

UPDATE "A ROUGH LEGACY"

by Giulio Valesini

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GIULIO VALESINI OFF SCREEN

More than 30 million women across the world live with breast implants. Anatomical, round or teardrop-shaped implants can be used. The surface of these implants can be smooth or textured - that is, rough or macro-textured, even more rough: they say that it adheres better to the tissue and gives a better aesthetic result. But a number of recent international studies have linked these implants to a new form of cancer: ALCL, Anaplastic Large-Cell Lymphoma. The French health authorities have opened the debate on this issue.

THIERRY THOMAS - DIRECTOR FOR MEDICAL DEVICES FOR ANSM (FRENCH NATIONAL AGENCY FOR THE SAFETY OF MEDICINES AND HEALTH PRODUCTS)

The question that we need to answer is this: in light of this risk, are there situations in which it is essential to use a textured implant?

WOLFGANG STEIMEL – CEO OF POLYTECH

We are asking governments to collect more data, but we can't stop using rough implants.

GIULIO VALESINI OFF SCREEN

As it currently stands, the cases reported to the FDA number 457. So far, 17 women have died. There have been 39 diagnoses in Italy. Around one in every 30 thousand implants, according to the Ministry of Health. Many patients have been treated at the Sant'Andrea University Hospital in Rome.

FABIO SANTANELLI DI POMPEO – DIRECTOR OF PLASTIC SURGERY, SANT'ANDREA HOSPITAL - ROME

In the clinical history of each of these women, we found that they had received macro-textured breast implants.

GIULIO VALESINI OFF SCREEN

The lymphoma appears on average seven years after the implant operation is performed, but can even appear 25 years after the initial breast surgery. It is therefore essential to receive a diagnosis as early as possible.

GIULIO VALESINI

What do you think of the failure to renew the CE mark for Allergan implants?

FABIO SANTANELLI DI POMPEO – DIRECTOR OF PLASTIC SURGERY, SANT'ANDREA HOSPITAL - ROME

When you don't know something, you can either distract yourself, or think the worst.

GIULIO VALESINI

What do you do?

FABIO SANTANELLI DI POMPEO – DIRECTOR OF PLASTIC SURGERY, SANT'ANDREA HOSPITAL - ROME

I usually don't get distracted. So if they haven't said anything, I fear that this failure to communicate is due to a desire not to stir up panic. And not to set off a bomb that subsequently becomes difficult to control.

GIULIO VALESINI OFF SCREEN

In Italy in 2012, the Minister for Health Renato Balduzzi, and so parliament, approved the establishment of a mandatory register of breast implants. This register called for the inclusion of the brand, model, date of surgery and the names of the surgeon and the patient.

PAOLO SANTANCHÈ – PLASTIC SURGEON

The register was never rolled out.

GIULIO VALESINI

But what happens then if the Ministry wants to know how many Allergan textured breast implants there are in Italy?

PAOLO SANTANCHÈ – PLASTIC SURGEON

They'd have to do what they did with the PIP implants: send NAS, the police anti-adulteration and health unit, to all the clinics, and get them to go through all the folders from the previous ten years with a fine-tooth comb, look through all the records to see what brand of implant... So, basically something that...

GIULIO VALESINI

So history teaches us nothing, doctor?

PAOLO SANTANCHÈ – PLASTIC SURGEON

No. That's what politicians are like. They're dense.

GIULIO VALESINI

600 reports of ruptured implants in tens of thousands is clearly a case of under-reporting. We don't have a register, so it's under-reporting by doctors, companies...we're a bit in the dark here, doctor.

MARCELLA MARLETTA - DIRECTOR GENERAL FOR MEDICAL DEVICES, MINISTRY OF HEALTH

The whole world is in the dark, your concern is shared globally.

GIULIO VALESINI

You keep saying this, but it's not making me feel reassured, doctor. On the contrary, it's worrying.

MARCELLA MARLETTA - DIRECTOR GENERAL FOR MEDICAL DEVICES, MINISTRY OF HEALTH

It's not meant to reassure you; rather one should be asking how a Ministry with the means of a public administration body can achieve what we have. And be admired by the rest of the world.

SIGFRIDO RANUCCI IN THE STUDIO

This was an investigation carried out in collaboration with the International Consortium of Investigative Journalism; Report and L'Espresso are the exclusive partners of the organisation in Italy. While Dr. Marletta was looking at the rest of the world, the French health authorities withdrew 13 implant models from sale, and a few

days ago wrote to a number of multinationals including Allergan, Polytech and Eurosilicone to ask them to "withdraw all the batches currently in circulation, due to the rare but serious danger they pose". Now our ministry has also become alarmed, and has requested an urgent opinion from the National Health Council, who will provide a response on 13 May. To date, there are 41 cases of lymphoma that have been confirmed in our country; 93% of women who have breast implants have the type of implant which could represent a risk. Unfortunately, Giulio Valesini has discovered a case of a death associated with breast implants.

GIULIO VALESINI OFF SCREEN

The Policlinico Umberto I hospital in Rome. Last autumn, a woman underwent surgery for anaplastic large-cell lymphoma; a few weeks later she died.

DOCTOR, POLICLINICO UMBERTO I HOSPITAL

The patient was in a very advanced stage of illness, these are extremely aggressive T-cell lymphomas.

GIULIO VALESINI

In your view, here at the Policlinico Umberto I, was her death due to anaplastic large-cell lymphoma linked or associated with breast implants?

DOCTOR, POLICLINICO UMBERTO I HOSPITAL

Absolutely.

GIULIO VALESINI

Was she a patient of the Policlinico Umberto I hospital?

DOCTOR, POLICLINICO UMBERTO I HOSPITAL

No, she wasn't a patient of ours: we saw her for the first time in October 2018, when the disease was already in an advanced state.

GIULIO VALESINI

Was the case immediately reported to the Ministry of Health?

DOCTOR, POLICLINICO UMBERTO I HOSPITAL

Absolutely.

GIULIO VALESINI

If you promptly communicated the fact to the them, why, in your opinion, has the Ministry of Health not yet disclosed this to the public?

DOCTOR, POLICLINICO UMBERTO I HOSPITAL

It's not me you need to ask. We reported it. In this case, the patient's illness was very advanced, that is, it was nothing like all the other forms that I've seen where removing the capsule has been curative.

GIULIO VALESINI OFF SCREEN

The woman had received the implants for aesthetic reasons twelve years ago. The report of the death was sent to the Ministry's director general for medical devices, Marcella Marletta.

MARCELLA MARLETTA - DIRECTOR GENERAL FOR MEDICAL DEVICES, MINISTRY OF HEALTH

We received the report on 14 February; the documentation arrived on 23 April, but we had already asked the Minister to go to Italy's National Health Council, on the first of April.

GIULIO VALESINI

So the hospital took that long to send you the documentation?

**MARCELLA MARLETTA - DIRECTOR GENERAL FOR MEDICAL DEVICES,
MINISTRY OF HEALTH**

Yes, 23 April. I checked myself.

GIULIO VALESINI

Medical sources told me "we promptly reported it to the Ministry".

**MARCELLA MARLETTA - DIRECTOR GENERAL FOR MEDICAL DEVICES,
MINISTRY OF HEALTH**

They may have reported it. But I can't act simply on the basis of a report.

GIULIO VALESINI

The point is to understand why the Ministry didn't inform the public.

**MARCELLA MARLETTA - DIRECTOR GENERAL FOR MEDICAL DEVICES,
MINISTRY OF HEALTH**

It's simple: because the Ministry is not obliged to. Do you think that..

GIULIO VALESINI

What do you mean no?

**MARCELLA MARLETTA - DIRECTOR GENERAL FOR MEDICAL DEVICES,
MINISTRY OF HEALTH**

...breast implants are devices. All devices can be subject to adverse reactions.

GIULIO VALESINI

I think the public have the right to know, doctor.

**MARCELLA MARLETTA - DIRECTOR GENERAL FOR MEDICAL DEVICES,
MINISTRY OF HEALTH**

Sure. But I'm not saying "no" to that. I'm saying that all drugs can also provoke adverse reactions. Some even fatal.

GIULIO VALESINI

Doctor, this is the first case of a death from anaplastic lymphoma associated with breast implants.

**MARCELLA MARLETTA - DIRECTOR GENERAL FOR MEDICAL DEVICES,
MINISTRY OF HEALTH**

Of course, but I can't inform the public first and then the National Health Council and my Ministry.

GIULIO VALESINI

But am I being impertinent if I say that was it not in the public interest to release the news before seeking the opinion of the National Health Council?

**MARCELLA MARLETTA - DIRECTOR GENERAL FOR MEDICAL DEVICES,
MINISTRY OF HEALTH**

Well, it is impertinent, because it doesn't work like that.

GIULIO VALESINI

What type of implant did the patient have?

**MARCELLA MARLETTA - DIRECTOR GENERAL FOR MEDICAL DEVICES,
MINISTRY OF HEALTH**

Textured.

GIULIO VALESINI

OK, look. What about the register?

**MARCELLA MARLETTA - DIRECTOR GENERAL FOR MEDICAL DEVICES,
MINISTRY OF HEALTH**

The register has now been rolled out, thanks to you.

GIULIO VALESINI

Oh...

**MARCELLA MARLETTA - DIRECTOR GENERAL FOR MEDICAL DEVICES,
MINISTRY OF HEALTH**

It has been rolled out.

GIULIO VALESINI

There we are.

**MARCELLA MARLETTA - DIRECTOR GENERAL FOR MEDICAL DEVICES,
MINISTRY OF HEALTH**

You like it when I tell you that, eh?

SIGFRIDO RANUCCI IN THE STUDIO

Yes, but it's not about self-satisfaction here. If the register of implants is rolled out, and monitoring patients becomes possible, it is due to the fact that Report has simply carried out its role as a public service provider. How can you monitor and inform patients of risks if you don't know who you need to inform, or how, where, when and what was implanted? Now, on 13 May the National Health Council will tell the public what needs to be done with these implants, and we will keep you updated on this issue. However, just remember, lymphoma doesn't need to be frightening, if it's caught in time. If any initial signs appear, which could just be inflammation, ask your doctor. Check yourself often. And finally, we can state that traceability, as we have understood, is fundamental in all fields.