The Human and Economic Burden of Melanoma

Malignant melanoma (MM) is **the most aggressive type of skin cancer** and presents a **fast** evolution from benign lesions to malignancies, being responsible for ~90% of total deaths produced by skin cancers[1]. MM carries a significant social toll for our society, with a **global incidence of 351,880 new cases in 2015** (5 new cases per 100,000 people) and being responsible for almost 60,000 deaths in that year (1 death every 100,000 people)[2]. Its **incidence has experienced an unprecedented growth** of **2,000%** in the last century [3], especially in Australia (incidence 54 per 100,000), North America (21 per 100,000) and Western Europe (16 per 100,000), which ranked the top-3 regions with highest MM incidence, mortality and prevalence[2]. More importantly, MM incidence keeps rising at a fast pace and it is predicted to keep going up at least until 2030, due to aging and increase of population[4].

Treating MM patients also carries a **heavy economic burden** for our healthcare systems, which must cover visits to dermatologists, biopsies, hospitalization, therapies and follow-up.

To promote economic savings in healthcare and to save precious lives of MM patients, the society needs **new, fast and reliable diagnostic methods for detecting early stages of MM**. The Swedish Med Tech company Corpus, have recognized this market opportunity and have developed **DermaProbe, a revolutionary melanoma diagnosis device easy to use by nurses and general practitioners (GPs) without any specific training. It is a safe device and >95% accurate when distinguishing between benign and tumor skin lesions, highest rating on the market.**

[1] Rutkowski P. and Kozak K. "News from the melanoma sessions of the European Cancer Congress 2017" BMC Medicine 2017

[2] Karimkhani C. et al., "The global burden of melanoma: results from the Global Burden of Disease Study 2015" British Journal of Dermatol. 2017

[3] http://melanomainternational.org/melanoma-facts/#.WsxpVtNubEY

[4] Autier P, et al, "Prediction of number of melanoma deaths by 2050", 2017, European Journal of Cancer

The unmet need of early melanoma diagnosis

If MM is caught in an early stage, the **prognosis is extremely positive** with almost 100% survival rate. However, the incidence and mortality of MM keep increasing at a fast pace, due to the lack of a robust and reliable **diagnostic** methodology, among other reasons. **Current diagnosis technologies** (Figure 1) are far from satisfactory and **hinder the correct management of MM by our healthcare systems.**

Detecting MM at an early stage greatly improves prognosis and decreases cost of treatment.

If MM is detected in an early stage (Stage I or In situ melanoma), the 5-years survival rate is very high (93-97%). However, if MM is detected at an advanced stage (Stage II and III), the survival rate drops drastically to 10-20%. In terms of economic value, treating a stage I MM accounts for ~€2,000-€14,000 while treating a stage III/IV MM goes up to ~€34,000-€154,000 (Figure 1).

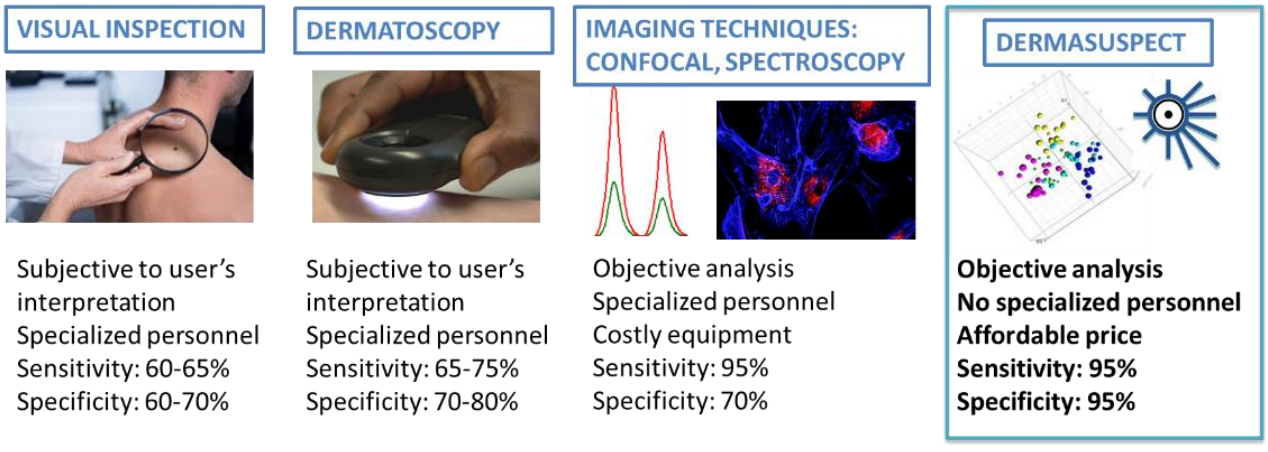

Figure 2: Current technique drawbacks compared with DermaProbe

- ✓ **Visual Inspection:** Consists on a dermatologist looking for specific signs of malignancy (*ABCDE rule* that checks mole Asymmetry, Border, Color, Diameter and Evolution). At early stages of MM, visual inspection poses a great challenge, as some of the MM characteristics are not fully developed yet and it can be confused with a benign skin lesion. Even for experienced dermatologists, visual inspections **only achieve ~60-65% sensitivity**[5]. Recently, new services are being implemented, such as First Derm, where the patient takes a photo of suspicious moles and sends it to a dermatologist for visual examination. **The sensitivity of this method is not higher, and it still needs a trained physician, which hence doesn't save expertise resources for the Health Care system.**
- ✓ **Dermatoscopy**, which consists on a magnifying lens and a light source held near the skin to detect skin morphology details not visible by the naked eye, is used in many dermatology departments as aid to visual inspection. Although it can increase sensitivity by 10% when used by an experienced specialist, its **sensitivity drops to 60% when used by inexperienced physician**[6]. This makes it unsuitable for a standard diagnostic method implemented in primary care and outpatient clinics and limits its use to dermatology specialized clinics and departments.
- ✓ **Imaging techniques** such as confocal microscopy, spectroscopy or electrical impedance, have been applied recently to diagnose MM. These methods detect morphological and/or chemical composition changes in healthy and tumor cells and rely on a more objective analysis of the results. However, they have not been widely adopted due to their **high costs** (ranging from €70,000 for simpler instruments to up €150,000 for more complex microscopy solutions), need for **highly technical experienced personnel to interpret the data** and **low rates of specificity** achieved.
- ✓ **Biopsies:** For final diagnosis, a biopsy of the lesion is obtained and analyzed histopathologically. Due to the low sensitivity of preliminary diagnostic methods, doctors adopt a ***"better safe than sorry" position***, excising unnecessary lesions that later, turn out to be benign on most of the cases. For **every case of MM detected**, there are **17 negative biopsies performed**[7]. These **biopsies have important human and economic consequences**: For patients, biopsies implicate discomfort, scars, pain and stress, and for hospitals biopsies implicate a high amount of unnecessary costs (2000 in Sweden, ~€29M were spent on 154,900 unnecessary biopsies[8]). Excision of the suspicious lesion and histopathology analysis takes **precious time that delays the diagnosis of MM and put patients' lives at unnecessary risk.**

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[5] Simon Kalouche, Vision-Based Classification of Skin Cancer using Deep Learning

[6] Bhattacharya et al, "PRECISION DIAGNOSIS OF MELANOMA AND OTHER SKIN LESIONS FROM DIGITAL IMAGES"

[7] L. Korb Ferris and R.J. Harris. New Diagnosis Aides in melanoma. NIH. Dermatol. Clin. 2012 July 30(3): 535-545.

[8] Lindelof B, Hedblad MA, Ringborg U. "Nevus or malignant melanoma? Correct diagnostic competence results in lower costs". Lakar. gen 2008