



High Precision Immobilization Put to the test



The
precision
expert



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INTRODUCTION

Today's imaging and target localization possibilities in radiation oncology allow you to see how your treatment plan corresponds with the location of the tumour. Based on these techniques, corrections can be made to spare healthy tissue. These innovative techniques can only be efficient if you are sure that your patient is immobilized during the delivery of the fraction.

Patient Immobilization Systems are an active component in achieving a high quality radiation therapy.

At Orfit, we use a combination of **thermoplastic materials with unique features, innovative 3D Shaped Head Supports** and **L-shaped** profiles that fix the mask in the **High Precision Hardware**. This combination offers the possibility of choosing the most suitable mask for your patient and for the type of treatment that is planned.

Various published studies show that the Orfit High Precision (HP) system ensures excellent **precision, reproducibility** and **patient comfort**. This white paper is a summary of the results of 3 different studies.



MATERIALS

Three components of the Orfit High Precision (HP) System are critical for achieving a high quality radiation therapy:

- Thermoplastic Masks
- 3D Shaped Head Supports
- L-shaped Profile

Thermoplastic masks

An extensive range of Orfit masks is available to meet specific patient requirements and your immobilization preferences:

Single layer masks

Available in Efficast and *Nanor*,
1,6 and 2 mm thickness.

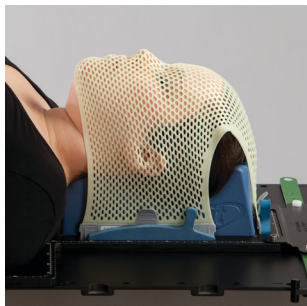
Hybrid masks

Reinforced mask for ultra-high precision.

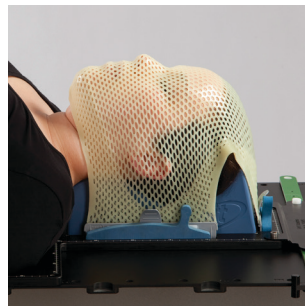
Open face masks

For patients who suffer from claustrophobia.

For treatments where a motion management system is used to track patient movement.



Single layer masks



Hybrid masks



Open face masks

Find the right mask for each patient with the **Mask Finder**. The diagram will lead you through various questions and at the end of the decision tree you will find the correct mask model for a specific patient.

3D Shaped Head Supports.

The shape of the Orfit **Head supports** helps to comfortably cradle the patient's head while the cranial stop allows a correct and reproducible position within the head support. The head supports are combined with Orfit blocks and wedges to allow high precision positioning.

Sometimes it is difficult to find the right combination of head support and a block or wedge to fully support the head and neck of the patient due to the anatomy of the patient. For those patients an individual head support such as a **small vacuum bag** or **Thermofit** in combination with an Orfit head support can offer a good solution.



Head support



Vacuum bag



Thermofit

Find the right Head support for each patient with the **Head Support Finder**. The diagram will lead you through various questions and at the end of the decision tree you will find the correct head support combination for a specific patient.

L-shaped profile

The **L-shaped profile** provides a secure and safe technology to fix the mask to the Orfit HP baseplates.



PRECISION, REPRODUCIBILITY AND PATIENT COMFORT

Thanks to a unique combination of advanced materials and innovative production methods, our HP-system achieves three critical goals for improving the quality of radiation therapy treatment:

Precision/Accuracy - Limit patient movement

- Overall mask stability limits patient displacement to less than 2 mm within the mask and approximately 1 mm when using Hybrid masks.*
- Low-stretch draping provides greater contouring and rigidity, preventing chin drop and shoulder rotation.
- L-profile technology secures more of the mask to the base plate.

Reproducibility - Reduce daily shifts

- Head Supports with cranial back stop that cradle the patient's head.
- Well-defined and indexable thermoplastic masks ensure consistent daily positioning.
- Openings at the cranial end of the mask provide space for patients with long hair.

Patient Comfort - Increase acceptance

- Antibacterial non-stick coating with soft surface feel.
- Comfortable foam head supports.
- Thermoplastic material with engineered limited shrinkage.
- Memory effect which allows the user to remould a mask when the patient's volume has changed.
- Low activation temperature of 65°-70°C (149°F-158°F).
- Quick release system allows for fast and safe removal of the mask from the patient.

METHOD

Study 1 and 2 , including Single layer masks and Hybrid masks, are based on the same research method. Therefore a comparison between both studies is possible.

Study 3 is based on open face masks. The studies used for comparison are referenced in this publication.

Verification definitions¹

Inter-fraction verification compares the set-up accuracy between different treatment fractions.

For the treatment it is important that the patient is positioned on a daily basis in a “**reproducible position**” and that there are no large translational and rotational deviations.

In modern radiation oncology translational deviations can be corrected thanks to imaging, such as Cone Beam CT. Rotational deviations can be corrected with a 6D table. The latter is an expensive option and is not always required (depends on which margins and treatment techniques are used).

Orfit 3D shaped head supports that cradle the patient’s head in combination with well-defined and indexable thermoplastic masks ensure consistent daily positioning.

Intra-fraction verification compares the set-up accuracy during a single treatment fraction.

Throughout everyday treatment it is important that patient displacement is limited during the treatment itself. Thermoplastic masks with a high stability assure a **precise** and **accurate** treatment.

Orfit thermoplastic masks provide high stability and close contouring around the face, so that it forms a rigid structure, preventing chin drop and shoulder rotation.

Set-up error definitions¹

Systematic error (Σ)

The systematic component of any error is a deviation that occurs in the same direction and is of a similar magnitude for each fraction throughout the treatment course.

The systematic error for a group of patients is an indication of the spread of individual mean errors.

Random error (σ)

The random component of any error is a deviation that can vary in direction and magnitude for each delivered treatment fraction.

The random error for a group of patients is calculated as the mean of the individual random errors.

STUDY 1

INSTITUUT VERBEETEN TILBURG, THE NETHERLANDS²

Research topics

Precision and patient comfort.

Materials

Orfit Single layer masks comparison.

1. Orfit 3D Head support MD
Blocks and wedges
Orfit HP Efficast micro perforation 1.6 mm
2. Orfit 3D Head support MD
Blocks and wedges
Orfit HP Efficast maxi perforation 2.0 mm
3. Orfit 3D Head support MD
Blocks and wedges
Orfit HP Nanor micro+ perforation 1.6 mm

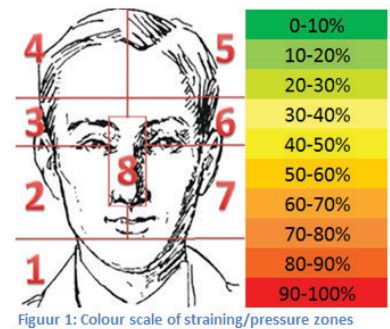
Intra-fraction results

type x	Translation (mm)						Rotation (°)					
	X (lat)		Y (Lng)		Z (Vrt)		Pitch		Rtn		Roll	
	Σ	σ	Σ	σ	Σ	σ	Σ	σ	Σ	σ	Σ	σ
1	0.34	0.44	0.40	0.45	0.45	0.45	0.24	0.15	0.08	0.15	0.14	0.18
2	0.51	0.40	0.30	0.49	0.55	0.37	0.26	0.18	0.08	0.12	0.08	0.16
3	0.31	0.48	0.25	0.58	0.34	0.32	0.24	0.17	0.05	0.17	0.05	0.17

Comfort level

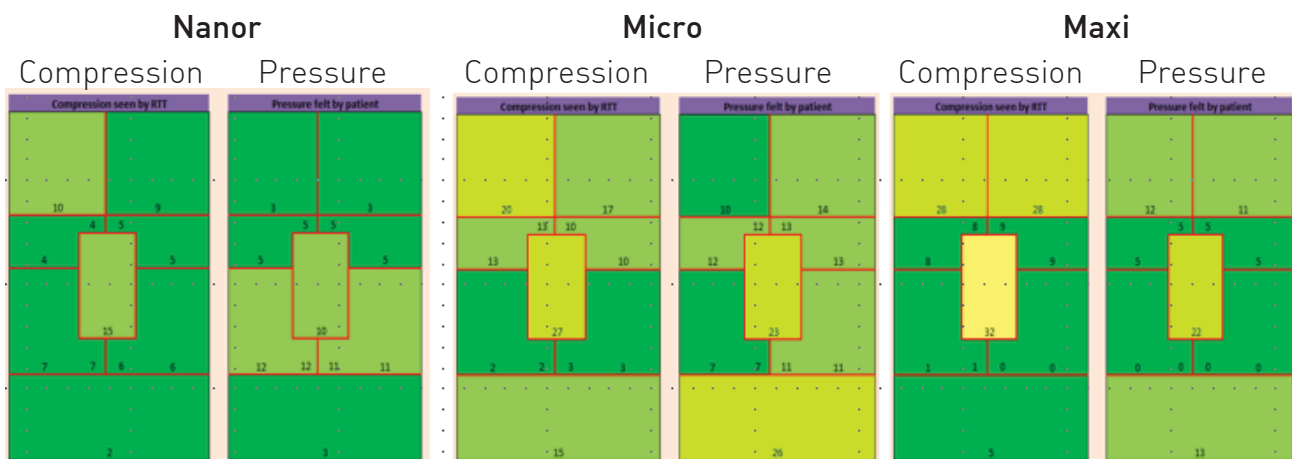
The comfort level in this study was measured with a scoring list:

- For each fraction:
 - Compression shown on face (visual for RTT)
 - Pressure felt by patient
- 0 = pressure in 0 fractions
- 50 = pressure in 50% of fractions
- 100 = pressure in 100% of fractions



Comfort level - Patients using dexamethasone

Patients with a brain tumour may suffer from a pressure increase in the brain causing discomfort. The drug dexamethasone provides a temporary effect of fluid expulsion around the tumour, in order to decrease the pressure. A common side effect is a swollen face. As a result, the mask feels tighter for the patient. So less pleasant.



Conclusion

- The stability of the “Orfit HP Nanor mask” is slightly better than the “Orfit HP Efficast Micro perforation mask” and “Orfit HP Efficast Maxi perforation mask”.
- Patient comfort is very good:
 - Comparable for all three masks.
 - Slightly better for Nanor for patients using dexamethason. Nanor masks feel more comfortable and softer than the Efficast micro perforation mask and in addition the stability is slightly better.

STUDY 2

CATHARINA HOSPITAL

EINDHOVEN, THE NETHERLANDS³

Research topics

Precision and reproducibility.

Materials

Head support comparison with Orfit Hybrid mask.

1. Orfit 3D Head support MD
Blocks and wedges
Orfit HP Hybrid mask
2. Orfit 3D Head support MD
Combined with "Thermofit"
Orfit HP Hybrid mask
3. Posifix Supine head rest
Combined with "head vacuum bag"
Orfit Push-pin Hybrid mask

Inter-fraction results

type x	Translation (mm)						Rotation (°)					
	X (lat)		Y (Lng)		Z (Vrt)		Pitch		Rtn		Roll	
	Σ	σ	Σ	σ	Σ	σ	Σ	σ	Σ	σ	Σ	σ
1	0.98	0.76	1.70	0.90	0.88	0.60	0.97	0.56	0.79	0.62	0.86	0.76
2	1.01	0.68	1.18	0.89	1.65	0.72	0.74	0.64	0.90	0.58	1.43	0.80
3	1.30	0.83	1.26	0.95	1.41	0.69	1.51	0.69	0.49	0.45	0.86	0.75

Intra-fraction results

type x	Translation (mm)						Rotation (°)					
	X (lat)		Y (Lng)		Z (Vrt)		Pitch		Rtn		Roll	
	Σ	σ	Σ	σ	Σ	σ	Σ	σ	Σ	σ	Σ	σ
1	0.13	0.24	0.12	0.25	0.07	0.18	0.13	0.24	0.12	0.12	0.14	0.26
2	0.05	0.27	0.17	0.31	0.08	0.16	0.10	0.18	0.07	0.16	0.07	0.22
3	0.26	0.36	0.26	0.34	0.20	0.31	0.21	0.27	0.18	0.18	0.25	0.26

Conclusion

- Intra-fraction translations were small for all systems and inter-fraction rotational errors are generally smaller than 1°.
- When using the correct 3D head support, individual moulds are not needed for stable fixation, but they have added value for patients with a deviating anatomy.

STUDY 3

MEMORIAL SLOAN-KETTERING

CANCER CENTER

NEW YORK, USA⁴

Research topics

Precision and patient comfort

Materials

Comparison Single layer mask with open face mask

Patient

1. Orfit 3D Head support MD, Blocks and wedges
Orfit HP Open face mask
Optical Surface Imaging
2. Orfit 3D Head support MD, Blocks and wedges
Orfit HP Open face mask
kV Imaging

Volunteer

3. Orfit 3D Head support MD, Blocks and wedges
Orfit HP Open face mask
Optical Surface Imaging

Intra-fraction results

type x	Translation (mm)		Rotation (°)	
	AVG	SDEV	AVG	SDEV
1	0.8	0.3	0.4	0.2
2	1.4	0.5	0.8	0.4
3	1.0	0.6	0.4	0.4

Conclusion

- Using real-time Optical Surface Imaging , absolute head motion during 15 minutes or more on the treatment couch was found to be approximately 1.0 ± 0.5 mm for both healthy volunteers and patients with claustrophobia.
- The open face mask opening (with reinforced strips) does not reduce the strength of the mask, in comparison with the full-head mask.
- The open face mask improves comfort and tolerability for patients, particularly those with moderate claustrophobic anxiety, and can be readily applied in clinical practice.

The conclusion above is based on open face masks. The studies used for comparison are referenced in this publication.

OVERALL CONCLUSION

The unique features of our thermoplastic materials, in combination with our 3D shaped Head supports with cranial stop and our L-profiles that fix the mask in the High Precision Hardware give you the possibility of choosing the most suitable mask for your patient and for the type of treatment that you have planned.

Below is a summary of the three critical goals for improving the quality of radiation therapy treatment:

Precision/Accuracy

An extensive range of Orfit masks allows for a perfect balance between patient comfort and restriction of movement.

The **intra-fraction** results of study 1 and study 2 show that for every type of treatment Orfit offers the right solution.

A **single layer mask** for the right balance between patient comfort and a High precision. A **Hybrid mask** for even more accuracy.

When you want even more comfort for a patient, study 3 shows that the **open face mask with reinforces stripes** has the same precision as a single layer mask, which improves comfort and tolerability for patients. Particularly those with moderate claustrophobic anxiety. Also the open face mask is compatible with modern motion management systems.

Reproducibility

A stereotactic treatment requires millimeter precision translations and rotations as low as possible.

Study 2 shows the **inter-fraction results**, based on the combination of the Orfit High Precision (HP) system and a **hybrid mask**. These reinforced thermoplastic masks offer the ease of use of a regular thermoplastic mask with an unparalleled horizontal stability and fixation force. In combination with the unique 3D shaped Head supports, one is able to really achieve a good immobilization and positioning of the patient in a reproducible way.

Patient Comfort

It is very important that a patient feels safe and comfortable in a mask, which results into a higher degree of relaxation during treatment. This will eventually lead to a more precise treatment and a more reproducible position.

Study 1 shows a comparison of results of patient comfort. All types of **single layer masks** give very good patient comfort.

When a patient is using medication for example dexamethasone the **Nanor single layer mask** gives even a slightly better comfort.

Study 3 shows that an **open face mask** improves comfort and tolerability for patients.

REFERENCES

1. Royal College of Radiologists (Great Britain), Institute of Physics and Engineering in Medicine (Great Britain), & Society and College of Radiographers (Great Britain). (2008). On Target: Ensuring Geometric Accuracy in Radiotherapy. Retrieved from https://www.rcr.ac.uk/system/files/publication/field_publication_files/BFCO%2808%295_On_target.pdf
2. Mesch, L., Essers, M., & Rozema, M. (2019). A clinical evaluation of the stability, patient comfort and ease in use of the new Nanor mask. *Journal of the European Society for Radiotherapy and Oncology*, 133 (1), S278.
3. Meessen, S., De Beer, F., Van Haaren, P., & Schuring, D. (2017). Immobilisation systems for brain treatment: are individual head supports needed for stable fixation? *Journal of the European Society for Radiotherapy and Oncology*, 123 (1), S546.
4. Li, G., Lovelock, DM., Mechalokos, J., Rao, S., Della-Biancia, C., Amols H., & Lee, N. (2013). Migration from full-head mask to “open-face” mask for immobilization of patients with head and neck cancer. *Journal of Applied Clinical Medical Physics*, 14 (5), 243-254

DISCLAIMER

This publication is based on different studies which investigate the precision and reproducibility of patient immobilization and estimate the comfort of a person when positioned on a head and neck immobilization device with a mask made with low melting thermoplastic materials. The publication is meant to help readers to show the results of those studies.

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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