Health economic Evaluation

The economic efficiency of Granulox

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SastoMed
INNOVATE THERAPY

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1. Initial situation

There is an urgent need for action on wound treatment in Germany. Every year, around 4 million patients suffer from chronic wounds.[1] Of these 4 million patients, around 3.5 million are not treated adequately. Every year, there are 30,000 ï 60,000 amputations of the lower limbs (minor or major amputations).[2] 22 % of the patients with major amputations die perioperatively.[3] The majority of amputations and thus amputation-related deaths could be avoided through adequate wound treatment.

Apart from the considerable limitations in outcome for the patients, amputations cause high costs for society as a whole. 70 % of the patients with major amputations are dependent on care after the intervention. Care is predominantly given on an inpatient basis here, mostly in old people's or nursing homes.

The main reasons for the inappropriate treatment of wound patients are:

- Unattractive reimbursement in the registered doctor sector in relation to the expenditure for care and materials;
- Insufficient number of interprofessional wound networks;
- Poor training on the subject of wound healing and wound management in medical studies and in advanced medical training;
- Unmanageable number of wound dressings, with a wide variety of different therapeutic approaches;
- Despite the large number of different wound dressings, hypoxia[4] is not alleviated as the common origin of almost all chronic wounds.

[1] Medical Data Institute (2012).
[2] Medical Data Institute (2012), Müchler, B. (2008) and Rüttermann, M. et al (2013), p. 25.
[3] cf. Reike, H. (1997), p. 14 et seq..
[4] cf. Kröger, K. et al (2012), p. 212 et seq.

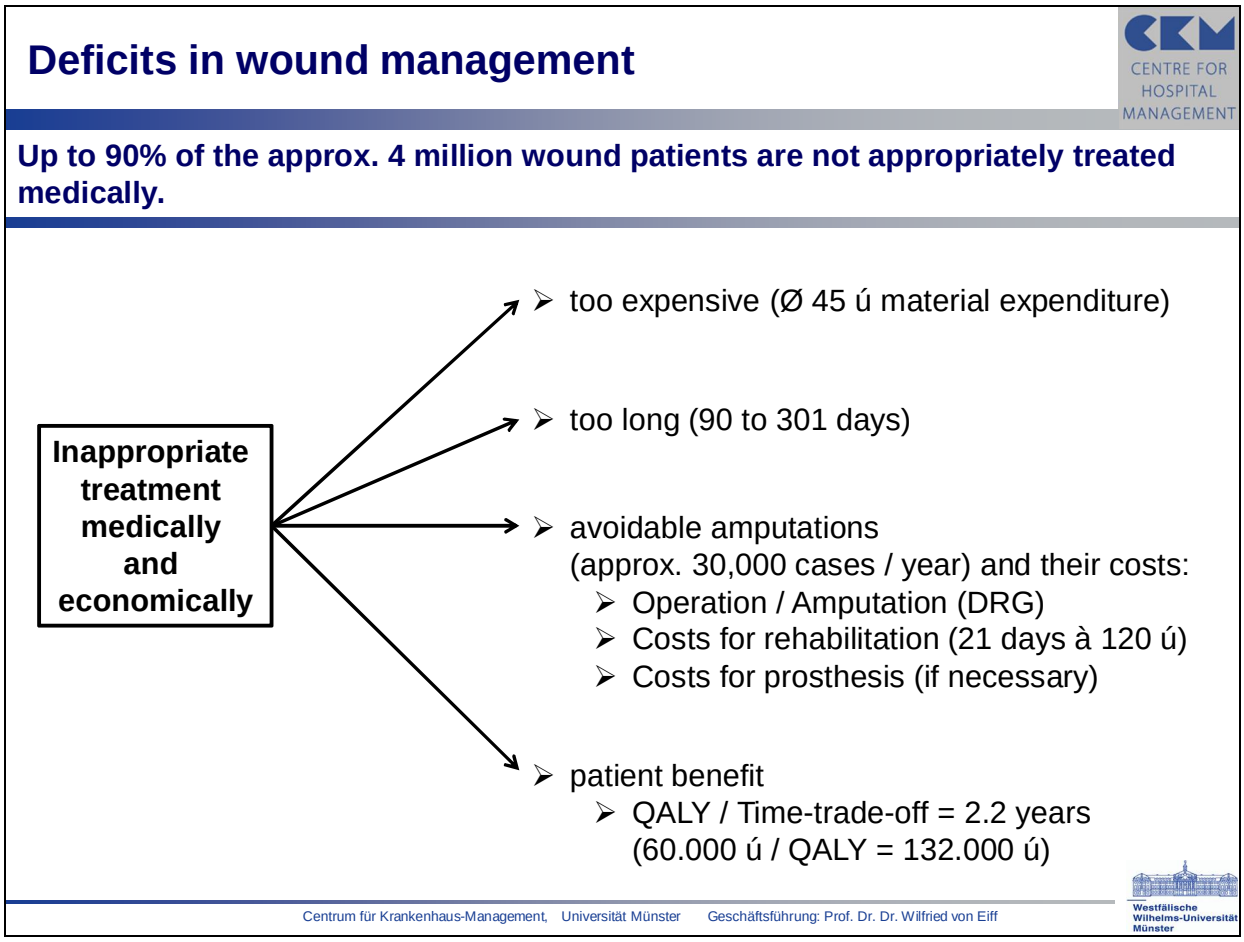

Figure 1: The treatment of wound patients in Germany is largely inappropriate.

The three most common wound types are crural ulcers, decubitus ulcers and diabetic foot ulcers (see Figure 1).

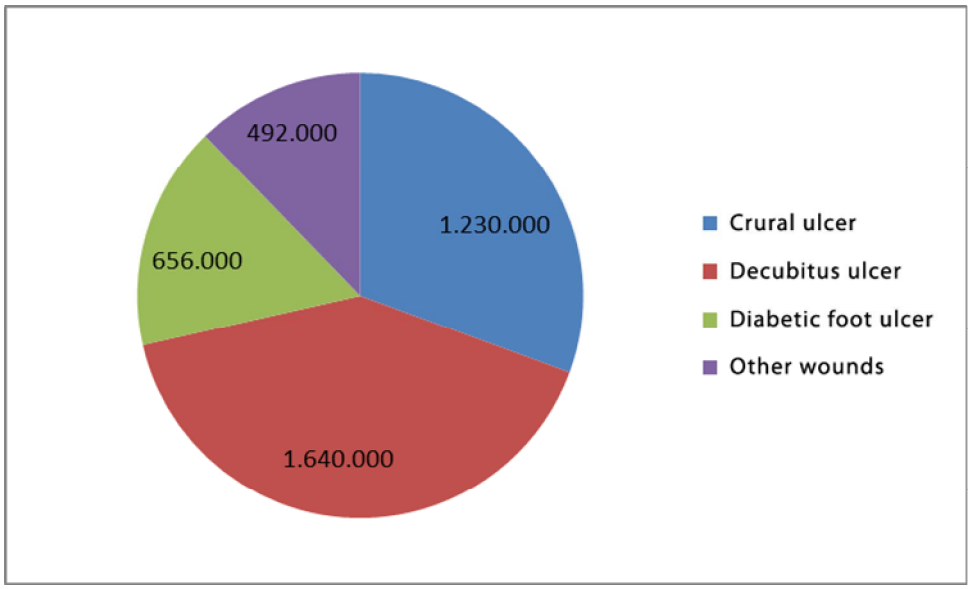

Figure 2: Distribution of the patients with chronic wounds according to wound type.

Crural ulcers

With a prevalence of 1.5%, crural ulcers account for 30% of all chronic wounds[5] .

Crural ulcers are a symptom of other primary diseases, which are distributed as follows:

Primary disease	Share	Number
Chronic venous insufficiency (CVI)	70%	861,000
Peripheral artery occlusive disease (PAOD)	10%	123,000
Mixed form	15%	184,500
Others	5%	61,500

Table 1: Distribution of the primary diseases underlying crural ulcers.

At present, there are no details about the treatment costs incurred. In a representative study for North Rhine Westphalia, a value of 16 million was determined just for the area of personnel costs in outpatient care. [6]

Decubitus ulcers

With a prevalence of 2%, decubitus ulcers (stage III and higher) are the most common cause of chronic wounds.[7] Their share of all chronic wounds is 41%.

In the hospital sector, the prevalence is 5-10%, in the sphere of old people's homes and geriatric institutions 30% and in home care 20%.[8]

However, it can be assumed that the number of unreported cases is considerably higher in all fields.

[5] cf. Heuzeroth, V., Janßen, H (2006).
[6] cf. Laible, J. et al (2002), p. 16 et seq.
[7] cf. Püschel, K. et al (1998) and Heinemann et al (2000), p. 45 et seq.
[8] cf. Robert Koch Institute (2002) and Schöffski, O. (2000).

Ulcers related to diabetic foot syndrome

In Germany, 4.6 million people are currently suffering from diabetes mellitus, of whom around 15% will develop a foot ulcer over the course of the disease. At 50%, peripheral polyneuropathy is the most common cause, PAOD is considered to be the main cause in 15% of all cases, and a mixed form is present in 35% of all cases.[9]

Approx. 40,000 amputations are performed in diabetics every year, 50% of them being major amputations[10], while perioperative mortality is 22% in the case of major amputations and 3% in the case of minor amputations.[11]

Costs in the health care system

The treatment of chronic wounds involves a high economic outlay: it leads to treatment costs of around 6 million EUR.[12] The treatment costs for the health insurance funds amount to an average of 5,000 EUR per wound.[13] As a result of demographic developments, a further worsening of the situation is to be expected.

Against this backdrop, it would be desirable to introduce innovative wound treatment products into the system that show increased efficacy compared with previous therapeutic approaches and are additionally of economic benefit.

Therefore, the aim of this study is to demonstrate the economic benefit of an innovative wound treatment product on the basis of a haemoglobin-containing wound dressing. The clinical-therapeutic efficacy of this product has been demonstrated by various studies (e.g. Arenbergerova, Karls-University of Prague[14]).

[9] cf. Protz, K.. (2011), p. 445.
[10] cf. Risse, A. (2007). p. 121.
[11] cf. Lawall, H., (2013), p. 95.
[12] Medical Data Institute (2012).
[13] cf. Janßen, H. (2012).
[14] Arenbergerova, M. et al (2013).

In addition, the clinical-therapeutic superiority of this product over traditional therapeutic approaches has been demonstrated in selected wound treatment centres (e.g. Mandl, Munich Pasing Hospital).

In particular, it has been found that the use of Granulox leads to a marked acceleration of the wound healing process.

The earlier Granulox is used, the more efficient the course of therapy and the lower the therapy costs incurred along the continuum of care.

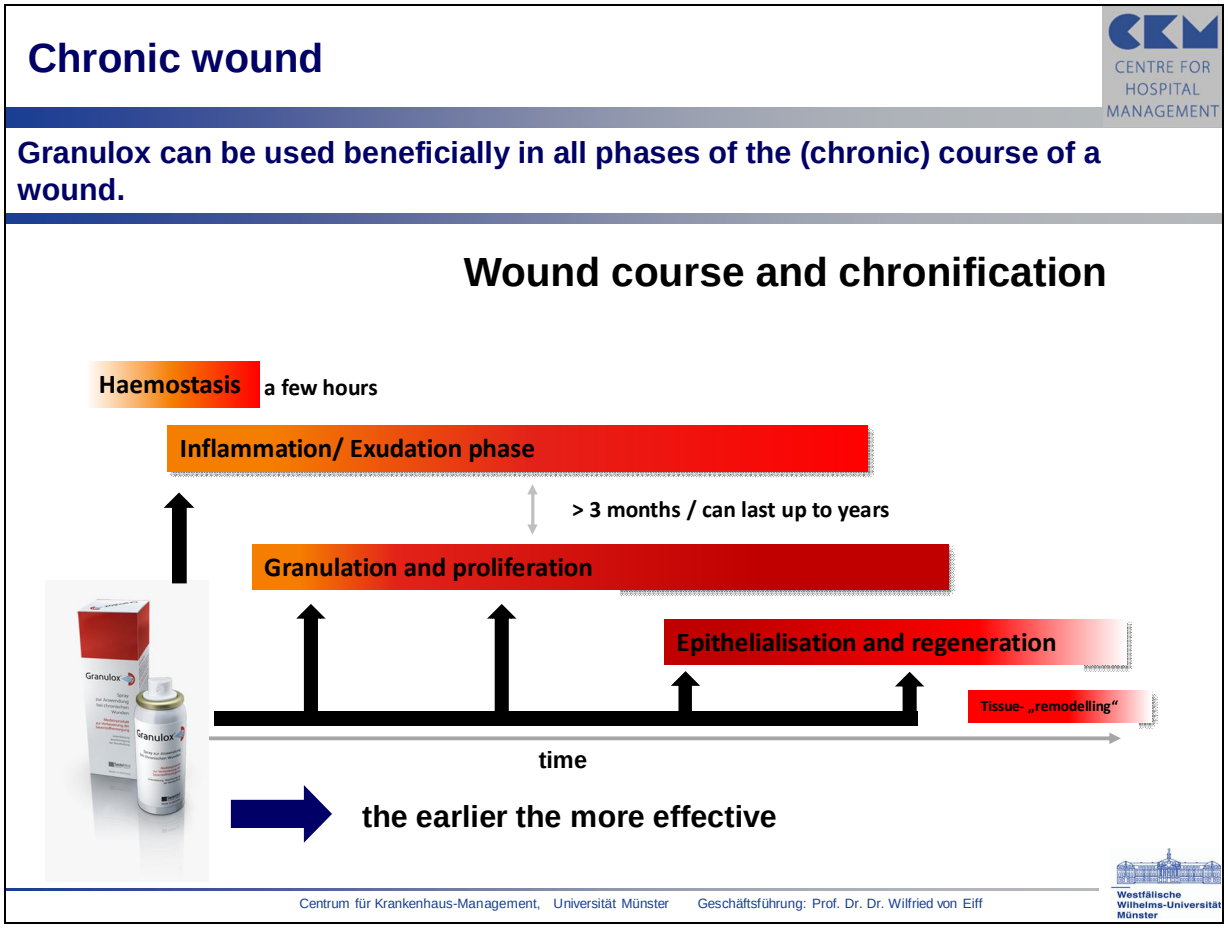

Figure 3: The course of a chronic wound.

[15] Mandl, C. (2012).
[16] cf. Arenbergerova, M. et al (2013), Mandl, C. (2012) and Mustafi, N. (2012).

2. Method

On the basis of randomly selected cases, the course of treatment, medical quality, direct and indirect costs as well as opportunity costs of alternative treatment regimens are compared. In addition, a major aspect of the evaluation is the criterion that patients may require amputation as a result of inadequate wound treatment. The risk of an avoidable amputation of a lower limb (minor or major) is to be illustrated.

Chronicity of the wounds is assumed after 8-12 weeks of treatment without a trend towards healing.[17] In addition, the patient's risk that a chronification of the wound will occur as a result of an inappropriate therapeutic approach also plays a role.

Risk-weighted process analysis (RPA) was used as an analytical method.[18]

[17] cf. Dissemond, J. (2012), p. 15 et seq.
[18] von Eiff, W. (2007), p. 438 and von Eiff, W. (2011), p. 249.

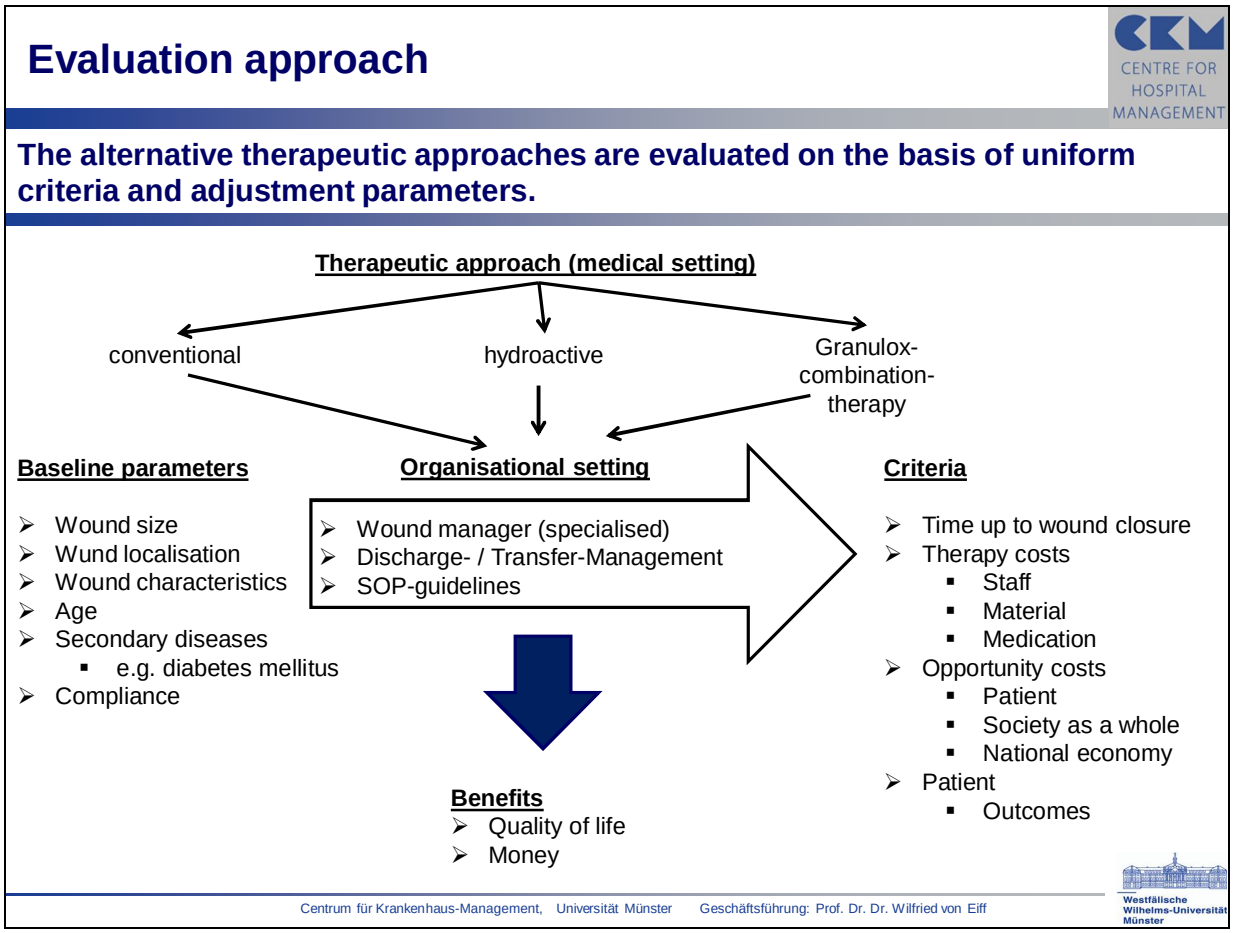

Figure 4: Evaluation criteria and adjustment parameters in the evaluation process.

RPA is an approach used in health technology assessments (HTA) and compares alternative therapeutic approaches with regard to quality, risk and cost effects. RPA is a holistic approach in which all aspects relevant to the health care system (medical quality, patient outcome, costs for society as a whole, individual patient costs) are correlated to each other.

The economic calculation is made on two levels. Initially, risk-weighted process analysis is performed on the basis of a standard calculation (therapeutic approach, materials used, especially change of dressings) of the alternative procedures. The results of the calculation are finally to be concretised and verified by means of a single case presentation on the basis of real treatment cases.

The various therapeutic and organisational settings are evaluated by means of reproducible criteria and adjusted with regard to baseline parameters and influences from the organisational setting (see Figure 4).

3. Results

3.1 Risk-weighted process analysis (RPA)

RPA is based on the one hand on a standard calculation[19] that comprises the resource consumption per change of dressing, taking into account the duration of treatment. Besides the direct costs per change of dressing (staff, material), indirect (administrative/coordination) costs are also included. The standard calculation considers the three different therapeutic approaches independently of each other.

The result of this standard calculation shows clear advantages in the total costs for the combination therapy (see Figure 5).

Standard calculation

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The standard calculation for determining the direct and indirect costs per change of dressing shows advantages for the combination therapy.

Therapeutic approach	Staff costs (per change of dressing)	Material costs (per change of dressing)	Ø Average duration of treatment up to success of therapy (wound closure)	Total costs
A conventional-dry	10,86 ú	5,62 ú	301 Tage	4.960,48 ú
B hydroactive	10,86 ú	9,67 ú	92 Tage	809,47 ú
C Granulox combination-therapy	10,86 ú	13,67 ú	60 Tage	630,77 ú

Approach:
- Daily change of dressing in setting A
- Change of dressing 3x per week in settings B and C

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Figure 5: Standard calculation of alternative therapeutic approaches (Basis: direct and indirect costs).

[19] The values for staff costs and material costs are taken from Sellmer, W. (2012) and from manufacturers' information

A variant of the standard calculation is the consideration of a refractory wound for which the therapeutic approach was switched to the Granulox combination therapy (Setting C) over the course of time (see Figure 6).

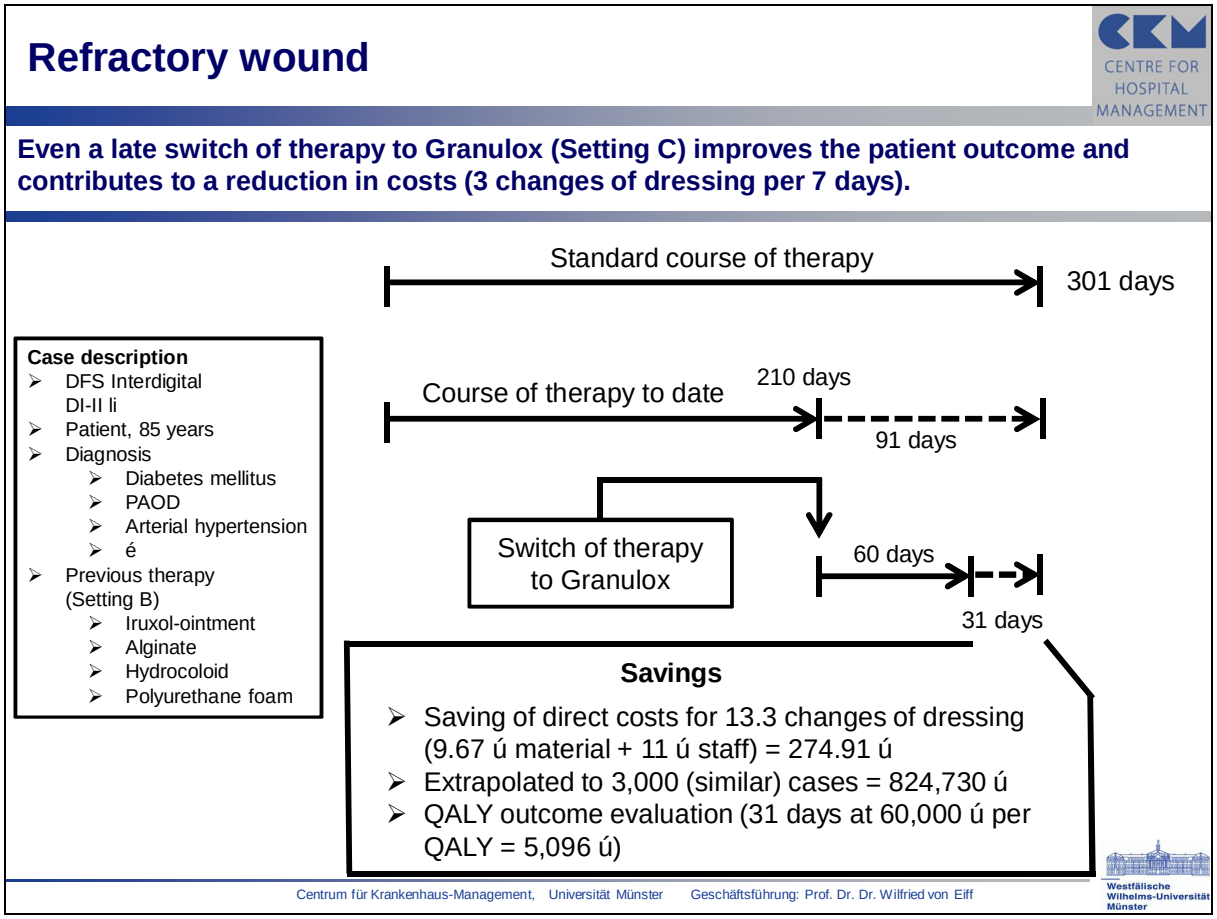

Figure 6: Evaluation schedule for the switch to Granulox therapy.

It becomes clear that even a late switch of therapy to Granulox still has positive effects on costs and patient outcome.

If the switch is made at an early stage, the potential for savings and the patient outcome improve considerably.

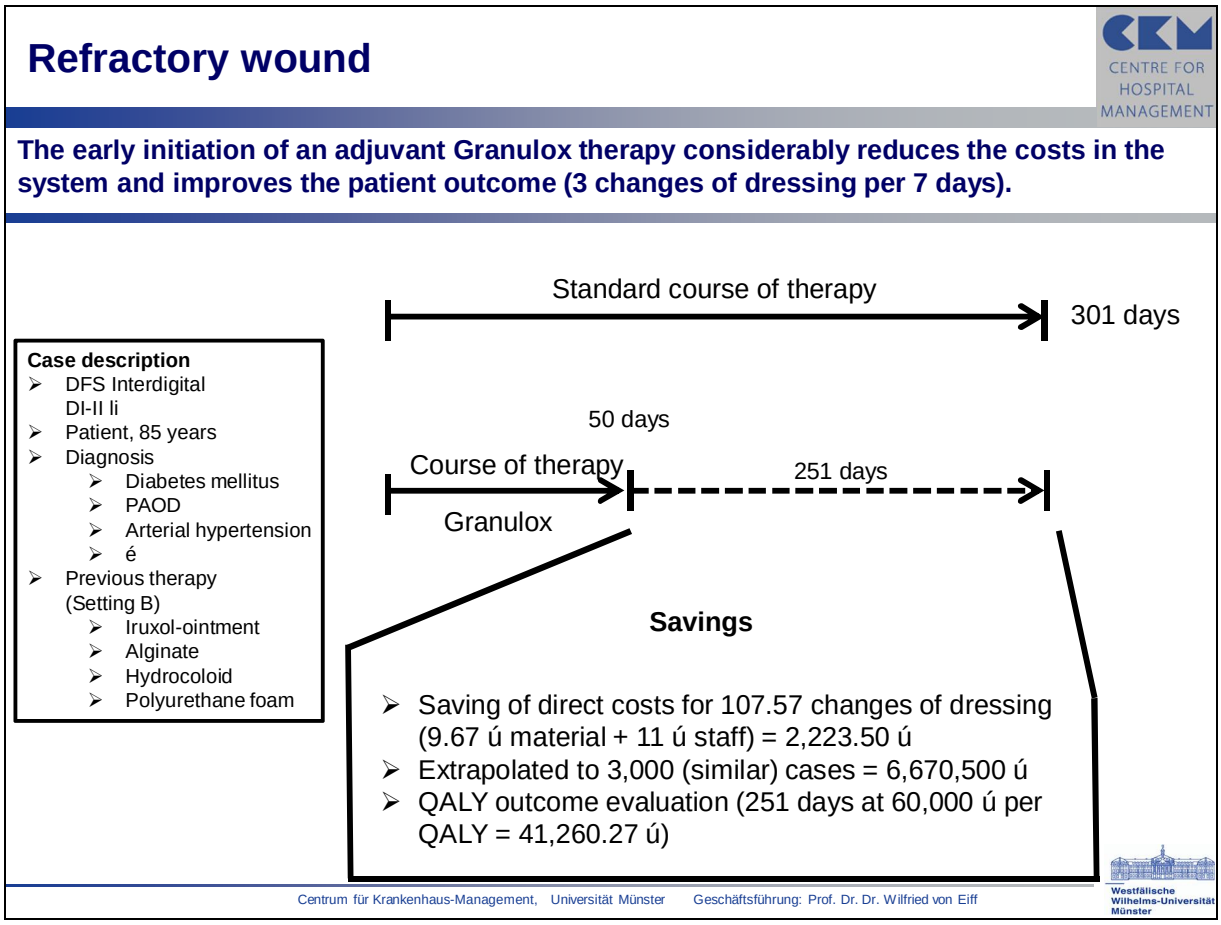

Figure 7: An early switch to Granulox opens up a major potential for savings.

On the other hand, aspects of medical quality (time up to wound closure), patient outcome (social mobility), risk (danger of amputation; postoperative mortality rate, infections) and process costs (employment disability costs, number of changed dressings, opportunity costs, costs to society as a whole) must be taken into account in the calculation (see Figure 8).

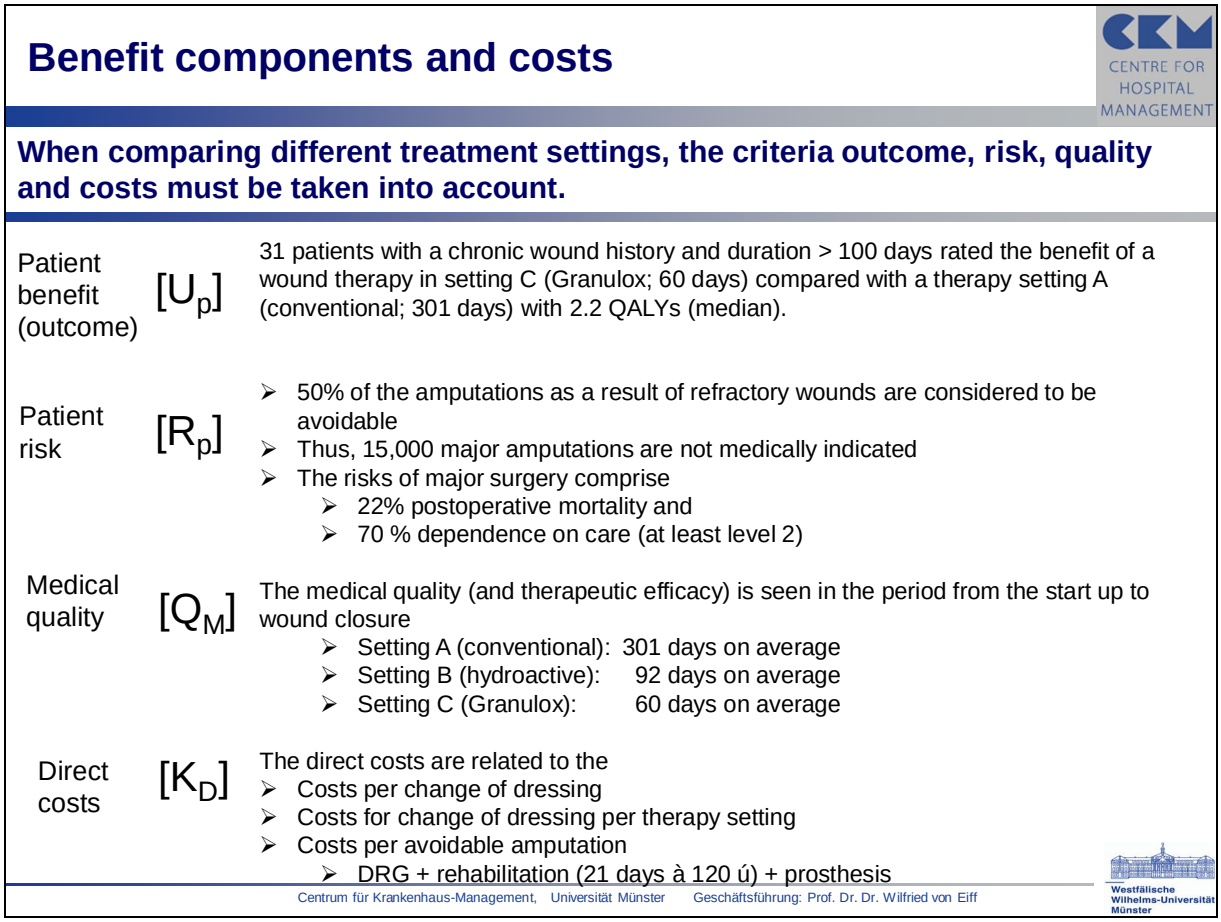

Figure 8: Overview of the criteria for the cost-benefit comparison.

If one rates the criteria outcome, risk, quality and costs in relation to the three different therapeutic approaches, the following result is produced:

Benefit comparison

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The combination therapy is superior to all other forms of therapy.

Therapeutic approach	Outcome (1= poor -10 = good) [social mobility]	Medical quality (1=poor - 10 = good) [wound closure/ time]	Risk (1 = high - 5 = low) [Amputation; infection]	Process costs (Setting A = 100 %)	Rating ratio
A conventional-dry	1-2	2	3,5	100% →1	7,5
B hydroactive	6-7	6	4	80 % → 3	19
C Granulox combination therapy	8-10	8	4,5	55 % → 6	26,5

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Figure 9: The table of ratings shows an improvement in the quality parameters by approx. 350 % upon a switch from the "classical" (Setting A) to the combination therapy (Setting C).

The model of risk-weighted process analysis highlights the previously calculated results on the levels of process costs, medical quality and risk (see Figure 10).

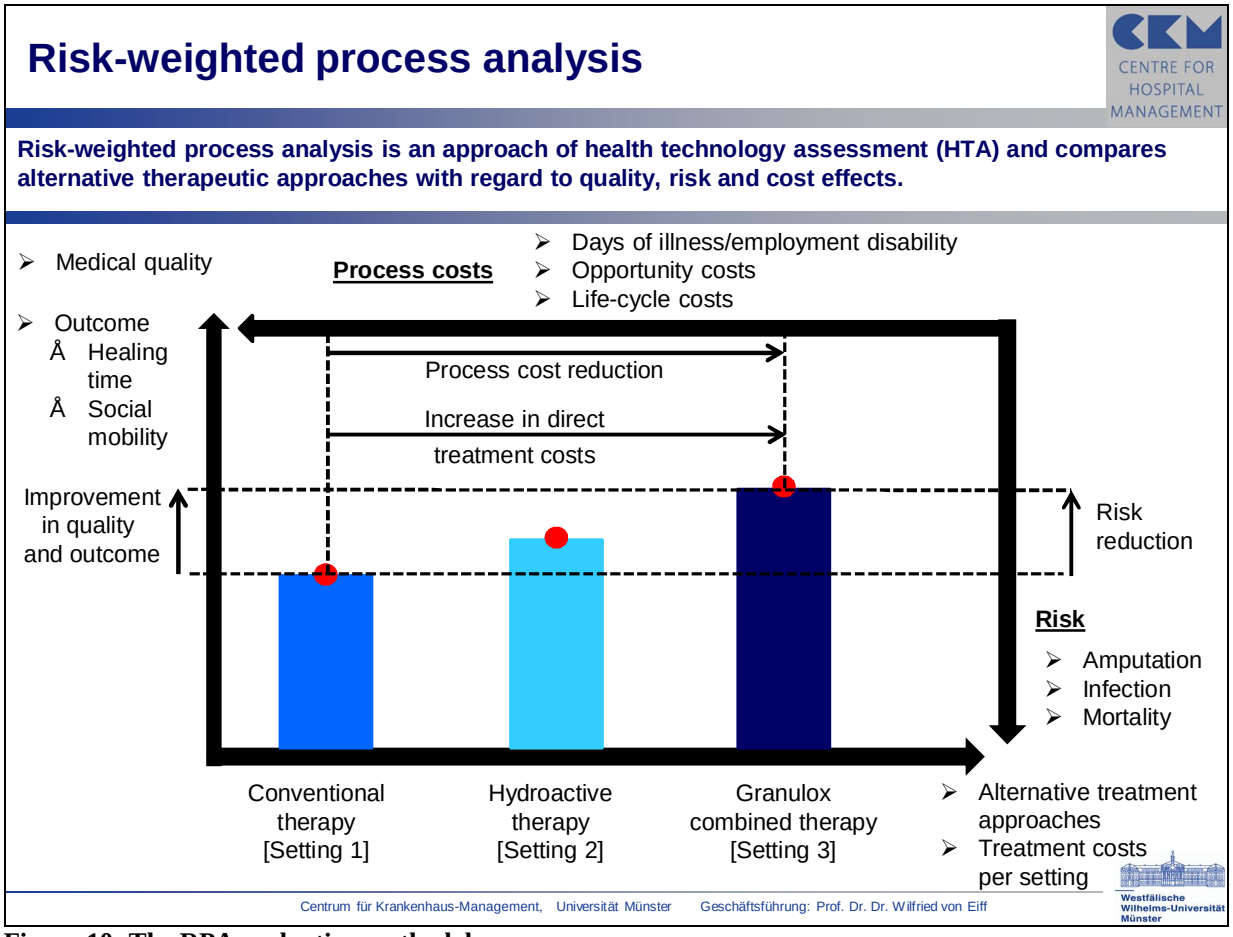

Figure 10: The RPA evaluation methodology.

3.2 Individual case studies[20]:

3.2.1 Case 1

Setting:

Patient: male, 74 years old

Primary disease: PAOD stage IV according to Fontaine

Wound: arterial crural ulcer of the left lower leg

Cycle for change of dressing: 2-3 days

Was treated unsuccessfully for 74 weeks before Granulox therapy.

Costs per dressing:

Without Granulox		With Granulox	
Material	**Price**	**Material**	**Price**
Amorphous gel	1,36 ú	Granulox	5,32 ú
Collagen	7,98 ú	Absorbent compress	3,18 ú
Superabsorber	5,37 ú		
Wound-edge protector	1,08 ú		
Total	**15,79 ú**	**Total**	**8,50 ú**

Table 2: Individual case study - Case 1

Calculation of the total treatment costs:

Without Granulox:

Duration of treatment 74 weeks. Assumed changes of dressing per week: 3

-> 74 weeks x 3 changes of dressing/week x 15.79 ú material = **3,505.38 ú**

With Granulox:

Duration of treatment 4 weeks. Assumed changes of dressing per week: 3

-> 4 weeks x 3 changes of dressing per week x 8.50 ú = **102,00 ú**

[20] The individual cases are taken from the study conducted by Mandl, C. (2012). The values have been presented in simplified form in some cases.

3.2.2 Case 2

Setting:

Patient: male, 75 years old

Primary disease: chronic venous insufficiency grade II according to Widmer

Wound: venous crural ulcer of the left lower leg

Changes of dressing per week: 3

Was treated unsuccessfully for 52 weeks before Granulox therapy.

Costs per dressing:

Without Granulox		With Granulox	
Material	**Price**	**Material**	**Price**
Silver calcium alginate	5,12 ú	Granulox	7,98 ú
PU-foam dressing	10,33 ú	PU-foam dressing (change only every fourth day)	10,33 ú
Wound-edge protector	1,08 ú		
Total	**16,53 ú**	**Total**	**18,31 ú**

Table 3: Individual case study - Case 2

Calculation of the total treatment costs:

Without Granulox:

Duration of treatment 52 weeks. Assumed changes of dressing per week: 3

-> 52 weeks x 3 changes of dressing/week x 16.53 ú material = **2,578.68 ú**

With Granulox:

Duration of treatment 4 weeks. Assumed changes of dressing per week: 3

-> 4 weeks x 3 changes of dressing per week x 18.31 ú = **219.72 ú**

3.2.3 Case 3

Setting:

Patient: female, 39 years old

Primary disease: chronic venous insufficiency grade II according to Widmer

Wound: venous crural ulcer of the left lower leg

Cycle for change of dressing: every 2 days

Was treated unsuccessfully for 3 weeks before Granulox therapy.

Costs per dressing:

Without Granulox		With Granulox	
Material	**Price**	**Material**	**Price**
Cellulose dressing with PHMB	11,33 ú	Granulox	2,66 ú
Paraffin gauze	0,59 ú	Compresses	
Compresses			
Total	**11,92 ú**	**Total**	**2,66 ú**

Table 4: Individual case study - Case 3

Calculation of the total treatment costs:

Without Granulox:

Duration of treatment 3 weeks. Assumed changes of dressing per week: 2

-> 3 weeks x 2 changes of dressing/week x 11.92 ú Material = **71.52 ú**

With Granulox:

Duration of treatment 3 weeks. Assumed changes of dressing per week: 3

-> 3 weeks x 3 changes of dressing per week x 2.66 ú = **23.94 ú**

3.2.4 Case 4

Setting:

Patient: male, 39 years old

Primary disease: PAOD stage IV according to Fontaine, type 2 diabetes mellitus, neuropathy

Wound: chronic stump ulcer after Chopart amputation on the right

Cycle for change of dressing: daily

Was treated unsuccessfully for 104 weeks before Granulox therapy.

Costs per dressing:

Without Granulox		**With Granulox**	
Material	**Price**	**Material**	**Price**
Silver calcium alginate tamponade	7,63 ú	Granulox	5,32 ú
Superabsorber	5,37 ú	Superabsorber	5,37 ú
Wound-edge protector	1,08 ú		
Total	**14,08 ú**	**Total**	**10,69 ú**

Table 5: Individual case study - Case 4

Calculation of the total treatment costs:

Without Granulox:

Duration of treatment 104 weeks. Assumed changes of dressing per week: 7

-> 104 weeks x 7 changes of dressing/week x 14.08 ú Material = **10,250.24 ú**

With Granulox:

Duration of treatment 7 weeks. Assumed changes of dressing per week: 3

-> 7 weeks x 3 changes of dressing per week x 10.69 ú = **224.49 ú**

3.3 Consideration of the subsequent costs

The following model calculation[21], which is based on the example of a major amputation, illustrates the considerable subsequent costs that arise from deficient wound management and can thus be saved.

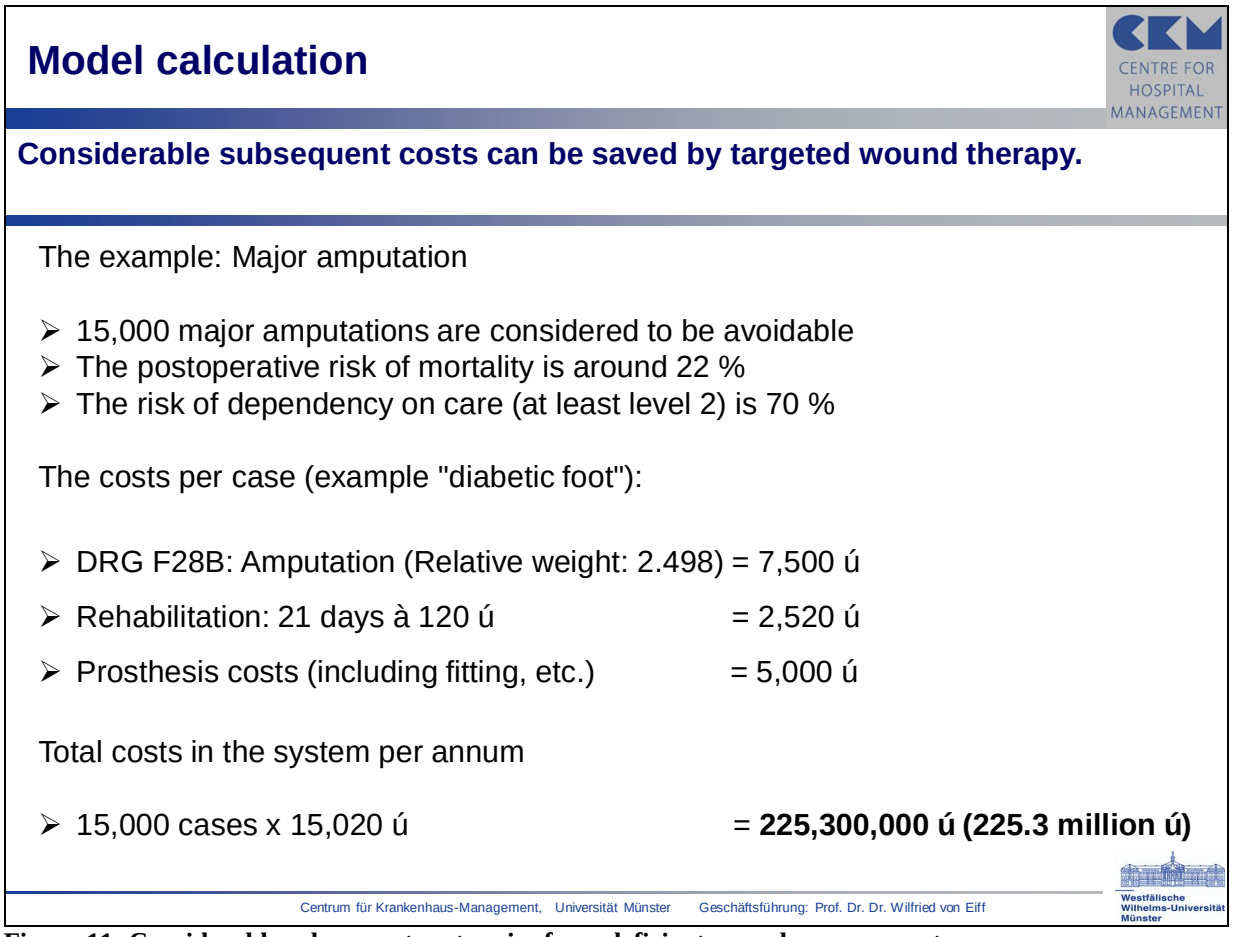

Figure 11: Considerable subsequent costs arise from deficient wound management.

[21] The case study originates from the study conducted by Mustafi, N. (2012).

4. Conclusion

Granulox combination therapy has proved to be economically markedly superior to all other therapeutic approaches, both in the HTA approach, taking into consideration quality and risk components, and in the standard calculation, as well as in the individual case studies.

The treatment time up to wound closure of 60 days is five times lower (conventional dry therapy) or 53.3 % shorter (hydroactive therapy) than in alternative therapy regimens. The costs of overall therapy are 10 times (conventional dry therapy) or 28.3 % (hydroactive therapy) lower.
On the basis of the surrogate parameters early wound closure, social mobility and low number of visits to the doctor, the patient outcome can be rated as significantly better than in all other alternative therapeutic approaches.

The present expert report impressively demonstrates the efficiency-boosting contribution made by innovations in the health care system. The mechanism of action of Granulox removes an obstacle to wound healing that delays the healing process, which could not be overcome by existing products. A complementary application of Granulox is therefore to be recommended on a broad front in order to achieve a sustained increase in the efficiency of existing therapy regimens and reduce the cost burden on the health care system.

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