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The use of Acellular Dermal Matrices in the Management of Complex Traumatic Wounds in a Paediatric Population

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Part A: Plagiarism Declaration

I, *Kamlen Pillay,* hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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Signed by candidate

Dr K. Pillay

26 March 2019

Part B: Final Abstract

The use of Acellular Dermal Matrices in the Management of Complex Traumatic Wounds in a Paediatric Population

Introduction
Complex soft tissue injuries are common in children. Paediatric wounds associated with large soft tissue defects pose a surgical challenge. This often necessitates extensive reconstructive surgery and frequently requires the use of microvascular free flaps. Local, regional and free flap surgery in children poses several challenges related to donor site morbidity, flap failure and the long-term sequelae of repeated surgeries for flap modification in a growing child.

The introduction of acellular dermal matrices (ADM's) in recent decades has dramatically influenced the management of complex soft tissue wounds. The dermis in skin represents the functional aspect of skin. ADM's represent dermal structures artificially, hence their incorporation into the wound should restore skin characteristics specifically pliability. Some authors believe that ADM's have improved prognosis and reduced morbidity in the treatment of open wounds. Combining the use of ADM's together with split-thickness skin grafting (SSG) is rapidly becoming an important method used to manage such complex wounds.

In this study, we explore whether the use of this technique has been a beneficial addition to the traditional management armamentarium for complex injuries in the extremities and report the rate of complications experienced by our patients at our paediatric hospital in Cape Town.

Objective
This study reviewed the number of complications experienced with the use of ADM's in treating complex wounds on the extremities of children. It includes 54 children treated between the years 2011 and 2016 at a national paediatric hospital.

Methodology
A retrospective folder review of children treated at our hospital between the years 2011 and 2016 with extremity injuries was conducted. A total of 189 patient folders were reviewed. Children (n= 54) with complex wounds in their extremities who had received an ADM were included in this study. Both short and long-term complications were identified. The patient age range was six months - 12 years, while the mean patient follow-up period was 390 days.

Results

All patients treated with ADMs for traumatic extremity injuries during this period were included in the study, irrespective of age or co-morbidities.
In 45 patients the ADM and SSG healed without any complication that is, not requiring revision surgery at 1 year follow up.
Seven patients who did not receive postoperative splinting and occupational / physiotherapy displayed wound contractures, requiring further reconstructive surgery, 4 of which were also in the group who experienced complete ADM or graft loss below.
Six patients experienced complete loss of the ADM due to infection, which led to graft failure, requiring revision surgery. Of the six patients that experienced complete loss of the ADM, five were not treated with NPWT dressings.
Noteworthy, is that all 45 patients who healed without any complication were treated with NPWT dressings.
Biopsies that were performed on 18 patients at 2 weeks post application of the ADM, showed only granulation tissue. No evidence of residual ADM or accessory dermal structures was found in any of the samples, which were obtained from multiple loci of the ADM in situ.
The mean time to closure with this method was 3 weeks and the mean hospital stay was 26 days.
Two patients were lost to follow-up and were excluded from the morbidity analysis arm of the study.

Discussion

We found that post-operative physiotherapy, occupational therapy and splinting are extremely important in preventing morbidity in particular scar contracture when associated with wounds treated with ADMs. There was no histological evidence to suggest that the ADM remains intact after 2 weeks post application. Our data reveals that vacuum assisted closure is a vital adjunct to this method, ensuring adequate ADM and graft take.

Conclusion

Complex wounds in the extremities of children pose a reconstructive dilemma to the plastic surgeon. In anatomically sensitive areas where traditional plastic surgery options are unavailable or undesirable, the use of ADMs and SSGs represent a realistic alternative for the reconstruction of large wounds associated with complex soft tissue injuries in the extremities of children.

Part C: Protocol

The use of Acellular Dermal Matrices in the Management of Complex Traumatic Wounds in a Paediatric Population

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1. Aim of the study:

The aim of this study is to assess the outcome by reviewing the results and complications of using Acellular Dermal Matrices in the management of complex traumatic wounds in a paediatric population.

2. Objectives of the study

The investigators anticipate confirming that Acellular Dermal Matrices (ADMs) may positively influence the management of complex soft tissue wounds.

Combining the use of ADMs together with split-thickness skin grafting (SSG) is rapidly becoming an important method used to manage such complex wounds. [1,2,3,4,5,6,7] Some authors believe that ADMs have improved prognosis and reduced morbidity in the treatment of open wounds. [1,2,3,4] However, currently there is no definitive paper or structured guideline on the use of ADMs in acute and chronic wounds.

There is international consensus that ADMs eventually gets integrated into the body and is completely replaced by the patient's own collagen resulting in a thicker, stronger layer of tissue than the one which would have developed in the absence of the ADM. [1,2,4] ADMs are usually made from natural sources and are bioresorbable, yet maintain their strength over time. Reasons advanced for this is that most ADMs are composed of organic tissues, are generally attached with absorbable sutures to the existing wound edges, anchoring it to its new position, and the matrix's components are susceptible to the natural human wound healing cascade. [3,4,] All these factors therefore contribute to complete resorption of the ADM, leaving behind only the patient's own natural tissue and has thus become a preferred procurement for the management of complex degloving wounds. [1,2,3,4]

3. Study background

The reconstructive options for complex traumatic soft tissue wounds on the dorsum of the foot and lower limb in general are traditionally known to be limited and challenging, more so in children. [3,7,8,9,10,11]

Since the 1990's the use of ADM's has been slowly changing the landscape of the management of complex traumatic wounds, especially in the lower limb.

4. Significance of the study

We have used ADMs in the management of complex traumatic wounds in many paediatric patients to date. Should we confirm that our complication rate when using this method is acceptable in managing complex wounds; this might influence our practice to adopt this method more rigorously.

5. Methodology

A retrospective folder review of patients with extremity injuries at Red Cross War Memorial Children's Hospital (RCWMCH) during the years 2011 and 2016 will be conducted over a period of six months. All the research will be done in accordance with the international convention on Harmonization Good Clinical Practice (ICH GCP) and Declaration of Helsinki Guidelines (DoH).

6. Study design

A retrospective folder audit will be conducted to evaluate the results, complications and problems of using ADMs in the management of complex traumatic wounds at the RCWMCH from 2011 and 2016

7. Study setting and study population:

All children (birth to 13 years, male and female) admitted for extremity injuries and treated at RCWMCH from 2011 to 2016.

8. Sample size

We anticipate a sample of approximately 50 patients; this will allow robust statistical analysis of the data obtained.

9. Inclusion and exclusion criteria

Inclusion criteria:
All children with extremity injuries admitted to the plastic surgery unit at RCWMCH from 2011 – 2016 will be included in this retrospective folder review.

Exclusion criteria: Patients who did not have all their surgery at RCWMCH and patients lost to follow up or with inadequate or incomplete data.

10. Research procedure and data collection

The study involves *a retrospective folder review* of all the patients who were treated for extremity injuries at RCWMCH from 2011 to 2016.
Please refer to data sheet for specific data collection.
In summary this will be a folder assessment, capturing the following:

- Patient demographic details including :
- Age, Sex
- Mechanism of Injury
- Anatomical Site of Injury
- Time to ADM application
- Time to SSG
- Reconstructive surgery performed
- Flaps performed
- vacuum vs. non-vacuum assisted closure with ADMs
- Complications Early (within first month post ADM application)
- Complications Delayed (after first month)

11. Statistical analysis

Information obtained will be recorded on an excel spread sheet by the primary researcher (K Pillay). Raw data will be analysed and descriptive statistics will be used to investigate and compare the outcomes.

12. Informed consent

This is an audit of patient records. No consent will be taken for review of patient records. As there will be no patient identification, and no altered management, I would request the REC and scientific review committee to waive the requirement for consent.

13. Data safety monitoring

Patient case records will be kept in the Department of Plastic Surgery. Relevant data will be entered on a database for statistical analysis. All information will be password protected.

14. Confidentiality

The need for confidentiality is essential. Patient data will not be kept together with identifying patient factors. In order to achieve this, two databases will be established on separate computers. The first with patient name and number and a corresponding study number, which will be password protected. The second database will have all clinical data with a corresponding study number as previously allocated.

15. Description of risks and benefits:

There are no foreseen risks to the parent or the patient. The risk to do harm is non-existing as the study consists only of a retrospective folder review.

The benefits of the study are:

i) Comparison between our results and that of other units available in the literature. [1, 2, 3, 4, 5]

ii) An audit of our results with regards to a possible change in future management.

iii) Documenting and analysing the results, advantages, disadvantages, complications and problems of using the ADMs in our patient population.

16. Reimbursement:

Not applicable to this retrospective folder review.

17. Emergency care of patients:

Not applicable to this retrospective folder review.

18. What happens at the end of the study?

The investigators anticipate that they will be able to confirm that **the use of ADMs in the management of complex traumatic wounds in a Paediatric Population is** beneficial and associated with satisfactory wound healing in our patient population with an acceptable complication rate. They will also confirm that the proper use of ADM and SSG has reduced morbidity in terms of length of hospital stay, amount of outpatient visits and amount of dressing changes). Should this be the case, we intend to change our current practice and use ADM and SSG, as advocated in the literature. [1, 2, 3, 4, 5, 6, 7]
The findings and information will be submitted for publication in an appropriate academic journal. It is not a study aim to inform parents/caregivers of the study findings at the end of the study.

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Part D: Acknowledgements

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3. Mrs. Vicky Pillay and Mr. Robert Abraham for their valuable input and for proofreading this thesis.
4. Everyone working at the Medical Records department at RCWMCH, who helped to find patient folders for data collection.
5. The Divisions of Paediatric Surgery and Plastic & Reconstructive Surgery at RCWMCH and theatre nursing and administration staff for all their assistance in helping locate the names of patients included in this study.

Part E: Abbreviations

1. UCT:	University of Cape Town
2. HREC:	Human Research Ethics Committee
3. Ref:	Reference
4. WHO:	World Health Organisation
5. et al.	and others
6. vs.	versus
7. SSG:	Split skin graft
8. STSG:	Split thickness skin graft
9. IP:	Immune Privilege
10. c-y:	child years
11. RCWMCH:	Red Cross War Memorial Children's Hospital
13. mm:	millimetres
14. µm:	micrometer
15. ml/kg:	millilitre per kilogram
16. sp.	species
17. LD_{50}:	Lethal Dose
18. ADM	Acellular Dermal Matrix
19. NPWT	Negative Pressure Wound Therapy

Part F: List of appendices

Part G: Introduction and Literature review

List of Contents of Literature review:

1. Objectives:

1. To determine the rate of complications in our patient cohort

2. Literature Search Methods:

- Search engines used to acquire the relevant journal articles: PubMed, Medline and Google Scholar.
- Search words and phrases used:
    - ADM
    - Donor site
    - Split skin graft (SSG)/ split thickness skin graft (STSG)
    - Children
    - Paediatric degloving wounds
    - Complications
    - Extremity Trauma
    - Vacuum Assisted Closure
    - Contractures
    - Lower Limb Trauma
    - Degloving wounds in children
    - Lower limb flaps

- Related citations suggested by the search engine were used.
- References cited in journal articles obtained were used to further broaden the search.
- Only articles cited in the English language were used.

3. Interpretation of the Literature

3.1. Introduction

Complex traumatic wounds in the extremities of children have traditionally posed an extremely daunting and complex challenge to the paediatric reconstructive surgeon. Inappropriate management can have lifelong sequelae with respect to form and function resulting in multiple repeat surgeries in many of these patients[1]. Disorders such as joint contractures, chronic wound breakdown and donor site morbidity may also have a considerable psychological impact on the quality of life of an individual [1,2, 3,4,5]. This makes the management of these wounds in the extremities of growing children extremely challenging.

Currently, there is no comprehensive classification system for the grading of complex traumatic wounds in children, this together with limited local, regional and distant flap options, makes the management of these wounds traditionally complicated and challenging [2, 4-7,9].

However, in 2013, a study conducted by Hutchinson et al. demonstrated that a dermal template combined with negative pressure wound therapy (NPWT) can safely and effectively be used to treat complicated wounds in children. [6] In their cohort, they obtained closure without flaps in the majority of their patients,' treatment time was spent in the outpatient setting, and their complication rate was reported as low (1 of 8 patients = 12,5%)

Further studies done more recently by Gümbel et al. [8] and Lee et al [9] with larger patient numbers than the previous study, 56 and 20 respectively, demonstrated that there are advantages in terms of aesthetic and functional outcomes in their patients with low complication rates. They also advocated single stage ADM and SSG application due to the success they had with this technique in their patients. We believe that the type of ADM used and the nature of the defect would determine whether an immediate SSG can be applied to the ADM, or whether the SSG should be delayed until complete macroscopic integration of the ADM with the recipient tissue is achieved.

A unique problem faced in children is that they go through periods of rapid growth. It is not known whether these growth spurts are replicated in ADM generated tissue, however anecdotal observation suggests that the incidence of joint contractures and asymmetrical growth when compared to contralateral limbs is more common. This problem does, however, also occur in children treated with traditional flaps, leading to multiple reoperations during the course of their childhood [6,10,11,21].

In major paediatric polytraumas, with a shortage of donor areas, local and regional flaps are often not available nor are rescue sites for the procurement of donor skin. [13]. This leads to prolonged hospital stays associated with a larger incidence of mortality and long term physical and psychological morbidity. [1,3,12,13,29] One of the biggest challenges in these patients is the dilemma of sacrificing an

uninjured, "good limb" for the sake of covering the injured and often compromised limb. The advent of ADMs largely negates the problem of a donor site morbidity, thereby also reducing overall recovery, potentially reducing morbidity, mortality and the length of hospital stay together with negative sequelae associated with this. [2,3,14, 15,].

It seems that international consensus towards using ADMs as a primary option, even for small wounds, is now growing [1-4,-16,23]. There are now a number of authors including Barber (2006) [3] and Phillips (2014) [16] who are recommending the use of ADMs as the primary option for cover, especially in children [1-7], due to low complication rates and quicker healing time [17, 22, 33].

3.2. Epidemiology of Paediatric injuries in Cape Town

Wesson and Van As reported that a total of 14,915 injured children with 15,414 injuries presented to Red Cross War Memorial Children's Hospital between 2007 and 2011. The mean age of their study cohort was 5.01 ± 3.5 years and 60.3% were male. They reported that the most common mechanisms of injury ranged from falls (n = 6,036; 40%), road traffic injuries (n = 1,939; 13%), burns (n = 1,885; 12.6%), and assault (n = 640; 4.3%). Comparing the period between 2011 to 2016, the incidence of road traffic injuries had decreased by 7% ($P < .05$) while burn injuries increased 11% ($P < .05$). Seventy-three percent (73%) of injuries that presented to Red Cross War Memorial Children's Hospital occurred in the Cape Flats area of Cape Town, where many informal settlements exist. [19]

Complex traumatic soft tissue injuries, are a common occurrence in South Africa and are mostly associated with poverty in communities where children play on the streets unsupervised. Household crowding, increased urbanisation with the subsequent proliferation of informal settlements, along with lower educational levels of the parents, all play a major role [34-36]. Children over the age of four years are at the highest risk of these injuries, with an average annual rate of 6.0/10 000 child-year [19].

The Red Cross War Memorial Children's Hospital (RCWMCH) is a tertiary hospital for children under the age of 13 years. During the last decade the annual admission rate was 1187 (1084 – 13910) with 3256 (1509 – 5221) outpatient visits and 766 (592-1046) operations performed. The average wound size including burn wounds was 15% (1-100%) total body surface area (TBSA), with 30% of the admissions, exceeding 25% TBSA [25].

3.3. The use of ADMs as a means of reconstructing wounds in the extremities of children

The survival of children who experience major traumatic injuries is often compromised by a deficit of autologous donor tissue available to obtain definitive wound cover expediently. Primary wound closure can usually be obtained in isolated wounds by debridement and immediate local or regional flap cover. Unfortunately, some anatomical sites, such as the dorsum of the foot and toes are extremely difficult to reconstruct with thin, pliable and durable reconstructive options. The traditional flap of choice for this area remains the reverse sural flap. This flap, however has a number of limitations, including often not being long enough to reach the toes, it bulkiness requires multiple repeat debulking surgeries, whilst at the same time resulting in difficulty wearing shoes (patients often require two different size shoes for each foot), and also donor site morbidity. [32]

To overcome this deficiency in available donor sites in polytraumatic patient's wounds, or in wounds located in anatomically sensitive areas not amenable to traditional flap options alternative methods are required. There are now a variety of ADMs available on the market, ranging from single stage to multistage applications, from animal derived to synthetically derived collagen, and from single layer to multi-layer applications. [31] All however require epidermal cover with the patients autologous skin. Negative Pressure Wound Therapy and xenografts have also been described as adjunct methods with ADMs, such as Pelnac® and Integra® to facilitate permanent wound cover. [2, 31]

However, among the many challenges in polytrauma patients and patients with large surface area burns, is the availability of epidermal donor sites to cover the ADM. In 1964 Crawford described the scalp as a rescue site for donor skin, if there was an extreme shortage of epidermal donor areas available [33]. Since then international consensus suggests the use of the scalp as primary donor site for even small split skin grafts [26-32]. The scalp's excellent healing properties, minimal scarring and the fact that the donor area is concealed by hair supports these arguments. When combined with ADMs, most wounds could thus be covered in the acute phase of major burns and polytrauma patients.

According to van Niekerk, in most paediatric burns the scalp is frequently uninjured and therefore provides a readily available donor site. If uninjured, the scalp offers a large surface area, has good healing properties and is easy to nurse. The scalp provides an excellent colour match for resurfacing of the face, heals with minimal scarring and is concealed by hair. Scalp donor healing time has been documented as <14 days [29, 31], even as low as 5 - 9 days [25, 26, 34], which makes it ideal for recurrent harvesting. In addition, the scalp has a large surface area in comparison to the rest of the body in children. The head contributes 18% to the TBSA in a new-born vs. 9% in an adult [30] and can provide skin cover for a substantial area of up to 800 cm^2 according to Berkowitz [34]. A relative contra-indication for using the scalp as donor site would be concomitant scalp burns [31].

Another challenge encountered by reconstructive surgeons when using ADMs is the integration of the ADM onto the wound surface, especially when the wound contained devascularised bone. This can often result in the loss of the ADM, which in turn delays wound closure and prolongs hospital stay and thus overall rehabilitation. Azzopardi [2] and Hutchinson [6] in their studies. both found that the additional use of negative pressure wound therapy (NPWT) in the integration phase of the ADM and SSG respectively, as an adjunct, resulted in far greater uptake of the ADM and SSG [2 ,5, 6, 8].

The benefits of NPWT in the management of complex wounds have been well established in the literature through the seminal work of Morykwas and Argenta. [35] Apart from improving vascularisation, contracting the wound surface and preventing contamination of the wound, the mechanisms by which NPWT positively influence the uptake of ADMs are poorly understood. There is however, both anecdotal and confirmed evidence that NPWT assists in the integration of ADMs and that of the split thickness skin graft (SSG). [5, 6, 8]

NPWT has also been shown to reduce the time in which the ADM takes to integrate into the tissue. [6] Although most ADM manufacturers do not necessarily advocate the use of NPWT as a standard adjunct to improve the integration of their ADM, many authors regularly state that NPWT to be a useful adjunct in the integration of the ADM and the SSG. [2,6,8]. Improved ADM integration, decreased infection, better SSG take and reduced time to rehabilitation, also helps reduce the overall hospital stay and also improved early and late complications. [7, 9, 15, 16]

Another important factor in preventing delayed complications such as joint contracture, functional deficits and poor scarring, is the early implementation of postoperative rehabilitation with a motivated occupational and/or physiotherapist.[18] Early mobilisation post graft take is paramount to prevent irretractable joint and soft tissue contraction, which is turn could lead to pain and a poorly compliant patient and thus ultimately, a poorly functioning patient.

Mobilisation requires a graded program of both active and passive joint and limb exercises which help to make the joint and soft tissue more pliable over time, resulting in better patient compliance and therefore long term functionality of the injured extremity. Most units have tailored rehabilitation programmes to suit their patient population, access to outpatient resources such as facilities and expertise available in their catchment areas.

A review of the relevant publications related to the use of ADMs in degloved extremity wounds in children is was conducted to corroborate our findings. Although the literature is extensive, only relevant articles that contained children in the patient profile were selected.

3.4. Conclusion

After evaluating the international literature, it is evident that ADMs can be used as a viable alternative to autologous tissue. The author concludes that the complications seen in the use of ADMs would be mitigated by use of negative pressure devices to avoid acute complications and by adequate physio- and occupational therapy to prevent delayed complications. The postulation is that the complications are directly related to the lack of the above interventions.

However, autologous flap surgery still remains as our gold standard to attain wound cover. Future research comparing different ADM brands will be important as some ADMs are synthetic and many come in different forms and may yield different results.

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Part J: Journal Article

The use of Acellular Dermal Matrices in the Management of Complex Traumatic Wounds in a Paediatric Population

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Abstract

Background: Since 2010 we have used Acellular Dermal Matices (ADMs) and split skin grafts (SSGs) to manage degloving wounds when there was a shortage of conventional donor areas available or when conventional flaps had failed us. However, we had initially seen a high incidence of complications contrary to international findings.

Objective: The aim of this study was to analyze the results and complications related to the use of ADMs in managing degloving wounds in children and to determine whether there is an association between our patient population, our technique and the number of complications that we encountered.

Methods: A retrospective review of our patients folders over a 7-year period was conducted. The cohort included 54 patients, 24 females and 30 males, of ages ranging from 6months old to 13 years old. The various complications were identified and classified in to early, referring to loss of the ADM or graft and late complications those relating to complications occurring more than a month after graft take. Most of our patients (47) were injured by motor vehicles related incidents. 6 of these patients were also treated with flap surgery and all received standard post op treatment. The SSG's were taken with an electric dermatome with a standard micrometric setting of 0.2 mm. Complications were categorized into early- or late, with a mean follow-up time of 1.48 years.

Results: The mean age of the 54 children was 6.35 years. 7 sustained complications and 6 required salvage flap surgery to cover their defect, none of our patients who were initially deemed to have salvageable wounds and treated with ADMs, ended up requiring amputations. A total of 4 early and 5 late complications occurred in our patient cohort of 54 patients. The median; healing time was 26.33 days in hospital, to ADM surgery 3 days and 11 days to SSG. Significant complications were encountered, including complete loss of the ADM mostly due to infection, non-healing wounds, no ADM adherence or "take", hypertrophic scars, late wound breakdown, joint contractures, hypertrophic

scarring and poor cosmesis were all observed. We found a strong correlation to the occurrence of early complications ie loss of adm and or graft when NPWT dressings were not used. Five children, 4 of whom did no return for their post-operative checkups and occupational therapy returned months later with various different complications including joint contracture, and poor cosmesis. 2 patients were lost to follow-up and were excluded from our data. Only statistically significant findings were related to the use of NPWT and post-operative rehabilitation / splinting, with a p-value of 0.005 and p=0002. The p-values for the healing times related to the adm and ssg take to discharge from hospital, were p=0.022, p=0.00032 and p<0.001 respectively.

Conclusion: Complex wounds in the extremities of children pose a reconstructive dilemma to the plastic surgeon. In anatomically sensitive areas where traditional plastic surgery options are unavailable or undesirable, the use of ADMs and SSGs represent a realistic alternative for the reconstruction of large wounds associated with degloving injuries in the extremities of children. Adjunctive therapy with NPTW and postoperative occupational / physiotherapy both play an important role in decreasing the overall complication rate.

Keywords

Complex Wound, Degloving, Acellular Dermal Matrix, Split Skin Graft, Negative Pressure Wound Therapy, Paediatric

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Tables and figures

Table 1: Breakdown of complications seen in 9 children

Complications		Total
Acute *** 5 patients (10%)**	Infection	3
	Complete loss of ADM (≥14 days, <3 months)	4
Long-term *** 4 patients (9%)**	Non-healing wounds (≥3 months)	2
	Joint Contracture	4
	Hypertrophic scar	5

*More than one complication were seen in a single patient

Table 2: CASES vs COMPLICATIONS vs NPWT PER YEAR

Year	2011	2012	2013	2014	2015	2016	2017	total
NPWT	0	0	1	0	4	31	13	49
no NPWT	1	3	1	0	0	0	0	5
complications	1	2	1	0	2	2	1	9
total cases	1	3	2	0	4	31	13	54

Table 3: Breakdown of Complications in patients treated with NPWT vs No NPWT

	Total	Acute Complication	NO Acute Complication
NPWT	49	1	48
No NPWT	5	4	1

Figure 1: No. of complications vs total no. of cases per year

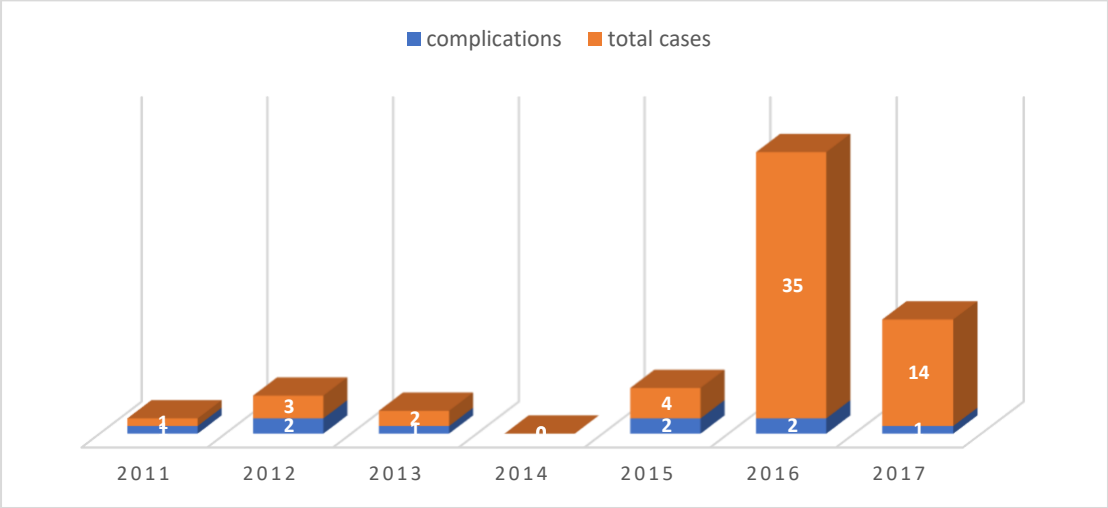


Figure 2: Complications in patients treated with NPTW vs NO NPWT

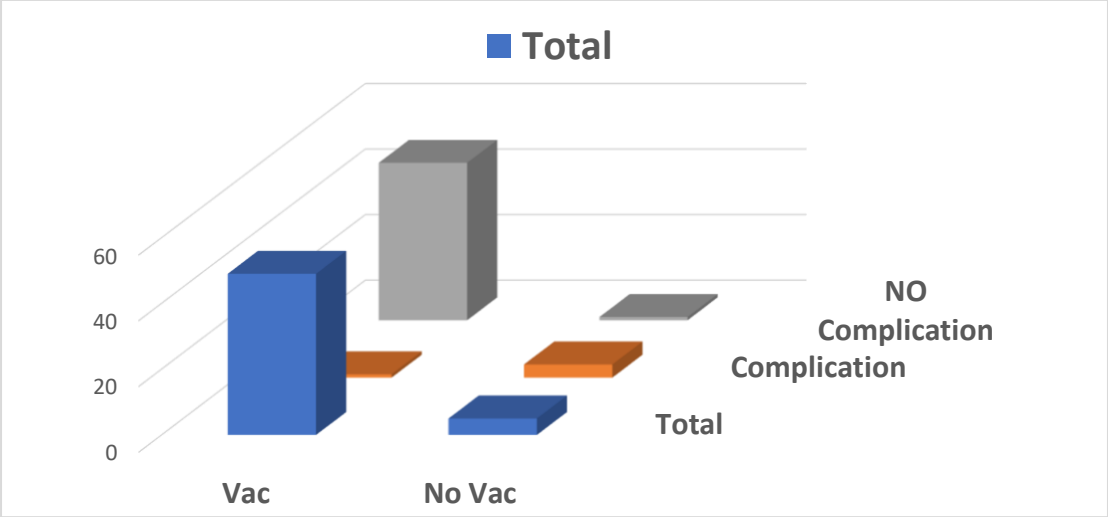


Figure 3: Duration of Hospital Stay

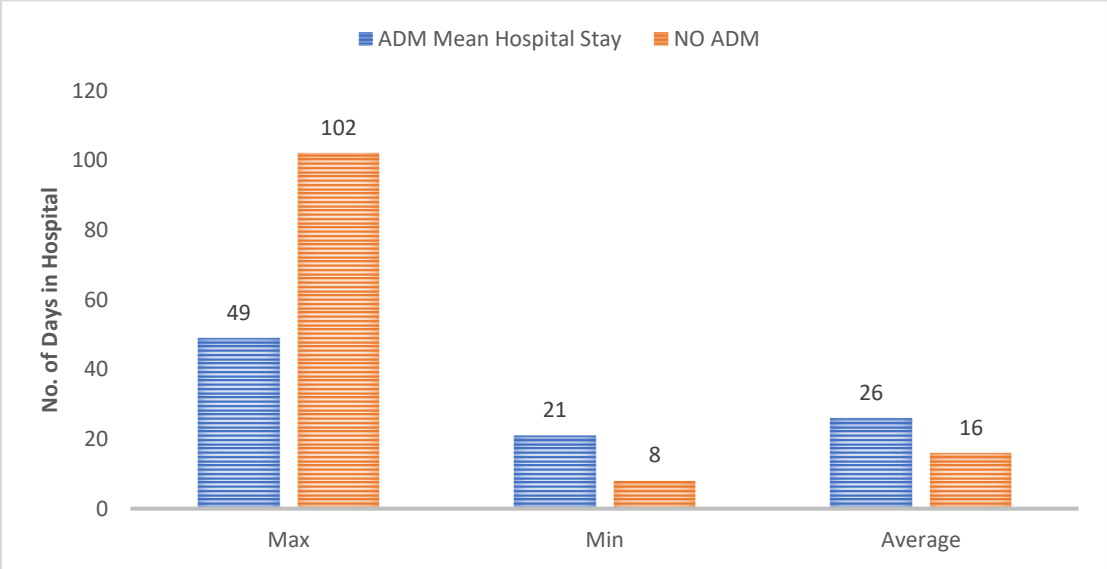


Figure 4: Pre and Post OP photo of ADM on Drosum of Foot

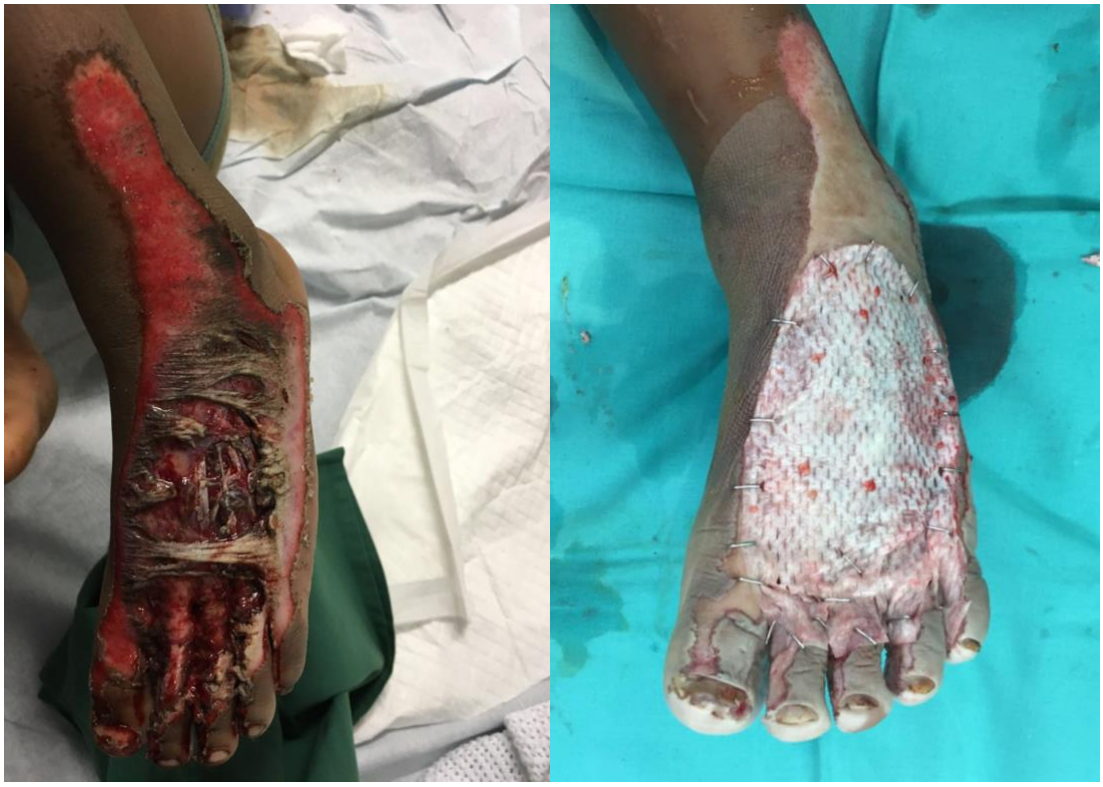
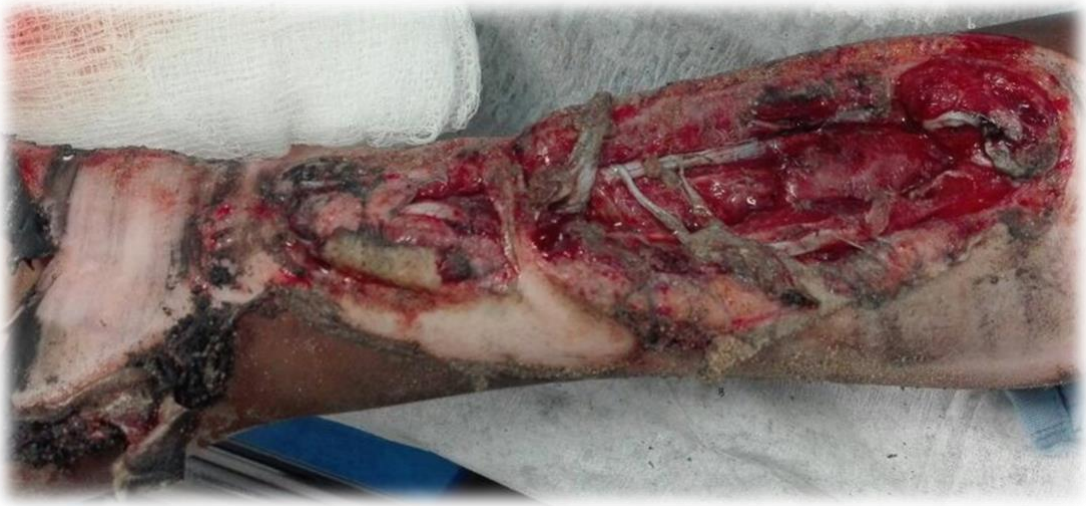
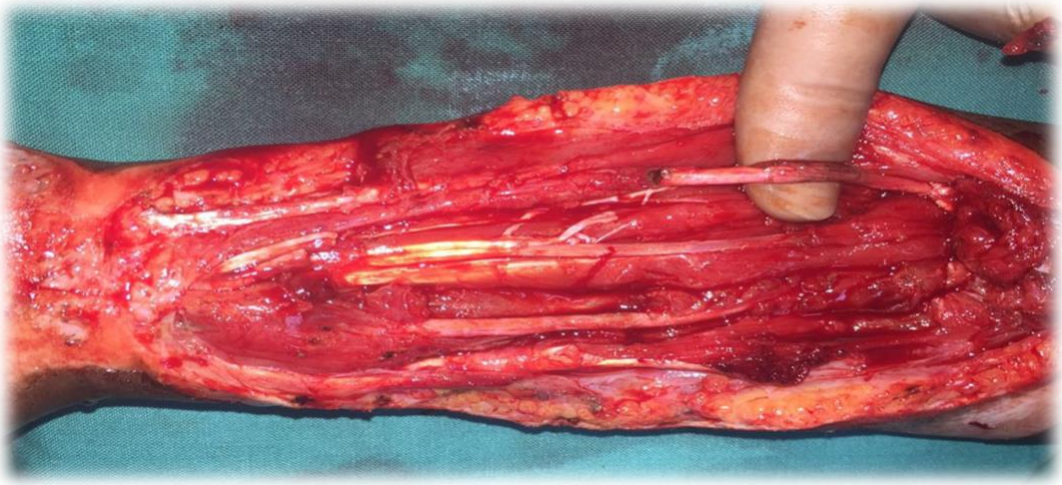


Figure 5: Pre and Post OP photo of ADM on Forearm

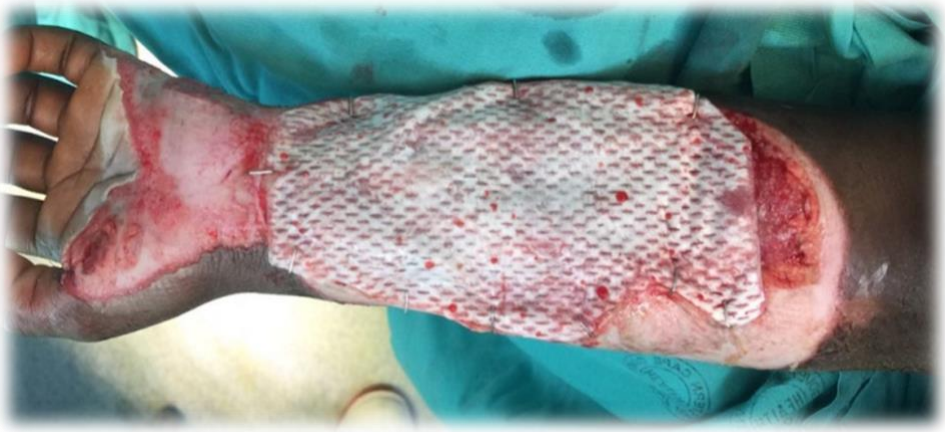
A: Preop



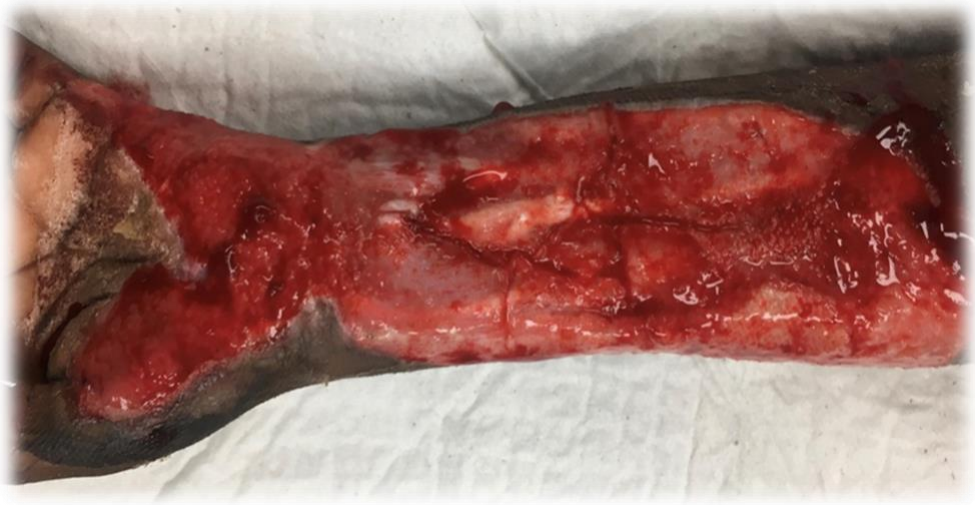
B: Post Debridement and Ulnar Nerve Repair



C: Post Application of ADM



D: Day 6 Post NPWT



E: 3 Months Post SSG and Rehabilitation

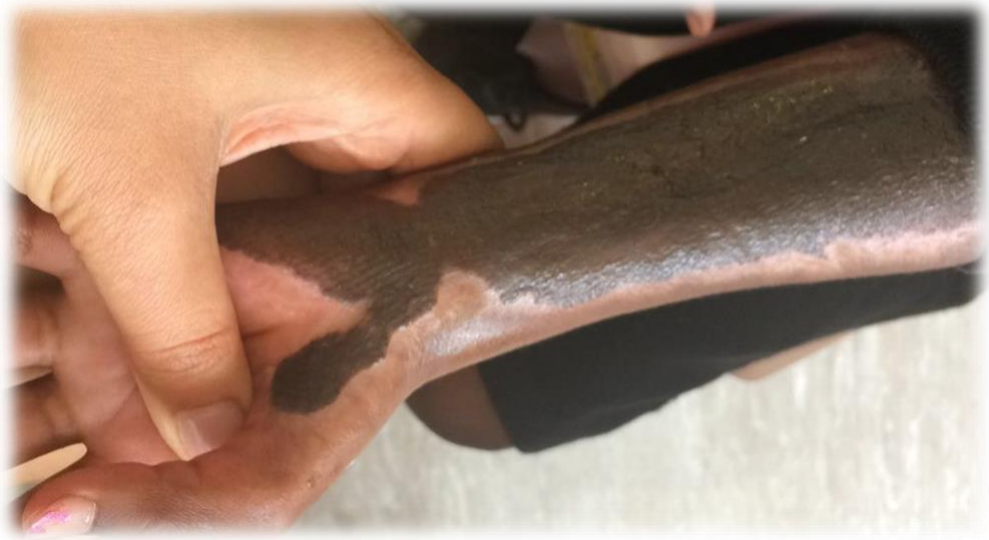
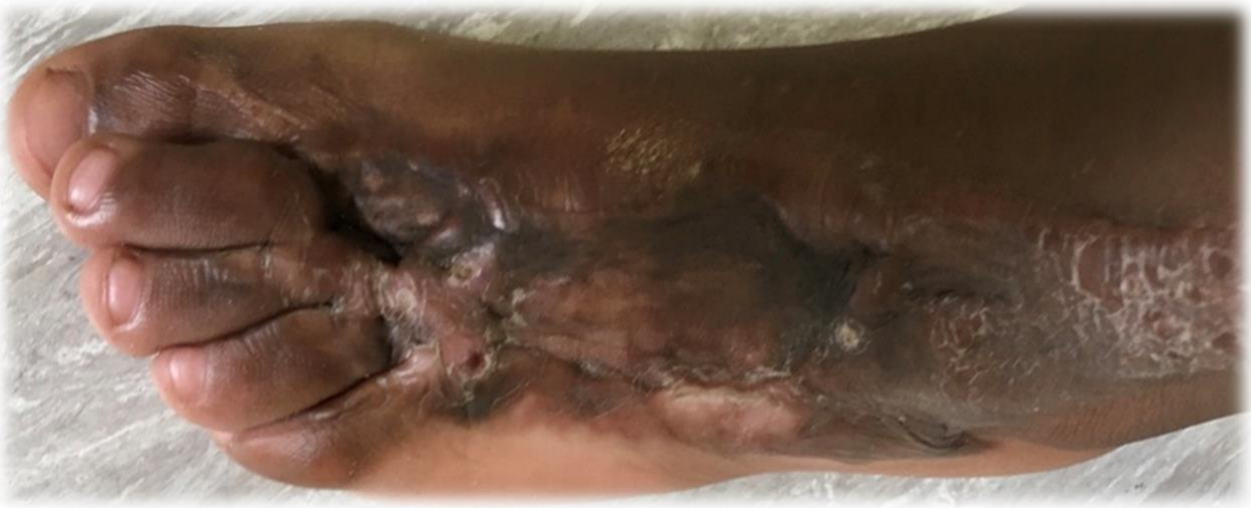


Figure 6: Delayed complication seen with ADM on Dorsum of Foot resulting in Contractures of Extensor Tendons seen at 5 months post op



Part I: Appendices
Appendix 1:
1.1. UCT HREC approval

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
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Website: www.health.uct.ac.za/fhs/research/humanethics/forms

07 February 2019

HREC REF: 071/2019

Dr S Adams
Division of Plastic and Reconstructive Surgery
H53 R69
OMB

Dear Dr Adams

PROJECT TITLE: THE USE OF ACELLULAR DERMAL MATRIX (PELNAC™) IN THE MANAGEMENT OF DEGLOVING WOUNDS IN A PAEDIATRIC POPULATION (MASTER'S DR K PILLAY)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 28 February 2020.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

We acknowledge that the student: Dr Kamlen Pillay will also be involved in this study.

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

Signature Removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB0000193R