

IN IMMOBILIZATION SYSTEMS FOR RADIATION ONCOLOGY

UNDERSTANDING THE BENEFITS **OF NANOR®**

The right balance between stability and comfort









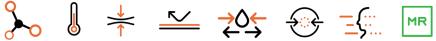
















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Thermoplastic masks are one of the most common immobilization devices used for head and neck radiation therapy, varying in thickness, material composition and perforation pattern.

'In general we can state that the higher the shrinkage of a mask, the lower the comfort for the patient.'

Comfort is of a big concern for both the patients and the radiation therapists. A patient who does not feel comfortable when immobilized, may move more. To solve this comfort issue, a higher modulus material, such as nano composite, can be used for an immobilization mask (Bogdan, Borghs, Jordaens, 2016). It offers a solution to the challenge of finding the right balance between stability and comfort.

HARNESS THE POWER OF THE NANOTECHNOLOGY



Nanotechnology is the science and engineering carried out on nanometre scale. It is difficult to imagine how small nanoscale really is (United States National Nanotechnology Initiative, n.d.). A human hair is approximately 80,000-100,000 nanometres wide and one nanometre is about as long as your fingernail grows in one second.

Things behave differently when you go "nano-small". The properties of materials are different at nanoscale because nanomaterials have a relatively large surface area when compared to the same mass of material produced in a larger form. This can make materials more reactive and affect their strength (United States National Nanotechnology Initiative, n.d.).

At Orfit, we discovered that nanotechnology can make a difference in the field of patient immobilization for radiation therapy.

A traditional thermoplastic mask is formed by a polymer matrix that shrinks once it has been cooled down to room temperature. A polymer matrix reinforced with nanoparticles forms a cluster network when exposed to room temperature and keeps the material more stable. It results in a mask with less shrinkage and hence less pressure on the patient's face.

Blending the small nanoparticles into our thermoplastic mask material, also establishes an ultra-rigid internal structure which allows us to create a very strong mask with a thickness of only 1.6 mm.

STABILITY, REPRODUCIBILITY AND PRECISION

Efficast and Nanor are the commercial names used for two different immobilization masks that are manufactured by Orfit. Efficast thermoplastic material is based on a low melting temperature polyester, ϵ -PCL. Nanor is based on the same polyester, but reinforced with exfoliated nano clay.

Nanor, the nano reinforced material, is characterized by a 100% increase of flexural modulus, which is the tendency for a material to resist bending. In radiation oncology the additional gain in flexural modulus of a mask improves the stability and reproducibility of patient immobilization.

The above has been investigated by Instituut Verbeeten, one of the largest Radiation Oncology Centres in The Netherlands. A team of physicists and radiation therapists compared the stability of Nanor masks to Efficast masks. It was concluded that Nanor masks show less intrafaction movement and as a result allow a 0.5 mm reduction in the margin¹ (from 1.5 mm to 1 mm).

Intrafraction motion stability mask¹

Type of Mask	Vrt margin (mm)	Lng margin (mm)	Lat margin (mm)
Nanor mask (1.6mm)	1.08	1.03	1.10
Efficast mask with micro perforation (1.6 mm)	1.43	1.30	1.17
Efficast mask with maxi perforation (2 mm)	1.62	1.10	1.54

Fig 1. Intrafraction motion stability mask (Instituut Verbeeten, 2018)

The stability and reproducibility of patient set-up in radiation oncology is extremely important for precise cancer treatment. Targeting the tumour and preventing damage of surrounding healthy tissue requires patient positioning and immobilization that provides (sub-) mm accuracy.

Thinner masks, like a Nanor mask, are easier to thermoform and follow the contours of the human face better than thicker masks. This was confirmed by therapists from Instituut Verbeeten (Tilburg, The Netherlands) who like the way the Nanor mask moulds and how it can be refitted on a daily basis.

The nano reinforced material is also extremely useful when radiation therapy is used in combination with medication that causes facial swelling. Nanor masks compensate the issues associated with a change in volume. This makes remoulding the mask and rescanning the patient during treatment less likely.

¹ Margin based on Van Herk formula.

MASK SHRINKAGE

After initial moulding, mask shrinkage is typical due to material crystallisation (Dovell, Bhutto, Doerwald-Munoz, Ostapiak, & Sawesky, 2014). Crystallisation is the physical transformation of the arrangement of the molecules. When heated, the molecules can move separately from one another. Once the material starts to cool down the molecules start to gather into clusters in a defined manner. These clusters (polymer crystalline structures) become stable at room temperature and thus form a rigid structured material.

Shrinkage is caused by (1) a decrease in volume of the material due to thermal contraction and polymer crystallisation and (2) the contraction of oriented/stretched polymer chains during relaxation at room temperature (Bogdan, Borghs, Jordaens, 2016).

A traditional mask is formed by a polymer matrix that shrinks once it is exposed to room temperatures. A polymer matrix reinforced with nanoparticles forms a cluster network when exposed to room temperatures and keeps the material more stable, which results in a mask with less shrinkage. A 1.6 mm Nanor mask shows about 40% less shrinkage than a conventional mask.

Figure 2 shows the shrinkage force for Efficast and Nanor after activation at storage at room temperature.

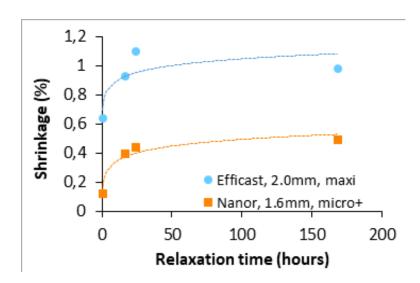


Fig 2. Percentage of shrinkage in time of samples in relaxed position after stretching to 70% at 65°C and cooled down in a fixed position to 21°C.

PATIENT COMFORT

The bending modulus of Nanor sheets is about 1GPa, which is two times higher than the bending modulus of Efficast sheets. The higher modulus of Nanor allows to reduce the thickness of the immobilization masks to 1.2 and 1.6 mm instead of 2.0 and 3.2 mm of Efficast, while keeping the same mechanical properties of the immobilization mask (Bogdan, Borghs, Jordaens, 2016). In other words, a 100% increase of Flexural modulus of Nanor material, allows the thickness of the sheets to be reduced by about 50%.

Patients at Instituut Verbeeten who suffered from facial swelling felt more comfortable under a Nanor mask than under a conventional Efficast mask.

A patient needs to endure the pressure of the mask and forced positioning with a mask during simulation and every day of treatment. This alone is reason enough to make one element of a stressful treatment more pleasant with a mask that is thinner, smoother and more comfortable overall. This degree of comfort will prevent patient movement, caused by being uneasy, within acceptable limits during the delivery of the dose (Bogdan, Borghs, Jordaens, 2016).

The importance of mask material

Fragment from "A focus group consultation round exploring patient experiences of comfort during radiotherapy for head and neck cancer" (Goldsworthy, Tuke, Latour, 2016).

The participants were then asked by the moderator to imagine that anything is possible. Would you replace your mask with anything? All participants engaged in this discussion. F1 suggested 'A softer mask, a softer material. There must be something out of a space program that's rigid but softer. A softer feel than hard plastic.'

Testimonial

The excellent material acceptance by our patients is one of the reasons why we opted for the Nanor immobilization masks for clinical use. The material feels smooth on the skin, is easily mouldable and can be perfectly shaped on the face of the patient. The newest Orfit material is shrink-free, adds to patient comfort and is just as stable as other thermoplastic masks".

Staff member of the Radiation Therapy Centre of the Saint Martin's Hospital in Frankfurt am Main (Germany)

Testimonial

After testing the Orfit Nanor masks for a year we could conclude that it has an improved stability compared to Efficast masks (0.5mm margin reduction). The patient comfort is very good, especially for patients that experience facial swelling due to medication. The radiation therapists liked the way the mask moulds and how it fits on the patient on a daily basis.

Marion Essers, Clinical Physicist at Instituut Verbeeten Tilburg (The Netherlands)

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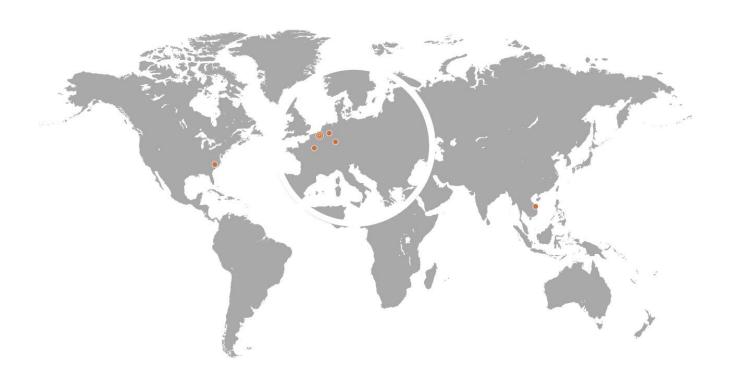
DISCLAIMER

This publication is based on the study of Bogdan, B., Borghs, K., & Jordaens, I. (2016). Precision, stability and comfort of patient immobilization in radiation oncology: immobilization devices base on nanotechnology. The study investigates the stability and precision of patient immobilization and estimates the comfort of a person when positioned on a head and neck immobilization device with a mask made with a new low melting thermoplastic nano composite material. The publication is meant to help readers understand the effects of a nano reinforced patient immobilization mask. It is not intended to exclude any particular patient immobilization approach. Any such approach should be determined by a qualified medical professional.

ABOUT ORFIT

Orfit Industries, a Belgium-based company, uses innovative technologies and polymers to develop and produce the most precise and reliable thermoplastic materials for medical devices that improve patient treatment around the world. The Orfit team provides systems for cancer patients in Radiation Oncology, orthotic fabrication materials for patients in Physical Rehabilitation and Prosthetic socket materials for amputee patients.

Orfit products are used in 105 countries worldwide and the company invests 15% of its annual revenue into R&D. Orfit has about 90 team members based in Belgium, the USA, Germany, France, the Netherlands and Hong Kong.





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