Technical note: Radiotherapy and Oncology

Precision, Stability and Comfort of Patient Immobilization in Radiation Oncology: Immobilization Devices based on Nano Technology

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A B S T R A C T

Purpose: To investigate the stability and precision of patient immobilization and to estimate the comfort of a person when positioned on a head and neck immobilization device with a mask that is based on a new low melting temperature thermoplastic nano composite material.

Method: A new test method, called Isometric Crystallization of a polymer sheet, was developed in order to measure the shrinkage force of a thermoplastic material during the time that it cools down from its activation temperature to room temperature.

Results: The stability of immobilization of nano composite masks is comparable to or better than the stability of immobilization of Efficast masks due to the higher modulus of ε -polycaprolactone (ε-PCL) nano composite material. The shrinkage force of thermoplastic nano composite based masks, which is related to the patient's comfort, is lower than the shrinkage force of Efficast masks.

Conclusions: ε-PCL nano composite masks provide a similar or better limitation of movement of a person than standard Efficast masks. The advantage over Efficast masks is that they provide less fixation force due to a low degree of shrinkage, resulting in less pressure on the person's face, and more comfort for the person.

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.

The degree of comfort of a patient plays a major role in keeping his/her movement within acceptable limits during the delivery of the dose. All thermoplastic materials shrink when cooling on the patient during the mask making process and influence comfort, in particular when the volume of the patient increases during the course of treatment.

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Different types of immobilization for head and neck are known: invasive stereotactic head ring [1], non-invasive fixation by three dimensional localization at zero fixation force ($F_{fix} = 0$) (cast, dental base stereotactic localizer, vacuum bag, patient –retention) [2-4] and non-invasive fixation by applying an amount of fixation force F_{fix} directly on a head [5-8]. In the majority of cases the immobilization of a "head and neck" patient is obtained by means of a thermoplastic mask that is individually moulded over the person and that is attached to a base plate whereby the patient's head rests on a specific head support [9-11].

Thermoplastic masks for head and neck immobilization require a polymeric material with certain specific properties: (1) low melting temperature for direct moulding on a human body, (2) biocompatibility of the mask surface (preferably antibacterial) and (3) certain mechanical properties like a sufficient bending modulus. The higher the modulus, the better the precision of immobilization and the better the degree of comfort of the patient, due to a lower fixation force needed to keep the patient still.

In recent years, polymer nano composites have attracted a lot of interest from both academia and industry. These composite materials generally comprise a polymeric matrix, reinforced with a dispersed phase of nano particles such as inorganic nano fibres and nano clay, or carbon nanotubes, having at least one dimension in the range of 1-200 nm. It is interesting to compare the properties of immobilization masks made of such new nano composite material with currently used low melting temperature thermo formable materials.

Methods and Materials

Different types of low melting temperature thermoplastic (LMTTP) immobilization masks with commercial names Efficast and NANOR (manufactured by Orfit Industries) were investigated. The currently used Efficast material (2mm in thickness) is based on the LMTTP ε-PCL. The new NANOR type is a nano composite material based on a polymer matrix of ε-PCL and exfoliated nano particles of organic modified nano clay in three different thickness 1.2, 1.6 and 2.0 mm. Both types of immobilization masks are perforated for better air and humidity ventilation of the skin of the patient.

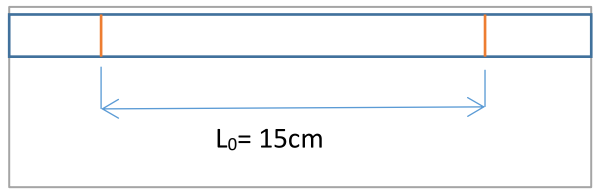
Activation of immobilization masks

A water bath (65°C, 3minutes) and dry heat oven (70°C, 10 minutes) were used to heat the immobilization masks before moulding them on a dummy head.

Different test methods were used to measure the shrinkage of the thermoplastic sheet materials and immobilization masks during cooling from activation temperature (65°-70°C) to room temperature (21°C).

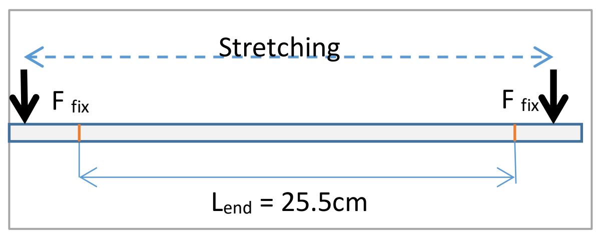
Shrinkage Percentage of sheet samples

Samples of 5 x 18 cm were cut from sheet materials. Prior to heating in a water bath at 65°C during 3 minutes, the samples are marked with a line to indicate an initial length of 15 cm (a).



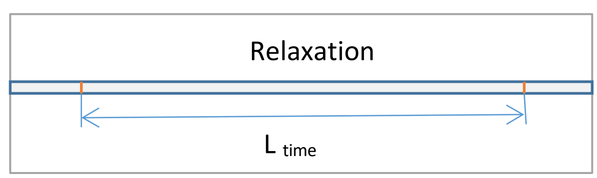
(a) **T=65°C**

When removed from the water bath, the samples are stretched to 70% of the original length (tot L_{end} =25.5 cm between marks) and cooled at the fixed stretched position during 2 minutes at room temperature (21°C)(b)



(b) **T=65°C -> 21°C**

The distance between two marks is measured in a free position (F_{fix} =0) after different relaxation times – from 30 minutes to 1 week (L_{time}) (c).



(c) **T=21°C**

The shrinkage of the samples (δL) at room temperature is calculated in percentage (%) (Equation 1):

$$\delta L = 100 - (L_{time} \times 100)/L_{end} \quad (\%) \qquad (1)$$

Shrinkage force and stability of positioning of real size immobilization masks

A new test method was developed in order to measure the shrinkage force of a thermoplastic material during the time that it cools down from its activation temperature to room temperature [12-13].
The patented test method [13], called Isometric crystallization of a polymer sheet, can be used to obtain information about shrinkage/fixation force of real size immobilization masks, which is related to the precision of immobilization and the comfort of the person under the mask. For this purpose a special device, based on the isometric crystallization method, was developed at Orfit Industries for measuring the shrinkage (fixation) force and stability of immobilization of real size thermoplastic masks with different base plates and head supports [13]. There are several studies using clinical methods (mostly X-ray scan pictures) to investigate precision and reproducibility of patient set-up [14- 16] which are applied in the course of radiotherapy treatment of the patient, but it is difficult to organize such clinical procedures to test a newly designed immobilization device based on advanced materials and to control the immobilization properties during the development and production stages of the device. Using the isometric crystallization method in laboratory conditions can easily achieve this.

The instrument for measuring the shrinkage (fixation) force and stability of immobilization of real size different thermoplastic masks in radiation oncology, allows measuring the stability and precision of immobilization of head, neck and shoulders in vertical and horizontal directions in combination with rotation under different values of fixation forces. The test results are obtained after moulding the immobilization masks on a dummy head. The isometric crystallization method allows measuring the fixation force of immobilization devices during cooling/hardening out of the thermoplastic material. The fixation force corresponds to the shrinkage of the immobilization mask. Horizontal displacement is measured by applying a standard value of 100N of horizontal force to the mask moulded on a dummy head. The value of this displacement in mm is used for evaluation of stability of the immobilization. In general we can state that the higher the shrinkage, the more stable the fixation of the patient is, but the lower the comfort. The comfort is of a big concern for both the patients and the radiation therapists and to solve this comfort issue a higher modulus material such as nano composite can be used for an immobilization device, which is an object of this study. A higher modulus results in a higher stability of fixation and this means a higher limitation of movement of immobilized parts of the body. As a result, a higher stability of fixation allows for a higher precision in cancer treatment with radiotherapy.

Thermal properties of thermoplastic materials

Differential Scanning Calorimetric (DSC) is used to evaluate melting and crystallisation properties of thermoplastic materials by the simulation of thermoforming conditions of immobilization masks.

Results

Properties of ε-PCL nano composite sheet materials

NANOR is a nano particles filled polymer material. The bending modulus of NANOR sheets is about 1GPa [17], which is two times higher than the bending modulus of Efficast sheets. The higher modulus of NANOR allows reducing the thickness of the immobilization masks to 1.2 and 1.6 mm instead of 2.0 and 3.2mm of Efficast, while keeping the same mechanical properties of the immobilization mask.

Thermal properties of nano composite sheet material

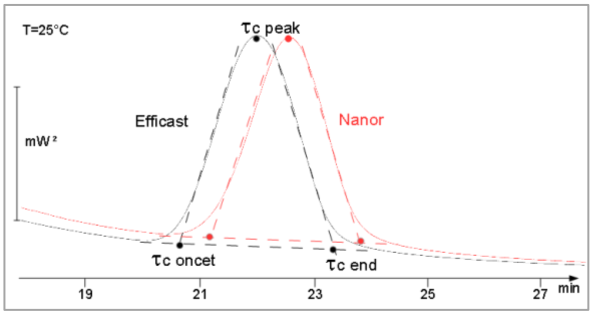


Fig. 1(a). DSC curve of isothermal crystallization of NANOR and Efficast at 25°C (Heating to 70°C, isothermal for 3 min; cooling 20°C/min to 25°C; isothermal at 25°C 30min)

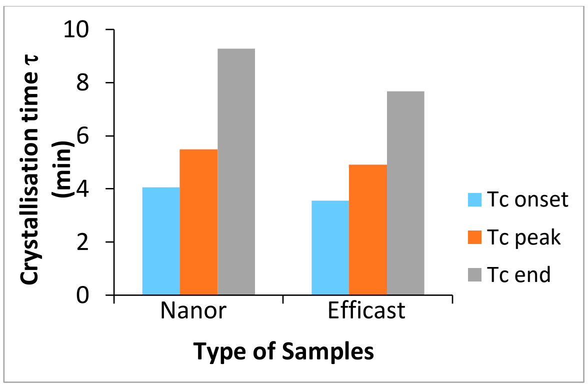


Fig. 1(b). Crystallization time τ of NANOR and Efficast determined from isothermal DSC curves at 25°C (Heating to 70°C, isothermal for 3 min; cooling 20°C/min to 25°C; isothermal for 30min)

The isothermal DSC curves of NANOR and Efficast are shown on Fig1(a). The crystallization time at isothermal crystallization of NANOR and Efficast materials is presented in Fig.1(b). The nano composite based NANOR crystallizes slowly in comparison with Efficast PCL based material.

Shrinkage of nano composite sheet material

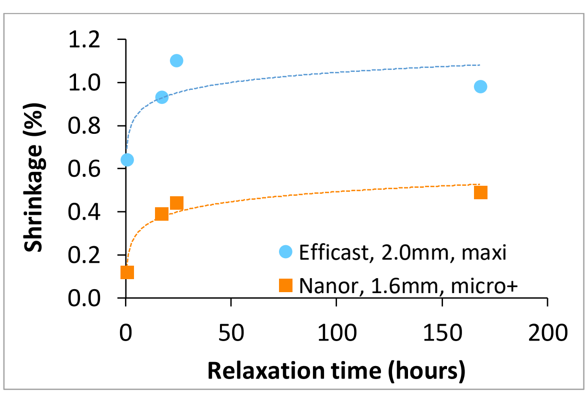


Fig. 2. Percentage of shrinkage in time of samples in relaxed position after stretching to 70% at 65°C and cooled down in a fixed position to 21°C.

The shrinkage of NANOR vs. Efficast flat sheet material is shown in Fig. 2.The shrinkage happens fast in the first 24 hours of relaxation at room temperature for both materials and continues at a very low speed until one week after relaxation. The shrinkage of NANOR after seven days is lower than the shrinkage of Efficast- respectively 0.5% vs. 1%.

Shrinkage/fixation force, stability and precision of immobilization of NANOR vs. Efficast masks

The shrinkage force of NANOR and Efficast masks, activated in a water bath and in a dry heat oven at 30 minutes after moulding and at 24 hours after storage at room temperature is presented in Fig 3(a, b). The shrinkage force of both types of immobilization masks increases to approximately double the value after 24 hours.

The shrinkage force and moulding time strongly depend on the type of the material, thickness of the mask and type of activation device.

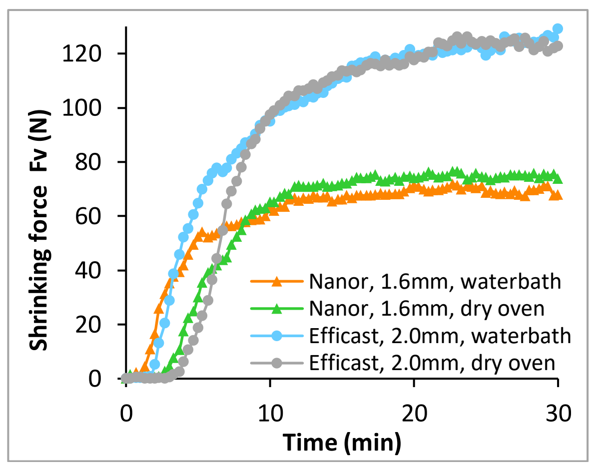


Fig. 3 (a) Shrinkage force of immobilization masks over 30 minutes.

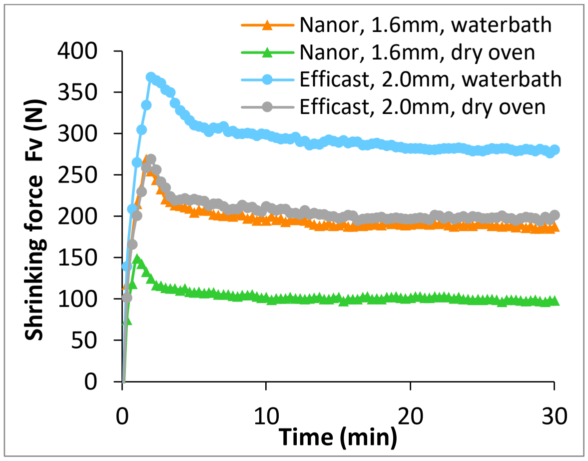


Fig. 3 (b). Shrinkage force of immobilisation masks 24 hours after molding.

Discussion

This study aims to compare the stability and precision of fixation of head and neck immobilization masks made of a new low melting temperature nano composite material with the currently used thermo formable masks by means of a specially developed method and laboratory instrument for measuring the fixation force and stability of fixation of immobilization devises.

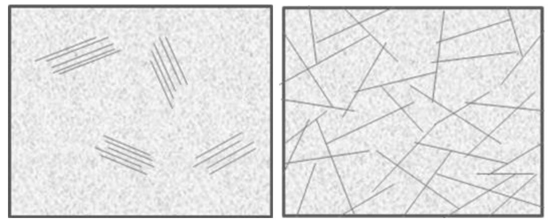
ε-PCL nano composites- properties

The thermoplastic nano composite material is based on a low melting temperature polyester ε-PCL reinforced with exfoliated nano clay. Such material is characterized by a high flexural modulus (up to 100% more than existing products), which allows reducing up to 50% the thickness of polymer sheet materials for immobilization masks [17,18].

In radiation oncology, the additional gain in flexural modulus improves the stability and reproducibility of immobilization of a patient. The existing LMTTP products allow a horizontal and rotational movement of the patient in the order of 1,5 to 2 mm. These values have to be kept the same or even decreased with thinner ε-PCL nano composite immobilization masks.

The nano composite NANOR crystalizes more slowly compared to the Efficast ε -PCL based material (Fig.1 a,b). In this case nano clay particles do not show any nucleation effect and slightly supress the crystallization rate of PCL. Such effect is positive because it increases the moulding time of nano clay based immobilization masks and allows using thinner material (1,2 and 1,6mm) in partial applications.

Shrinkage of nano composite material



a) **b)**

Fig.4 (a,b). Schematic presentation of non-exfoliated (a) and fully exfoliated (b) nano clay composite material

Non-exfoliated nano clay particles behave as micro filler particles (Fig.4 a). The thermal shrinkage that takes place during cooling/crystallization of the polymer matrix does not differ significantly from one type of inorganic filler to the other. On the contrary, the fully exfoliated nano clay particles form a micro cluster network (Fig. 4 b) that reinforces the polymer matrix and keeps the micro volume sizes more stable. The exfoliated nanoparticles show also strong nucleation effect and decrease the size and perfection of the crystalline phase. This dramatically reduces the thermal shrinkage during the crystallization of such reinforced polymer matrix.

Fixation force and stability of NANOR head and neck masks

The lower percentage of shrinkage of NANOR material is the major reason for lower shrinkage/fixation force of NANOR masks (1.2 and 1.6mm), i.e. 60N and 75N respectively after 30 minutes of cooling at room temperature against 120N for Efficast masks (Fig. 3 a). The results presented in Fig. 3a show that the hardening time of masks (time when the shrinkage force of the masks reach a plateau on the curve Fv vs. Time) is about 10-15 min after the start of the moulding process on a person. This is the minimal time to keep the immobilisation mask on the person without any doubt that the mask will be deform when it is removed. It is interesting to note that the shrinkage force of these immobilization masks increases during storage at room temperature for about 24 hours due to the completion of crystallization of the polymer matrix and the relaxation of stretched/oriented polymer material (Fig. 3 b).

The moulding time (time when Fv= 0, Fig. 3a) of immobilization masks heated in water bath is shorter than the moulding time of the masks heated in a dry heat oven.
The shrinkage force after 24h of masks activated in a water bath is higher than the shrinkage force of masks that are activated in a dry oven.
The nano composite immobilization masks show less shrinkage than the Efficast masks (Fig. 3 a).
The shrinkage of immobilization masks continues for more than 24 h till complete stabilization (Fig. 5 a).

As already mentioned above the fixation force of a thermoplastic mask that is directly moulded on a person is due to the shrinkage of the thermoplastic material that takes place during the cooling process at room temperature. The causes of the shrinkage are (1) a decrease in volume of the material due to the thermal contraction and the polymer crystallization and (2) the contraction of oriented/stretched polymer chains during relaxation at room temperature, above the glass transition temperature of ε- PCL (Tg= -61°C). The relaxation of polymer chains is the reason for a significant difference in the shrinkage force value between masks, depending on whether they are activated in a water bath or in a dry heat oven. Masks that are activated in a water bath crystallize faster during moulding on a person due to the more intensive cooling, forced by evaporation of the thin water layer on the surface of the mask. Faster cooling of the mask results in faster crystallization and fixation of a bigger part of the stretched /oriented polymer chains in the amorphous domains. The relaxation of such internal tension of oriented material causes a higher shrinkage force after moulding of the mask. The faster crystallization of a wet mask results in an imperfect crystalline structure, which can re-crystallize at room temperature and which increases the shrinkage of a mask. A dry heat oven activated immobilization mask crystallizes slower than a wet mask, creates a more perfect crystalline phase and the stretched polymer chains partially relax already before hardening of the polymer material at room temperature. This leads to less shrinkage at room temperature.
Based on these phenomena, the shrinkage/fixation force, the stability and precision of immobilization and the comfort of the patient can be controlled by using different types of activation. Using a water bath results in higher shrinkage, while using a dry heat oven results in lower shrinkage. (Fig 3. a, b and 5. a, b).

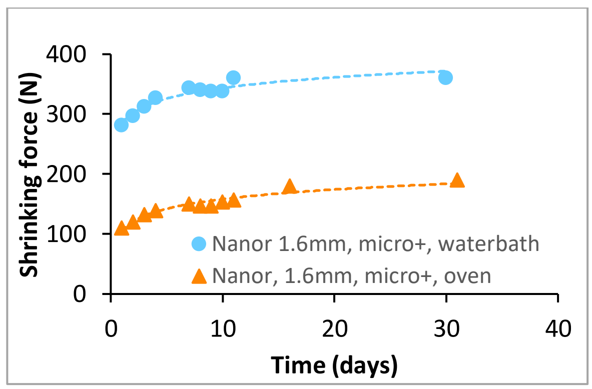


Fig. 5 (a) Shrinkage force of a NANOR mask at room temperature over time

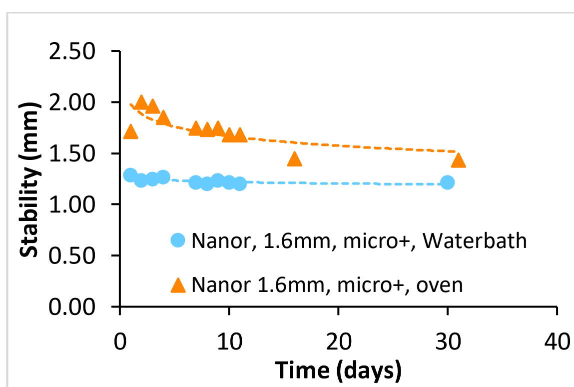


Fig. 5 (b) Limitation of movement in a NANOR mask at room temperature over time

Comfort of immobilization with NANOR masks

The instrument for measuring the shrinkage and stability of immobilization masks that are moulded on a dummy head allows to simulate swelling of the person's head by vertically lifting the dummy head against the moulded masks. The results of such measurements of Efficast and NANOR masks are presented in Fig. 6. The fixation force of Nanor masks after vertical lifting of the dummy head (0.8mm) against the immobilization mask is equal for masks heated in water and even much lower for masks activated in a dry heat oven in comparison with the fixation force of Efficast masks at normal (non- lifted) position.

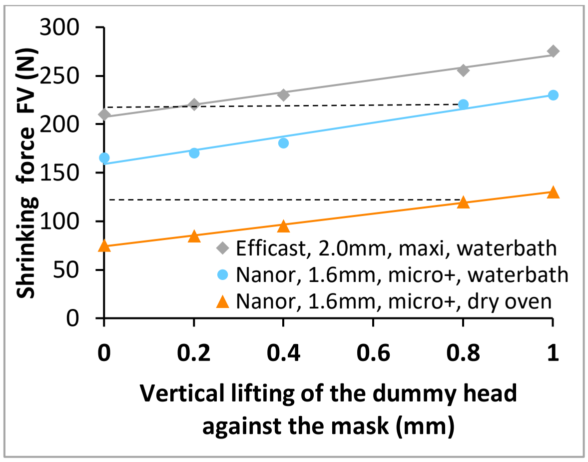


Fig. 6. Fixation force of immobilisation masks when lifting a dummy head to simulate swelling

The lower shrinkage of 1.6mm NANOR immobilization mask gives better comfort for a patient but keeps the same or higher stability of fixation (Fig 5 b) as the 2.0mm Efficast masks. The thinner NANOR masks are also easier to thermoform and follow the contours of the human face better than the existing Efficast masks.

Conclusions:

Due to a 100% increase of Flexural modulus of NANOR material, the thickness of the sheets can be reduced by about 50%. Immobilization masks based on nano composite NANOR crystallize / harden slower than Efficast masks at room temperature. The moulding time and the hardening time of NANOR masks are higher when activated in a dry heat oven than when activated in a water bath and they increase with the thickness of the mask. The shrinkage/fixation force of NANOR masks is lower than the shrinkage/fixation force of Efficast masks, which results in a higher degree of comfort for the patient. The stability of NANOR masks increases when the thickness of the mask increases and it is in the same range or better that the stability of the Efficast masks.

Based on presented results and conclusions a clinical test of stability and precision of immobilization of the patients with NANOR mask is planned to be performed.

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