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Confirmed Utility of Tissue Oxygen Saturation Assessments for Predicting Healing Capability in Below Knee Amputation

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***Abstract*- Aim: Deciding amputation level can be clinically challenging. Visible light spectrophotometry tissue oxygen saturation (TOS) measurements can be used to help guide selection of lower limb amputation level assessment. These measurements are made at Freeman Hospital using the LEA O2C device, a portable vascular optical device for measuring tissue oxygen saturation in superficial tissue.**

The aim of this study was to evaluate the effectiveness of amputation level assessment using optical tissue oxygen saturation in predicting wound healing in those undergoing below knee amputations (BKA).

Methods: A retrospective analysis of all patients who underwent amputation level assessment at a tertiary vascular unit between January 2009 and February 2017. All patients who underwent below knee amputations were included in the study (39 patients). Four patients were lost to follow up and 1 patient died before healing took place (in total 5).

Results: 39 patients who underwent BKA were included in the study. 37 had long posterior flaps and 2 had skew flaps. Amputation level assessment (ALA) correctly predicted outcome of wound healing in 87% (34/39). Sensitivity of the test was for BKA assessment was 90% (95% confidence intervals [CI] 75%, 97%) and specificity 75% (CI 41%, 96%). Positive predictive value, i.e. a BKA would heal, was 93% (CI 79%, 99%) and negative predictive value 67% (CI 35%, 88%). The likelihood ratio is 3.6. Three BKAs were converted to above knee amputation. The conversion rate from BKA to AKA was < 10%.

Conclusion: ALA is a good tool in predicting wound healing in patients undergoing major limb amputation. It gives the clinician an objective assessment and assist in decision making on level of amputation especially on borderline cases.

***Index Terms*- Tissue oxygen saturation, BKA, AKA**

I. Introduction

90% of amputations are due to peripheral vascular disease. The UK national amputation statistical data base reported a total of 5000 new amputation referrals in 2005 – 2006. Seventy two percent of these are due to peripheral arterial disease, 9 % trauma, 7% infection and 2% neoplasia (10% were "other" and not specified). More than two thirds of lower limb amputees referred were male (70%). The incidence of amputation is reported to be 8 to 12 times higher in diabetic patients compared to non-diabetics. A half of diabetic patients who have a major amputation will end up losing their contralateral leg within 5 years.

Good assessment of rehabilitation potential should be performed since this is critical in making the decision about the level of amputation. If the patient cannot undergo rehabilitation or mobilise then there is no advantage in offering them a below knee amputation which may be slow to heal, not heal or result in a fixed flexion deformity. Very frail patients may be better served with an above knee amputation as a definitive treatment.

Patients who undergo BKA have >80% chance of restoring ambulation. Their energy expenditure is about 10 to 40 % above normal depending on the length of the stump. Patients who undergo above knee amputations have 50 % or less chance of restoring ambulation especially in patients with peripheral vascular disease. Their energy expenditure is about 63% above normal. So due to these reasons, attempts should be made to perform more BKA if possible rather than above knee amputation (AKA).

The aim of this study is to evaluate the effectiveness of a microvascular amputation level assessment using optical tissue oxygen saturation in predicting wound healing in Northern Vascular Centre patients having a below knee amputation procedure.

II. METHODS

All patients who underwent amputation level assessment at a tertiary referral vascular surgery unit between January 2009 and February 2017 were identified from a prospectively maintained vascular database. Those who underwent below knee amputation (BKA) were included in the study. Patients lost to follow up (n=4) and those who died before wound healing took place (n=1) were excluded.

A retrospective review of case notes and electronic documentation was performed. The criteria for wound healing was documented wound healing after review by the vascular team.

Vascular optical measurements – tissue oxygen saturation (StO2)

Visible light spectrophotometry tissue oxygen saturation (SO2) measurements can be used to help guide selection of lower limb amputation level assessment. Measurements were made with the patient supine and rested for at least 10 minutes in a temperature controlled microvascular measurement facility (normothermic setting at 23.5^{o}C). A single operator (JA) used an LEA O2C optical probe for

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measurements of tissue oxygen saturation along the leg to a standardised protocol. This consisted of measuring 2 parameters; the mean SO2 levels ("MSO2") – measure in a matrix (9 points in a 3 cm square, points at 1 cm spacing in x and y orientation) centred at a point 10 cm distal to knee (i.e. tibial tuberosity, TT) and 3 cm medial to the midline between the TT and the big toe. Next, locate a similar matrix but at a point 3 cm lateral to the midline giving 18 measurements in total and an average used to represent an equivalent flap area; the Degree of Tissue Hypoxia ("DTH") – using measurements at 1 cm intervals from knee i.e. TT down to the big toe pad following the mid-line with the percentage below a cut-off threshold giving the DTH.

StO2 Amputation level assessment prediction

The range forms a quasi-rectangular box with values inside the box highlighting lack of confidence in a BKA succeeding, and those outside the box predicting that a BKA procedure was likely to heal. The box shape is defined on an X-Y plot with DTH at the graph X axis and MSO2 at the graph Y axis : ≥40% MSO2 and ≤15% DTH as key cut-off values for a BKA having capacity to heal. However, a high DTH value i.e. >30% is also associated with an AKA prediction whatever the MSO2. These values are for the LEA O2C system and based on using the O2C LF-2 probe for superficial tissue oxygen level measurement.

III. STATISTICAL ANALYSIS

Data summarized using mean and standard error of the mean (SEM) values. Data was analysed using GraphPad Prism 7 and statistical analysis included the unpaired t-test, Fisher's exact test and Wilson-Brown and with 95% confidence intervals were calculated. A p value <0.05 was considered statistically significant.

IV. RESULTS

A total of 39 patients were included in this study. Patient demographics and comorbidities are shown in table 1.

Table 1:

Patient demographics, n=39		
Age, years (mean ± SD)	66 (11)	
Sex		
Male	30	77
Female	9	23
Comorbidities, n		
Number of comorbidities, mean ± SD	2.7 (1.4)	
Hypertension	29	74
Hypercholesterolemia	20	51
Diabetes	18	46
Ischemic heart disease	16	41
MI (< 6 months)	1	3
Dyspnoea		
On exertion	14	36
Limiting	4	10
Renal transplant	1	3
Renal dialysis	1	3

Operative details are listed in table 2. Standard BKA using long posterior flap was performed in 37 cases and skew BKA in 2 cases.

Table 2:

Operation details	
Elective (planned)	11
Urgent unplanned	24
Emergency usually within 2hrs admission	2
Timing of operation	
Within working hours	30
Outside of normal working hours	9
Procedure length, mean minutes (range)	75 (25-325)
Indication	
Distal gangrene	26
Rest pain	19
Deep infection	3
Osteomyelitis	3
Previous ipsilateral intervention	
Angioplasty - patent	4
Angioplasty - occluded	9
Surgery - occluded	10
Embolectomy	1

Figure 1a shows patients whose wound healed had a mean DTH of 7.6% (SEM 1.8) and patients whose wound did not heal had mean DTH of 28.6% (SEM 7.3). The difference between these groups is highly significant (p<0.001).

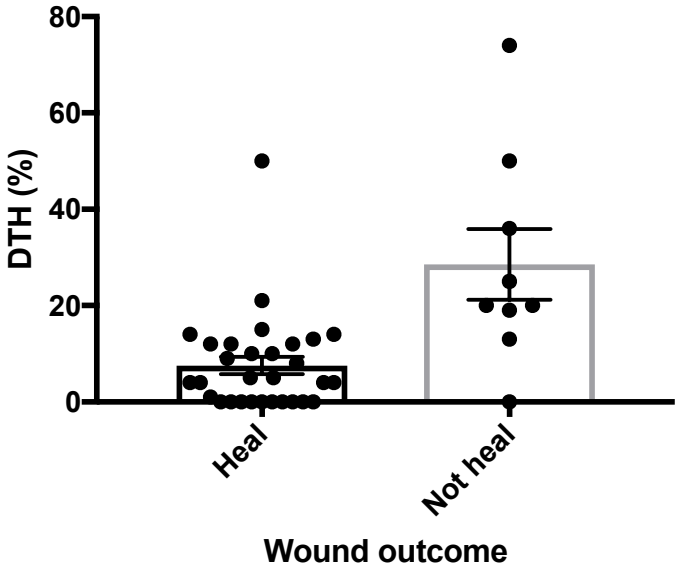

Figure 1a: degree of tissue hypoxia (DTH) – with unpaired t-test the groups were highly significantly different (p<0.001)

Figure 1b shows patients whose wound healed had an mSO2 of 33.6% (SEM 2.4) and patients whose wound did not heal had mean mSO2 of 28.3% (SEM 3.4). The difference between these groups was not significant (p=0.28).

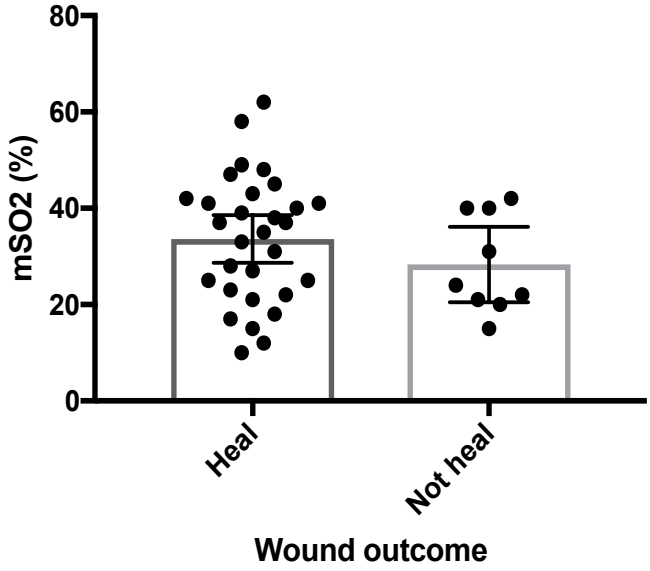

Figure 1b: mean visible light spectrophotometry tissue oxygen saturation measure (mSO2) – with unpaired t test there was no significant difference (p=0.28)

Amputation level assessment correctly predicted outcome of wound healing in 87% (34/39) cases. Figure 2 shows actual outcome of wound healing compared to predicted outcome.

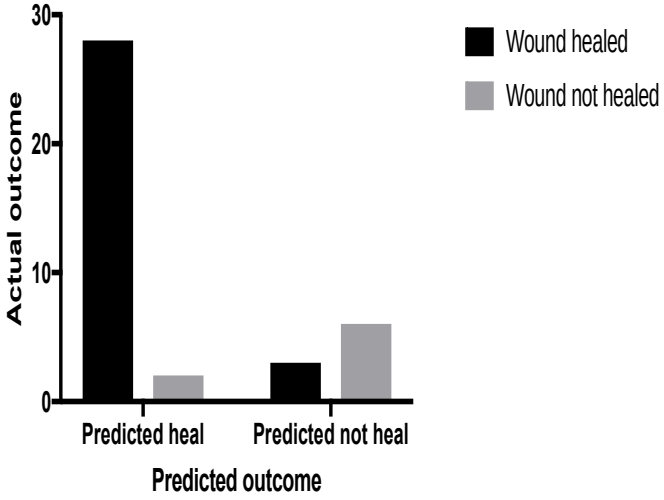

Figure 2: sensitivity and specificity of test. Wound predicted to heal and was documented to have healed (n=28) and not healed (n=3). Wound predicted to not heal and healed (n=6) and not healed (n=2).

Sensitivity of this test for BKA assessment is 90% (95% confidence intervals [CI] 75%, 97%) and specificity 75% (CI 41%, 96%). Positive predictive value, i.e. a BKA would heal, was 93% (CI 79%, 99%) and negative predictive value 67% (CI 35%, 88%). The likelihood ratio is 3.6.

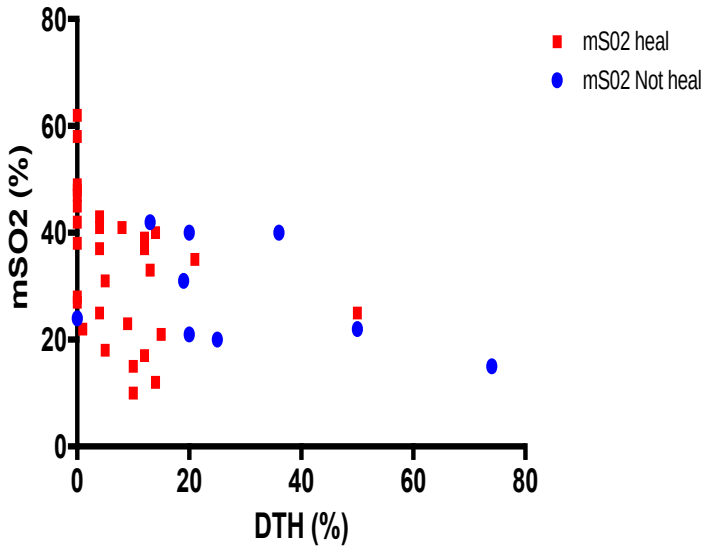

Figure 3 – XY scatter plot of measured mSO2 and DTH and actual wound outcome

V. DISCUSSION

An above-knee or through-knee amputation is usually the best option for a frail patient who is only ever likely to be mobile in a wheelchair. Most patients requiring amputations have significant comorbidities and amputation carries an appreciable risk of morbidity and mortality. By better identifying those with BKA healing potential second procedures can be avoided and associated morbidity and mortality avoided. A protracted period of attempting to wait for BKA healing followed by conversion to AKA or TKA will not only have a substantial resource and economic cost for health services it will also often result in a de-conditioned patient, loss of muscle bulk and strength and a consequent reduction in rehabilitation potential and return to independent living.

Conversion rates of below knee to above knee amputations is between 9 to 15 %. This can increase to above 20% in patients who had failed bypass operations. Dardik *et al* quoted 23.5 % conversion rate in his series of patients who had failed surgical bypasses who ended up with below knee amputation. This probably is due to damage of collaterals during the bypasses. The conversion rate in our tertiary centre was 9.8% (7/71).

Twenty patients went to have AKA straight away. The cause of that was multifactorial. Clinical and amputation level assessment. 70% (14/20) had an ALA assessment which suggested that a BKA would not heal so the patients went to have a primary above knee amputation (AKA). Although the other 30 percent (6/20) who had an ALA which predicted healing of a BKA stump did not go for it for reasons such as patient will not be able to walk when assessed by the physiotherapy team. Other reasons such as frailty, critical condition, the lack of rehab potential, and patients with fixed flexion deformity of the knee. Patients with fixed flexion deformity of the knee may develop ulceration of the BKA stump due to friction and may end up needing revision of the stump so it is advisable in such circumstances to proceed to AKA.

59 % of the patients who had BKAs were diabetic (23/39). The ALA was performed in 17 of these patients (74%) (17/23). The test was accurate in predicting the outcome of healing in 16/17 patients (94%). In the non-diabetic patients the test was accurate in 18/22 patients (81.8%). It is difficult to conclude from such small numbers if there is a trend that the test is more accurate in diabetic patients.

Although the pattern and level of arterial disease will usually have been assessed the additional contribution to healing potential of associate co-morbidities such as respiratory disease, oedema and cardiac failure are not be appreciated or quantified by the surgeon team.

VI. LIMITATIONS OF THE STUDY

From this study there is a clear indication that ALA provides a very useful means to predict wound healing. TOS tests are not really available in the district general hospitals (DGHs) and it would be valuable if such tests can be conducted in them but it needs significant staff resource to provide them. The study as well did not include if the ALA had any impact on length of stay in the hospital as this could be a major driving factor in making these tests more available.

Further work is needed to assess if the test is helpful in predicting healing of AKA in patients with severe aorto-iliac disease. In such unfortunate patients with unhealed AKA stumps the next step would be hip disarticulation which is associated with high mortality, morbidity and ambulation potential is exceedingly low.

It is interesting to speculate that the assessment could be extended to assessment of healing of forefoot amputations. Although we have no protocol for this, anecdotally we have found it helpful on occasion.

VII. CONCLUSION

Amputation level assessment by visible light spectrophotometry tissue oxygen saturation (TOS) measurements is a good tool to help the clinician in making a decision about level of amputation. It is particularly useful if there are any doubts or concerns about the potential of stump healing and provides also an objective way of assessment the healing potential of a stump.

REFERENCES

[1] Beckert S, Konigsrainer A, Witte MB, Coerper S. The impact of the micro-lightguide O2C for the quantification of tissue ischaemia in diabetic foot ulcers. Diabetes Care 2004;27:2863-67

[2] Hanson JM, Harrison DK, Hawthorn IE; Tissue spectrophotometry and thermographic imaging applied to routine clinical prediction of amputation level viability; In “Functional Monitoring and Drug Tissue Interaction”; SPIE Proc. Series 2002;4623:187-194

[3] Harrison DK, Evans SD, Abbott NC, Swanson Beck J, McCollum PT. Spectrophotometric measurements of haemoglobin saturation and concentration in skin during the tuberculin reaction in normal human subjects. Clin Phys Physiol Meas 1992;13:349-63

[4] Harrison DK, McCollum PT, Newton DJ, Hickman P, Jain AS. Amputation level assessment using lightguide spectrophotometry. Prosthetics and Orthotics International 1995;19:139-47

[5] Harrison DK. Optical measurements of tissue oxygen saturation in lower limb wound healing. Adv Exp Med Biol. 2003;540:265-9

[6] Harrison DK, Hawthorn IE. Amputation level viability in critical limb ischaemia: setting new standards. Adv Exp Med Biol. 2005;566:325-31

[7] Aulivola B[1], Hile CN, Hamdan AD, Sheahan MG, Veraldi JR, Skillman JJ, Campbell DR, Scovell SD, LoGerfo FW, Pomposelli FB Jr. Major lower extremity amputation: outcome of a modern series.

[8] Herbert Dardik, M.D, Mark Kahn, M.D.,Irving Dardik, M.D Barry **a.**, SussmanM.D., M.D. Influence of failed vascular bypass procedures on conversion of below-knee to above-knee amputation levelsNathan DM. long-term complications of diabetes mellitus. *N Engl j Med* 1993; 328: 1676 - 85

[25] Scremin OU, Figoni SF, Norman K, Scremin AM, Kunkel CF, Opava-Rutter D,Schmitter ED, Bert A, Mandelkern M. Preamputation evaluation of lower-limb skeletal muscle perfusion with H(2) (15)O positron emission tomography. Am J Phys Med Rehabil. 2010 Jun;89(6):473-86. doi: 10.1097/PHM.0b013e3181d89b08. PubMed PMID: 20357647.

[26] Wilkinson D, Parkin A, Wowden P, Robinson PJ, Kester RC. The application of a new method of limb blood flow measurement using a radioactive isotope and a gammacamera. J Cardiovasc Surg (Torino). 1989 Jul-Aug;30(4):618-23. PubMed PMID:2777870.

[27] Dwars BJ, Rauwerda JA, van den Broek TA, den Hollander W, Heidendal GA, van Rij GL. A modified scintigraphic technique for amputation level selection in diabetics. Eur J Nucl Med. 1989;15(1):38-41. PubMed PMID: 2917582.

[28] Harris JP, McLaughlin AF, Quinn RJ, Page S, May J. Skin blood flow measurement with xenon-133 to predict healing of lower extremity amputations. Aust N Z J Surg. 1986 May;56(5):413-5. PubMed PMID: 3459451.

[29] Figoni SF, Scremin OU, Kunkel CF, Opava-Rutter D, Johnson J, Schmitter ED,Scremin AM. Preamputation evaluation of limb perfusion with laser Doppler imaging and transcutaneous gases. J Rehabil Res Dev. 2006 Nov-Dec;43(7):891-904. PubMed PMID: 17436175.

[30] John Chamberlain. The diabetic foot, how can it be saved (chapter) Vascular Surgery current questions