by Nylon/Lycra and polyurethane foam have been proposed to reduce air leaks. In addition, to reduce pressure sores and skin breakdown some nasal pads made by thermoplastic polyester elastomer – oil-filled material have been proposed too.

An anti-asphyxia valve is always positioned in all oronasal and total full-face "vented mask" usually in the swivel connector. This valve automatically opens to prevent rebreathing in the case of pressure failure or when the airway pressure falls below a given value (e.g., 3 cm $H_2O$) [37].

As mentioned above, home care mouth-piece ventilation is recommended on the condition that patients are equipped with a dedicated self-supporting harness. Finally, due to the integrated applications of diagnostic and therapeutic bronchoscopy during nPPV [129, 130], after the initial experiences based on personal re-arrangements of the interface (i.e., holes in the mask or in the mouth-catheter connected to the mask), some manufacturing companies have produced specific adaptors that may be connected to the mask to allow the passage of the bronchoscope, while others have designed a large hole directly in the mask. Efforts have been made in the study of interface design re-arrangements to allow also interventional procedures by means of upper digestive endoscopy. A new type of full-face mask is projected to be used in endoscopic procedures both for elective ventilation and for emergencies. This is theoretically possible because this new interface is made of 2 symmetrical parts that can be joined even after the insertion of the endoscopic probe (Fig. 17) [131, 132].

As the amount of leaks throughout the large port seems to be not irrelevant during the endoscopic procedure, a ventilator with good air leak compensation is required, and the supportive ventilation should be limited to the interventional manoeuvres (e.g., percutaneous endoscopic gastrostomy for patients with motoneuron diseases) [130–132]. Recently, a new gastric feeding tube adaptor applied to an oronasal nPPV mask in patients with 1 or 2 naso-enteral tubes improved patient comfort and significantly decreased the air leakage volume as compared to conventional interfaces [133].

### Dead Space, Interface Volume, and "Vented and Non-Vented Mask"

In normal human beings, alveolar ventilation decreases as dynamic $V_D$ increases. During nPPV dynamic $V_D$ can be the sum of the physiologic $V_D$ plus the apparatus $V_D$. The physiologic $V_D$ depends on $V_T$, whereas the apparatus $V_D$ should depend on the inner volume of the interface. Navalesi et al. [31] by measuring the differences in mask $V_D$ between a nasal mask and a full-face mask found that although the in vitro difference was significantly different (full-face mask 205 mL vs. nasal mask 120 mL), the in vivo results (which took into account anatomical structures) were similar (full-face mask 118 mL vs. nasal mask 97 mL). Interestingly, nasal pillows were found to add very little $V_D$ and reduced $PaCO_2$, while increasing pH as well as the oronasal mask. However, Fodil et al. [134] in a very elegant study postulated that due to the streaming effects of the gas passing throughout the interface, the effective $V_D$ interface could be quite different from the volume delimited by the interface and the part of the anatomical structures embedded in this interface (called interface gas region). To test this assumption, they used numerical simulations with computational fluid dynamics (CFD) software to describe pressure, flow and gas composition in 4 types of interfaces regularly used to deliver nPPV. CFD has the advantage of allowing this set of interfaces to be tested under strictly identical conditions. They found that effective dead space is not related to the internal gas volume included in the interface, suggesting that this internal volume should not be considered as a limiting factor for their efficacy during nPPV. The effective $V_D$, which was never higher than the interface gas volume, can be much smaller due to the streaming effect presently calculated by CFD. For all the

interfaces the effective dead space was under 370 mL for a tidal volume of 750 mL. Importantly, their results also showed that with a tidal volume of 750 mL, the less voluminous mask clearly remains the most favourable in terms of rebreathing because the $V_D$ is reduced by a factor of 3.4 when compared to the $V_D$ of the most voluminous masks. Nevertheless, this beneficial effect decreases quasi-linearly as tidal volume decreases. For example, with a tidal volume of 400 mL, the previous factor is as low as 1.8. The authors concluded that the choice of interface based only on the effective $V_D$ is probably questionable. Factors such as patient's comfort, tolerance and air leaks should also be taken into account during the decision-making process.

A larger anatomical dead space of total-face mask may potentially interfere with nPPV efficacy and patient-ventilator interaction [37]. However, some studies have shown that a larger inner volume of the mask does not impact on clinical efficacy and does not require ventilatory setting modifications [74, 99]. The use of a total-face mask that shares the same connector for the inflow and outflow [135] may increase dead space.

A new total full-face mask is designed, aiming to reduce rebreathing with 2 different ports, 1 for the inflow fresh gas and 1 for the outflow exhaled gas (Fig. 13). In the bench study of Signori et al. [136] the rebreathing can be mitigated by a full-face mask design with separate ports for inflow and outflow. This design is effective if the ventilator delivers a sufficient amount of bias flow (continuous flow circulating between the inspiratory and expiratory limbs of the respiratory circuit), independently of the inspiratory demand of the patient. Nonetheless, in most ventilators that use a double-limb circuit to deliver nPPV, bias flow can be increased only by modifying trigger flow sensitivity [136, 137].

Therefore, low inspiratory trigger sensitivity would allow a better $CO_2$ washout. When leaks decrease, the patient's inspiratory effort might become insufficient to trigger the inspiratory phase, which results in missed inspiratory efforts and poor patient-ventilator interaction. This is a highly relevant issue because, to the best of our knowledge, only one double-limb ventilator allows the bias flow to be set independent of the inspiratory flow trigger setting [137].

In "vented masks," the exhalation system is composed by holes/slots inside the mask or in the swivel connector at the proximal part of the mask to avoid the $CO_2$ rebreathing [31, 53, 64, 138]. While at the beginning the "vent system" was just a 4-mm hole or multiple slots, it now consists in sophisticated technology allowing less noise and patient's comfort. A company manufactures a circular diffuse "vent system" featuring 60 individual holes, all aimed at different angles, which quietly disperse airflow with far less velocity. The potential advantages of this new "vent system" is significantly less bed partner disturbance and subjective vent noise and direction preference.

In "vented" masks, different ventilator settings may influence dynamic $V_D$. Saatci et al. [139] found that a face mask significantly increased dynamic $V_D$ during unsupported breathing. The addition of positive end-expiratory pressure lowered dynamic $V_D$ nearly to physiologic $V_D$. On the contrary, nPPV delivered in pressure support mode without positive end-expiratory pressure reduced dynamic $V_D$ to less extent, which left dynamic $V_D$ higher than physiologic $V_D$[129]. Always in "vented masks," other studies confirmed the importance of the site of the exhalation ports on $CO_2$ rebreathing. $CO_2$ clearance was better with the exhalation port built into the mask [140]. As a matter of the fact, in the last 10 years, the position of the "vent system" featuring ventilators working with intentional leak circuit [64] during nPPV switched from the distal part of the respiratory circuit to either the body mask or to the swivel connector.

Furthermore, the choice of an intentional leaks circuit with a "vented mask" avoids the risk of under-assistance of patients receiving NIV in a pressure-controlled volume-target mode [141] in the presence of unintentional leaks. Helmet use entails different rebreathing problem related to its internal dead space. Compared to the face mask, the helmet, due to its larger internal volume as a semi-closed environment, could facilitate carbon dioxide ($CO_2$) rebreathing. Inspired partial pressure of $CO_2$ in a helmet depends on the amount of $CO_2$ produced by the subject(s) and the flow of fresh gas that flushes the environment (helmet ventilation). Approximately, helmet ventilation may require doubling the minute ventilation to maintain an end-tidal $PCO_2$ value similar to that with mask ventilation [142, 143].

Thus, the volume of the helmet does not directly affect the inspired partial pressure of $CO_2$, but only the rate at which the predicted inspired partial pressure of $CO_2$ is reached [141]. In addition, reducing the size of the helmet did not necessarily prevent $CO_2$ rebreathing. Anything that increases helmet ventilation (i.e., air leak and delivery of fresh gas) may decrease the inspired partial pressure of $CO_2$. An anti-suffocation valve, a safety valve that allows air to enter into the helmet during any interruption of gas flow, may limit $CO_2$ rebreathing [144–146].

During either nCPAP or nPPV, a helmet affects $CO_2$ clearance. High gas flow (45–60 L/min) is required to maintain a low inspired partial pressure of $CO_2$ ($PiCO_2$) during helmet CPAP [136]. In contrast, when CPAP is delivered, a double-limb circuit with an ICU high pressure gas driven ventilator, Taccone et al. [147] found considerable $CO_2$ rebreathing. Therefore, a critical care ventilator with a double-limb circuit should not be used to deliver helmet CPAP. Racca et al. [142] have shown that is possible to improve $CO_2$ washout, reducing $PiCO_2$ and $PetCO_2$ during both CPAP and PSV delivered by helmet by using a turbine-driven ventilator with an intentional leak "vented" circuit whose intentional leak is placed at the helmet expiratory port [124–126, 142].

## Conclusions

The choice of the interface is crucial for the success of nPPV in both the acute and chronic setting. Type (oral, nasal, nasal pillows, oronasal, hybrid mask, and helmet), size, design, material and headgears may affect the patient's comfort with respect to many aspects, such as air leaks, claustrophobia, skin erythema, eye irritation, skin breakdown, and facial deformity in children. Masks are also often the most important component of a home care CPAP therapy, and therefore, they are often responsible either for the good success or the failure of the therapy. Therefore, companies are paying great attention to mask development, in terms of shape, materials, comfort, and leaks reduction. Lightest and smart weight masks may help patients to stay on therapy. Masks with less components (elbow, swivel, forehead support, etc.) help patients to clean and reassemble the product in a more easy and intuitive way. However, although the continuous development of new products has increased the availability of interfaces and the chance to meet different requirements, in patients necessitating several daily hours of nPPV, both in acute and in chronic home setting, the rotational use of different interfaces may remain an excellent strategy to decrease the risk of skin breakdown and to improve patient's tolerance.

## Conflict of Interest Statement

R.S. declares no conflicts of interest. G.A. declares a patent pending, in association with the University of Palermo, Italy (No. 102019000020532; Italian Ministry of Economic Development), related to a configuration for CPAP delivering. M.I. declares no conflicts of interest. A.C. declares a patent pending, in association with the University of Palermo, Italy (No. 102019000020532; Italian Ministry of Economic Development), related to a configuration for CPAP delivering. P.I., F.V., and L.G. declare no conflicts of interest. C.G. declares a patent pending, in association with the University of Palermo, Italy (No. 102019000020532; Italian Ministry of Economic Development), and received payments by Philips for consultancies in the developing process of the EVO Ventilator and fees for lectures or consultancies from Resmed, Vivisol, and Air Liquide.

## Author Contributions

R.S. and C.G. designed and wrote the body of the article. M.I. reproduced the interfaces in the figures. G.A., A.C., P.I., F.V., and L.G. contributed to search the references from the literature.

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