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Mechanical clamp stress on PVC infusion tubing: impact on the surface degradation

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Abstract

Several commercial infusion tubes made of plasticized PVC were shown to present a layer of bloomed species on their internal wall (lubricants and stabilizers), which are poorly soluble in water. During infusion, tubes are crushed and pinched to regulate the flow. The impact of mechanical stress on these layers infusion was studied.

Device inner surfaces were characterized by AFM in order to put into evidence surface degradations before and after infusion.

Because of the clamp stress, the deposits were highly damaged and injecting water into the damaged tubing increased the layer degradation. Rolling clamp and clamp may have very different effects on the inner layer morphology and degradation and this may be modulated by the initial layer morphology.

Injecting water into clamp stressed tubing may increase the risk of detaching parts of the internal layer and be a supplementary factor of particulate contamination for the patient.

Key words

PVC - Mechanical stress - Surface degradation – Blooming – Particulate contamination — Atomic force microscopy

Introduction

Infusion is a very common act in hospitals. Its benefits are widely recognized for the patient in particular in emergency cases, for unconscious patients and for the nutrition of critically ill patients. Infusion is performed by using transparent flexible tubing made in plasticized PVC. This PVC contains several additives such as plasticizers but also stabilizers and lubricants. In a previous paper [1], we showed that the internal walls of several infusion tubes were covered by a layer made of additives that bloomed onto the PVC surface (metallic stearates and bis amide lubricant). Water contact damaged this layer and we suspected it to conduct to a particulate contamination of the infused solution. This particulate contamination is

potentially harmful to the patient: depending on the particle's size and shape, on the patient's health and age, it may damage different organs; it may lead to a thrombo-embolization or to the formation of granulomas [2] [3] [4] [5]. During the infusion, mechanical stress on the tubing can occur because of the use of clamps. Pinch clamps are used to stop the flow by pinching the tubing (fig 1a). Roller clamps are equipped with a small roller which allows the tube to be more or less crushed in order to incrementally occlude it (fig. 1b). This allows a regulation of the flow rate. In this paper, we characterize the effect of both kinds of mechanical stresses on the layers found on the internal wall of several infusion tubes and what happens as water is injected into the tubing after this kind of stress: we suspected it may lead to a potential higher and faster degradation of the layer with a higher risk of particulate contamination. Indeed, the effect of repeated compression of plastic tubing was studied in the case of hemodialysis circuit [6]; because of the high and complex stress exerted by the peristaltic pump, cracks were observed on the plastic surface and particles were then shed from these defects because of the shear stress exerted on the inner wall of the tubing [7] [8] [9]. These particles may then be injected into the bloodstream. This complication is well known in dialysis and is called spallation; it was studied by several authors mainly between 1980 and nowadays; it can be implicated in brain dysfunction, granulomatosis hepatitis, macrophage activation...long-term treated patients could show up to 250 mg of silicone particles lodged in organs because of the use of silicone tubing [10] [11]. But, the PVC used to replace it produces particles too: they were mainly below 5 μm in diameter but they can reach 50 μm [12]. Moreover, in another publication, Madsen et al. [13] advised against the stripping of PVC infusion sets with a pair of scissors, by compressing the tubing between the thumb and a scissor blade, a clinical practice used to manage with flow malfunctions: because of this, an increased number of particles (5 to 100 μm) in the infused liquid were detected.

Material and methods

Material

Different infusion tubes were used for this study: Infusomat® Space line (old reference with DEHP), Intrafix® SafeSet (BBraun, Germany) and Volumat® Line (Fresenius Kabi, Germany). These sets were chosen because we showed in a previous paper [1], they had internal layers with very distinct morphologies.

Mechanical stress

It was applied using a pinch clamp and a roller clamp. The roller clamp was applied on the whole length of the tubing several times (around 5) and the tubing was pinched every 3 mm.

To study the impact of stress followed by water injection on the layer morphology, the tubing was first pinched and then crushed; then, 10 mL of filtered water (Direct Q UV ultrapure water type 1 equipped with a biopack polisher) was injected into the tubing using a glass syringe. After letting the sample dry, it was analyzed by AFM.

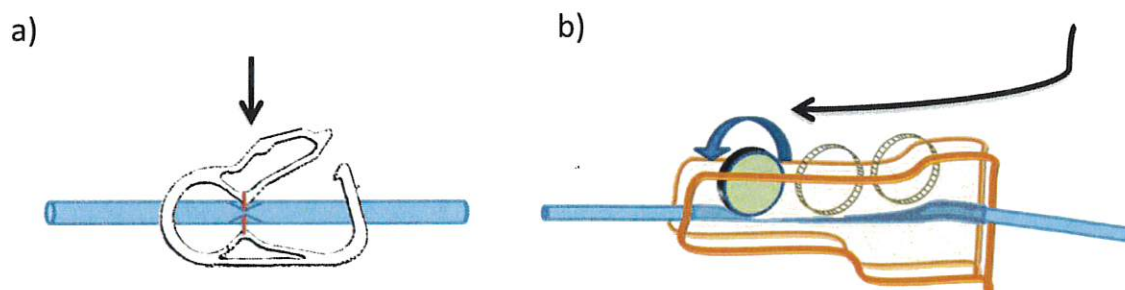


Figure 1: a) pinch clamp that allows stopping the flow by pinching the tube b) roller clamp: the drawing shows the movement of the roller along the tube which it crushes to regulate the flow rate.

AFM

Tapping mode

The analyses were performed with an Innova AFM (Bruker, Palaiseau, France). The tapping mode in air was used (cantilever frequency= 320 kHz, stiffness= 42 N/m, NCHV probe from Bruker). At least six different zones of each sample were imaged using a scan rate between 0.5 and 1 Hz.

Force imaging mode

The AFM used was a Nanowizard III (JPK Instruments AG, Berlin, Germany) using Quantitative Imaging® (QI) mode which is a force curve imaging mode. Force distance curve was realized for every pixel of the image. The probes were CSC 37 (Micromasch, stiffness around 0.35 N/m). The stiffness data were calculated from the slope of the force versus scanner elongation curves. For every point, the maximum applied force (set-up value) to the sample was 2nN.

Results and discussion

Initial texture of the layer

As already mentioned in a previous paper [1] the morphology of the inner layer was very different depending on the tubing reference. But the topography was quite uniform along the same tubing with very consistent images, especially at the 20*20 or 10*10 μm^2 scales. Textures might vary depending on the batch of the product (that is why for more convenience and accuracy, we compared only the results obtained with the same tubing), but we obtained great similarities with the previous analyzed tubing of the same reference (see paper [1]), even if some differences exist that may come from small variations in the production process or in the aging of the sample (time between production and analysis, temperature...)

For the layer of Intrafix® (fig 2.a.b) big ovoid and smooth nodules (20-30 nm high) were still present (mostly around 3-6 μm in length and 2 μm in width), surrounded with thin protrusions (less than 0.2 to 1 μm wide and between 20-50 nm high) ; the roughness was equal to 9.5 ± 0.6 nm for R_q and 7 ± 0.5 nm for R_a (20*20 μm^2). For Volumat®, a kind of network of protrusions (5-10 nm high and less than 1 μm wide) was still observed but the layer was less uniform and smooth than samples previously analyzed from another batch (fig 2.cd): the roughness was 6.3 ± 1.4 nm for R_q and 4.6 ± 1.1 nm for R_a (20*20 μm^2). For Infusomat® the layer shows the same kind of needle- like structure previously observed

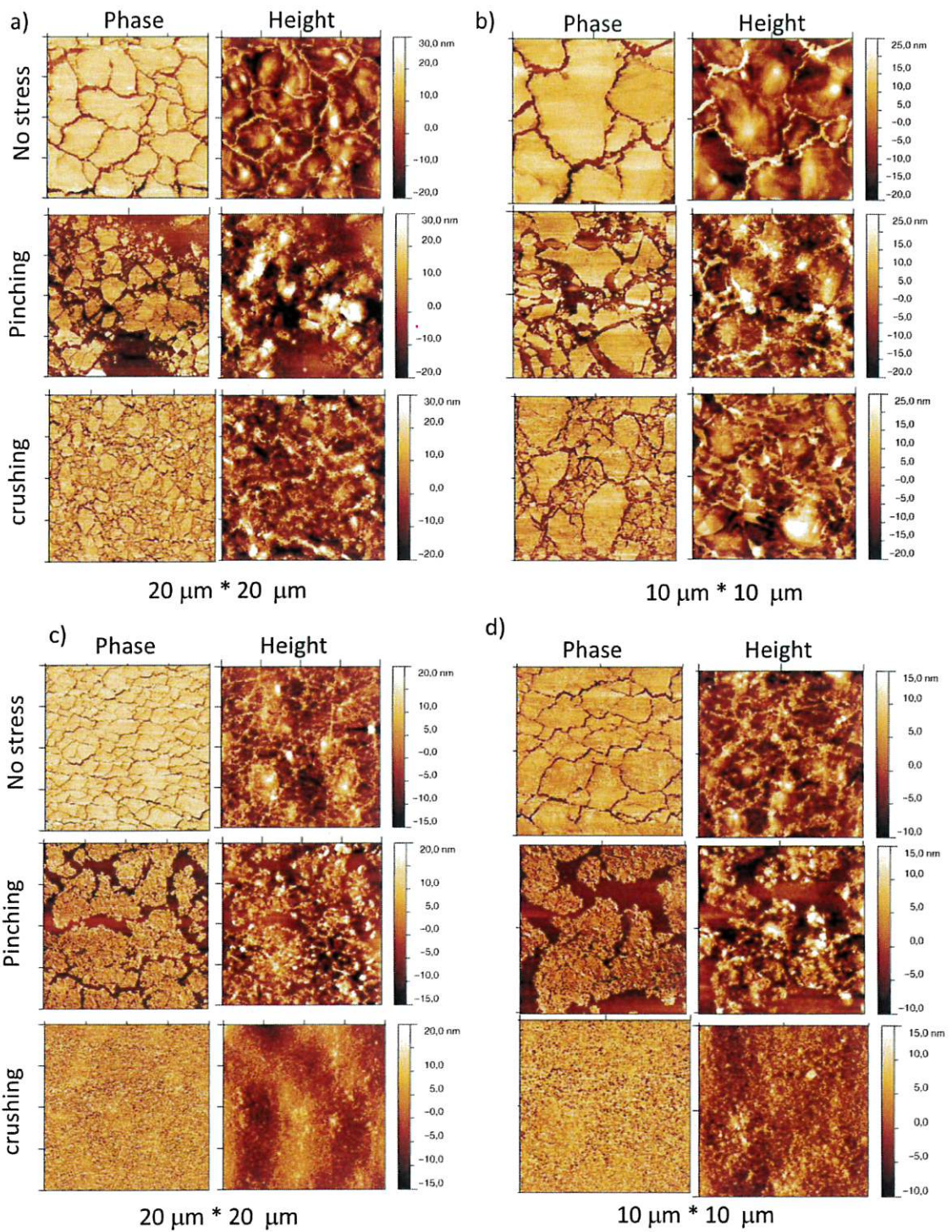


Figure 2: AFM images (height and phase) in tapping mode of the internal layer a) of the Intrafix® tube 20*20 μm². b) of the Intrafix® tube 10*10 μm² c) of the Volumat® tube 20*20 μm² d) of the Volumat® tube 10*10 μm²

but with a lower density of these needles (fig 3) The roughness of the surface was thus lower: 7.1 ± 1 nm for R_q and 5.3 ± 0.9 nm for R_a ($10 \times 10 \mu\text{m}^2$). It was previously showed that these layers were made of bis amide lubricant and of zinc and calcium stearates [1], which are additives contained in PVC and that bloom and recrystallize onto the surface.

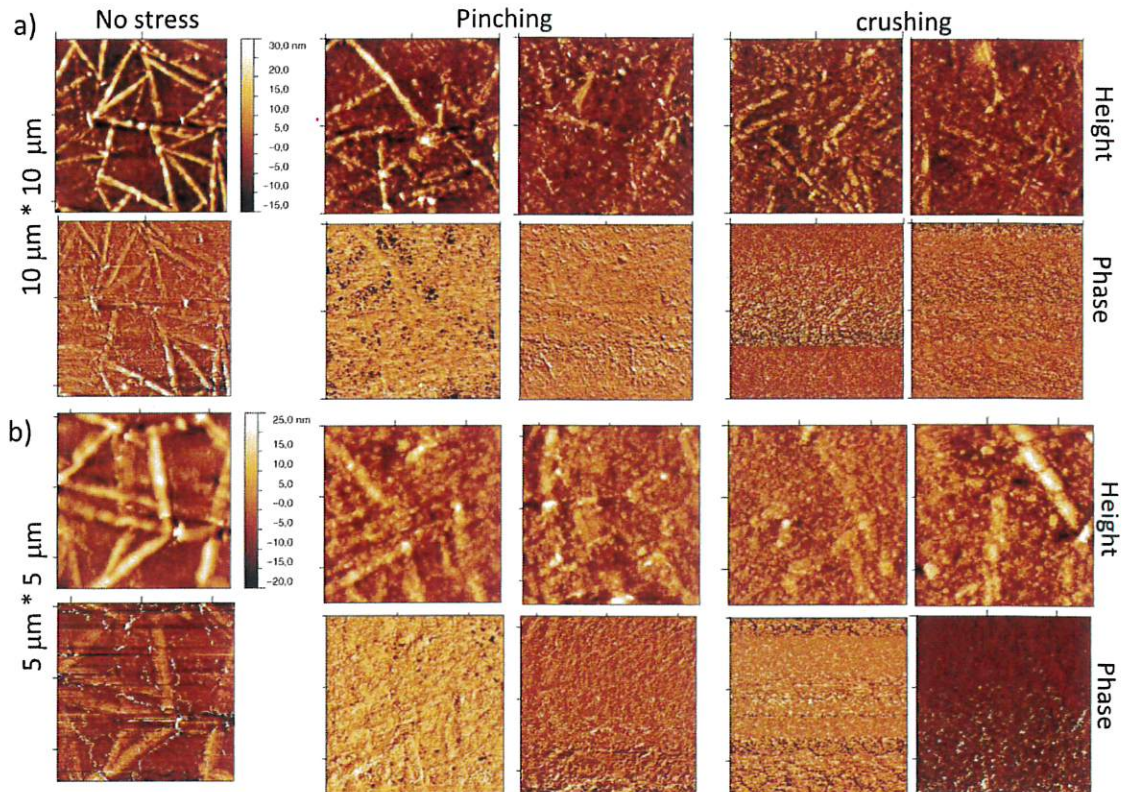


Figure 3: AFM images in tapping mode (height and phase) of the internal layer of the Infusomat® tube. Scan sizes are either a) $10 \times 10 \mu\text{m}^2$ or b) $5 \times 5 \mu\text{m}^2$

Impact of pinching and crushing

The topography (roughness and texture) was impacted by the mechanical stress but it may differ depending on the initial layer topography and on the nature of the applied stress (pinching or crushing). For example, the pinching has a trend to increase the roughness (fig 4.a.b) and to locally dislocate the layer with significant parts of it that were clearly detached from the PVC surface (this can be seen by analyzing conjointly phase and height images on the fig 2). This was true for Intrafix® and Volumat® layers. However, this was not the case for the Infusomat® layer: the kind of needle-like structure seems to

be crushed, flattened and it seems that no part of the layer was removed (fig 3). As a consequence, in this case, the roughness was slightly decreased (fig 4c). In a general way, the crushing of the tubing by roller clamp has a trend to reduce the roughness by crushing, flattening and smoothing efficiently the layer (fig 2-3). This was very significant for Infusomat® and Volumat® tubing: the layer was much more homogenous and uniform after crushing (fig 2c.d-4) and the roughness decreased from 25%-30% for R_q (fig 4 b.c). This decrease in roughness was not observed for Intrafix®, because, by crushing the surface, the very smooth initial surface of nodules was lost because of their fragmentation by the stress (see phase and height images of the fig.2.a.b).

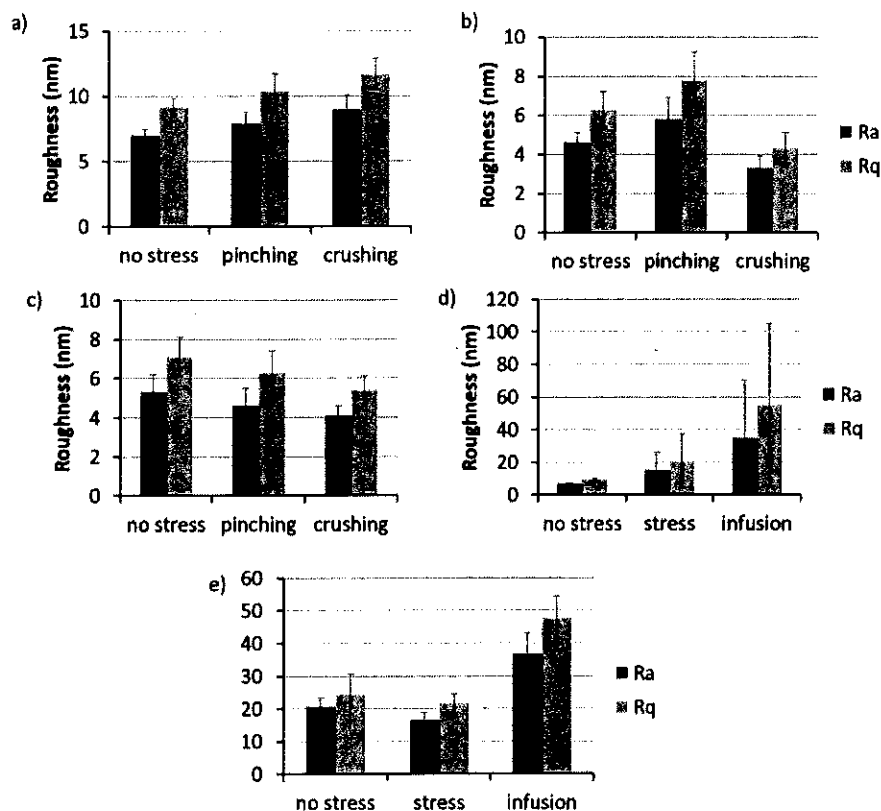


Figure 4: Roughness R_a and R_q of the inner surface a) for stressed and not stressed Intrafix® 20*20 μm^2 b) for stressed and not stressed Volumat® 20*20 μm^2 c) for stressed and not stressed Infusomat® 10*10 μm^2 d) for pinched and crushed pre infusion and post infusion Intrafix® 20*20 μm^2 e) for pinched and crushed pre infusion and post infusion Infusomat® 10*10 μm^2

Impact of both mechanical stresses followed by water injection into the tubing on the surface morphology

Intrafix[®], for which both stresses conduct to a higher roughness and Infusomat[®] for which the opposite trend was observed, were subjected successively to both stresses (first pinching and then crushing) and then water was injected into the tubing. The appliance of the successive stresses led to the same trend as before: the stress on the smooth nodules of the Intrafix[®] layer led to a rougher and more heterogeneous surface (fig 4d and 5b). On the contrary, the Infusomat[®] layer was flattened and smoothed (fig 4e and 6d).

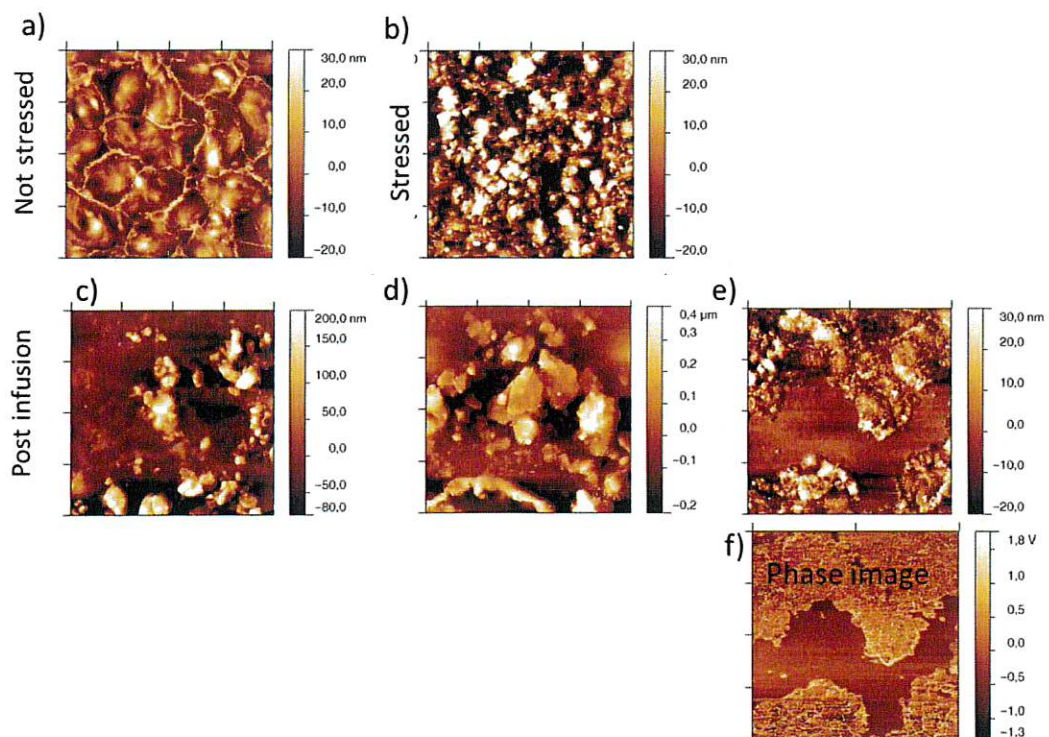


Figure 5: AFM images in tapping mode of the internal layer of the Intrafix[®] tube. a) Initial state b) after both stresses (pinching+crushing) pre infusion c-f) after both stresses post infusion. Height images except of f) which is the phase image of e).

However, after the water injection, an increase in roughness was clearly observed for the both tubes (fig 4 d,e). Their surfaces become much more chaotic, with the presence of big deposits (fig 5 c-d and 6g). In the case of Intrafix®, the layer was in part detached after the infusion (fig 5 e-f). For Infusomat®, big deposits observed had different properties than the pre-infusion layer: they were less stiff and had higher interactions with the AFM tip (fig 6 h.i), certainly because of a lower hydrophobicity. Moreover, at a small scan size, we observed that the residual layer of Infusomat® became very different in texture with small nodules on its surface (fig 6.j,k).

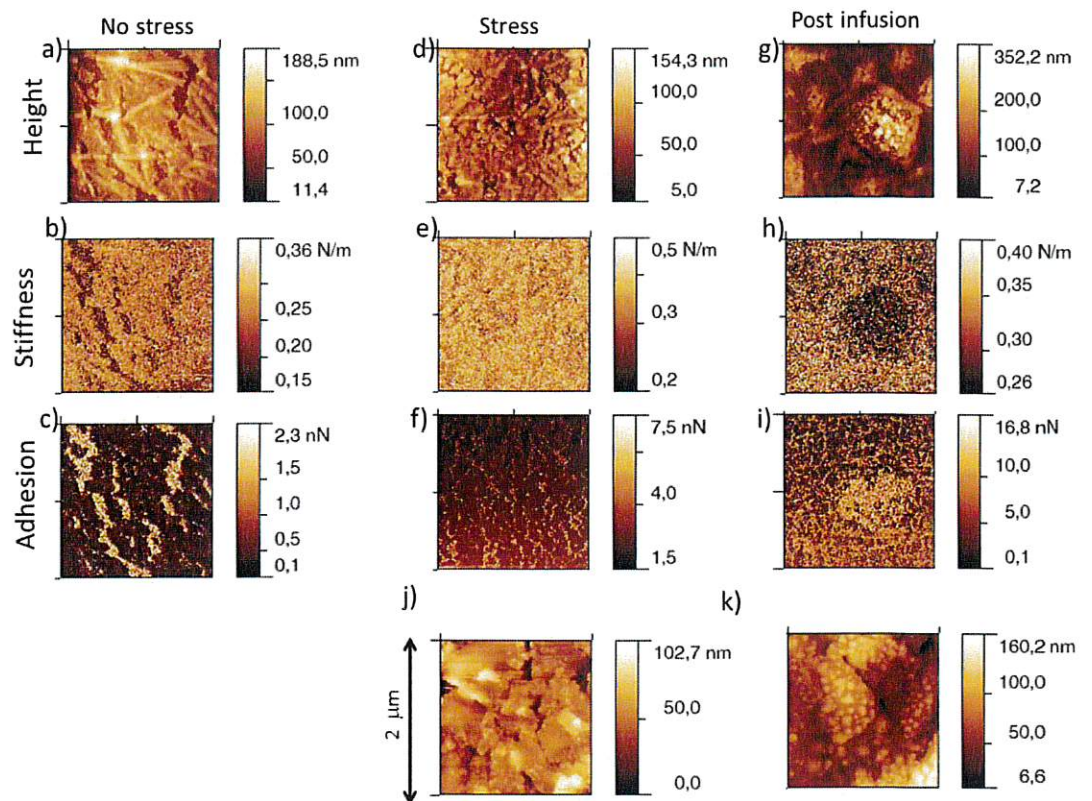


Figure 6: Infusomat® tube a-k) AFM images in force imaging mode of the internal layer of the tubing. a-c) Initial state d-f)j) after both stresses (pinching+crushing) pre infusion g-i)k) after both stresses post infusion.; a, d, g, j, k are height images ; b, e, h are stiffness images and c,f, i are adhesion images. Scan size is 10*10 μm^2 except for j) and k) (2*2 μm^2)

Conclusion

This study proves the internal layer of infusion tubing made of bloomed lubricant and stearates is quite fragile and can be damaged by the stress exerted by the clamps during the infusion act. It must be kept in mind that this stress is not only applied once on the tubing, because readjusting the flow rate is necessary during infusion for several reasons: bent or kinked tubing, venous pressure change, decreasing fluid volume in the bottle, and change in arm position... Flow rate has to be checked hourly and adjusted if necessary. Moreover, as the rate is readjusted, the clamp should be repositioned along the tubing on a new part of it, because of the cold creep of the plastic that can have a pinched section [14]. This means that, during one infusion, the internal layer will be damaged in several parts of the tubing, increasing the risk of leaching solid particles into the solution. It was indeed shown in this paper that injecting water into the damaged tubing may increase the risk of detaching parts of the internal layer and increase the level of particulate contamination.

The authors confirm that the data supporting this work are available within the article

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