3-Dimensional Scanning for a Phase-2 Clinical Trial in Mycetoma in Sudan

Niels Liberton[1], Maureen van Eijnatten[1], Sjoerd te Slaa[1], Eiman Siddig[2], Rowa Hassan[2], Ahmed Fahal[2], Jan Wolff[1], Ed Zijlstra[3]

1) Department of Oral and Maxillofacial Surgery/Oral Pathology - 3D InnovationLab, VU University Medical Center, Amsterdam, The Netherlands.
2) Mycetoma Research Centre, University of Khartoum, Khartoum, Sudan
3) Drugs for Neglected Diseases *initiative*, Geneva, Switzerland

Introduction

Mycetoma is a serious neglected tropical disease that is caused by a chronic and progressively destructive infection of the subcutaneous tissues, usually in the foot area. To date, mycetoma-induced lesions are commonly monitored clinically or by using magnetic resonance imaging (MRI) that is considered the gold standard. However, MRI is expensive, has limited availability in developing countries and cannot be used outside clinical settings.

Novel 3-dimensional (3D) scanning technologies are being increasingly used for a wide range of different medical purposes such as the diagnosis of growth defects, assessment of melanomas and designing patient-specific prosthetics. 3D scanners are relatively inexpensive, portable and easy-to-use, and can create high-resolution 3D surface models of virtually any body part. Such 3D surface models allow objective, quantitative 3D analysis of body parts over time.

Methods

In this study we examined the usability of 3D optical scanning in patients with lower limb eumycetoma with limited size lesions (2-10 cm) who were recruited in a randomized controlled phase-2 drug trial in Khartoum, Sudan. MRI scans of the subcutaneous lesions on the lower limb were acquired at regular time intervals (t= 0, 3, and 6 months). Furthermore, 3D scans were acquired at t= 0,1,2,3 weeks and 1,2,3, and 6 months. The 3D scans were aligned with the MRI scan to measure the volume of the lesion. (Fig1) Changes in volume of the lesion and skin texture was measured by comparing sequential 3D scans. (Fig 2)

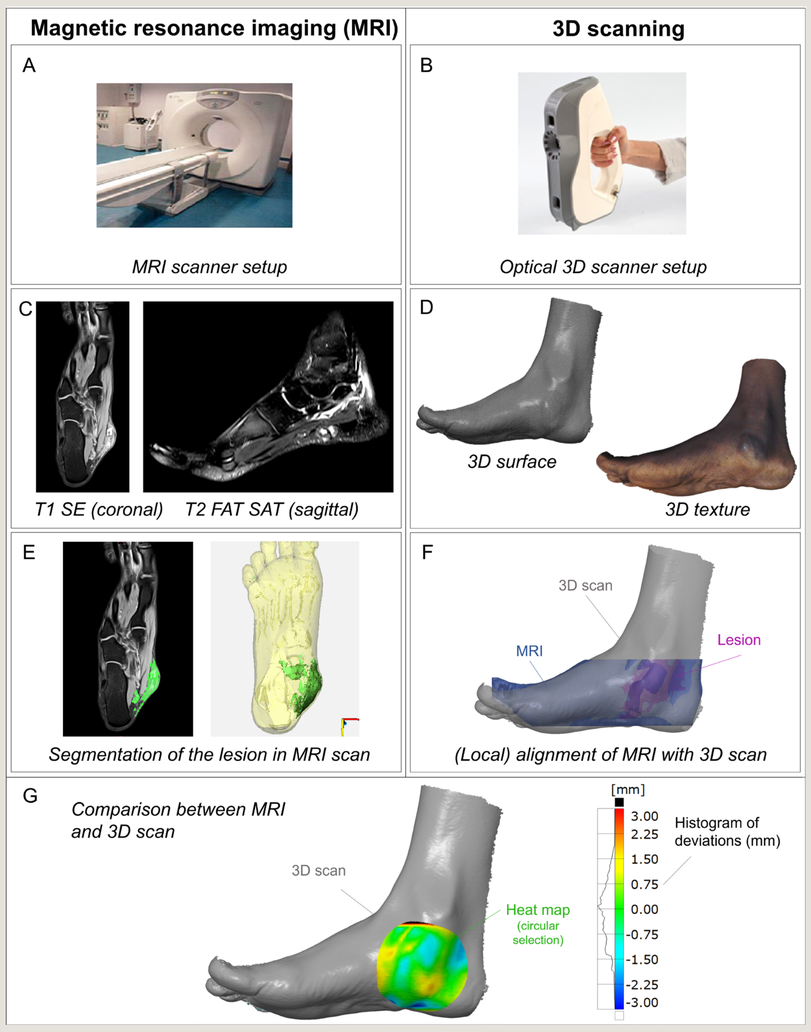


Fig 1. An innovative application of optical 3D scanning and MRI to assess a mycetoma lesion.
A) MRI scanner
B) Setup with handheld 3D surface scanner and laptop
C) MRI scan (T1 spin-echo and T2 fat-saturated sequences
D) 3D scan (3D surface and 3D texture)
E) Segmentation of the lesion in MRI scan
F) Local alignment of the MRI-based with 3D scan-based STL model
G) Heat map of geometric deviations between the MRI-based and the 3D scan-based STL model.

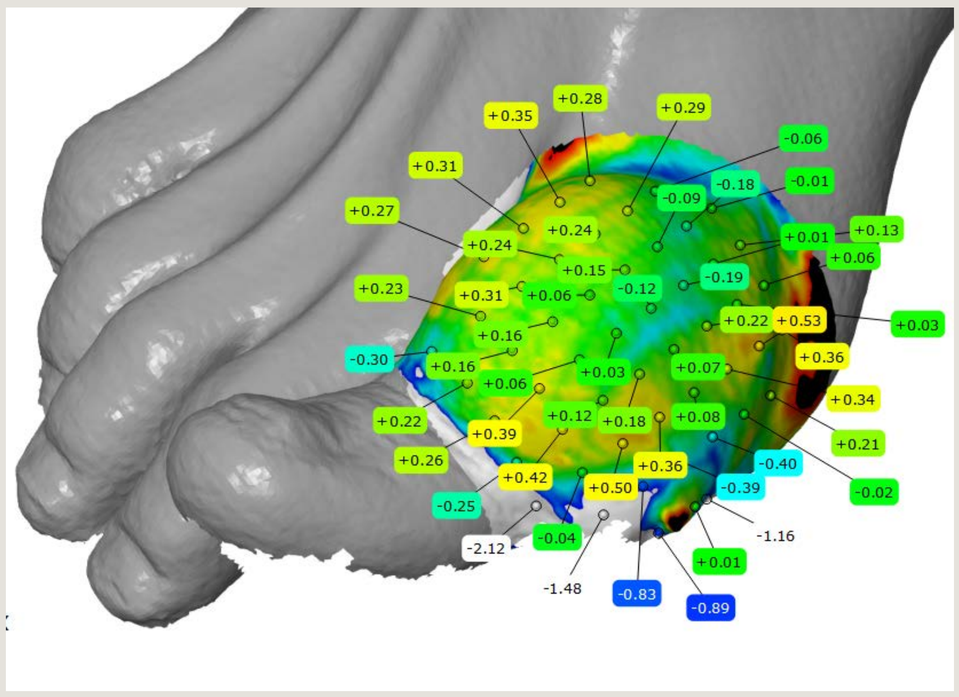
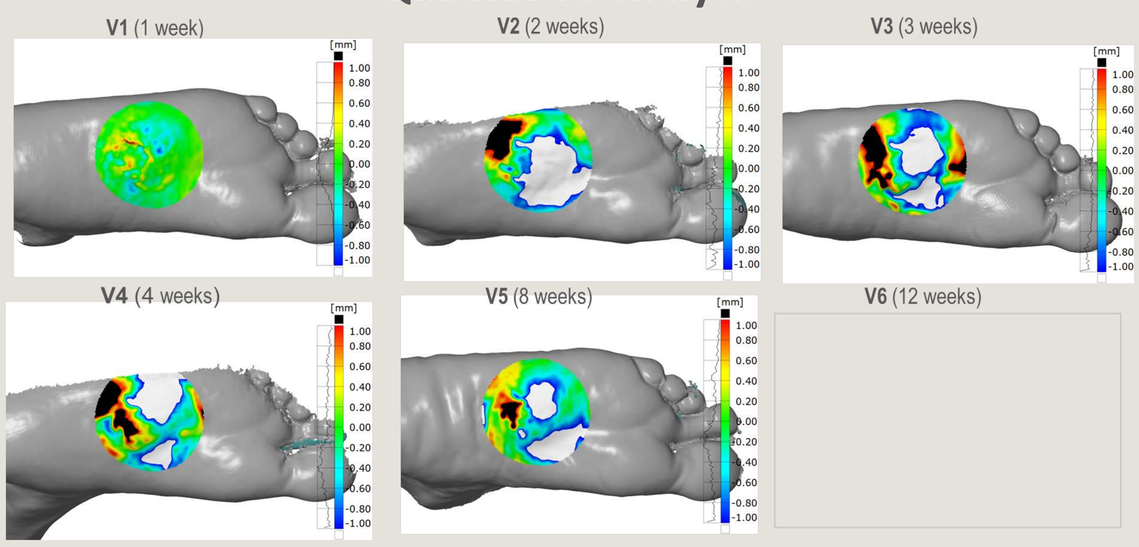


Fig 2. In order to quantify the change in the mycetoma lesion between two 3D scans (e.g. V0 and V1), the following steps were taken:
1) The 3D scans were locally aligned using a local best-fit operation in GOM software
2) Approximately 50 points were selected on the surface of both 3D scans (see image)
3) For each point, the difference (in mm) was calculated between both 3D scans
• Positive (+) differences indicate that the lesion became larger at that spot
• Negative (-) differences indicate that the lesion became smaller at that spot (remission)
4) The average difference (in mm) was calculated by adding all differences and dividing the sum by the number of points

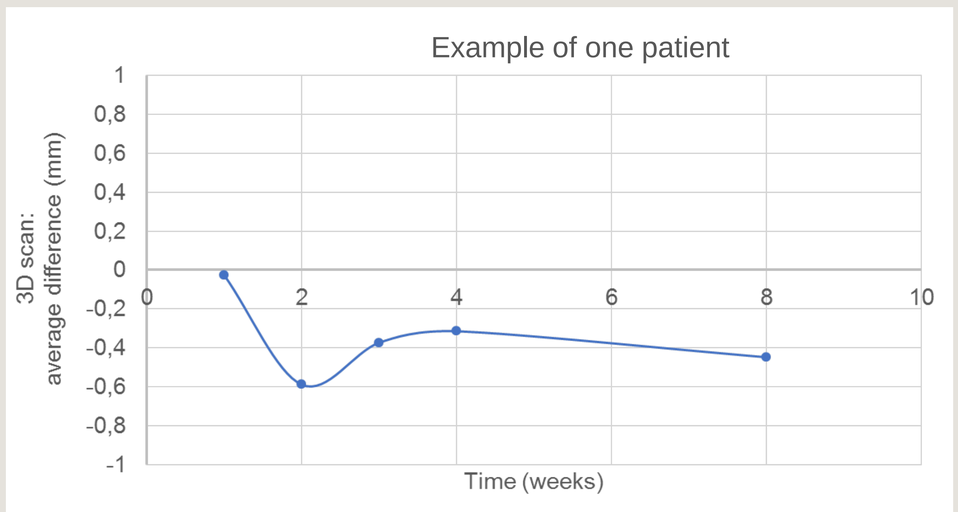
Results

Alignment of the 3D scans with the corresponding MRI scans proved to be feasible and allowed quantitative assessment of the entire lesion. In the first ten patients studied the volume of the lesion varied between 3 and 30 ml.
Second, repeated 3D scans allowed the assessment of the superficial part of the lesion. In those with minimum 3 months follow-up, 7 of the lesions were unchanged; in 3 cases the lesions showed reduction in size, between month 1 and 2.

Qualitative analysis



Quantitative analysis



Conclusions

3D scanning can offer a safe, accurate and easily repeatable alternative to existing medical imaging technologies such as MRI in monitoring clinical progress in mycetoma. This cutting-edge digital technology could also be valuable for the evaluation of other skin lesions, and has the potential for use under field conditions in developing countries.

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