Bigger, More Impactful Research Projects via Transatlantic Collaboration: A Case of an European Company

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Experience and Current Products of Protip SAS

- We are a biomedical company located in Strasbourg, France
- We have 10 years of experience on Titanium implants and in ORL field
- We have two CE-marked products

NewBreez: An Intralaryngeal Implant: It has been implanted in France, Germany, Belgium, Jordan and Turkey

ENTegral: An artificial Larynx which is at clinical trial stage

(5 implantations in humans in France)

actualite/2013/10/07/21345-premier-larynx-artificiel-monde-est-francais

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Le premier larynx artificiel du monde est français

Mots clés : greffe, Larynx artificiel, Implant, prothèse, Cancer de la gorge

Par Pauline Fréour - le 07/10/2013

VIDEO - Les premières greffes de larynx artificiel en titane ont permis aux malades de respirer et manger presque normalement pendant quelques mois.

Les personnes à qui l'on doit ôter **le larynx**, le plus souvent en raison d'un **cancer de la gorge**, n'ont guère qu'une option de prise en charge. Elles subissent en quasi-totalité une trachéostomie, une technique qui a des répercussions non négligeables sur leur qualité de vie. C'est pourquoi la prothèse de larynx mise au point par l'équipe du Pr Christian Debry, chef du service de chirurgie ORL au CHU de Strasbourg, suscite beaucoup d'espoir. Unique au monde, elle a été posée pour la première fois sur un patient il y a plus d'un an, en juin 2012. Quatre autres volontaires ont suivi depuis. La société ProTip, qui a participé à la mise au point de l'implant, en a communiqué les résultats lundi.

Ce larynx artificiel est l'aboutissement d'une quinzaine d'années de travail. Constitué de titane, il se pose en deux temps. Une première opération consiste à retirer le larynx du patient et à le remplacer par une sorte de «bague» que le chirurgien accolé à l'extrémité de la trachée. Après un délai minimal de six semaines, un deuxième élément, comportant un système de valves, est fixé sur la bague. Ces valves, qui ont représenté le plus gros défi technique pour les chercheurs, permettent au patient de respirer et déglutir, les deux fonctions du larynx les

Le larynx artificiel est composé de titane poreux, bien toléré par les tissus environnants. DR

A Short History of Protip

1993- 1995 ***Material Design***

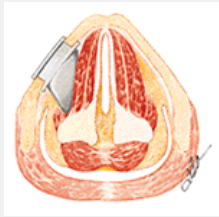
Design and Development of a Special Microbead-based Porous Titanium Structures

1995- 2005 ***Animal Test***

Biocompatibility Tests with rats and Sheep

2005 ***First Clinical Tests***

- *Mandibular Reconstruction*
- *Thyroplasty*



2011 ***First implantation in Human (Artificial Larynx)***

A Multicenter Clinical trial is in Progress

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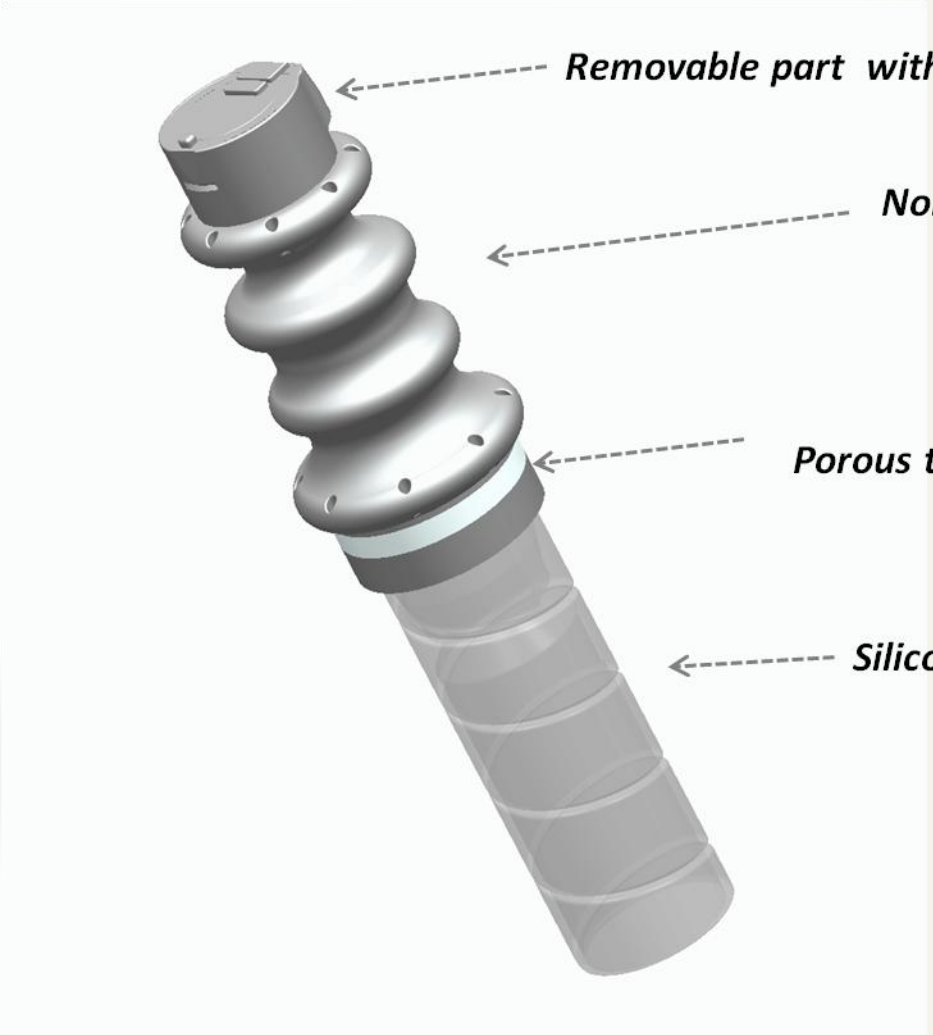
Entegral© Artificial Larynx



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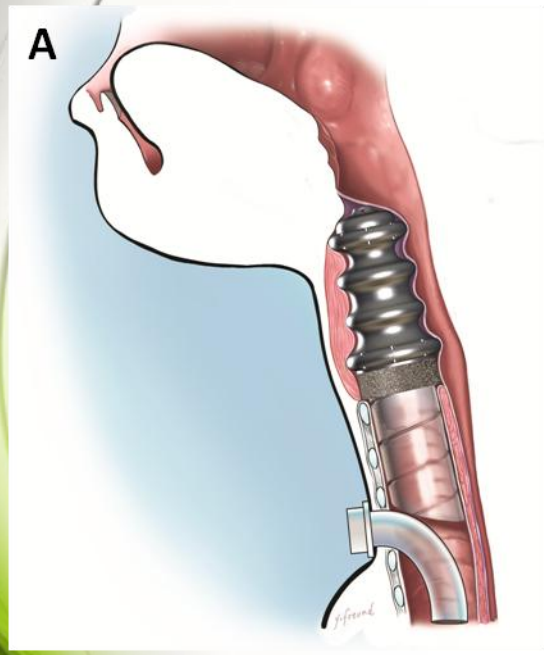
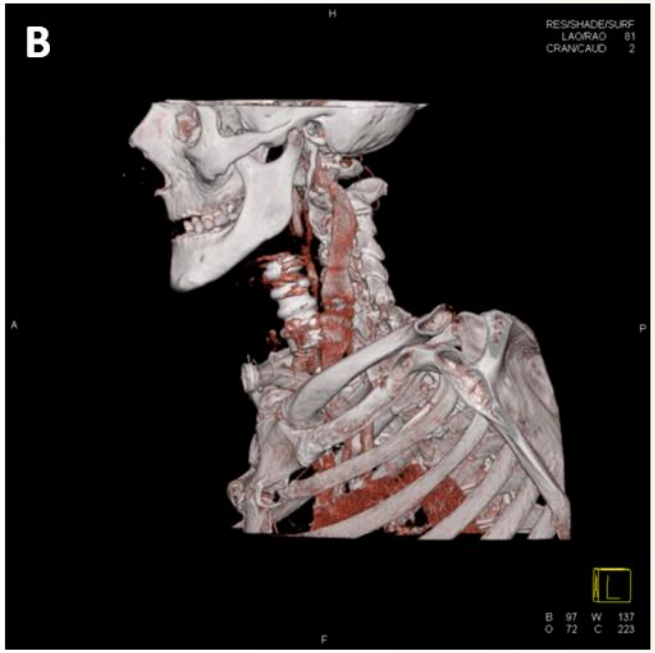
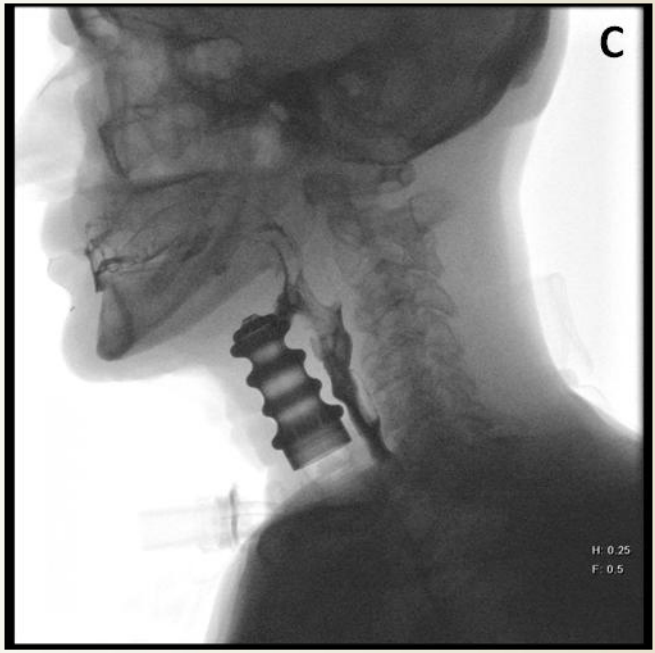
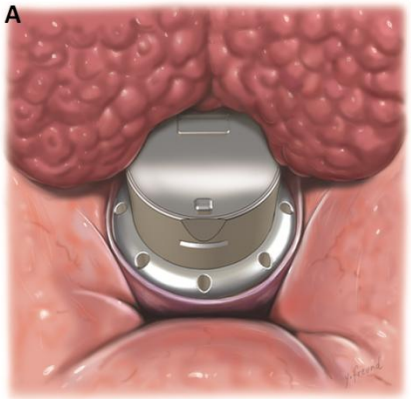
First Step

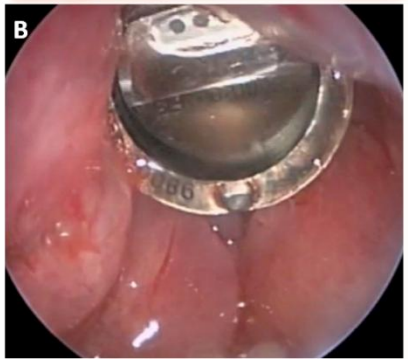


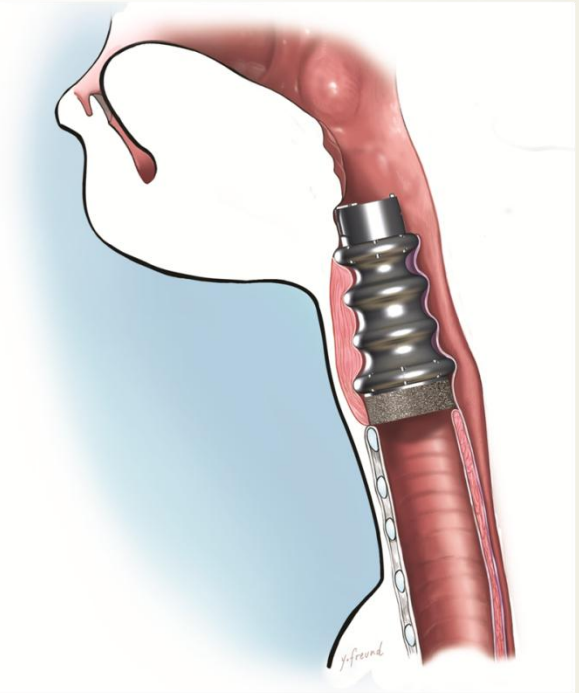




Second Step







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Aims of Our Fundamental Research Unit

- To develop a better understanding of the underlying scientific principles for better implant design and biomaterial choices.
- To develop a network of Universities, Research Institutes and SMEs with a wide range of capacities to respond to our immediate needs and future products
- To capitalize on our ORL biomaterial experience in order to develop breakthrough biomaterials-based products (**Smart Implants**, **Batch Processing Methods for Implants**, **Fundamental Solutions to the Implant Related Problems** (Adverse Immune Responses))

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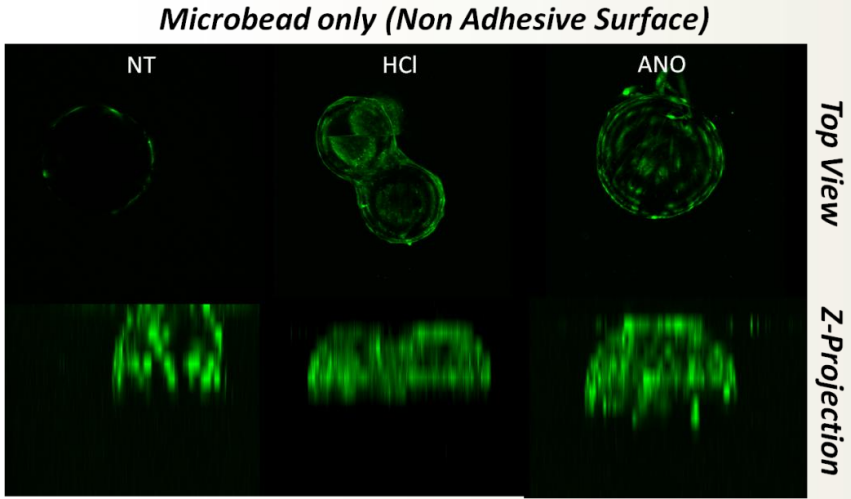
Current Capacity

- 3 Full-Time Researchers hired by Protip SAS directly.
- 2 Post-Docs, 1 Technician,1 PhD, 1 M.Sc. Student in University of Strasbourg working Full-Time on Protip-related Research Projects
- Access to high quality research equipment and animal facilities via INSERM and University of Strasbourg.
- Involved in 3 EU-funded international Projects with a total budget of 10 million Euros (Scientific Coordinator in 2 of them).
- More than 40 Scientists directly involved in Protip-Related projects in our Partner Universities (in Germany, Hungary, UK, France and USA) and SMEs (Czech Republic, Lithuania, Hungary, Estonia, UK, Germany). (Some in BWH).
- Our network includes Harvard Medical School, Heidelberg University, University of Dresden, University of Nottingham.



Why Do We Want More Impactful Projects?

- With our experience we want to address bigger problems in the field of implantology such as adverse immune reactions to implants
- Such big challenges cannot be tackled within small collaborations as they require diverse expertises and equipment: Thus multinational projects are necessary
- To embark on such ambitious goals, for a company, it is important to see the possibility of a big market access in the near future: As volumewise US is the biggest market in the health sector, access to US is important: Having US partners in such projects will make them more impactful

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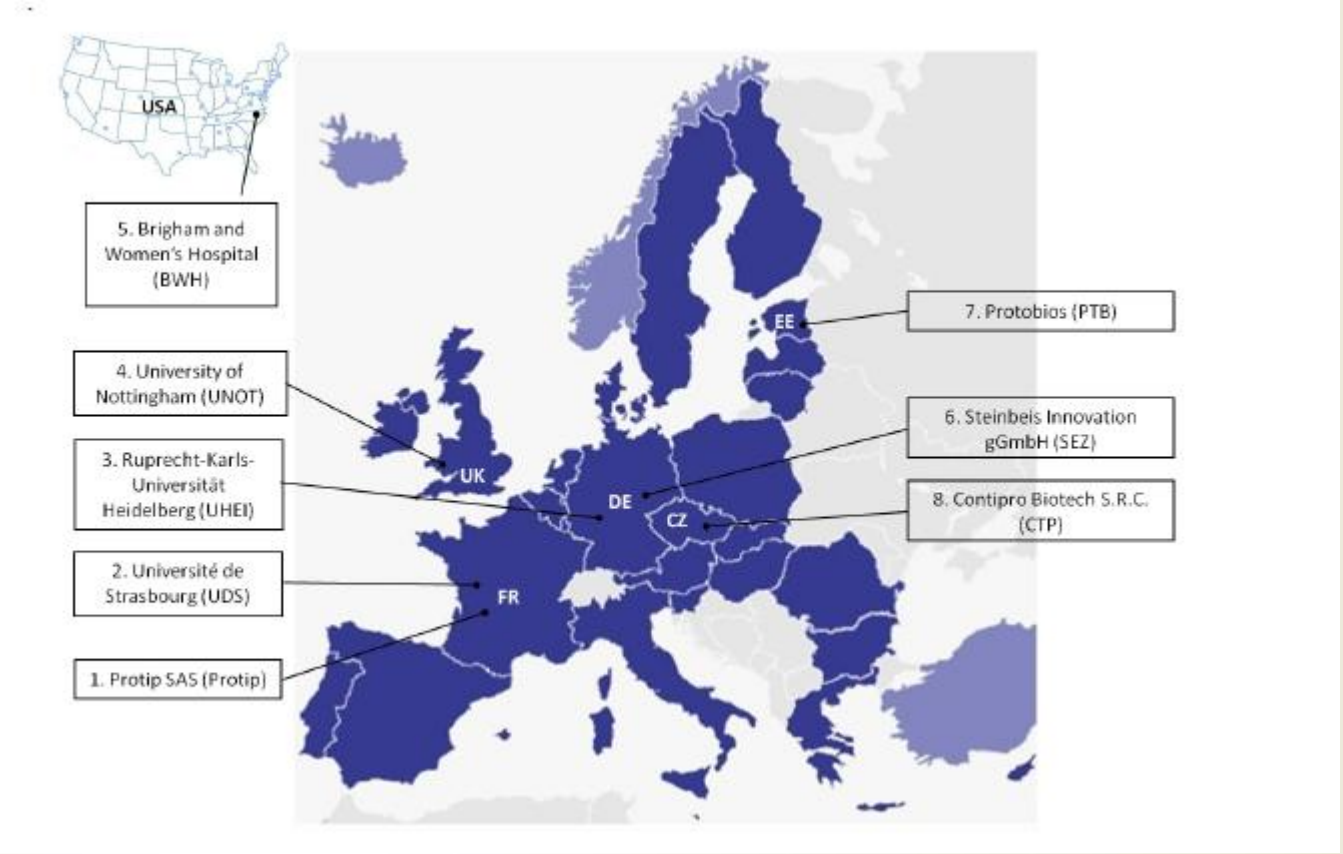
EU FP7 Project
IMMODGEL
www.immodgel.org

INSPIRING LARYNGOLOGY

The Consortium including Harvard Medical School (BWH)



Team Identification-The History of Collaboration Between BWH and Protip

- Decision to Establish a Direct Link with a prestigious US research Lab
- Khademhosseini Lab was selected due to its prominence in the field of Tissue Engineering and Regenerative Medicine
- First Contact: September 2011
- Mutual Decision to send a post-doc from Protip to Boston for a 1 year period for active development of the projects(in 2012)
- Proposed projects (Bioprinting)/ Immunomodulation (Current topic of the ongoing EU project)
- Results: 6 journal publications and a common project with another in preparation.

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Advantages of having a US partner

- Access and Exposure to US research network (Harvard-MIT as an incubator for future Faculty and Entrepreneurs)
- The commercial Aspects of the final results and restrictions in the US can be handled during the project, not after
- Distinctive approaches of US and EU research institutes create an unique synergy (But can also create problems)
- It is a good starting point for EU companies to establish a presence in US

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Project Set-up: Obstacles during the Establishment of the Collaboration

- ***What do you offer me that I cannot find in US/EU?***

You need to have something specific to offer

- ***There is too much paperwork involved; why should I bother with this?***

Yes, but now you can enter in a competition that was closed to you before. With the level of internal competition at the moment, it is good to look at other opportunities

- ***I have no idea if this is going to work, I do not even know the success rates. Why should I invest time/money on this?***

This is more about the quality of the project also mutual trust between the Transatlantic partners established via smaller prior collaborations

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Implementation: Technical Problems

- Material Exchange- Customs and Price Barrier
- Differences in the approach to IP issues, rather rigid stance from both US and EU institutes
- For Clinical Data, difficulties in synchronizing the approval processes and related delays
- Lack of Common Documentation which puts a lot of strain on the coordinator to have US partners accepted by EU Commision (Most probably vice versa too)
- The documentation problem is further evident during the money transfer stage

Immediate Actions that can improve the process

- From EU Commission side: A list of documents that US partners can actually provide
- From US/NIH side: Formation of the administrative officers about the handling of EU projects, so that they will know what is going on. Also formation for EU Commission employees to handle US documents
- A model consortium agreement that would cover the concerns of both EU and US partners

What will we do differently in our next Transatlantic Collaboration?

- A consortium agreement that is more in line with both our and US partner's priorities
- Involvement of the US partner in the clinical aspects of the project to learn the necessary processes
- More clear description of subcontracting for the US partner as the understanding of this process is different in US and EU.
- An earlier contact with the US partner's administrative staff with concise and clear information on what we need from them.
- A robust business plan to carry the results of the research project to US market.

Conclusion

- Transatlantic Collaborations open new doors to SMEs and something that should be pursued strongly
- There is a steep learning curve for the processes involved, but they are worth the trouble
- Establishment of prior contact in the form of personnel exchange has a tremendous effect on furthering the collaboration

Thank You For Your Attention

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