AREA CENTRALE REGIONALE DI ACQUISTO

Dirigente Responsabile: *Dott. Riccardo ZANELLA tel. 010/548 8536*
e-mail: riccardo.zanella@regione.liguria.it
Funzionario referente: Sig.ra Patrizia Villa tel. 010/548 8544
e-mail: patrizia.villa@regione.liguria.it

DETERMINAZIONE n. 350 del 09/10/2017

Oggetto: Gara a procedura aperta, ai sensi dell'art. 55 del D.Lgs n. 163/2006, per l'affidamento della della fornitura di Medicazioni Avanzate per le aziende sanitarie della Regione Liguria per un periodo di anni tre (con opzione di rinnovo per ulteriori 1 anno) - Lotti n. 108 Numero gara 6066183
Modifica codici lotto 57 ditta COLOPLAST e approvazione aggiornamento tecnologico Ditta HARTMANN

IL DIRETTORE DELL'AREA

Vista la Legge della Regione Liguria 06/11/2012 n. 34 con la quale le funzioni di Centrale regionale di Acquisto (CRA), ai sensi dell'art. 37 del D.Lgs. 18/04/2016, n. 50, già disciplinate dalla L.R. n.14/2007 e s.m.i. sono state assegnate, a decorrere dall'01/01/2013 ad apposita area dell'Agenzia Sanitaria Regionale (ARS);

Visto l'art. 11 comma 16 della legge Regione Liguria 29/07/2016, n. 17 con la quale le funzioni di Centrale Regionale di Acquisto esercitate da ARS sono svolte a far data dal 01/10/2016 da A. Li.Sa. fino alla revisione della normativa regionale in materia di centrale di committenza;

Vista la deliberazione n. 22 del 30/12/2016 del Commissario Straordinario di A.Li.Sa. rubricata "Ulteriori provvedimenti relativi al provvisorio esercizio delle funzioni dell'Azienda Ligure Sanitaria della Regione Liguria, nelle more dell'adozione della dotazione organica definitiva e degli atti previsti dall'art. 11, c. 11, della Legge Regionale 29 luglio 2016, n. 17" con la quale sono state definite in via transitoria le competenze del Direttore e dei Dirigenti dell'Area CRA;

Atteso che con determinazione n. 142 del 11/06/2016 rettificata con determinazione n. 186 del 31/047/2016 è stata aggiudicata in via definitiva la gara per l'affidamento della fornitura di Medicazioni Avanzate occorrenti per le necessità delle AA.SS.LL. EE.OO. e I.R.C.C.S. della Regione Liguria per un periodo di anni tre (con opzione di rinnovo per un ulteriore anno);

Preso atto che la ditta COLOPLST SPA con nota acquisita agli atti della Centrale con protocollo 5039 del 05/04/2017, ha inviato le seguenti modifiche di codici dei prodotti giudicati relativamente al lotto n. 57 come di seguito specificato:

DESCRIZIONE	NUOVO CODICE ARTICOLO	VECCHIO CODICE ARTICOLO
COMFEEL PLUS	33110	3110
	33115	3115
	33120	3120
	33285	3285
COMFEEL PLUS TRASPARENTE	33530	3530
	33533	3533
	33536	3536
	33539	3539
	33542	3542
	33545	3545
	33548	3548
COMFEEL PLUS CONTOUR	33280	3280
	33283	3283
COMFEEL PLUS SOLLIEVO	33350	3350
	33353	3353
	33356	3356

Preso altresì atto che la ditta HARTMANN con nota acquisita agli atti della Centrale con protocollo 7102 del 17/05/2017, ha inviato un aggiornamento tecnologico relativamente al lotto n. 35 come di seguito specificato:

""A seguito di aggiornamento tecnologico del proprio assortimento prodotti, ha sostituito le medicazioni TenderWet plus e TenderWet plus cavity, oggetto di aggiudicazione, con le medicazioni HydroClean plus e HydroClean plus cavity, già commercializzate in alcuni paesi della Comunità Europea...""

Atteso che in data 31/05/2017, le proposte sopra richiamate sono state inviate per le vie brevi ai componenti della Commissione giudicatrice nominati con determinazione n. 217 del 18/09/2016, e che gli stessi hanno espresso parere favorevole a quanto proposto con note acquisite agli atti della Centrale;

Ritenuto, sulla scorta di quanto sopra evidenziato, di autorizzare la richiesta di cambio codici e aggiornamento tecnologico rispettivamente delle ditte Coloplast Spa ed Hartmann Spa dei prodotti sopra specificati, alle medesime condizioni economiche di aggiudicazione;

Su proposta del Dirigente responsabile;

D E T E R M I N A :

1) Di autorizzare la richiesta di cambio codici sotto riportata relativamente al lotto 57, presentata dalla ditta Coloplast Spa:

DESCRIZIONE	NUOVO CODICE ARTICOLO	VECCHIO CODICE ARTICOLO
COMFEEL PLUS	33110	3110
	33115	3115
	33120	3120
	33285	3285
COMFEEL PLUS TRASPARENTE	33530	3530
	33533	3533
	33536	3536
	33539	3539
	33542	3542
	33545	3545
	33548	3548
COMFEEL PLUS CONTOUR	33280	3280
	33283	3283
COMFEEL PLUS SOLLIEVO	33350	3350
	33353	3353
	33356	3356

2) Di autorizzare l'aggiornamento tecnologico relativamente al lotto n. 35 aggiudicato alla Ditta Hartmann sostituendo le medicazioni TenderWet plus e TenderWet plus cavity, con le medicazioni HydroClean plus e HydroClean plus cavity,

3) Di notificare alle Ditte interessate e ad AA.SS.LL., EE.OO. e IRCCS della Regione Liguria la presente determinazione.

4) Di dare atto che il presente atto consta di 4 (quattro) pagine escluso l'allegato.

IL DIRETTORE DELL'AREA
CENTRALE REGIONALE DI ACQUISTO
(Dott. Giorgio SACCO)

ALLEGATO:
Nota prot. 5039 del 5/04/2017 ditta Coloplast SpA
Nota prot. 7102 del 14/05/2017 ditta Hartmann Spa

Coloplast

Ostomy Care
Continence Care
Wound & Skin Care
Urology Care

A.Li.Sa. – Azienda Ligure Sanitaria Regione Liguria
Via D'Annunzio, 64
16121 Genova
Fax 010.5488566

1 marzo 2017

Coloplast S.p.A.
Via Trattati Comunitari Europei 9
40127 Bologna BO
Italy
Tel: +39 051 4138000
www.coloplast.it

Cambio Codici Prodotti Coloplast aggiudicati in Gara Wound Care

Coloplast Spa, BU Wound Care, comunica che a partire da Aprile 2017 i prodotti Comfeel aggiudicati in gara Wound Care Rif "Procedura aperta per la fornitura di Medicazioni avanzate per un periodi di mesi 36, con opzione di rinnovo per ulteriori 12 mesi - Lotti n. 108" Delibera di aggiudicazione n. 154 del 10/06/2016, cambieranno i loro codici come da tabella indicata di seguito:

Descrizione	Nuovo Codice Articolo	Vecchio Codice Articolo
Comfeel Plus	33110	3110
	33115	3115
	33120	3120
	33285	3285
Comfeel Plus Trasparente	33530	3530
	33533	3533
	33536	3536
	33539	3539
	33542	3542
	33545	3545
	33548	3548
Comfeel Plus Contour	33280	3280
	33283	3283
Comfeel Plus Sollievo	33350	3350
	33353	3353
	33356	3356

Il nome commerciale resta lo stesso, viene aggiunto un 3 davanti agli attuali codici.

- I codici cambiano, viene aggiunto un 3 davanti al vecchio codice
- Il nome e la composizione del prodotto restano gli stessi, abbiamo aggiornato i confezionamenti primari e secondari, e la modalità di applicazione in 3 parti per rendere ancora più semplice l'utilizzo da parte dei professionisti sanitari.

Vi preghiamo quindi di **aggiornare i Vostri Database con i nuovi codici** in modo da rendere questa transizione il più semplice possibile.

La Gamma Comfeel Plus ha una capacità storicamente comprovata nel garantire una protezione sicura delle lesioni e della cute a rischio e nel gestire al tempo stesso l'essudato per una guarigione più rapida. Da oggi il suo utilizzo sarà ancora più semplice ed intuitivo.

Da Aprile per circa sei mesi le nuove confezioni dei prodotti Comfeel avranno applicata un'etichetta che indica in modo molto chiaro ed intuitivo il cambiamento. Insieme all'etichetta sarà presente anche un inserto interno per ricordare l'upgrade del prodotto.

Domenico Laurenza
Business Unit Director

WC Market

R.E.A. BO 0333119
Reg Imp. BO 56162
P.IVA 00691781207
C.F.04029180371
Cap. Soc. € 1.500.000 i.v.

Società soggetta
a direzione
e coordinamento di
Coloplast A/S

Coloplast

Ostomy Care
Continence Care
Wound & Skin Care
Urology Care

Nella certezza che questa innovazione semplificherà il lavoro quotidiano del personale clinico all'interno della Sua struttura, Le ricordiamo che i responsabili di zona e il nostro servizio clienti **(051.4138.100)** sono sempre a disposizione per fornirLe eventuali ulteriori informazioni.

Nel ringraziarLa per la cortese attenzione, Salutiamo cordialmente

Domenico Laurenza
Business Unit Director Wound Care

HARTMANN

HARTMANN
Italia

PAUL HARTMANN S.p.A., Via della Metallurgia, 12 - 37139 Verona - Italia

Vs. Rif.	
Vs. scritto del	
Ns. Rif	Prot. n. 104/BOF/bf
Data	10/05/2017
Tel. diretto	045 8182411
Fax diretto	045 8510733
E-mail:	ufficiogare@hartmann.info

Spettabile
A.LI.SA. LIGURIA
AREA CENTRALE REGIONALE DI ACQUISTO
VIA G. D'ANNUNZIO, 64
16121 GENOVA

Dirigente Responsabile
Dott. Riccardo Zanella
Referente contratto
Sig.ra Patrizia Villa

Oggetto: Procedura aperta per l'affidamento della fornitura di Medicazioni Avanzate occorrente alle AA.SS.LL. EE.OO. e I.R.C.C.S. della Regione Liguria per un periodo di anni tre (con opzione di rinnovo per ulteriore anno). Numero gara 6066183.
Lotto 35 "Poliacrilati: medicazione idroattiva a base di poliacrilati contenuti in una medicazione pluristratificata" – CIG 6285880844 - Aggiornamento tecnologico.

Spettabile Ente,

con riferimento alla Convenzione stipulata in data 14/09/2016, per la fornitura di Medicazioni Avanzate ed in particolare all'assegnazione, a nostro favore, del lotto n. 35 *"Poliacrilati: medicazione idroattiva a base di poliacrilati contenuti in una medicazione pluristratificata"*, con la presente Vi comunichiamo che Paul Hartmann AG, Casa Madre del Gruppo Hartmann, a seguito aggiornamento tecnologico del proprio assortimento prodotti, ha sostituito le medicazioni *TenderWet® plus* e *TenderWet® plus cavity*, oggetto di aggiudicazione, con le medicazioni *HydroClean® plus* e *HydroClean® plus cavity*, già commercializzate in alcuni paesi della Comunità Europea e a breve anche in Italia.

HydroClean® plus e *HydroClean® plus cavity* hanno le medesime caratteristiche di *TenderWet® plus* e *TenderWet® plus cavity* per quanto riguarda destinazione d'uso e meccanismo d'azione. *HydroClean® plus* e *HydroClean® plus cavity* si presentano, altresì, con alcune caratteristiche che ne migliorano l'utilizzo e l'efficacia:

1. Medicazione più sottile

   Spessore medio
   - TenderWet® plus e TenderWet® plus cavity 8 mm +/- 2
   - HydroClean® plus e HydroClean® plus cavity 6 mm +/- 2

   Il diverso spessore garantisce maggior adattabilità alle diverse parti del corpo su cui si trova la ferita da trattare, garantendo maggior capacità di impiego nel caso di lesioni collocate in prossimità o all'interno di pliche cutanee.

Paul Hartmann S.p.A.
Via della Metallurgia, 12
37139 Verona - Italia

Tel 045 8182411
Fax 045 8510733

E-mail: info@it.hartmann.info
www.hartmann.it

Reg. Imp. VR n. 28911 – REA n. 180939
Cod. Fiscale 07179150151
Partita IVA 02136540230
Capitale sociale € 250.000 i.v.
a socio unico

2. Medicazione più leggera (cfr tabella comparativa)

Misura	TenderWet® plus & TenderWet® plus cavity (peso)	HydroClean® plus & HydroClean® plus cavity (peso)
Ø 4 cm	9 g	**5.5 g**
Ø 5,5 cm	18.5 g	**10.7 g**
7,5 cm x 7,5 cm	42.2 g	**20.4 g**
10 cm x 10 cm	75 g	**36.7 g**

Tale caratteristica assicura:

- maggior maneggevolezza nel posizionamento della medicazione, l'operatore potrà utilizzarla senza intervento di altro personale;
- maggiore stabilità al momento del fissaggio della medicazione con medicazione secondaria: si evitano rischi di dislocazione, con conseguente maggior aderenza al letto della ferita e minor rischio di macerazione dei bordi perilesionali.
- minor pressione sui tessuti (quando utilizzata sotto bendaggio elastocompressivo) con conseguente maggior comfort del paziente durante la permanenza in situ nei tre giorni del trattamento.

Per una migliore comparazione delle caratteristiche tecniche, alleghiamo la scheda del prodotto aggiudicato *"TenderWet® plus e TenderWet® plus cavity"* e la scheda del prodotto sostitutivo *"HydroClean® plus e HydroClean® plus cavity"*.

Alla luce di quanto sopra esposto e a quanto previsto dall'art. 28 della Convenzione *"Aggiornamento tecnologico"* (che, per Vostro uso, si allega), chiediamo che ci venga concessa la possibilità di fornire la medicazione *"HydroClean® plus e HydroClean® plus cavity"* in sostituzione totale della medicazione *"TenderWet® plus e TenderWet® plus cavity"*.

Restiamo in attesa di un Vostro cortese riscontro in merito e con l'occasione porgiamo cordiali saluti.

PAUL HARTMANN S.p.A.
Sales Manager Hospital
Sig. Luca Mauro Ariotti

HARTMANN		Scheda tecnica

HydroClean® plus HydroClean® plus cavity Medicazione idroattiva a base di poliacrilati e PHMB	Protocollo n.	TenderWet p.
	Reparto	MWC
	Data	21.03.2017

1. Descrizione generale

HydroClean® plus
HydroClean® plus è una medicazione idroattiva che contiene, come componente di base, un poliacrilato superassorbente (SAP) legato a fibre di cellulosa. L'agente antibatterico poliesametilene biguanide (PHMB) è associato al SAP che è attivato (pre-inumidito) con soluzione di Ringer. Lo strato della medicazione a contatto con la ferita consiste in un tessuto di polipropilene al quale sono state applicate delle strisce in silicone. Lo strato di contatto con la ferita e le strisce di silicone impediscono l'adesione al letto della ferita. Sul lato opposto alla ferita un film in polipropilene impermeabile ai liquidi, rivestito con un tessuto in polipropilene idrofobico, previene che la medicazione si asciughi troppo presto. Questo permette all'umidità di essere rilasciata sulla ferita per tre giorni. HydroClean® rilascia soluzione di Ringer sulla ferita per tre giorni. Durante il tempo di permanenza della medicazione sulla ferita avviene una continua e interattiva irrigazione della ferita, assorbendo anche l'essudato della ferita grazie al cuscinetto della medicazione. Il PHMB associato al SAP di base ha un effetto antibatterico e inibisce la crescita batterica all'interno della medicazione riducendo allo stesso tempo il rischio di ricontaminazione durante l'intero periodo di applicazione sino a tre giorni. Il SAP utilizzato in HydroClean® plus inattiva la matrice della metalloproteasi (MMP) che impedisce la guarigione della ferita. Come conseguenza possono essere riattivate ferite stagnanti o croniche.

HydroClean® plus
HydroClean® plus cavity è una medicazione idroattiva che contiene, come componente di base, un poliacrilato superassorbente (SAP) legato a fibre di cellulosa. L'agente antibatterico poliesametilene biguanide (PHMB) è associato al SAP che è attivato (pre-inumidito) con soluzione di Ringer. La medicazione è rivestita con un film in polipropilene su entrambi i lati. Proprietà e meccanismo d'azione di HydroClean® cavity sono caratterizzati dal rilascio di soluzione di Ringer sulla ferita per tre giorni. Durante il tempo di permanenza della medicazione sulla ferita avviene una continua e interattiva irrigazione della ferita, assorbendo anche l'essudato della ferita grazie al cuscinetto della medicazione. Il PHMB associato al SAP di base ha un effetto antibatterico e inibisce la crescita batterica all'interno della medicazione riducendo allo stesso tempo il rischio di ricontaminazione durante l'intero periodo di applicazione sino a tre giorni. Il SAP utilizzato in HydroClean® plus inattiva la matrice della metalloproteasi (MMP) che impedisce la guarigione della ferita. Come conseguenza possono essere riattivate ferite stagnanti o croniche.

Classificazione

Dispositivo Medico sterile classe IIb conforme alla Direttiva 92/42/CEE s.m.i.
Codice Classificazione Nazionale dei Dispositivi Medici M040499

Prodotto in Svizzera da Paul Hartmann AG - 89522 Heidenheim – Germania.

Distributore per l'Italia: Paul Hartmann S.p.A. – Verona.

2. Destinazione d'uso

HydroClean® plus
Per il trattamento umido delle ferite con un'alterata tendenza alla guarigione.
HydroClean® plus è una medicazione particolarmente adatta per il trattamento di ferite croniche e di difficile guarigione nella fase di detersione.
Inoltre, è possibile utilizzarla per la riattivazione di processi di guarigione stagnanti, nel caso in cui questi siano causati da un'attività eccessivamente intensa delle MMP.

HydroClean® plus cavity
Per il trattamento umido delle ferite con un'alterata tendenza alla guarigione.
HydroClean® plus cavity è una medicazione particolarmente adatta per il trattamento di ferite croniche e di difficile guarigione nella fase di detersione.
Inoltre, è possibile utilizzarla per la riattivazione di processi di guarigione stagnanti, nel caso in cui questi siano causati da un'attività eccessivamente intensa delle MMP.

Controindicazioni

Fino ad ora non si conoscono controindicazioni. Non va comunque utilizzata in caso di ipersensibilità ai suoi componenti.

All'inizio del trattamento si possono osservare:

Aumento della misura della ferita: la misura della ferita può aumentare a causa della rimozione del tessuto necrotico dai bordi, tessuto già irrimediabilmente danneggiato prima del trattamento. Questo fenomeno può tuttavia indicare che il processo di guarigione della ferita è in corso.

Arrossamento della pelle: durante il trattamento umido possono presentarsi arrossamenti dei margini della ferita, che di norma sono un segnale della riattivazione della circolazione sanguigna durante la detersione e dovuta al processo di guarigione della ferita.

Emorragie: le ferite possono sanguinare spontaneamente durante il trattamento con HydroClean® plus in quanto stimola la proliferazione delle cellule. E' oppurtuno, comunque, valutare la situazione caso per caso.

Dolore: HydroClean® plus non causa di per sé nessun dolore in quanto ha un'azione lenitiva e la medicazione ha una bassa aderenza.
Le ferite possono comunque essere dolorose e sensibili alle sollecitazioni meccaniche. In caso di dolore persistente può essere utile inumidire la medicazione dall'esterno dopo alcune ore, senza rimuoverla.

Istruzioni d'uso

- Scegliere la misura e la versione più adeguata per il tipo di lesione. HydroClean® plus non deve essere tagliata né danneggiata meccanicamente in altro modo.
- Applicare HydroClean® plus direttamente sulla lesione, con il lato bianco sulla ferita e il lato marcato con caratteri verde rivolto verso l'esterno.
- Fissare HydroClean® plus con una medicazione secondaria, un bendaggio coesivo (Peha-haft) o un cerotto adesivo (Omnifix).

- Il trattamento umido con soluzione Ringer non determina la macerazione di cellule vitali, ma qualora HydroClean® plus dovesse sovrapporsi ai brodi perilesionali, si consiglia di proteggerli con una pomata grassa, idratante o un'emulsione idro-oleosa.

- HydroClean® plus cavity va utilizzato in ferite profonde associato a una medicazione secondaria assorbente come HydroClean® plus al fine di garantire una più lunga e costante azione di detersione o a una schiuma in poliuretano (HydroTac® o Permafoam®) o una qualsiasi medicazione assorbente.

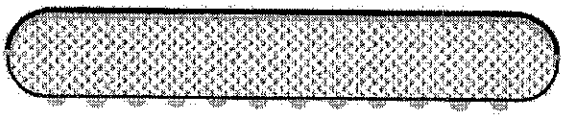
3. Caratteristiche tecniche

Copertura	Strato in polipropilene laminato con una trama in polipropilene (colore verde chiaro)
Corpo assorbente	Corpo centrale costituito da cellulosa con poliacrilati superassorbenti (SAP) e fibre di polipropilene, attivato con soluzione Ringer con PHMB 0,1 % w/w
Peso (comprensivo di Soluzione di Ringer)	
4 cm, Ø	9 gr
5,5 cm , Ø	18,5 gr
7,5 x 7,5 cm	43,2 gr
10x10 cm	75 gr
Biocompatibilità	Conforme allo Standard UNI EN ISO 10993:1 - Valutazione biologica dei dispositivi medici - Valutazione e prove
Sterilizzazione	A vapore
Scadenza	Il prodotto correttamente conservato in confezione integra ha una vita utile di 3 anni
Tempo di permanenza in situ	Fino ad un massimo di 72 ore
Lattice	**Assente** nella medicazione e nel confezionamento

HARTMANN		Scheda tecnica

HydroClean® plus HydroClean® plus cavity Medicazione idroattiva a base di poliacrilati e PHMB	Protocollo n.	TenderWet p.
	Reparto	MWC
	Data	21.03.2017

HydroClean®



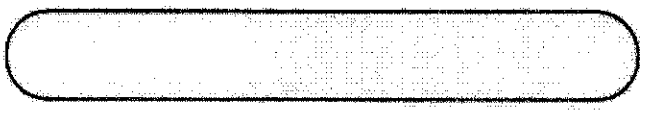
2 Strati in polipropilene (uno bianco e uno con stampa blu)
film in polipropilene (colore bianco, impermeabile, barriera ai batteri)

Corpo centrale (cellulosa, poliacrilati superassorbenti e fibre di polipropilene, attivato con soluzione Ringer con PHMB)

Trama idrofobica in polipropilene

Strato a contatto con la ferita, strisce in silicone

HydroClean® plus cavity



Corpo centrale (cellulosa, poliacrilati superassorbenti e fibre di polipropilene, attivato con soluzione Ringer con PHMB)

Trama idrofobica in polipropilene

4. Confezionamento

Medicazione sigillata singolarmente in buste tipo "peel-to-open" in PET/ALU/PP, inserite in scatole di cartoncino e imballate in cartone da trasporto conforme DIN, sigillato con nastri adesivi, su europallet.

HydroClean® plus			
codici	**misure**	**pezzi per confezione**	**confezioni per cartoni**
609590	Ø 4 cm	10 pezzi	6 conf
609591	Ø 5,5 cm	10 pezzi	6 conf
609593	7,5 cm x 7,5 cm	10 pezzi	6 conf
609594	10 cm x 10 cm	10 pezzi	6 conf

HydroClean® plus cavity			
codici	**misure**	**pezzi per confezione**	**confezioni per cartoni**
609550	Ø 4 cm	10 pezzi	6 conf
609553	7,5 cm x 7,5 cm	10 pezzi	6 conf

Lotto di produzione: codice a 9 cifre

Scadenza

Es.		2015	06
		anno	mese

5. Metodo di conservazione

Conservare in luogo asciutto e ben areato, lontano da fonti luminose, ad una temperatura compresa tra 5 °C e 25 °C.

6. Smaltimento

Dopo l'uso, in presenza di essudati e/o liquidi organici, lo smaltimento deve essere effettuato secondo le disposizioni di legge vigenti.

PAUL HARTMANN S.p.A.

Scheda Tecnica
TenderWet® plus cavity

Lotto 35 rif. 1 - 3

MEDICAZIONE IDROATTIVA A BASE DI POLIACRILATI E PHMB

Protocollo-No.:	TenderWet plus cavity
Reparto:	MW
Data:	10.10.2013

REGISTRO DEGLI AGGIORNAMENTI

Pagine /Documento	Sostituisce Pegine/Documento	Motivo dell'aggiornamento
1-5 10.10.2013	.....	Nuova scheda tecnica

04/12/15

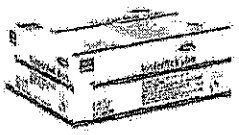
PAUL HARTMANN S.p.A.
Dr. Giovanni Rebua
Amministratore Delegato

Scheda Tecnica
TenderWet® plus cavity

Lotto 35 rif. 1 - 3

MEDICAZIONE IDROATTIVA A BASE DI POLIACRILATI E PHMB

Protocollo-No.:	TenderWet plus cavity
Reparto:	MW
Data:	10.10.2013



1. Descrizione generale

TenderWet plus cavity è una medicazione idroattiva preattivata con soluzione Ringer, che può essere mantenuta sulla ferita fino a 72 ore.

La componente centrale è costituita da un poliacrilato superassorbente (SAP) attivato con soluzione Ringer e impregnato di poliesametilene biguanide (PHMB),
La soluzione Ringer viene rilasciata in continuazione sulla ferita e l'essudato viene assorbito. In questo modo la ferita viene ripulita in continuazione e ne vengono allontanati i fattori che influenzano negativamente la guarigione, e cioè germi, detriti cellulari e tossine.
Il poliesametilene biguanide svolge un'azione antibatterica all'interno della medicazione impedendo così la ricontaminazione della ferita.

Il rivestimento del corpo assorbente centrale è realizzato in polipropilene che impedisce un'essicazione prematura della medicazione, in modo che l'azione idratante sulla ferita possa durare fino a 72 ore. Allo stesso tempo, il rivestimento impedisce efficacemente la fuoriuscita di liquido o essudato raccolto.

TenderWet plus cavity supporta e non contrasta il processo di riparazione tissutale e inibisce l'attività delle metalloproteasi (MMP).

Classificazione

Dispositivo Medico sterile classe IIb secondo le Direttive CEE.
Codice Classificazione Nazionale dei Dispositivi Medici M040499
RDM:

codici	numero
609295	627070/R
609296	627072/R

Prodotto in Svizzera da Paul Hartmann AG - 89522 Heidenheim – Germania.

Distributore per l'Italia: Paul Hartmann S.p.A. – Verona.

MEDICAZIONE IDROATTIVA A BASE DI POLIACRILATI E PHMB

Protocollo-No.:	TenderWet plus cavity
Reparto:	MW
Data:	10.10.2013

2. Destinazione d'uso

Per il trattamento umido delle ferite con un'alterata tendenza alla guarigione.
TenderWet plus cavity è una medicazione particolarmente adatta per ferite cavitarie e per il trattamento di ferite croniche e di difficile guarigione nella fase di detersione.
Inoltre, è possibile utilizzarla per la riattivazione di processi di guarigione stagnanti, nel caso in cui questi siano causati da un'attività eccessivamente intensa delle MMP.

Istruzioni d'uso

- Scegliere la misura e la versione più adeguata per il tipo di lesione. TenderWet plus cavity non deve essere tagliata né danneggiata meccanicamente in altro modo.

- TenderWet plus cavity viene applicata tamponata sulla ferita o inserita tamponando e quindi coperta con una medicazione a cuscinetto TenderWet plus.

- TenderWet plus cavity deve trovarsi a contatto diretto con l'intera superficie della ferita. Le due medicazioni a cuscinetto, possibilmente, non devono superare i margini della ferita e devono essere fissate con materiali appropriati, ad esempio con una benda o un cerotto.

- Le due medicazioni a cuscinetto devono essere sostituite al più tardi dopo 72 ore. Se la ferita richiede un'intesa idratazione, tuttavia, può essere necessario sostituire le medicazioni con maggior frequenza. TenderWet cavity può essere rimossa senza problemi dalla ferita. Qualora necessario, in caso di anticipata essiccazione, è possibile bagnarla con soluzione Ringer, in modo tale che dopo qualche minuto possa essere rimossa senza provocare dolore.

- Il trattamento umido con soluzione Ringer non determina la macerazione di cellule vitali, ma qualora TenderWet plus dovesse sovrapporsi ai brodi perilesionali, si consiglia di proteggerli con una pomata grassa, idratante o un'emulsione idro-oleosa.

MEDICAZIONE IDROATTIVA A BASE DI POLIACRILATI E PHMB

Protocollo-No.:	TenderWet plus cavity
Reparto:	MW
Data:	10.10.2013

Controindicazioni

Fino ad ora non si conoscono controindicazioni. Non va comunque utilizzata in caso di ipersensibilità ad uno dei suoi componenti.

All'inizio del trattamento si possono osservare:

Aumento della misura della ferita: all'inizio del trattamento con TenderWet plus cavity potrebbe osservarsi un aumento delle dimensioni della ferita, dovuto alla degradazione del tessuto già irrimediabilmente danneggiato prima del trattamento. Questo fenomeno può tuttavia indicare che il processo di guarigione della ferita è in corso.

Arrossamento della pelle: durante il trattamento umido possono presentarsi arrossamenti dei margini della ferita, che di norma sono una segnale della riattivazione della circolazione sanguigna durante la detersione e dovuta al processo di guarigione della ferita.

Emorragie: durante il trattamento con TenderWet plus cavity le ferite possono presentare la tendenza a sanguinare spontaneamente. Di norma si tratta di un segnale del processo di guarigione della ferita, ma è opportuno, comunque, valutare la situazione caso per caso.

Dolore: TenderWet plus cavity in quanto tale non causa nessun dolore in quanto ha un'azione lenitiva e la medicazione ha una bassa aderenza.
Spesso, però, una ferita aperta è di per sé molto sensibile alle sollecitazioni meccaniche. In caso di dolore persistente può essere utile inumidire la medicazione dall'esterno dopo alcune ore, senza rimuoverla; altrimenti, in rari casi, è indicata la somministrazione di analgesici adeguati.

Scheda Tecnica
TenderWet® plus cavity

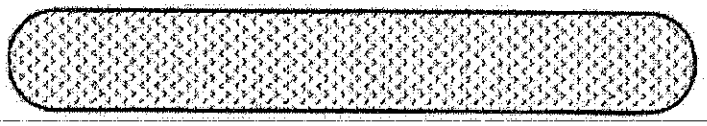
Lotto 35 rif. 1 - 3

MEDICAZIONE IDROATTIVA A BASE DI POLIACRILATI E PHMB

Protocollo-No.:	TenderWet plus cavity
Reparto:	MW
Data:	10.10.2013

3. Caratteristiche tecniche

Rivestimento	Strato tessuto in polipropilene idrofobico
Corpo assorbente	Corpo centrale costituito da cellulosa con poliacrilati superassorbenti e polipropilene, attivato con soluzione Ringer contenente PHMB
Peso	
4 cm, ø	9 g
7,5 x 7,5 cm	43,2 gr
Biocompatibilità	Conforme allo Standard UNI EN ISO 10993:1 - Valutazione biologica dei dispositivi medici - Valutazione e prove
Lattice	Assente
Sterilizzazione	A vapore
Scadenza	il prodotto correttamente conservato in confezione integra ha una vita utile di 2 anni
Tempo di permanenza in situ	Fino ad un massimo di 72 ore



Corpo centrale costituito da cellulosa con poliacrilati superassorbenti e polipropilene, attivato con soluzione Ringer contenente PHMB

Strato in polipropilene tessuto, resistente all'acqua

MEDICAZIONE IDROATTIVA A BASE DI POLIACRILATI E PHMB

Protocollo-No.:	TenderWet plus cavity
Reparto:	MW
Data:	10.10.2013

4. Confezionamento

Medicazione sigillata singolarmente in buste peel-pack, inserite in scatole di cartoncino e imballate in cartone da trasporto conforme DIN, sigillato con nastri adesivi, su europallet.

codici	misure	pezzi per confezione	confezioni per cartone
609295	ø 4 cm	10	6
609296	7.5 cm x 7.5 cm	10	6

5. Numero di lotto - scadenza

Lotto di produzione: codice a 9 cifre

Scadenza
Es. ⧖ 2015 anno 06 mese

6. Metodo di conservazione

Conservare in luogo asciutto e ben areato, lontano da fonti luminose, ad una temperatura tra i 5 °C e i 25 °C. Il contenuto è sterile finché la confezione a strappo resta intatta.

7. Smaltimento

Dopo l'uso, in presenza di essudati e/o liquidi organici, lo smaltimento deve essere effettuato secondo le disposizioni di legge vigenti.

PAUL HARTMANN S.p.A

Scheda Tecnica
TenderWet® plus

Lotto 35 rif. 2 - 4

MEDICAZIONE IDROATTIVA A BASE DI POLIACRILATI E PHMB



Protocollo-No.:	TenderWet plus
Reparto:	MW
Data:	16.10.2012

REGISTRO DEGLI AGGIORNAMENTI

Pagine /Documento	Sostituisce Pagine/Documento	Motivo dell'aggiornamento
1-5 16.10.2012	.....	Nuova scheda tecnica

04/03/15

PAUL HARTMANN S.p.A.
Dr. Giovanni Renna
Amministratore Delegato

Scheda Tecnica TenderWet® plus

Lotto 35 rif. 2 - 4

MEDICAZIONE IDROATTIVA A BASE DI POLIACRILATI E PHMB

Protocollo-No.:	TenderWet plus
Reparto:	MW
Data:	16.10.2012

1. Descrizione generale

TenderWet plus è una medicazione idroattiva preattivata con soluzione Ringer, che può essere mantenuta sulla ferita fino a 72 ore.

La componente centrale è costituita da un poliacrilato superassorbente (SAP) attivato con soluzione Ringer e impregnato di poliesametilene biguanide (PHMB).
La soluzione Ringer viene rilasciata in continuazione sulla ferita e l'essudato viene assorbito. In questo modo la ferita viene ripulita in continuazione e ne vengono allontanati i fattori che influenzano negativamente la guarigione, e cioè germi, detriti cellulari e tossine.
Il poliesametilene biguanide svolge un'azione antibatterica all'interno della medicazione impedendo così la ricontaminazione della ferita.

Le strisce di silicone applicate sullo strato a contatto con la ferita impediscono che la medicazione aderisca alla ferita stessa e garantiscono, così, una rimozione atraumatica della medicazione.

Sul lato esterno, non rivolto verso la ferita, una pellicola di polipropilene impermeabile impedisce un'essiccazione prematura della medicazione a cuscinetto, in modo che l'azione idratante sulla ferita possa durare fino a 72 ore. Allo stesso tempo, la pellicola impedisce efficacemente la fuoriuscita di liquido.

TenderWet plus supporta e non contrasta il processo di riparazione tissutale e inibisce l'attività delle metalloproteasi (MMP).

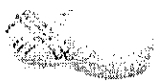
Classificazione

Dispositivo Medico sterile classe IIb secondo le Direttive CEE.
Codice Classificazione Nazionale dei Dispositivi Medici M040499
RDM:

codici	numero
609291	627027/R
609292	627067/R
609293	627068/R
609294	627069/R

Prodotto in Svizzera da Paul Hartmann AG - 89522 Heidenheim – Germania.

Distributore per l'Italia: Paul Hartmann S.p.A. – Verona.



2. Destinazione d'uso

Per il trattamento umido delle ferite con un'alterata tendenza alla guarigione. TenderWet plus è una medicazione particolarmente adatta per il trattamento di ferite croniche e di difficile guarigione nella fase di detersione.
Inoltre, è possibile utilizzarla per la riattivazione di processi di guarigione stagnanti, nel caso in cui questi siano causati da un'attività eccessivamente intensa delle MMP.

Controindicazioni

Fino ad ora non si conoscono controindicazioni. Non va comunque utilizzata in caso di ipersensibilità ai suoi componenti.

All'inizio del trattamento si possono osservare:

Aumento della misura della ferita: la misura della ferita può aumentare a causa della rimozione del tessuto necrotico dai bordi, tessuto già irrimediabilmente danneggiato prima del trattamento. Questo fenomeno può tuttavia indicare che il processo di guarigione della ferita è in corso.

Arrossamento della pelle: durante il trattamento umido possono presentarsi arrossamenti dei margini della ferita, che di norma sono una segnale della riattivazione della circolazione sanguigna durante la detersione e dovuta al processo di guarigione della ferita.

Emorragie: le ferite possono sanguinare spontaneamente durante il trattamento con TenderWet plus in quanto stimola la proliferazione delle cellule.E' oppurtuno, comunque, valutare la situazione caso per caso.

Dolore: TenderWet plus non causa di per sé nessun dolore in quanto ha un'azione lenitiva e la medicazione ha una bassa aderenza.
Le ferite possono comunque essere dolorose e sensibili alle sollecitazioni meccaniche. In caso di dolore persistente può essere utile inumidire la medicazione dall'esterno dopo alcune ore, senza rimuoverla.

Istruzioni d'uso

- Scegliere la misura e la versione più adeguata per il tipo di lesione. TenderWet plus non deve essere tagliata né danneggiata meccanicamente in altro modo.
- Applicare TenderWet plus direttamente sulla lesione, con il lato bianco sulla ferita e il lato marcato con strisce verdi rivolto verso l'esterno.
- Fissare TenderWet plus con una medicazione secondaria, un bendaggio coesivo (Peha-haft) o un cerotto adesivo (Omnifix).

MEDICAZIONE IDROATTIVA A BASE DI POLIACRILATI E PHMB

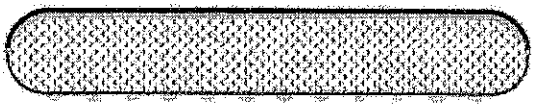


Protocollo-No.: TenderWet plus
Reparto: MW
Data: 16.10.2012

- Il trattamento umido con soluzione Ringer non determina la macerazione di cellule vitali, ma qualora TenderWet plus dovesse sovrapporsi ai brodi perilesionali, si consiglia di proteggerli con una pomata grassa, idratante o un'emulsione idro-oleosa.

3. Caratteristiche tecniche

Copertura	Strato in polipropilene (resistente all'acqua e impermeabile ai germi, colore verde scuro) laminato con una trama in polipropilene (colore verde chiaro)
Corpo assorbente	Corpo centrale costituito da cellulosa con poliacrilati superassorbenti (SAP) e fibre di polipropilene, attivato con soluzione Ringer con PHMB 0,1 % w/w
Peso	
4 cm, Ø	9 gr
5,5 cm , Ø	18,5 gr
7,5 x 7,5 cm	43,2 gr
10x10 cm	75 gr
Biocompatibilità	Conforme allo Standard UNI EN ISO 10993:1 - Valutazione biologica dei dispositivi medici - Valutazione e prove
Lattice	Assente
Sterilizzazione	A vapore
Scadenza	Il prodotto correttamente conservato in confezione integra ha una vita utile di 2 anni
Tempo di permanenza in situ	Fino ad un massimo di 72 ore



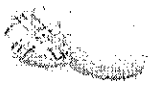
Strato in polipropilene (colore verde scuro) laminato con una trama in polipropilene (colore verde chiaro)

Corpo centrale (cellulosa, poliacrilati superassorbenti e fibre di polipropilene, attivato con soluzione Ringer con PHMB 0,1 % w/w)

Trama idrofobica in polipropilene

Strato a contatto con la ferita, strisce in silicone

MEDICAZIONE IDROATTIVA A BASE DI POLIACRILATI E PHMB



Protocollo-No.:	TenderWet plus
Reparto:	MW
Data:	16.10.2012

4. Confezionamento

Medicazione sigillata singolarmente in buste peel-pack (in PET/ALU/PP), inserite in scatole di cartoncino e imballate in cartone da trasporto conforme DIN, sigillato con nastri adesivi, su europallet.

codici	misure	pezzi per confezione	confezioni per cartoni
609291	Ø 4 cm	10 pezzi	6 conf
609292	Ø 5,5 cm	10 pezzi	6 conf
609293	7,5 cm x 7,5 cm	10 pezzi	6 conf
609294	10 cm x 10 cm	10 pezzi	6 conf

5. Numero di lotto - scadenza

Lotto di produzione: codice a 9 cifre

Scadenza

Es.	15	2015	06
		anno	mese

6. Metodo di conservazione

Conservare in luogo asciutto e ben areato, lontano da fonti luminose, ad una temperatura compresa tra 5 °C e 25 °C.

7. Smaltimento

Dopo l'uso, in presenza di essudati e/o liquidi organici, lo smaltimento deve essere effettuato secondo le disposizioni di legge vigenti.

PAUL HARTMANN S.p.A

5. Le Amministrazioni contraenti individuano il Responsabile del procedimento nell'Ordinativo di fornitura. In mancanza di individuazione, Responsabile del Procedimento è il Dirigente apicale del Settore Acquisti/Approvvigionamenti competente per materia.

6. Il Fornitore può individuare per le singole Amministrazioni contraenti distinti Responsabili della fornitura.

Articolo 28 - Aggiornamento tecnologico

1. Il Fornitore si impegna ad informare periodicamente e tempestivamente la Centrale e le Amministrazioni Contraenti sulla evoluzione tecnica dei prodotti oggetto della Convenzione e delle conseguenti possibili variazioni da apportare alle forniture ed alla prestazione dei servizi oggetto della medesima Convenzione.

2. Nel caso vengano apportate variazioni sostanziali nella produzione di quanto aggiudicato o vengano introdotti sul mercato prodotti sostitutivi o innovativi, la ditta aggiudicataria, previo invio di scheda tecnica e parere favorevole degli utilizzatori, si impegna a immettere nella fornitura il nuovo prodotto, alle stesse condizioni contrattuali.

Articolo 29 - Conciliazione presso la CCIAA

1. Per tutte le controversie concernenti la presente Convenzione, che dovessero insorgere tra il Fornitore e la Centrale, le parti si impegnano a ricorrere alla conciliazione, prima di dare impulso a qualsiasi procedimento giudiziale, presso la CCIAA di Genova ed in conformità al Regolamento di Conciliazione, che si richiama integralmente.

2. Per tutte le controversie relative ai rapporti tra il Fornitore e le Amministrazioni contraenti, le parti si impegnano a ricorrere alla conciliazione, prima di dare impulso a qualsiasi procedimento giudiziale, presso la CCIAA territorialmente competente.

journal of wound care JWC
VOLUME 25. NUMBER 4. APRIL 2016

The effect of Ringer's solution within a dressing to elicit pain relief

M. Colegrave,[1] PhD, Freelance Medical Writer and Researcher;
M.G. Rippon,[2] PhD, Visiting Clinical Research Fellow; **C. Richardson**,[3] BSc, AUS, RGN, MSc, PG Cert (HE), PhD; Senior Lecturer;
1 Molecular Cell Research, Lincoln
2 School of Human and Health Sciences, Institute of Skin Integrity and Infection Prevention. University of Huddersfield
3 The School of Nursing, Midwifery and Social Work, University of Manchester

Email: www.molecularcellreaserch.co.uk

The effect of Ringer's solution within a dressing to elicit pain relief

Clinical studies suggest that dressings containing Ringer's solution, such as the TenderWet and HydroClean families, provide relief from wound pain. This report reviews the available evidence and possible mechanisms for the relief of wound pain by these dressings. The ability of dressings containing Ringer's solution to provide pain relief is likely to be through providing a moist environment that is favourable for wound healing; furthermore, the dressing augments the protective barrier function by having additional fluid under the dressing, which covers exposed nerve endings and protects against friction damage. Ringer's solution will have a dilution effect and an influence on the pH of exudate. Diluting cytokines within the exudate would be expected to decrease inflammation in chronic wounds and reduce the influence of caustic components such as matrix metalloproteases (MMPs). Altering the pH of the wound bed could inactivate proteins and glycoproteins implicated in the pain response such as MMPs and sodium and calcium channels. The moist environment may also be better at recruiting leukocytes that release natural painkillers at areas of injury. These mechanisms are likely to act in combination to explain why dressings containing Ringer's solution can have analgesic effects.
• **Declaration of interest:** This paper was supported by Paul Hartmann Ltd . The authors have provided consultative services to Paul Hartmann Ltd .

pain; analgesics; Ringer's solution; occlusive dressings

The main functions of a wound dressing are to protect the wound and allow rapid healing; however, another important role is the dressing's ability to reduce wound pain. Pain is a major concern for patients with a wide range of both acute and chronic wounds.[1,2] Acute wounds, such as burns, and chronic wounds, such as pressure ulcers (PUs), are often considered to be particularly painful. Nevertheless, until recently, pain was often considered to be of secondary importance to the healing process in the minds of wound care providers.[3] For chronic wounds in particular, pain is often under-recognised and under-treated.[4] If pain is long-term it can result in a decrease in activity and loss of independence, a lack of energy and appetite, mood changes and depression.[4] It is now clear that pain relief is important for effective wound healing; as the anxiety and stress over wound pain increases, so does the likelihood of experiencing pain and this cycle is detrimental to the healing process.[5,6]

Wound-related pain may involve persistent pain that is usually associated with the underlying wound aetiology. Cyclic acute pain is induced by repeated interventions such as cleaning and dressing change, while non-cyclic acute pain results from one-off procedures such as debridement.[7] Alongside the direct pain resulting from the wound, additional factors may increase wound-related pain, including infection in the wound and cellulitis in the periwound skin.[8,9]

The stress and anxiety of wound pain is a particular concern for patients at dressing change.[10] One method of pain relief is the use of analgesic drugs, such as non-steroidal anti-inflammatory drugs. These may produce some unwanted side effects such as gastric ulcers and heart problems in patients with a history of cardiac failure or those receiving other medications;[11,12] especially if in high doses and/or long-term use is needed. The analgesic effect of wound dressings can improve the patient's quality of life (QoL), reduce the need to provide analgesic drugs and even speed healing. For these reasons, pain has become an important consideration, along with improved outcomes, in favour of using advanced wound dressings.[13]

A number of advanced dressings have been developed that assist healing and some of these have been developed with the aim of reducing wound pain. As pain at dressing change is often of most concern to patients,[10] the use of non-traumatic wound dressings reduces pain and anxiety.[14] These prevent the damage that often occurs with traditional dressings that adhere to the wound bed or periwound skin, requiring painful removal.[15] Other dressings have been designed to reduce persistent wound pain while in place. These include foam dressings containing ibuprofen, an analgesic and anti-inflammatory drug, which is released into the healing wound bed.[16,17] Their use, while likely to be beneficial to many patients, may have side effects, although this is likely

M. Colegrave,[1] PhD, Freelance Medical Writer and Researcher;
M.G. Rippon,[2] PhD, Visiting Clinical Research Fellow;
C. Richardson,[3] BSc, AUS, RGN, MSc, PG Cert (HE), PhD; Senior Lecturer;
1 Molecular Cell Research, Lincoln
2 School of Human and Health Sciences, Institute of Skin Integrity and Infection Prevention. University of Huddersfield
3 The School of Nursing, Midwifery and Social Work, University of Manchester

Email: www.molecularcellreaserch.co.uk

reduced by local release at low doses.[4] However, due to the anti-inflammatory action, they have the potential to inhibit the inflammation required to progress wound healing.[18]

Previous theoretical work has suggested ten potential mechanisms for the analgesic effect of a dressing.[19] These mechanisms include aspects common to most wound dressings, such as covering the wound to remove it from sight, which decreases anxiety and acting as a barrier to mechanical stimuli. However, some mechanisms are likely to be influenced by the properties of different dressings, for example occlusive dressings maintain a moist wound environment and accumulate fluid around the wound and this has been shown to reduce wound pain.[20,21]

Dressings such as TenderWet and HydroClean (Paul Hartmann Ltd) incorporate Ringer's solution with the aim of providing an optimal wound healing environment with active wound cleansing.[22] They are designed to clean the wound and be non-traumatic, reducing the chance of pain by the dressing being in place for longer periods and not causing damage to the wound or periwound skin on removal.[22] By maintaining a regulated moist wound healing environment, it is likely that a dressing containing a carefully balanced isotonic solution such as Ringer's solution may provide analgesia for persistent wound pain. The moist barrier may have an additional cushioning effect and protect against friction,[19] dilute pain-causing factors such as prostaglandins, kinins, cytokines and matrix metalloproteases (MMPs) and reduce inflammation.[23,24,25] A pH balanced Ringer's solution would be expected to modify the pH of exudate and this will influence the action of sodium and calcium channels involved in the pain response.[26] The nature of the isotonic solution might also be expected to recruit leukocytes that release natural painkillers.[27,28]

Clinical studies suggest that Ringer's solution within a wound dressing does reduce wound pain as patients experienced decreased pain after treatment and low levels of pain at dressing change.[29–32] Here we review the available studies and present the suggested mechanisms by which these dressings may provide an analgesic effect that is beneficial to the patient and to the progression of wound healing.

Methods

To investigate the analgesic nature of dressings containing Ringer's solution a search of the literature was performed, including those listed in PubMed/Medline, to find studies that reported pain in terms of wound pain and pain at dressing change when dressings containing Ringer's solution were used. The terms 'Ringer's solution', 'dressing', 'pain' were used for the search. The search was undertaken in September 2015 and included all reports up to that time point. Reports available from the dressing manufacturer were also consulted (Paul Hartmann Ltd). In these cases the clinical data was assigned the status of 'Data on file'.[33] A review of the available literature was then performed to assess the mechanisms by which the dressings with integrated Ringer's solution might provide pain relief. We identified 10 studies, four clinical studies and six case studies.

Clinical evidence

Data is available from four clinical studies to suggest dressings with Ringer's solution provided some degree of wound pain relief.[29–32] However, it should be noted that each of these studies was observational, without comparisons between the dressings with Ringer's solution and alternative advanced dressings, so the quality of the evidence presented is low.

In a multicentre observational study, 403 patients with chronic wounds (average duration of 2 months) were treated for an average of 1 month with a dressing containing Ringer's (data on file).[30] A reduction in pain was observed; at the start of the treatment 65% reported 'mild' or 'severe' pain; this was significantly reduced at the end of treatment to 13%. The dressing was atraumatic and pain at dressing change was reported as low, with 89% of patients rating the dressing as 'good' or 'very good' with regard to pain during dressing change.

A second multicentre observational study (170 patients) also reported decreased wound pain.[31] A variety of chronic wounds that had persisted for an average of 5 months were treated with a dressing containing Ringer's for an observational period of 8 days (data on file).[31] At the start of the treatment, 35% of patients suffered 'moderate' to 'severe' wound pain, whereas at the end of the treatment this was reduced to 19%. Parallel to wound pain, the proportion of 'moderate' to 'severe' pain at dressing change decreased from 28% at the start to 11% at the end of treatment.

In a single-centre observational study, 37 patients with venous leg ulcers (VLUs) were treated with a dressing containing Ringer's for an average of 19 days. Most patients (89%) experienced low or no pain.[32] There was no record of how much pain was experienced before this treatment, so we cannot compare before and after treatment in the study. However, as pain is the biggest problem faced by patients with these wounds, and the reported levels of high pain are between 29–64% with chronic VLUs,[34] these figures are encouraging.

The final study was a prospective open-label observational study of 221 patients with a variety of chronic wounds. The wounds were treated for 1 month with a dressing containing Ringer's. Pain reported as 'intermediate' to 'high' decreased from 64% to 19% of patients.[29]

Case reports also provide additional information that suggests wound pain experienced by patients is lowered with dressings containing Ringer's. Again

these presentations give no comparison between dressings and so the quality of the evidence is, low. There are six reports available (data on file).[35–40]

In a report of two cases, the first was a 40-year-old patient with a VLU who had suffered with recurrent ulcers for four years, [36] who was treated with a dressing containing Ringer's over a 3-week period. Upon the initial examination the patient complained of very severe wound pain, which had been treated with ibuprofen and morphine. During the 3-week treatment period, the slough and wound exudate levels were reduced and wound pain decreased significantly. At the end of the treatment, the patient considered the wound pain to be 'moderate'. The second was a 45-year-old with a chronic wound after an insect bite. The wound had not healed after 45 days and the patient complained of severe wound pain. Before the application of dressing containing Ringer's, necrotic tissue was surgically debrided. Using the dressing re-epithelialisation progressed. The patient tolerated the dressing well and the wearing comfort was assessed as very good, and wound pain decreased.[36]

A case series of five patients with second- and third-degree burns compared the level of pain experienced before and after use of the dressing in four of the five patients.[35] Of the four patients three reported decreased pain while the remaining patient already had low pain levels.[35]

Other single clinical case studies have also noted some level of pain relief, using a variety of different dressings containing Ringer's.[37–40] A 74-year-old patient with a VLU complicated by pyoderma gangrenosum noted pain relief upon application;[40] a 82-year-old who had significant skin tear due to trauma experienced pain relief upon application providing a moist wound environment.[39]

A 72-year-old patient had developed a sacral PU due to complete immobility. The PU was partially covered by black/yellow necrotic tissue and was very painful. The dressing containing Ringer's promoted autolytic debridement, with eventual reduction in exudate production levels and reduction in wound margin inflammation. The patient reported accompanying pain relief with improvement of the wound bed.[37] Finally, in a 69-year-old patient who had suffered a wound to the tibia region of leg and developed tissue necrosis and periwound inflammation, it was found that because of the minimal number of dressing changes and the atraumatic nature, that dressing changes were accompanied by little or no pain.[38]

Limitations

In summary, there is low-quality evidence that dressings containing Ringer's solution reduce wound pain. However, there are no detailed comparisons with other dressings, so we cannot conclude that these dressings are superior to others. As a wound heals, the pain would be expected to decrease, so more evidence is needed in terms of the pain relief provided by the dressings rather than it being the normal result of rapid wound healing. High-quality research is required; in particular, randomised controlled trials would provide the highest level of evidence for the use of these dressings.

Mechanisms for the analgesic effect

The effect of Ringer's solution can be studied by examining ten potential mechanisms for the analgesic effect of wound dressings,[19] and adapting them based on the physical properties of the solution. The mechanisms that are likely to be the most influential are those that involve the moist environment encouraged by the Ringer's solution. It is well established that a moist wound environment promotes acute wound healing by increasing re-epithelialisation and reducing scar tissue formation. This process probably involves encouraging cell proliferation and supporting conditions favourable for growth factors.[41] With this in mind, there are four main mechanisms worth consideration.

Mechanism 1: protective barrier

The barrier formed by a dressing is critical to its function of protecting the wound from further mechanical injury or infection;[42] this barrier also provides a cover to exposed nerve endings.[19] By augmenting the natural fluid created under the dressing the effect of the Ringer's solution is to create an additional barrier similar to a cushion effect we speculate. An analgesic effect may be elicited by this extra barrier in a similar way to other occlusive dressings that maintain a moist environment.[43] Increasing the barrier formed by the dressing would also be expected to reduce friction. Friction is a major cause of damage to periwound skin and the edges of wounds; supplementing the moist environment with a solution with a balanced pH could protect the wound against the pain and damage caused by friction and produce analgesia as a result.

Mechanism 2: dilution of exudate

The damage to the skin can also be increased by caustic wound exudate.[44] Cytokines are a large, diverse group of small proteins that are secreted from cells involved in the immune and inflammatory responses, such as macrophages, and have a wide range of different roles in cell signalling.[45] They are vital for the process of wound healing, which involves a balance between pro- and anti-inflammatory cytokines released from cells that are in and around the wound bed and cells recruited to the wound bed.[46] This robust inflammatory response, while required for wound healing, can also have detrimental effects in terms of the pain experienced by the patient. Cytokines are implicated in causing pain,[27,28,47] and pro-inflammatory

References

1 Shukla, D., Tripathi, A.K., Agrawal, S., et al. Pain in acute and chronic wounds: a descriptive study. Ostomy Wound Manage 2005; 51: 11, 47–51.

2 Wales, S. A world of pain. Nurs Stand 2006; 20: 36, 24–25.

3 Coulling, S. Fundamentals of pain management in wound care. Br J Nurs 2007; 16: 11, :S4–6, S8, S10 passim.

4 Coutts, P., Woo, K.Y., Bourque, S. Treating patients with painful chronic wounds. Nurs Stand 2008; 23: 10, 42–46.

5 Upton, D., Solowiej, K., Hender, C., Woodyatt, K.Y. Stress and pain associated with dressing change in patients with chronic wounds. J Wound Care 2012; 21: 2, 53–4, 56,58 passim.

6 Woo, K.Y. Unravelling nocebo effect: the mediating effect of anxiety between anticipation and pain at wound dressing change. J Clin Nurs 2015; 24: 13–14, 1975–1984.

7 Woo, K., Sibbald, G., Fogh, K. et al. Assessment and management of persistent (chronic) and total wound pain. Int Wound J 2008; 5: 2, 205–215.

8 Carter, K., Kilburn, S., Featherstone, P. Cellulitis and treatment: a qualitative study of experiences. Br J Nurs 2007; 16: 6, S22–S28.

9 Young, T. Assessment of wound pain: overview and a new initiative. Br J Nurs 2007; 16: 8, 456–461.

10 Kammerlander, G., Eberlein, T. Nurses' views about pain and trauma at dressing changes: a central European perspective. J Wound Care 2002; 11: 2, 76–79.

11 Battelli, D., Riccardi, R., Piscaglia, A.C. et al. Analgesic, antiulcer, antithrombotic drugs and organ damage: a population-based case-control study. Minerva Med 2015; 106: 6, 323–331.

12 Kearney, P.M., Baigent, C., Godwin, J. et al Do selective cyclo-oxygenase-2 inhibitors and traditional non-steroidal anti-inflammatory drugs increase the risk of atherothrombosis? Meta-analysis of randomised trials. BMJ 2006; 332: 7553, 1302–1308.

cytokines, by increasing inflammation, will induce pain.[20,23,43] The presence of Ringer's solution is likely to dilute the cytokines within the wound exudate, which may cause a decrease in inflammation in the types of wounds where excessive inflammation may be detrimental, such as in chronic wounds.[47] In addition, dilution could reduce the influence of the caustic molecules such as MMPs. Similar to cytokines, MMPs have a vital role in acute wound healing; in this case, they are involved in the breakdown of the extracellular matrix proteins such as collagen and elastin;[48] however, MMPs are known to cause pain,[49] and in chronic wounds they can be overexpressed, resulting in damage to periwound skin and increased inflammation.[50] Therefore, by considering these roles of cytokines and MMPs in inflammation it may be concluded that their dilution could reduce pain.

Mechanism 3: balancing the exudate pH and ionic composition

Ringer's solution is isotonic and by diluting the wound exudate it may influence the pH and maintain the ionic composition of the wound bed. In the original description Sydney Ringer examined beating frog hearts.[51] His newly reported solution kept the heart beating much longer compared with simple saline solution. From his description the ionic composition of the Ringer's solution supported cellular depolarisation and repolarisation processes in the heart muscle.[51] Depolarisation and repolarisation also underlie pain perception originating from free nerve endings.

Modifying the pH will also affect the function of sodium and calcium channels in the nerve endings, ion channels known to play a role in pain.[52–56] Also, changes in acidity are known to denature proteins, and as ion channels are glycoproteins there is a chance that even if they are not fully denatured they may be structurally altered by a modified pH affecting their function. In addition to depolarisation and repolarisation processes, cell functions are maintained for longer periods when cells are exposed to Ringer's solution compared with normal saline fluid.[57,58] By modulating the extracellular ion composition and pH together, Ringer's solution could contribute to pain reduction by stabilising nerve endings and supporting their cellular synthetic functions.

Furthermore, sodium bicarbonate-containing solutions may also have a direct pain-reducing effect, and have been included in combination with other drugs to reduce pain in many different conditions such as cancer, sore throats and carpal tunnel syndrome;[59–61] for example, a study investigating methods of reducing the intense discomfort experienced during administration of intravenous rocuronium, an anaesthetic agent, found when 8.4% sodium bicarbonate was added to the agent, pain was markedly reduced.[62]

Mechanism 4: recruiting leukocytes

The isotonic nature of Ringer's solution may recruit natural painkillers. It is well known that leukocytes (a type of white blood cell) are rapidly recruited to wounds as part of the immune and inflammatory responses, by proteins and chemokines released at the site of injury.[63] However, leukocytes have an additional role in pain relief. Leukocytes contain natural opioids and when reaching a wound bed they migrate to the inflamed areas and release the opioids to produce analgesia.[28,64,65] This is a natural process that occurs in response to injury, but it can be expected to be enhanced by the favourable moist conditions provided by the dressing, because migration of leukocytes requires provision of functional adhesion molecules such as integrins, which need a moist environment for their correct structural integrity and action as attraction molecules.[66]

Summary

It is likely that a combination of all four mechanisms will contribute to the analgesia experienced by patients treated with Ringer's solution within a dressing, rather than any one individual effect. In fact in many respects these mechanisms overlap as they all rely on the provision of a controlled moist environment. The importance of each mechanism is likely to be dependent upon the type of wound. For example, in acute wounds the initial protective function and provision of an environment that is favourable for rapid wound healing are likely to be most important while in chronic wounds controlling the detrimental cascade of the inflammatory response is likely to be most important, not just for relief of wound pain, but also for developing conditions that are favourable for eventual wound healing.

Conclusion

Wound dressings provide pain relief by a variety of different mechanisms. A controlled moist environment that is favourable for rapid healing would be expected to provide a high degree of pain relief and is the basis of many advanced dressings available today. Dressings containing Ringer's solution would be expected to offer additional protection to the nerve endings in the wound, decrease friction, dilute the detrimental effects of wound exudate and encourage the recruitment of leukocytes that provide endogenous pain relief. The reported level of wound pain in patients treated with dressings containing Ringer's solution in clinical studies was low and this data needs to be supported by more studies and comparisons with other dressings. Controlled randomised trials are needed to reveal the true value of these dressings for pain relief. ■

13 Wodash, A.J. Wet-to-Dry Dressings Do Not Provide Moist Wound Healing. J Am Coll Clin Wound Spec 2012; 4: 3, 63–66.

14 Kaur, I.P., Sandhu, S.K., Deol, P.K., et al. Material couture for wound healing and regeneration: an overview. Curr Pharm Des 2015; 21: 12, 1556–1574.

15 Cutting, K.F. Impact of adhesive surgical tape and wound dressings on the skin, with reference to skin stripping. J Wound Care 2008; 17: 4, 157–162.

16 Gottrup, F., Jørgensen, B., Karlsmark, T., et al. Reducing wound pain in venous leg ulcers with Biatain Ibu: a randomized, controlled double-blind clinical investigation on the performance and safety. Wound Repair Regen 2008; 16: 5, 615–625.

17 Shemesh, M., Zilberman, M. Structure-property effects of novel bioresorbable hybrid structures with controlled release of analgesic drugs for wound healing applications. Acta Biomater 2014; 10: 3, 1380–1391.

18 Kaushal, M., Kutty, N.G., Rao, C.M. Nitrooxyethylation reverses the healing-suppressant effect of Ibuprofen. Mediators Inflamm 2006; 2006: 4, 24396.

19 Richardson, C., Upton, D.A. discussion of the potential mechanisms for wound dressings' apparent analgesic effects. J Wound Care 2010; 19: 10, 424–430.

20 Eaglstein, W.H. Moist wound healing with occlusive dressings: a clinical focus. Dermatol Surg 2001; 27: 2, 175–181.

21 Boateng, J., Catanzano, O. Advanced therapeutic dressings for effective wound healing--a review. J Pharm Sci 2015; 104: 11, 3653–3680.

22 Cooper, P. TenderWet: an innovation in moist wound healing. Br J Nurs 1998; 7: 20, 1232–1255.

23 Junker, J.P., Caterson, E.J., Eriksson, E. The microenvironment of wound healing. J Craniofac Surg 2013; 24: 1, 12–16.

24 de Oliveira, C.M., Sakata, R.K., Issy, A.M. et al. Cytokines and pain. Rev Bras Anestesiol 2011; 61: 2, 255–259, 260–265, 137–142.

25 Parks, W.C., Wilson, C.L., López-Boado, Y.S. Matrix metalloproteinases as modulators of inflammation and innate immunity. Nat Rev Immunol 2004; 4: 8, 617–629.

26 Lee, Y., Lee, C.H., Oh, U. Painful channels in sensory neurons. Mol Cells 2005; 20: 3, 315–324.

27 Machelska, H. Targeting of opioid-producing leukocytes for pain control. Neuropeptides 2007; 41: 6, 355–363.

28 Rittner, H.L., Machelska, H., Stein, C. Leukocytes in the regulation of pain and analgesia. J Leukoc Biol 2005; 78: 6, 1215–1222.

29 Kaspar, D., Dehiri, H., Tholon, N. et al Efficacité clinique du pansement irrigo-absorbant HydroClean active contenant du polyacrylate superabsorbent dans le traitement des plaies chroniques – étude observationnelle conduit sur 221 patients. [Artilce in French] Journal des Plaies et Cicatrisations 2008; 63, 21–24.

30 Paul Hartmann AG. Effective wound cleansing with TenderWet active – observational study with 403 patients. HARTMANN Marketing Document. 2008. [Data on file]. Available at: http://bit.ly/1RswiLY (accessed September 2015).

31 Kaspar, D. TenderWet plus. Therapeutic effectiveness, compatibility and handling in the daily routine of hospitals or physician's practices. HARTMANN Marketing Document 2011. [Data on file].

32 Scholz, S., Rompel, R, Petres, J. A new approach to wet therapy of chronic leg ulcers. Arzt & Praxis 1999; 816: 517–522.

33 White, R., Cutting, K., Eyre, M. Is "data on file" a valid reference? Wounds UK 2005; 1: 128–129.

34 Herber, O.R., Schnepp, W., Rieger, M.A. A systematic review on the impact of leg ulceration on patients' quality of life. Health Qual Life Outcomes. 2007; 5: 44.

35 Azevedo, M., Simoes, L., Sousa, R., Sampaio, R. Quemaduras en fase inicial – TenderWet® active en quemaduras de 2° y 3° grado. HARTMANN Marketing Document 2004. [Data on file, Spanish].

36 Kapp, H. Effective cleansing, better handling – clinical observations using new TenderWet active. HARTMANN WundForum HARTMANN Marketing Document. 2005 [Data on file] Available at: bit.ly/1Lv1gRd (accessed February 2016).

37 Meuleneire, F. Clinical evaluation of TenderWet plus. HARTMANN Marketing Document. 2011 [Data on file].

38 Meuleneire, F. TenderWet plus in the treatment of patients with problem wounds. HARTMANN WoundForum 1. 2013; 20. [Data on file].

39 Scherer, R., Kagi, M, Geiges, R., et al. HydroTherapy. Anwendungsbeobachtung. HARTMANN Marketing Document. 2015. [Data on file, German].

40 Zollinger, C., Schwab, R., Locherer, E., et al. HydroTherapy. Anwendungsbeobachtung. HARTMANN Marketing Document. 2014 [Data on file, German].

41 Junker, J.P., Kamel, R.A., Caterson, E.J., Eriksson, E. Clinical Impact Upon Wound Healing and Inflammation in Moist, Wet, and Dry Environments. Adv Wound Care (New Rochelle). 2013; 2: 7, 348–356.

42 Brett, D.W. A review of moisture-control dressings in wound care. J Wound Ostomy Continence Nurs 2006; 33: 6 Suppl, S3–S8.

43 Dissemond, J., Augustin, M., Eming, S.A. et al. Modern wound care - practical aspects of non-interventional topical treatment of patients with chronic wounds. J Dtsch Dermatol Ges 2014; 12: 7, 541–554.

44 Woo, K.Y., Chakravarthy, D. A laboratory comparison between two liquid skin barrier products. Int Wound J 2014; 11: 5, 561–566.

45 Marques-Rocha, J.L., Samblas, M., Milagro, F.I. et al. Noncoding RNAs, cytokines, and inflammation-related diseases. FASEB J 2015; 29: 9, 3595–3611.

46 Martin, P., Leibovich, S.J. Inflammatory cells during wound repair: the good, the bad and the ugly. Trends Cell Biol 2005; 15: 11, 599–607.

47 Fletcher, J. Differences between acute and chronic wounds and the role of wound bed preparation. Nurs Stand 2008; 22: 24, 62–68.

48 Toy, L.W. Matrix metalloproteinases: their function in tissue repair. J Wound Care 2005; 14: 1, 20–22.

49 Folgueras, A.R., Valdés-Sánchez, T., Llano, E. et al. Metalloproteinase MT5-MMP is an essential modulator of neuro-immune interactions in thermal pain stimulation. Proc Natl Acad Sci U S A 2009; 106: 38, 16451–1656.

50 Rushton, I. Understanding the role of proteases and pH in wound healing. Nurs Stand 2007; 21: 32, 68, 70, 72 passim.

51 Ringer, S. Concerning the Influence exerted by each of the Constituents of the Blood on the Contraction of the Ventricle. J Physiol 1882; 3: 380–393.

52 Park, J., Luo, Z.D. Calcium channel functions in pain processing. Channels (Austin) 2010; 4: 6, 510–517.

53 Schaible, H.G., Ebersberger, A., Natura, G. Update on peripheral mechanisms of pain: beyond prostaglandins and cytokines. Arthritis Res Ther 2011; 13: 2, 210.

54 Lampert, A., O'Reilly, A.O., Reeh, P., Leffler, A. Sodium channelopathies and pain. Pflugers Arch 2010; 460: 2, 249–263.

55 Dib-Hajj, S.D., Cummins, T.R., Black, J.A., Waxman, S.G. Sodium channels in normal and pathological pain. Annu Rev Neurosci 2010; 33: 325–347.

56 Rahman, W., Dickenson, A.H. Voltage gated sodium and calcium channel blockers for the treatment of chronic inflammatory pain. Neurosci Lett 2013; 557: Pt A, 9–26.

57 Bulstra, S.K., Kuijer, R., Eerdmans, P., van der Linden, A.J. The effect in vitro of irrigating solutions on intact rat articular cartilage. J Bone Joint Surg Br 1994; 76: 3, 468–470.

58 Gulihar, A., Bryson, D.J., Taylor, G.J. Effect of different irrigation fluids on human articular cartilage: an in vitro study. Arthroscopy 2013; 29: 2, 251–256.

59 Burnett, I., Schachtel, B., Sanner, K., et al. Onset of analgesia of a paracetamol tablet containing sodium bicarbonate: A double-blind, placebo-controlled study in adult patients with acute sore throat. Clin Ther 2006; 28: 9, 1273–1278.

60 Hoang, B.X., Le, B.T., Tran, H.D., et al. Dimethyl sulfoxide-sodium bicarbonate infusion for palliative care and pain relief in patients with metastatic prostate cancer. J Pain Palliat Care Pharmacother 2011; 25: 4, 350–355.

61 Ozer, H., Solak, S., Oguz, T. et al. Alkalinisation of local anaesthetics prescribed for pain relief after surgical decompression of carpal tunnel syndrome. J Orthop Surg (Hong Kong) 2005; 13: 3, 285–289.

62 Chiarella, A.B., Jolly, D.T., Huston, C.M., Clanachan, A.S. Comparison of four strategies to reduce the pain associated with intravenous administration of rocuronium. Br J Anaesth 2003; 90: 3, 377–379.

63 Venereau, E., Schiraldi, M., Uguccioni, M., Bianchi, M.E. HMGB1 and leukocyte migration during trauma and sterile inflammation. Mol Immunol 2013; 55: 1, 76–82.

64 Uçeyler, N., Schäfers, M., Sommer, C. Mode of action of cytokines on nociceptive neurons. Exp Brain Res. 2009; 196: 1, 67–78.

65 Martin, L., Augé, C., Boué, J., et al. Thrombin receptor: An endogenous inhibitor of inflammatory pain, activating opioid pathways. Pain 2009; 146: 1–2, 121–129.

66 Trepat, X., Chen, Z., Jacobson, K. Cell migration. Compr Physiol 2012; 2: 4, 2369–2392.

HARTMANN		Scheda tecnica

HydroClean® plus HydroClean® plus cavity Medicazione idroattiva a base di poliacrilati e PHMB	Protocollo n.	TenderWet p.
	Reparto	MWC
	Data	21.03.2017

1. Descrizione generale

HydroClean® plus
HydroClean® plus è una medicazione idroattiva che contiene, come componente di base, un poliacrilato superassorbente (SAP) legato a fibre di cellulosa. L'agente antibatterico poliesametilene biguanide (PHMB) è associato al SAP che è attivato (pre-inumidito) con soluzione di Ringer. Lo strato della medicazione a contatto con la ferita consiste in un tessuto di polipropilene al quale sono state applicate delle strisce in silicone. Lo strato di contatto con la ferita e le strisce di silicone impediscono l'adesione al letto della ferita. Sul lato opposto alla ferita un film in polipropilene impermeabile ai liquidi, rivestito con un tessuto in polipropilene idrofobico, previene che la medicazione si asciughi troppo presto. Questo permette all'umidità di essere rilasciata sulla ferita per tre giorni. HydroClean® rilascia soluzione di Ringer sulla ferita per tre giorni. Durante il tempo di permanenza della medicazione sulla ferita avviene una continua e interattiva irrigazione della ferita, assorbendo anche l'essudato della ferita grazie al cuscinetto della medicazione. Il PHMB associato al SAP di base ha un effetto antibatterico e inibisce la crescita batterica all'interno della medicazione riducendo allo stesso tempo il rischio di ricontaminazione durante l'intero periodo di applicazione sino a tre giorni. Il SAP utilizzato in HydroClean® plus inattiva la matrice della metalloproteasi (MMP) che impedisce la guarigione della ferita. Come conseguenza possono essere riattivate ferite stagnanti o croniche.

HydroClean® plus
HydroClean® plus cavity è una medicazione idroattiva che contiene, come componente di base, un poliacrilato superassorbente (SAP) legato a fibre di cellulosa. L'agente antibatterico poliesametilene biguanide (PHMB) è associato al SAP che è attivato (pre-inumidito) con soluzione di Ringer. La medicazioen è rivestita con un film in polipropilene su entrambi i lati. Proprietà e meccanismo d'azione di HydroClean® cavity sono caratterizzati dal rilascio di soluzione di RInger sulla ferita per tre giorni. Durante il tempo di permanenza della medicazione sulla ferita avviene una continua e interattiva irrigazione della ferita, assorbendo anche l'essudato della ferita grazie al cuscinetto della medicazione. Il PHMB associato al SAP di base ha un effetto antibatterico e inibisce la crescita batterica all'interno della medicazione riducendo allo stesso tempo il rischio di ricontaminazione durante l'intero periodo di applicazione sino a tre giorni. Il SAP utilizzato in HydroClean® plus inattiva la matrice della metalloproteasi (MMP) che impedisce la guarigione della ferita. Come conseguenza possono essere riattivate ferite stagnanti o croniche.

Classificazione

Dispositivo Medico sterile classe IIb conforme alla Direttiva 92/42/CEE s.m.i.
Codice Classificazione Nazionale dei Dispositivi Medici M040499

Prodotto in Svizzera da Paul Hartmann AG - 89522 Heidenheim – Germania.

Distributore per l'Italia: Paul Hartmann S.p.A. – Verona.

2. Destinazione d'uso

HydroClean® plus
Per il trattamento umido delle ferite con un'alterata tendenza alla guarigione.
HydroClean® plus è una medicazione particolarmente adatta per il trattamento di ferite croniche e di difficile guarigione nella fase di detersione.
Inoltre, è possibile utilizzarla per la riattivazione di processi di guarigione stagnanti, nel caso in cui questi siano causati da un'attività eccessivamente intensa delle MMP.

HydroClean® plus cavity
Per il trattamento umido delle ferite con un'alterata tendenza alla guarigione.
HydroClean® plus cavity è una medicazione particolarmente adatta per il trattamento di ferite croniche e di difficile guarigione nella fase di detersione.
Inoltre, è possibile utilizzarla per la riattivazione di processi di guarigione stagnanti, nel caso in cui questi siano causati da un'attività eccessivamente intensa delle MMP.

Controindicazioni

Fino ad ora non si conoscono controindicazioni. Non va comunque utilizzata in caso di ipersensibilità ai suoi componenti.

All'inizio del trattamento si possono osservare:

Aumento della misura della ferita: la misura della ferita può aumentare a causa della rimozione del tessuto necrotico dai bordi, tessuto già irrimediabilmente danneggiato prima del trattamento. Questo fenomeno può tuttavia indicare che il processo di guarigione della ferita è in corso.

Arrossamento della pelle: durante il trattamento umido possono presentarsi arrossamenti dei margini della ferita, che di norma sono un segnale della riattivazione della circolazione sanguigna durante la detersione e dovuta al processo di guarigione della ferita.

Emorragie: le ferite possono sanguinare spontaneamente durante il trattamento con HydroClean® plus in quanto stimola la proliferazione delle cellule. E' oppurtuno, comunque, valutare la situazione caso per caso.

Dolore: HydroClean® plus non causa di per sé nessun dolore in quanto ha un'azione lenitiva e la medicazione ha una bassa aderenza.
Le ferite possono comunque essere dolorose e sensibili alle sollecitazioni meccaniche. In caso di dolore persistente può essere utile inumidire la medicazione dall'esterno dopo alcune ore, senza rimuoverla.

Istruzioni d'uso

- Scegliere la misura e la versione più adeguata per il tipo di lesione. HydroClean® plus non deve essere tagliata né danneggiata meccanicamente in altro modo.
- Applicare HydroClean® plus direttamente sulla lesione, con il lato bianco sulla ferita e il lato marcato con caratteri verde rivolto verso l'esterno.
- Fissare HydroClean® plus con una medicazione secondaria, un bendaggio coesivo (Peha-haft) o un cerotto adesivo (Omnifix).

- Il trattamento umido con soluzione Ringer non determina la macerazione di cellule vitali, ma qualora HydroClean® plus dovesse sovrapporsi ai brodi perilesionali, si consiglia di proteggerli con una pomata grassa, idratante o un'emulsione idro-oleosa.

- HydroClean® plus cavity va utilizzato in ferite profonde associato a una medicazione secondaria assorbente come HydroClean® plus al fine di garantire una più lunga e costante azione di detersione o a una schiuma in poliuretano (HydroTac® o Permafoam®) o una qualsiasi medicazione assorbente.

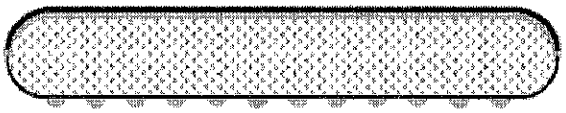
3. Caratteristiche tecniche

Copertura	Strato in polipropilene laminato con una trama in polipropilene (colore verde chiaro)
Corpo assorbente	Corpo centrale costituito da cellulosa con poliacrilati superassorbenti (SAP) e fibre di polipropilene, attivato con soluzione Ringer con PHMB 0,1 % w/w
Peso (comprensivo di Soluzione di Ringer)	
4 cm, Ø	5.5 gr
5,5 cm , Ø	10.7 gr
7,5 x 7,5 cm	20.4 gr
10x10 cm	36.7 gr
Biocompatibilità	Conforme allo Standard UNI EN ISO 10993:1 - Valutazione biologica dei dispositivi medici - Valutazione e prove
Sterilizzazione	A vapore
Scadenza	Il prodotto correttamente conservato in confezione integra ha una vita utile di 3 anni
Tempo di permanenza in situ	Fino ad un massimo di 72 ore
Lattice	**Assente** nella medicazione e nel confezionamento

HARTMANN		Scheda tecnica

HydroClean® plus HydroClean® plus cavity Medicazione idroattiva a base di poliacrilati e PHMB	Protocollo n.	TenderWet p.
	Reparto	MWC
	Data	21.03.2017

HydroClean®



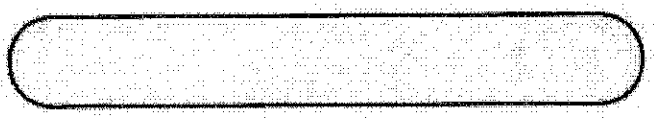
2 Strati in polipropilene (uno bianco e uno con stampa blu)
film in polipropilene (colore bianco, impermeabile, barriera ai batteri)

Corpo centrale (cellulosa, poliacrilati superassorbenti e fibre di polipropilene, attivato con soluzione Ringer con PHMB)

Trama idrofobica in polipropilene

Strato a contatto con la ferita, strisce in silicone

HydroClean® plus cavity



Corpo centrale (cellulosa, poliacrilati superassorbenti e fibre di polipropilene, attivato con soluzione Ringer con PHMB)

Trama idrofobica in polipropilene

4. Confezionamento

Medicazione sigillata singolarmente in buste tipo "peel-to-open" in PET/ALU/PP, inserite in scatole di cartoncino e imballate in cartone da trasporto conforme DIN, sigillato con nastri adesivi, su europallet.

HydroClean® plus			
codici	**misure**	**pezzi per confezione**	**confezioni per cartoni**
609762	Ø 4 cm	10 pezzi	6 conf
609766	Ø 5,5 cm	10 pezzi	6 conf
609768	7,5 cm x 7,5 cm	10 pezzi	6 conf
609772	10 cm x 10 cm	10 pezzi	6 conf

HydroClean® plus cavity			
codici	**misure**	**pezzi per confezione**	**confezioni per cartoni**
609550	Ø 4 cm	10 pezzi	6 conf
609553	7,5 cm x 7,5 cm	10 pezzi	6 conf

Lotto di produzione: codice a 9 cifre

Scadenza

Es. 2015 06

anno mese

5. Metodo di conservazione

Conservare in luogo asciutto e ben areato, lontano da fonti luminose, ad una temperatura compresa tra 5 °C e 25 °C.

6. Smaltimento

Dopo l'uso, in presenza di essudati e/o liquidi organici, lo smaltimento deve essere effettuato secondo le disposizioni di legge vigenti.

PAUL HARTMANN S.p.A

Introducing HydroClean® plus for wound-bed preparation: a case series

Maintaining adequate moisture at the wound bed is important in facilitating the removal of slough and necrosis. In clinical practice, this is addressed through cleansing and one of a number of debridement techniques. Autolytic debridement is recognised as the most frequently used technique, but is criticised for being slower than other methods. The results of a small evaluation using HydroClean® plus — a hydro-responsive dressing suggest that there may be opportunities for an alternative method of autolytic debridement.

Authors:
Pam Spruce, Lindsey Bullough, Sue Johnson, Debra O'Brien

The role of moisture in wound healing has become well established since the original study by Winter was published in 1962[1]. The concept of moist wound healing has been an integrated part of clinical practice for many years; a moist environment is considered to increase the rate of healing faster than a drier environment[2].

The concept of maintaining the correct moisture balance was developed further with the introduction of wound bed preparation, which provided a framework within which clinicians can address the local conditions in the wound to promote an environment in which healing can occur[3]. Throughout this process, the role of fluid balance is significant, as inadequate moisture can contribute to a dehydrated wound bed and the subsequent development of devitalised tissue[4]. The presence of devitalised tissue in the wound can interfere with the healing process by prolonging the inflammatory response, and blocking the migration of epithelial cells[5]. It can also lead to other problems, as it provides a suitable environment for bacterial growth, thereby increasing the risk of infection[6], and can encourage increased exudate production[4]. Devitalised tissue can also impede wound assessment as its presence can hide the true area and depth of a wound[7]. Introducing fluid to the wound bed is one of the simplest methods of preparing the wound bed when there is an increased necrotic burden.

Wound cleansing in wound bed preparation

Wound cleansing is a simple way to deliver moisture to the wound to facilitate the removal of devitalised tissue and contaminants such as bacteria, proteases and tissue debris[8]. This practice was reviewed, and while it was recognised that it made an important contribution to wound bed preparation, it was suggested that current practice may be ritualistic, is unsupported by evidence and its therapeutic value has not been fully investigated[8,9].

Clinical practice in the 1980s and 90s focused on wound cleansing to assist with the removal of adhered dressings, facilitate wound assessment and rehydrate the wound bed, and it was only recommended if the wound was diagnosed as clinically infected. In comparison to current knowledge, it was thought that all exudate contained nutrients and bacteria that were beneficial and should be left on the wound bed[10]. However, with current studies demonstrating the detrimental effects of proteases in chronic wound exudate which may delay wound healing[11,12], and the risk of biofilm formation from bacteria in the wound potentially increasing the risk of wound infection[13–15], effective wound cleansing is important. It is also recognised that further research in this area is required[16].

Using moisture in wound debridement

Wounds will naturally debride through the process of autolysis, as proteolytic enzymes and macrophages facilitate the separation of necrosis and slough from the wound bed[4]. By employing one or more of the techniques available to speed up this process, the progression to healing can be improved[17].

Wound debridement is an essential intervention in promoting progression in wounds where healing is delayed, and may be considered the most important concept of wound bed preparation[18]. The speed of debridement is important[19], however, the

Acknowledgement
This evaluation was supported by HARTMANN

***Pam Spruce** is Clinical Director TVRE Consulting; **Lindsey Bullough** is Clinical Nurse Specialist, Tissue Viability, Wrightington, Wigan and Leigh Foundation Trust; **Sue Johnson** is Clinical Lead, Wound Care, Doncaster and Bassetlaw Hospitals NHS Foundation Trust; **Debra O'Brien** is Clinical Service Manager (Podiatry), Solent NHS Trust*

Table 1. Wound aetiology of the participating patients.

Wound aetiology	Number of patients (n=20)
Foot ulcer	3
Venous leg ulcer	3
Mixed leg ulcer	2
Arterial leg ulcer	1
Surgical wound	5
Grade IV pressure ulcer	3
Grade III pressure ulcer	1
Cellulitic lesion	2

was used as a measure of clinical efficacy in a review by the National Institute for Health and Care Excellence[26].

The wound aetiology, size, location, duration, exudate level, wound-bed status and periwound skin condition were also documented. The patient's pain related to the wound was established at baseline through the use of a visual analogue scale. Any wound care products used immediately before the use of HydroClean plus were also recorded.

The wound outcomes were assessed and recorded at each dressing change, using basic techniques that are reflective of routine practice. At each dressing change, the wound size (area and depth) was recorded to demonstrate wound progression. The area was estimated by measuring the maximum length and width of the wound, then multiplying this figure to give the area in cm^2. Any pain associated with application, during wear or the removal of HydroClean plus was established using the visual analogue scale, and was also documented.

Results/outcome

A total of 20 patients were recruited from a range of treatment settings, which included acute and community hospitals, their home and wound clinics. Sixty-five per cent (n=13) of patients were male and 35% (n=7) female, with ages ranging from 28 to 95 years (mean 68.3 years). Relevant comorbidities were recorded in 19 patients. Seven patients had diabetes. Of the 20 participants, five were taking systemic antibiotics for an existing wound infection, nine required analgesia for wound pain and two required immunosuppressant therapy for pre-existing conditions, one of which was retroviral therapy for HIV.

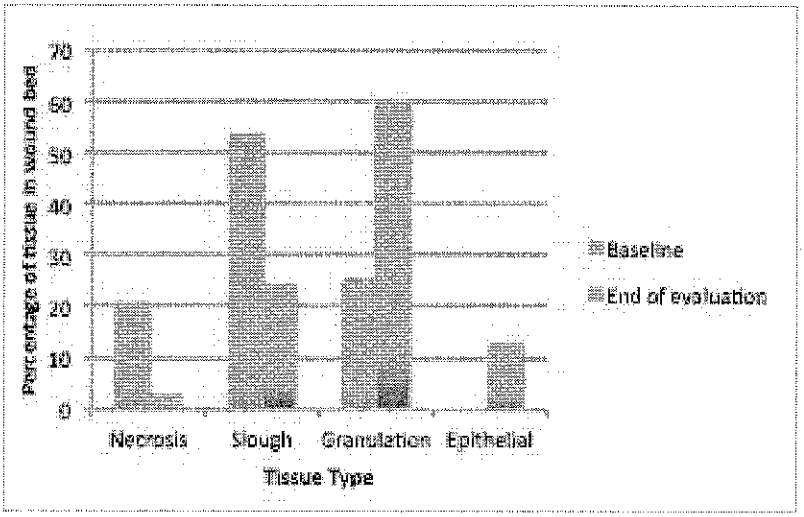


Figure 1. *Overall percentage of devitalised and healthy tissue at baseline and end of the study.*

The patients presented with a wide range of wounds *[Table 1]*. The wound duration was recorded in 18 cases, and ranged from 4 to 75 weeks (mean 20 weeks). Despite less than half of the patients taking analgesia, 19 patients were experiencing wound pain, with an overall mean of 2.5 using a pain scale where 0 is no pain and 5 the worst pain. Twelve patients (60%) had wounds that were malodorous.

Overall data were collected on 97 dressing changes, with the evaluation period ranging from 4 to 31 days (mean 15 days). The number of applications of HydroClean plus ranged from two to nine (mean five) per patient, with 72 (74%) dressing changes undertaken every 3 days and the remaining 25 (26%) on alternate days. Of the dressing changes, 55 (56%) were undertaken by nursing staff, 23 (24%) by podiatrists and 19 (20%) by the patient or his/her informal carer.

The reason for the dressing change was recorded at each episode of care, with 84% (n=81) of dressing changes undertaken routinely. Seven patients experienced strikethrough. This was resolved by increasing the frequency of dressing change in four patients.

The dressing was evaluated within 'standard' care. Wound cleansing was recorded in 74 dressing changes (76%); antimicrobial solutions were used in 66 procedures, 0.9% normal saline for one procedure and tap water for seven procedures.

A range of secondary dressings were used, depending on the aetiology and location of the wound, the exudate level, and the use of other devices. In 29 changes (30%), adhesive foam dressings were used. Gauze or non-woven dressings were used in 34 applications (35%), where the patient required less bulky dressings in diabetic foot ulcer treatment within offloading footwear. Wool padding with a retention or reduced compression bandage was used in 29 dressing changes (30%) in patients with mixed aetiology or venous leg ulceration. Although full compression therapy had been recommended for three patients, it was refused by two of them because the wound was painful. After treatment, however, the wound pain had reduced and the patients were able to progress to a higher level of compression. An adhesive film dressing was used on one patient for five dressing changes.

Supporting therapies, such as compression bandaging or offloading of pressure, were used where it was assessed as necessary and recorded in 35 dressing changes (36%). Additional debridement was undertaken during 13 dressing changes. This was sharp debridement, which involved the removal of devitalised tissue

Table 2. Exudate levels in patients (n=20) at the start and at the end of the evaluation.

Level of exudate	Baseline	End
High	3	2
Moderate	13	6
Low	4	10
None	0	2

and callus from the wound margins. It was performed by the podiatrists as part of their 'best practice' for foot ulcer management[16].

Wound progression

The primary aim of the evaluation was to observe whether HydroClean plus could facilitate wound bed preparation and wound progression. Two patients (10%) progressed to healing. A reduction in wound size and/or depth was achieved in a further nine (45%) patients. Two wounds (10%) were totally debrided (100% granulation tissue in the wound bed) and six wounds (30%) were debrided to 80–99% healthy tissue. The overall percentage of healthy and non-viable tissue at the start and end of the evaluation is shown in *Figure 1*. In two patients (10%), there was no improvement, but this was associated with their general condition and was not thought to be product related.

Exudate management

HydroClean plus was used on wounds with all levels of exudate. It is recommended by the manufacturer for all levels of exudate. In 95% (n=92) of dressing changes, the clinicians were satisfied with the way in which HydroClean plus managed exudate. The remaining 5% (n=5) of changes were undertaken by the patient and no information was recorded. *Table 2* gives the exudate levels at baseline and at the end of the evaluation period. At the start of the evaluation, 16 patients had wounds with high or moderate exudate, whereas only eight had these exudate levels at the end of the study. One of the three wounds with high exudate levels improved during this time.

Periwound skin condition

HydroClean plus was used on patients with both healthy and damaged skin, and the condition of the surrounding skin was recorded at each dressing change. There was an increase in the percentage of patients with healthy periwound skin from 25% to 55%.

Pain and odour

Initially 95% (n=19) of patients were experiencing some degree of wound pain. This proportion had dropped to 35% (n=7) of patients at the end of the evaluation. The mean pain score, which was 2.5 at the start of the evaluation, had reduced to less than 1, with the number of patients taking analgesia dropping from nine to four.

Malodour was observed in 12 patients (60%) at the start of the evaluation, whereas at the end there were no malodorous wounds. This is an encouraging observation.

Patient and clinician satisfaction

Both clinicians and patients were highly satisfied with the way in which HydroClean plus performed on application, removal and during wear. Of the dressing applications, 92 (95%) were recorded as being easy. Of the remaining five changes, four were rated as average and one as difficult. The dressing was reported as conforming to the wound in 94 out of 97 instances. The difficulties reported in dressing application and conformity related to the patient self-treating a wound in a difficult-to-dress location.

Patients reported that the dressing was comfortable to wear at 99% (n=96) of dressing changes. The dressing stayed in place and was easy to remove in all 97 instances. None of the patients reported pain on dressing removal.

At the end of each evaluation, the clinician was asked to rate the overall performance of the dressing on the relevant patient, using a scale of 1 (poor) to 10 (excellent) against pre-set parameters. *Table 3* indicates the level of satisfaction, with the maximum score being 200. The scores were realistic, with ease of application and removal and maintaining a moist wound environment all achieving 197 out of a possible 200. Patient satisfaction and the ability of the dressing to manage exudate were slightly lower, but as they were still over 190 were acceptable.

Healing progression

Although the maximum evaluation period for HydroClean plus was 4 weeks, only five patients used the product for this length of time. None of the patients requested that the dressing be discontinued, so the decision to change the dressing was made on the basis of clinical judgement or patients being discharged from the service. At the end of the evaluation:

- Two patients (10%) had progressed to healing
- Fourteen (70%) were discharged or had progressed to other therapies
- One patient (5%) was lost to follow up
- Three patients (15%) continued to use HydroClean plus. This continued use was at their request because the dressing was comfortable and the patients could observe their wounds improving.

Cost–benefit analysis

The cost of care was estimated using a cost–benefit analysis for three health states. The price of dressings used were those already

Table 3. Overall satisfaction with dressing performance (maximum score = 200).

Aspect of dressing performance	Rating given by clinician
Management of exudate	183
Maintenance of moist wound bed	197
Ease of application	197
Ease of removal	197
Patient satisfaction	192

available and listed in the *UK Drug Tariff*[27] or those proposed for reimbursement. Clinician time costs were those recommended by the Personal Social Services Research Unit[28], and time for dressing changes were based on those used by National Institute for Health and Care Excellence[26]. Using these times and costs, the following figures were estimated:

- 10% (n=2) of patients progressed to healing with a mean time to debride and achieve healing of 7.5 days, producing an overall cost saving of £87.78
- 10% (n=2) of patients reached 100% granulation tissue in the wound bed, and therefore total debridement of the wound had been achieved at a mean time of 5.5 days. As there was no previous cost of treatment for one patient, the cost of treatment was £37.68 more expensive when HydroClean plus was used; however as the patient was previously receiving no treatment, it could be assumed that the wound may have deteriorated and required treatment, which would have eventually incurred a cost
- In 35% (n=7) of patients, 80–99% of devitalised tissue was removed by the dressing, and this was considered to be a successful outcome[29]. The actual cost saving compared to standard treatment with this patient group was £289.52 overall or £41.36 per patient.

Discussion

The results of this 20-patient clinical evaluation suggest that HydroClean plus was effective in removing devitalised tissue from the wound bed, and in facilitating wound progression in the cases observed. The results also suggest that it may provide an alternative method of autolytic debridement to those currently in use, with a potentially faster mode of action. Within the evaluation, the mean time to debride to 100% granulation tissue for four patients in the study was 6.5 days. This compares favourably with other products used for debridement[29]. This is important for non-specialist nurses, who may not have access or the skills to undertake the speedier methods of debridement and rely on traditional products that promote autolysis.

HydroClean plus was highly acceptable to both clinicians and patients, who found it easy to apply and remove. All of the patients reported that it was comfortable on application, wear and removal, and it performed well with other supporting therapies relevant to managing complex wounds. Within the evaluation, a reduction in both pain and malodour was observed with use.

There were no adverse events in this evaluation, indicating that the product is safe for use by non-specialist practitioners. As a primary dressing product, it also performed well with a range of secondary dressings.

Although there are limitations to the cost-benefit analysis used, the data suggests that there are potential cost savings associated with using this dressing.

The dressing appeared to be 'moist' on presentation, but in use did not seem to increase the levels of exudate, negatively influence the frequency of dressing changes, or present a high number of episodes of strikethrough. It was used successfully on a small number of patients with diabetic foot ulcers, where the use of moist dressings is often discouraged[16].

Changes to the periwound skin were observed in some patients, which may have developed as a result of the high fluid content of HydroClean plus. The mode of action of the dressing where the wound fluid is diluted and the deleterious effects of Matrix Metalloproteases are absorbed into the superabsorbent particles within the dressing, would suggest that these are consistent with hyperhydration rather than maceration as described by Rippon et al[30].

Conclusion

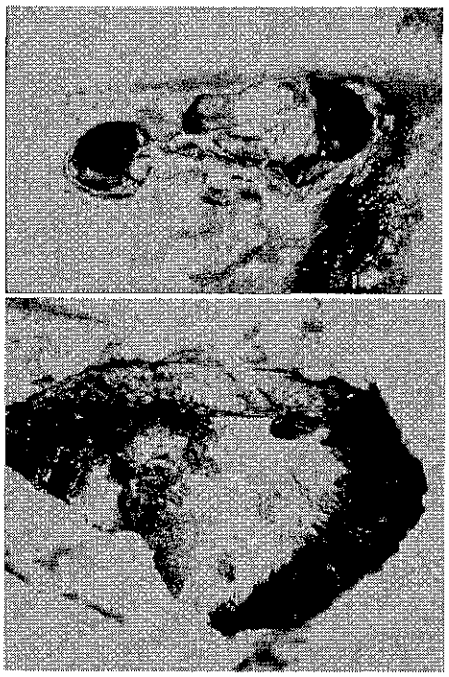
This evaluation explored the outcomes when HydroClean plus was used on a small cohort of patients with varying wound types. Overall the outcomes were good, demonstrating that the dressing was effective at removing devitalised tissue, was comfortable for patients and easy to use. It also suggests that there may be potential cost savings associated with the use of this dressing because of the speed of debridement and reduction in clinical time, all of which merit further investigation.

The outcome of using this dressing, which the manufacturer suggests can cleanse–debride–absorb has stimulated a number of discussions into elements of treatment associated with the delivery of moisture to the wound. Further research into wound cleansing, and consideration of the benefits of hyperhydration need further investigation[30]. WINT

References

1. Winter G (1962) Formation of scab and the rate of epithelialization of superficial wounds in the skin of the young domestic pig. *Nature* 193: 293–4
2. Atiyeh BS, Hayek SN (2005) Intérêt d'un Onguent Chinois (MEBO) dans le Maintient Local de

Case study 2: HydroClean plus when used as a cavity dressing on a grade IV pressure ulcer.



The patient was a 74-year-old female with a grade IV pressure ulcer. The wound had been present for 4 weeks and was extremely painful (scoring 4 on the Wong–Baker pain rating scale). On presentation the wound was malodorous with a high level of exudate, which resulted in maceration of the periwound skin (top).

Over a period of 9 days, HydroClean plus was used for three dressing changes. HydroClean plus was used under an adhesive foam dressing, which was used to secure it. At the end of this period, the wound bed was prepared and the full extent of the cavity could be assessed (bottom). The exudate level was low, there was no odour and the periwound skin was observed to be healthy. The patient was also pain free.

l'Humidité. *Journal des Plaies et Cicatrisation* 9: 7–11

3. Falanga (2000) Classifications for wound bed preparation and stimulation of chronic wounds. *Wound Repair Regen* 8: 347–52
4. Atkin L (2014) Understanding methods of wound debridement. *Br J Nur* 23(12): S10–4
5. Moore Z (2012) Technology update: The important role of debridement in wound bed preparation. *Wounds International* 3(2): 19–23
6. White R, Cutting K (2008) Critical colonisation of chronic wounds: microbial mechanisms. *Wounds UK* 4(1): 70–8
7. Dowsett C, Newton H (2008) Wound bed preparation: TIME in practice. *Br J Community Nurs* 13(6): S15–6, S18
8. Cutting KF (2010) Addressing the challenge of wound cleansing in the modern era. *Br J Nurs* 19(11): S24–9
9. Lloyd Jones M (2012) Wound cleansing: is it necessary or just a ritual? *Nurs Res Care* 14(8): 396–9
10. Flanagan, M (1997) Wound cleansing. In: Morison M, Moffat C, Bridel-Nixon J, Bale, S, eds. *Nursing Management of Chronic Wounds.* Mosby, London
11. Trengove NJ, Stacey MC, Macauley S, et al (1999) Analysis of the acute and chronic wound environments: the role of proteases and their inhibitors. *Wound Repair Regen* 7(6): 442–52
12. McCarty SM, Percival S (2013) Proteases and delayed wound healing. *Adv Wound Care (New Rochelle)* 2(8): 438–47
13. Bjarnsholt T, Kirketerp-Møller K Jensen PØ et al (2008) Why chronic wounds will not heal: a novel hypothesis. *Wound Repair Regen* 16(1): 2–10
14. James GA, Swogger E, Wolcott R et al (2008) Biofilms in chronic wounds. *Wound Repair Regen* 16(1): 37–44
15. Cooper R (2009) Biofilms: hard to detect, easy to underestimate, but most definitely here to stay. *Wounds UK* 5(1): 12
16. Wounds International (2013) *International Best Practice Guidelines: Wound Management in Diabetic Foot Ulcers.* Wounds International, London
17. Panuncialman J, Falanga V (2009) The science of wound bed preparation. *Surg Clin North Am* 89(3): 611–26
18. Gottrup F, Jørgensen B (2011) Maggot debridement: an alternative method for debridement. *Eplasty* 11: e33
19. Steed DL, Donohoe D, Webster MW, Lindsley L (1996) Effect of extensive debridement and treatment on the healing of diabetic foot ulcers. *J Am Coll Surg* 183(1): 61–4
20. Chadwick P, Clarke M, Fumarola S et al; Expert Working Group (2013) *Effective debridement in a changing NHS: a UK consensus.* Wounds UK, London
21. Vowden K, Vowden P (2011) Debridement made easy. *Wounds UK* 7(4): S1–4
22. Young T (2012) Skin failure and wound debridement. *Nurs Res Care* 14(2): 74; 84–5
23. Scholz S, Rompel R, Petres J (1999) A new approach to wet therapy of chronic leg ulcers. *Arzt Praxis* 816: 517–22
24. Kaspar D (2011) *TenderWet plus. Therapeutic effectiveness, compatibility and handling in the daily routine of hospitals or physician's practices.* HARTMANN Document (data on file)
25. World Medical Association (2013) World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA* 310(20): 2191–4
26. National Institute for Health and Care Excellence (2014) *NICE medical technology guidance 17. The Debrisoft monofilament debridement pad for use in acute or chronic wounds.* https://www.nice.org.uk/guidance/mtg17 (accessed 23.01.2015)
27. NHS Business Services Authority and NHS Prescription Services (2015) *UK Drug Tariff.* Department of Health, London
28. Curtis L (2014) *Unit Costs of Health and Social Care 2014.* Personal Social Services Research Unit: 175–82
29. Bahr S, Mustaffi N, Hättig P et al (2011) Clinical efficacy of a new mononofilament fibre-containing wound debridement product. *J Wound Care* 20(5): 242–8
30. Rippon MG, Ousey K, Cutting KF (2016) Wound healing and hyperhydration: a counter intuitive model. *J Wound Care* 25(2)

The importance of hydration in wound healing: reinvigorating the clinical perspective

Balancing skin hydration levels is important as any disruption in skin integrity will result in disturbance of the dermal water balance. The discovery that a moist environment actively supports the healing response when compared with a dry environment highlights the importance of water and good hydration levels for optimal healing.

The benefits of 'wet' or 'hyper-hydrated' wound healing appear similar to those offered by moist over a dry environment. This suggests that the presence of free water may not be detrimental to healing, but any adverse effects of wound fluid on tissues is more likely related to the biological components contained within chronic wound exudate, for example elevated protease levels.

Appropriate dressings applied to wounds must not only be able to absorb the exudate, but also retain this excess fluid together with its protease solutes, while concurrently preventing desiccation. This is particularly important in the case of chronic wounds where peri-wound skin barrier properties are compromised and there is increased permeation across the injured skin. This review discusses the importance of appropriate levels of hydration in skin, with a particular focus on the need for optimal hydration levels for effective healing.

• **Declaration of interest:** This paper was supported by Paul Hartmann Ltd. The authors have provided consultative services to Paul Hartmann Ltd.

wound healing; hydration; moist wound healing; wound fluid

This article describes the importance of hydration in biological processes, particularly in skin homeostasis. It underlines the significance of the moist environment in the wound healing response and highlights the evidence suggesting that a 'wet' or 'hyper-hydrated' wound environment offers benefits similar those of a moist environment. The concept that it is the biological components, for example proteinases, contained within chronic wound exudates and not the presence of free fluid at the wound site that are responsible for the deleterious effects on ulcers is discussed.

The literature search

The scope of this article is limited and was not designed to be a systematic review of the literature. The databases used to search the literature were limited to Medline and Google Scholar. The search terms used included 'skin structure', 'moist wound healing', 'hydration', 'moisture', 'chronic wound' and 'ulcer'. The number of retrievals for each search term were not recorded. No limits were applied in relation to the year of publication. References were also selected from a range of scientific/clinical publications that were recorded in the authors' personal bibliographic databases. Results from all sources were analysed and the relevant articles retrieved.

Clinical case studies are used as illustrative examples in support of the concepts discussed.

The importance of hydration in skin

It was in the 1940s that the precise mechanism by which the skin acts as a barrier to water loss was identified. Tape stripping studies provide evidence of the importance of the stratum corneum (SC), (Fig 1) as the region responsible for the skin's barrier properties.[1–3]

Water is essential for the normal functioning of the skin and for maintaining a healthy skin.[4] Since the discovery of the stratum corneum's (SC) importance in water homeostasis, there has been a significant body of work describing the precise mechanisms by which it functions in this role.[4–7] The skin contains approximately 30% water, but in the viable epidermis the water content can be as high as 70%. Moving outwards from the dermal-epidermal junction, this high level of water falls off quickly at the junction between the stratum granulosum (SG) and the SC where water content ranges between 15–30%.[8,9] The SC maintains the stable gradient of water and solutes throughout the layers of the epidermis[8,10,11] and it is thought that the sudden change at the SG-SC junction isolates the SC from the rest of the body and helps to conserve important solutes and water within the viable epidermis.[4] The SC's ability to hold on to water depends upon two major components of this skin layer: (1) the presence of a number of water-attracting (hygroscopic) components, collectively called natural moisturising factor (biochemical components of skin that aid skin

K. Ousey,[1] PhD, Reader Advancing Clinical Practice;
K.F. Cutting,[2] M.N. R.G.N, Clinical Research Consultant Perfectus Biomed and Wound Care 4 Heroes;
A.A. Rogers,[3] BSc (Hons), Independent Wound Care Consultant,
M.G. Rippon,[1] PhD, Visiting Clinical Research Fellow;
1. School of Human and Health Sciences, Institute of Skin Integrity and Infection Prevention, University of Huddersfield, Queensgate, Huddersfield
2 Hertfordshire, UK
3 Flintshire, UK

Email: woundspecialist@gmail.com

Fig 1. Structure of skin showing stratum corneum as outermost barrier layer of skin

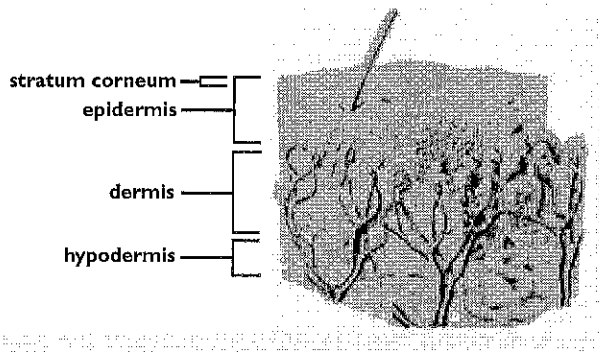
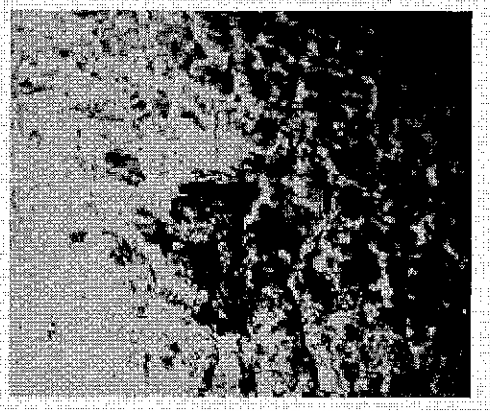


Fig 2. Dry, flaky skin as a result of inadequate hydration



homeostasis) located within the terminally differentiated, non-viable corneocytes of the SC and, (2) intercellular lipids which act as a barrier to transepidermal water loss (TEWL).

Water also plays a particularly important role in the correct functioning of the epidermis. For example, normal water content in the SC is required for the correct maturation of the epidermis and the formation of the SC and skin desquamation.[4] The enzymatic processes that are needed for normal desquamation are impaired when moisture levels in the skin are reduced, leading to the appearance of dry, flaky skin (Fig 2). Disrupted function of the enzymes responsible for making the components of natural moisturising factor can also lead to the development of dry skin. An imbalance of the water content in the epidermis resulting from a disturbance of the SC, e.g., skin stripping from adhesive tape, increases TEWL with a corresponding alteration in gene expression in epidermal keratinocytes.[12,13] A recent study by Xu and co-workers[14] reports that hydration status of the skin directly affects the expression of inflammatory signals in the epidermis. Additionally there are several reports of the inflammatory response being elevated under conditions of water loss[15–17] with a corresponding increase in a variety of cytokines.[14,18–21]

Skin injury

Maintaining an optimal hydration level in skin

Optimal skin hydration is an orchestrated interplay between several mechanisms with the integrity of the skin key to maintaining moisture balance.[22] Within the dermal component of the skin, the water of the interstitial fluid is mainly absorbed into the extracellular matrix (ECM)/connective tissue components, some of which have large capacities for water binding.[23,24] Although the reservoir of water in the interstitial fluid is kept in balance, it is not a static reservoir. Maintaining this level of dermal hydration is an active process, with water constantly being supplied from the blood system and drained via the lymphatic system. Any disruption of this dynamic balance in tissue hydration control can result in clinical problems. For example, the uncontrolled influx of water from the blood circulation and/or deficient lymphatic drainage can lead to build-up of excessive levels of tissue water, as a result of overwhelming the water-absorbing capacity of the interstitial matrix, leading to tissue oedema.[22,24] When considering how tissue hydration levels are controlled in normal skin, there is a tightly controlled interplay between the interstitial fluid pressure, the capillary filtration pressure and the rate of lymphatic drainage, with the additional factor of the absorption capacity of the ECM.[24]

The interstitial fluid pressure is maintained largely by the integrity of the skin and dependent upon the barrier properties of the skin as a whole. These are both cellular and intracellular; between the various layers of the skin, down to the interaction of cellular components in the skin's layers and chemical contributors (for example skin lipids). Once the integrity is compromised, for example by physical wounding, the mechanisms responsible for maintaining the appropriate levels of tissue hydration are significantly challenged:[22]

- There is a reduced ability to maintain the interstitial fluid pressure needed to control fluid inflow from the blood circulation and removal via lymphatic system
- Blood vessel dilation resulting from inflammation increases the leakage of fluid from the blood circulation into the surround tissue
- The majority of this 'water' will be held by the high water-absorbing ECM components therefore acting as a large reservoir.

Wound healing and hydration

It has been suggested hydration is the single most important external factor responsible for optimal healing.[25] The increased drying effect that results from a physical breach of the skin barrier properties, can to some extent, compensate for the increased

References

1 Winsor, T., Burch, G.E. Differential roles of layers of human epigastric skin on diffusion rate of water. Arch Intern Med 1944; 74: 6, 428–436.

2 Blank, I.H. Further observations on factors which influence the water content of the stratum corneum. J Invest Dermatol 1953; 21: 4, 259–271.

3 Madison, K.C. Barrier function of the skin: 'la raison d'être' of the epidermis. J Invest Dermatol 2003; 121: 2, 231–241.

4 Verdier-Sévrain, S., Bonté, F. Skin hydration: a review on its molecular mechanisms. J Cosmet Dermatol 2007; 6: 2, 75–82.

5 Harding, C.R. The stratum corneum: structure and function in health and disease. Dermatol Ther 2004; 17: Suppl. 1, 6–15.

6 Rawlings, A.V., Harding, C.R. Moisturization and skin barrier function. Dermatol Ther 2004; 17: Suppl. 1, 43–48.

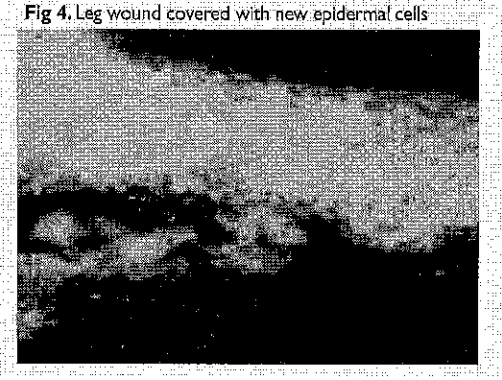
7 Elias, P.M. Stratum corneum defensive functions: an integrated view. J Invest Dermatol 2005; 125: 2, 183–200.

8 Warner, R.R., Myers, M.C., Taylor, D.A. Electron probe analysis of human skin: determination of the water concentration profile. J Invest Dermatol. 1988; 90: 2, 218–224.

9 Caspers, P.J., Lucassen, G.W., Puppels, G.J. Combined in vivo confocal Raman spectroscopy and confocal microscopy of human skin. Biophys J 2003;

Fig 3. Wound of the leg with a scab covering the wound

Fig 4. Leg wound covered with new epidermal cells



fluid outflow from blood vessels in these circumstances. However, outflow of fluid from blood vessels can quickly overwhelm the fluid-absorbing capacity of the tissue and lymphatic drainage and excess fluid is drained from the wounded tissue as exudate.

Following a breach of skin integrity, haemostasis is initiated and physical plugging of the defect with a fibrin mesh (scab) seals the breach (Fig 3). In parallel an influx of inflammatory cells starts a cascade of signalling pathways resulting in cell proliferation and deposition of the ECM. The synthesis of collagen generates a new tissue matrix where granulation tissue is laid down. The stimulation of new blood vessels into the highly vascularised granulation tissue provides the oxygen and nutrients needed to sustain the tissue synthesis that occurs during the granulation phase of healing. Tissue remodelling and re-epithelialisation of the wound leads to the reconstitution of the physical barrier of the skin at the original wound site. Over the subsequent days/weeks, tissue is further remodelled and the barrier properties of the skin are reinstated at a level close to that of the pre-wounded skin (Fig 4).

Moist wound healing

Landmark studies by George Winter in the 1960s showed that wounds exposed to the air and allowed to dry tend to heal slowly with poor cosmesis when compared with wounds that heal in a moist environment.[26–28] The examination of tissue biopsies from these preclinical studies highlighted that re-epithelialisation of 'dry' wounds was impaired leading to a delay in the healing response and suggested that the physical barrier of the dry eschar tissue was an important determinant for the delayed healing response.[27,29] Thus, there is a clear dependency on adequate hydration if optimal healing is sought.[22,26–28] In Winter's studies, the air-dried partial-thickness wounds were compared with wounds that were occluded with polyurethane film dressing maintaining a moist environment and ensuring adequate hydration. Since development of the concept that a moist environment aids wound healing, there has been growing evidence in support of this notion[30] and the wound care community has broadly accepted the concept and the need for exudate management.[30,32] There have been numerous laboratory, preclinical and clinical studies providing evidence for the benefits of moist wound healing (Table 1) with positive outcomes for healing being achieved in a variety of wound types when wound dressings designed to provide optimal hydration levels in the wound are used as part of the wound care regimen. Fig 5 shows a schematic representation of some of the key differences between healing in a moist versus dry environment and Fig 6–9 show representative examples of wounds treated with hydration-optimising wound dressings.

Concern that occlusion of wounds and the maintenance of a level of hydration within the wound would lead to an increase in bacterial number and infection appear to be unfounded, with studies showing that wounds treated with dressings promoting a moist wound healing environment are associated with a lower infection rate despite the wounds being colonised by bacteria.[33–35] Skin dermatitis has been reported after prolonged exposure to water.[36,37] A number of studies have suggested sustained exposure to skin leads to changes to the layers of the skin, particularly in the SC, and these changes include altered permeability and flexibility, viscoelastic properties, weakened intercellular attachment and changes in electrical impedance properties.[38–44] The physical structure of the epider-

Table 1. Benefits of moist wound healing

Faster wound healing [26,81,82]
Promote epithelialisation rate [26,27,83]
Promote dermal/wound bed healing responses, e.g. cell proliferation, extracellular matrix synthesis [84–100]
Reduces scarring [100,101]
Retention of growth factors at wound site [84,91,94,97,102]
Lower wound infection rates [33–35]
Reduces pain perception [103–105]
Enhances autolytic debridement [106,107]

85: 1, 572–580.
10 Warner, R.R., Bush, R.D., Ruebusch, N.A. Corneocytes undergo systematic changes in element concentrations across the human inner stratum corneum. J Invest Dermatol 1995; 104: 4, 530–536.
11 Warner, R.R., Myers, M.C., Taylor, D.A. Electron probe analysis of human skin: element concentration profiles. J Invest Dermatol 1988; 90: 1, 78–85.
12 Barel, A.O., Clarys, P. Study of the stratum corneum barrier function by transepidermal water loss measurements: comparison between two commercial instruments: Evaporimeter and Tewameter. Skin Pharmacol 1995; 8: 4, 186–195.
13 Wong, R., Tran, V., Talwalker, S., Benson, N.R. Analysis of RNA recovery and gene expression in the epidermis using non-invasive tape stripping. J Dermatol Sci 2006; 44: 2, 81–92.
14 Xu, W., Jia, S., Xie, P. et al. The expression of proinflammatory genes in epidermal keratinocytes is regulated by hydration status. J Invest Dermatol 2014; 134: 4, 1044–1055.
15 De Fine Olivarius, F., Agner, T., Menné, T. Skin barrier function and dermal inflammation. An experimental study of transepidermal water loss after dermal tuberculin injection compared with SLS patch testing. Br J Dermatol 1993; 129: 5, 554–557.
16 Haratake, A., Uchida, Y., Mimura, K. et al. Intrinsically aged epidermis displays diminished UVB-induced alterations in barrier function associated with decreased proliferation. J Invest Dermatol 1997; 108: 3, 319–323.
17 de Jongh, C.M., Jakasa, I., Verberk, M.M., Kezic, S. Variation in barrier impairment and inflammation of human skin as determined by sodium lauryl sulphate penetration rate. Br J Dermatol. 2006; 154: 4, 651–657.
18 Wood, L.C., Stalder, A.K., Liou, A. et al. Barrier disruption increases gene expression of cytokines and the 55 kD TNF receptor in murine skin. Exp Dermatol 1997; 6: 2, 98–104.

Fig 5. Comparison of processes in wound healing under moist/hydrated and dry healing environments

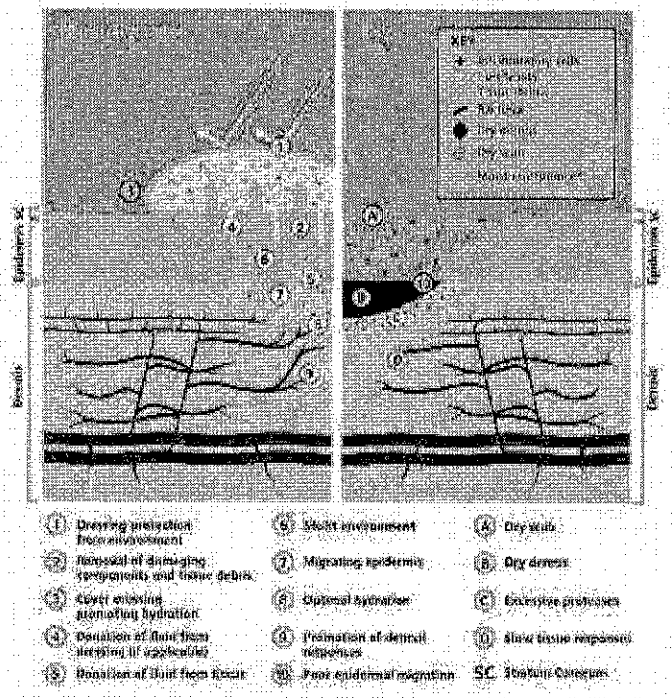
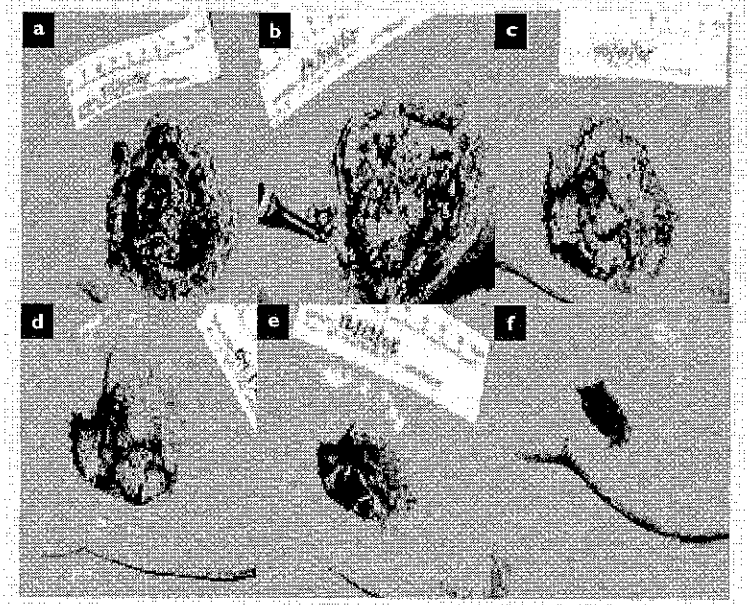


Fig 6. Patient with a stage 4 pressure ulcer showing healing progress during treatment with dressing that optimises wound hydration levels. Day 0 (a), day 8 (b), day 22 (c), day 43 (d), day 55 (e), and 2.5 months (f)



mis can be particularly affected.[45,46] However, other studies have suggested that hydration-induced changes to the epidermis are quickly reversed upon removal of the cause.[44,47,48]

Hyper-hydration of tissue and healing

The adoption of the concept of moist wound healing has led to the development of a number of classes of dressings that have been designed to effectively manage the various levels of wound exudate produced by both acute and chronic wounds. Effective wound dressings must be able to cope with the volume of wound exudate while at the same time maintain a level of tissue hydration that is consistent with a moist environment. This is despite the fact that there is no clear definition of what constitutes an 'optimal' or 'balanced' moist environment.[22] When considering wound dressing selection, clinicians are required to focus on the capability of the dressing to absorb and retain a large volume of fluid while at the same time avoiding maceration of the peri-wound skin. Maceration of the peri-wound skin can occur as a result of prolonged contact of wound exudate, which may be a result of poor dressing performance or unrealistic expectations of the dressing.

Tissue hydration and maceration may be difficult to differentiate at first glance. However, these are important concepts to separate as the former, i.e., maceration, has distinct physiological and clinical implications in terms of treatment options, whereas hydration is beneficial to wound healing. Rippon et al. have recently defined the important differences between hydration and maceration, they argue that the deleterious effects of maceration on wounds and peri-wound skin is as a result of the presence of damaging biological components fluids that cause maceration and not the presence of water.[49]

Irrespective of the cause, the presence of maceration has led to the assumption that a excess of moisture will inevitably lead to sustained tissue damage. However, a number of studies have indicated that a wound that is overly hydrated may not result in tissue damage,[50–52] and rather suggest that a wound bathed in a hyper-hydrated environment may benefit from the advantages of moist wound healing (Fig 10).[30]

Chambers that seal fluid over the wound site creating a hyper-hydrated wound environment have been used to examine tissue responses to being exposed to saline solution. In preclinical and clinical studies, the hyper-hydrated wound environment proved to be safe for the treatment of a number of wounds. Wound healing under these conditions progressed in a similar manner to those where moist conditions were used:[30,52] the wounds showed less tissue necrosis, faster healing rates and a better quality of healing, compared with dry wounds.

The concept of creating a hyper-hydrated environment to support wound healing has been suggested for a number of years. Junker et al.[30] highlighted work from the mid-19th century where patients with major burn wounds were submerged in bathtubs[54] and also the treatment of second world war wounded servicemen where fluid was applied to the surrounding wounded tissue.[55] The application of a hyper-hydrated environment to a wound has become increasingly prevalent in the treatment of wounds with the development of irrigation systems designed for the delivery of fluid to wounds, particularly to promote wound cleansing. The addition of supplementary components to irrigation fluid, such as antimicrobials, growth factors and insulin, could expand the potential for wound irrigation devices.[30] Topical wound irrigation with saline solutions have been used successfully in promoting wound healing in a number of different wound types, including acute traumatic wounds,[56,57] infected wounds[58] and diabetic foot ulcers.[59] The introduction of a hydrated wound environment as part of negative pressure wound therapy (NPWT) has been shown to enhance the uptake of wound exudate, removal of foreign material, devitalised tissue and bacterial contaminants as well as providing a hyper-hydrated environment.[60] 'Instillation therapy' intermittently delivers fluid to the wound being treated by NPWT, acting as an adjunct to the therapy.[61,62] This therapy has been suggested to provide a unique (hyper-hydrated) wound environment promoting wound bed preparation.[63] Continuous-instillation NPWT is a modification of the original instillation therapy concept whereby the hydrating fluid is constantly being replenished and renewed via an inflow-outflow tube system.[61] The development of NPWT with instillation and a dwell time (NPWTi-d) offers the delivery of a timed, predetermined volume of topical solution that is intermittently delivered and allowed to dwell in the wound bed while NPWT is paused for a predetermined time.[64] The NPWTi-d system promotes wound cleansing, loosening wound contaminants and facilitating their removal via the negative pressure phase.[65] With regard to the benefits of the presence of the instilled fluid on the wound environment, a panel of experts proposing a set of international consensus guidelines for negative pressure wound therapy with instillation achieved >80% consensus on the use of a number of antimicrobial solutions for instillation.[66] The benefits of the hyper-hydrated environment when saline alone is used as the instilled solution, have been noted.[65]

There are other examples where a hyper-hydrated environment results in timely, scar-free wound healing and where the wounds do not appear to sustain long-term damage from the effects of over-hydration. Studies have suggested scarless healing in skin wounds *in utero* is an intrinsic property of the foetal skin itself,[67] foetal skin wounds which are bathed in a sterile, nutrient-rich amniotic fluid show no signs of over-hydration. Furthermore, the

Fig 7. Patient with surgical wound after the amputation of diabetic foot showing wound healing progress during treatment with dressing that optimises wound hydration levels. Day 0 (a), day 5 (b), day 40 (c), and day 68 (d)

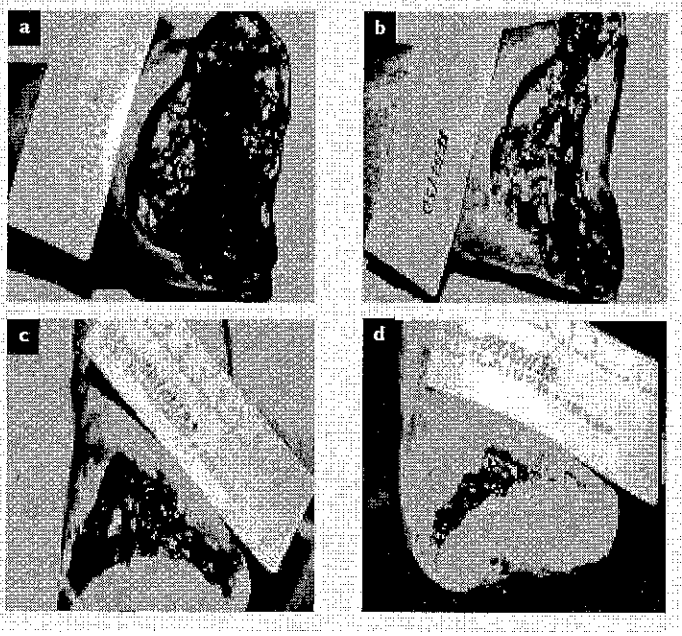


Fig 8. Patient with wound dehiscence after abdominal surgery showing wound healing progress during treatment with dressing that optimises wound hydration levels. Day 0 (a), day 8 (b), day 27 (c) and 1.5 months (d)

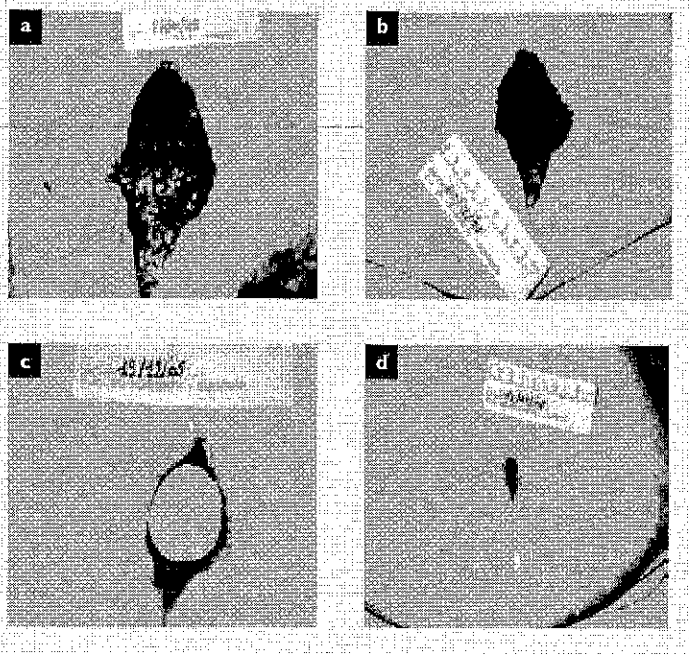


Fig 9. Patient with traumatic wound after falling from moped showing wound healing progress during treatment with dressing that optimises wound hydration levels. Day 1 (a and b), day 3 (c), and day 26 (d)

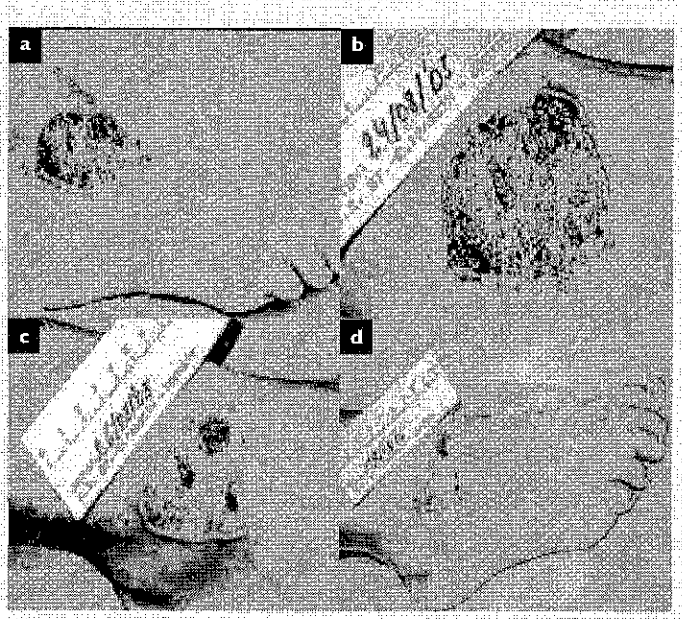


Fig 10. A wound showing signs of a possible under-hydrated state (a) and wound progression when a hydro-responsive wound dressing applied (b)

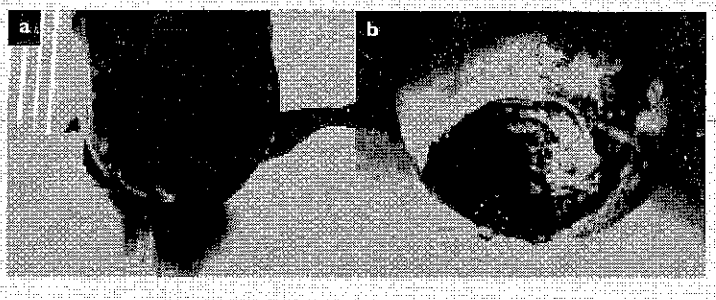
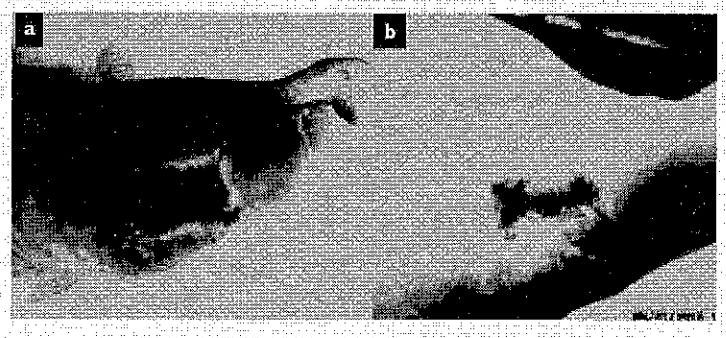


Fig 11. An amputation wound site on the foot of a diabetic patient showing good wound progression after 6 weeks' treatment with a hydro-responsive wound dressing



environment of the oral mucosa is one that is bathed in saliva. This saliva ensures that a hyper-hydrated environment is maintained over the delicate tissues inside the oral cavity. As with foetal wounds, oral wounds heal quickly and with less scarring than skin wounds,[68] with no indications of detrimental effects of the hyper-hydrated environment in which they are found.

Exudate-dependent tissue damage

The findings suggesting that hyper-hydration is as beneficial to the wound healing response as a moist healing environment may be surprising as, clinically, excessive exudate in prolonged contact with the peri-wound skin has been associated with poor healing and the exacerbation of problems such as maceration.[69,70] It is clear that wounds maintained in a moist or hyper-hydrated environment do not appear to be suffer unduly (Fig 11). The studies examining the effect of a hyper-hydrated environment were carried out using synthetic tissue culture medias and are very different in composition from chronic wound exudates,[50–53] and it has been demonstrated that ulcer-derived exudate is fundamentally different from acute wound fluids.[71,72] The underlying pathological processes involved means that chronic exudate is highly damaging to tissues with its high content of protein-degrading enzymes.[73] While proteases are necessary for normal wound healing,[74] the highly inflamed nature of the chronic wound bed is partly as a result of elevated and uncontrolled levels of proteases such as matrix metalloproteases (MMPs),[75,76] neutrophil elastase[73,77,78] and pro-inflammatory cytokines in chronic wound exudate.[79] The combined presence of these corrosive components within chronic wound fluid leads to damage of the ulcer bed and wound margin. It should be noted also that the peri-wound skin of chronic wounds has a compromised barrier function when compared with undamaged skin[80] and is therefore its susceptibility to damage from chronic wound exudate is enhanced. In addition to the development of wound dressings which provide effective fluid management and limit the exposure of tissues to these corrosive fluids,[32] new areas of research have focused on developing dressing technologies designed to specifically target and inhibit the excessive and damaging proteases present in chronic wounds.[81–84]

Conclusion

The establishment and maintenance of an optimal level of hydration is key to maximising efficient progress of biological processes, including those found in the skin. When skin wounding occurs, an important aspect of the body's response to trauma is to re-establish skin barrier function, minimise fluid loss and safeguard hydration levels. Studies have shown that both moist and hyper-hydrated wounds heal at a faster rate than those exposed to the air and

allowed to dry. These and other studies have indicated that water per se is not responsible for the deleterious effects of wound exudate found in the recalcitrant wound, but rather, the biological components, contained within wound fluid, are responsible for the tissue damage that can be present during inefficient exudate management.

Optimisation of hydration balance at the wound site is a key property of modern wound dressings. Those capable of controlling both the fluid level and the damaging components of chronic wound exudate maximise the management of these potentially harmful fluids while at the same time provide an optimal hydration balance. ■

19 Kloeters, O., Schierle, C., Tandara, A., Mustoe, T.A. The use of a semiocclusive dressing reduces epidermal inflammatory cytokine expression and mitigates dermal proliferation and inflammation in a rat incisional model. Wound Repair Regen 2008; 16: 4, 568–575.

20 Buraczewska, I., Berne, B., Lindberg, M. et al. Moisturizers change the mRNA expression of enzymes synthesizing skin barrier lipids. Arch Dermatol Res 2009; 301: 8, 587–594.

21 Elias, P.M. Therapeutic implications of a barrier-based pathogenesis of atopic dermatitis. Ann Dermatol 2010; 22: 3, 245–254.

22 Bishop, S.M., Walker, M., Rogers, A.A., Chen, W.Y.J. Importance of moisture balance at the wound-dressing interface. J Wound Care 2003; 12: 4, 125–128.

23 Plante, G.E., Chakir, M., Ettaouil, K. et al. Consequences of alteration in capillary permeability. Can J Physiol Pharmacol 1996; 74: 7, 824–833.

24 Faria, D., Fowler, E., Carson, S.N. Understanding edema and managing the edematous lower leg. In: Krasner, D. Sibbold, G. (eds). Chronic Wound Care: A clinical source book for healthcare professionals, (3rd edn) HMP Communications, 2001.

25 Atiyeh, B.S., Hayek, S.N. Intérêt d'un onguent chinois (MEBO) dans le maintient local de l'humidité. J Plaies Cicatrisation. 2005; 9: 7–11. Available at: http://bit.ly/1RSPhoa (accessed February 2016).

26 Winter, G.D. Formation of the scab and the rate of epithelialization of superficial wounds in the skin of the young domestic pig. Nature 1962; 193: 293–294.

27 Winter, G.D. Effect of air exposure and occlusion on experimental human skin wounds. Nature 1963; 200: 378–379.

28 Winter, G.D., Scales, J.T. Effect of air drying and dressings on the surface of a wound. Nature 1963; 197: 91–92.

29 Hinman, C.D., Maibach, H. Effect of air exposure and occlusion on experimental human skin wounds. Nature 1963; 200: 377–378.

30 Junker, J.P., Kamel, R.A., Caterson, E.J., Eriksson, E. Clinical impact upon wound healing and inflammation in moist, wet, and dry environments. Adv Wound Care (New Rochelle) 2013; 2: 7, 348–356.

31 Butcher, M. Moist wound healing, exudate and management of the wound bed. J Wound Care 2010; 19: Suppl. 1, 10–13.

32 Sibbald, R.G., Elliott, J.A., Ayello, E.A., Somayaji, R. Optimizing the moisture management tightrope with Wound Bed Preparation 2015©. Adv Skin Wound Care. 2015; 28: 10, 466–476.

33 Hutchinson, J.J., Lawrence, J.C. Wound infection under occlusive dressings. J Hosp Infect. 1991; 17: 2, 83–94.

34 Lawrence, J.C. Dressings and wound infection. Am J Surg 1994; 167: 1A, 21S–24S.

35 Kannon, G.A., Garrett, A.B. Moist wound healing with occlusive dressings. A clinical review. Dermatol Surg 1995; 21: 7, 583–590.

36 Willis, I. The effects of prolonged water exposure on human skin. J Invest Dermatol 1973; 60: 3, 166–171.

37 Rietschel, R.L., Allen, A.M. Effects of prolonged continuous exposure of human skin to water: a reassessment. J Invest Dermatol 1977; 68: 2, 79–81.

38 Scheuplein, R., Ross, L. Effects of surfactants and solvents on the permeability of epidermis. J Soc Cosmet Chem 1970; 21: 853–873.

39 Evans, M.E., Roth, R. Shaping the skin: the interplay of mesoscale geometry and corneocyte swelling. Phys Rev Lett 2014; 112: 3, 038102.

40 Park, A.C., Baddiel, C.B. Rheology of stratum corneum – II. A physico-chemical investigation of factors influencing the water content of the corneum. J Soc Cosmet Chem 1972; 23: 1, 13–21.

41 Christensen, M.S., Hargens, C.W. 3rd, Nacht, S., Gans, E.H. Viscoelastic properties of intact human skin: instrumentation, hydration effects, and the contribution of the stratum corneum. J Invest Dermatol 1977; 69: 3, 282–286.

42 Wildnauer, R.H., Bothwell, J.W., Douglass, A.B. Stratum corneum biochemical properties. I. Influence of relative humidity on normal and extracted human stratum corneum. J Invest Dermatol 1971; 56: 1, 72–78.

43 Weigand, D.A., Gaylor, J.R. Removal of stratum corneum in vivo: an improvement on the cellophane tape stripping technique. J Invest Dermatol 1973; 60: 2, 84–87.

44 Björklund, S., Ruzgas, T., Nowacka, A. et al. Skin membrane electrical impedance properties under the influence of a varying water gradient. Biophys J 2013; 104: 12, 2639–2650.

45 Egawa, M., Hirao, T., Takahashi, M. In vivo estimation of stratum corneum thickness from water concentration profiles obtained with Raman spectroscopy. Acta Derm Venereol 2007; 87: 1, 4–8.

46 Warner, R.R., Stone, K.J., Boissy, Y.L. Hydration disrupts human stratum corneum ultrastructure. J Invest Dermatol 2003; 120: 2, 275–284.

47 Thomas, S. (2008-). The role of dressings in the treatment of moisture-related skin damage. World Wide Wounds. Available at: http://bit.ly/1wRQThs (accessed on February 2016).

48 Tan, G., Xu, P., Lawson, L.B. et al. Hydration effects on skin microstructure as probed by high-resolution cryo-scanning electron microscopy and mechanistic implications to enhanced transcutaneous delivery of biomacromolecules. J Pharm Sci 2010; 99: 2, 730–740.

49 Rippon, M.G., Ousey, K., Cutting, K.F. Wound healing and hyper-hydration: a counterintuitive model. J Wound Care 2016: 25; 2, 68–75.

50 Breuing, K., Eriksson, E., Liu, P., Miller, D.R. Healing of partial thickness porcine skin wounds in a liquid environment. J Surg Res 1992; 52: 1, 50–58.

51 Svensjö, T., Pomahac, B., Yao, F. et al. Accelerated healing of full-thickness skin wounds in a wet environment. Plast Reconstr Surg 2000; 106: 3, 602–612.

52 Vranckx, J.J., Slama, J., Preuss, S. et al. Wet wound healing. Plast Reconstr Surg 2002; 110: 7, 1680–1687.

53 Vogt, P.M., Andree, C., Breuing, K. et al. Dry, moist, and wet skin wound repair. Ann Plast Surg 1995; 34: 5, 493–499.

54 Hebra, F. Ueber kontinuierliche allgemeine Bäder und deren Anwendung bei Behandlung von Verbrennungen Allgemeiner [In German] . Wiener Medizinische Zeitung 1861, 6: 351–354.

55 Bunyan, J. Treatment of burns and wounds by the envelope method. Br Med J 1941; 2: 4200, 1–7.

56 Dulecki, M., Pieper, B. Irrigating simple acute traumatic wounds: a review of the current literature. J Emerg Nurs 2005; 31: 2, 156–160.

57 Hall, S. A review of the effect of tap water versus normal saline on infection rates in acute traumatic wounds. J Wound Care 2007; 16: 1, 38–41.

58 Tao, Q., Ren, J., Ji, Z. et al. Continuous topical irrigation for severely infected wound healing. J Surg Res 2015; 198: 2, 535–540.

59 Zelen, C.M., Stover, B., Nielson, D., Cunningham, M. A prospective study of negative pressure wound therapy with integrated irrigation for the treatment of diabetic foot ulcers. Eplasty 2011; 11: e5.

60 Gabriel, A., Kahn, K.M. New advances in instillation therapy in wounds at risk for compromised healing. Surg Technol Int 2014; 24: 75–81.

61 Huang, C., Leavitt, T., Bayer, L.R., Orgill, D.P. Effect of negative pressure wound therapy on wound healing. Curr Probl Surg 2014; 51: 7, 301–331.

62 Scimeca, C.L., Bharara, M., Fisher, T.K. et al. Novel use of insulin in continuous-instillation negative pressure wound therapy as 'wound chemotherapy' J Diabetes Sci Technol 2010; 4: 4, 820–824.

63 Raad, W., Lantis, J.C. 2nd, Tyrie, L. et al. Vacuum-assisted closure instill as a method of sterilizing massive venous stasis wounds prior to split thickness skin graft placement. Int Wound J 2010; 7: 2, 81–85.

64 Gabriel, A., Kahn, K., Karmy-Jones, R. Use of negative pressure wound therapy with automated, volumetric instillation

for the treatment of extremity and trunk Wounds: Clinical outcomes and potential cost-effectiveness. Eplasty 2014; 14: e41.

65 Wolvos, T. The evolution of negative pressure wound therapy: negative pressure wound therapy with instillation. J Wound Care 2015; 24: 4 Suppl, 15–20.

66 Kim, P.J., Attinger, C.E., Steinberg, J.S. et al. Negative-pressure wound therapy with instillation: international consensus guidelines. Plast Reconstr Surg 2013; 132: 6, 1569–1579.

67 Leung, A., Crombleholme, T.M., Keswani, S.G. Fetal wound healing: implications for minimal scar formation. Curr Opin Pediatr 2012; 24: 3, 371–378.

68 Brand, H.S., Ligtenberg, A.J., Veerman, E.C. Saliva and wound healing. Monogr Oral Sci 2014; 24: 52–60.

69 Cutting, K.F. The causes and prevention of maceration of the skin. J Wound Care 1999; 8: 4, 200–201.

70 Cutting, K.F., White, R.J. Maceration of the skin and wound bed 1: Its nature and causes. J Wound Care 2002; 11: 7, 275–278.

71 Trengove, N.J., Stacey, M.C., MacAuley, S. et al. Analysis of the acute and chronic wound environments: the role of proteases and their inhibitors. Wound Repair Regen 1999; 7: 6, 442–452.

72 Hart, J. Inflammation 2: its role in the healing of chronic wounds. J Wound Care 2002; 11: 7, 245–249.

73 McCarty, S.M., Percival, S.L. Proteases and delayed wound healing. Adv Wound Care 2013; 2: 8, 438–447.

74 Schultz, G.S., Sibbald, R.G., Falanga, V. et al. Wound bed preparation: a systematic approach to wound management. Wound Repair Regen 2003; 11; Suppl 1, S1–S28.

75 Caley, M.P., Martins, V.L.C., O'Toole, E.A. Metalloproteinases and wound healing. Adv Wound Care 2015; 4: 4, 225–234.

76 Gibson, D.J., Schultz, G.S. Molecular wound assessments: matrix metalloproteinases. Adv Wound Care 2013; 2: 1, 18–23.

77 McDaniel, J.C., Roy, S., Wilgus, T.A. Neutrophil activity in chronic venous leg ulcers – a target for therapy? Wound Repair Regen 2013; 21: 3, 339–351.

78 Wilgus, T.A., Roy, S., McDaniel, J.C. Neutrophils and wound repair: positive actions and negative reactions. Adv Wound Care 2013; 2: 7, 379–388.

79 Eming, S.A., Krieg, T., Davidson, J.M. Inflammation in wound repair: molecular and cellular mechanisms. J Invest Dermatol 2007; 127: 3, 514–525.

80 Walker, M., Hulme, T.A., Rippon, M.G. et al. In vitro model(s) for the percutaneous delivery of active tissue repair agents. J Pharm Sci 1997; 86: 12, 1379–1384.

81 Vasconcelos, A., Cavaco-Paulo, A. Wound dressings for a proteolytic-rich environment. Appl Microbiol Biotechnol 2011; 90: 2, 445–460.

82 Wiegand, C., Hipler, U.C. A superabsorbent polymer-containing wound dressing efficiently sequesters MMPs and inhibits collagenase activity in vitro. J Mater Sci Mater Med 2013; 24: 10, 2473–2478.

83 Wiegand, C., Abel, M., Ruth, P., Hipler, U.C. Superabsorbent polymer-containing wound dressings have a beneficial effect on wound healing by reducing PMN elastase concentration and inhibiting microbial growth. J Mater Sci Mater Med 2011; 22: 11, 2583–2590.

84 Edwards, J.V., Caston-Pierre, S. Citrate-linked keto- and aldo-hexose monosaccharide cellulose conjugates demonstrate selective human neutrophil elastase-lowering activity in cotton dressings. J Funct Biomater 2013; 4: 2, 59–73.

85 Dyson, M., Young, S., Pendle, C.L. et al. Comparison of the effects of moist and dry conditions on dermal repair. J Invest Dermatol. 1988; 91: 5, 434–439.

86 Beam, J.W. Occlusive dressings and the healing of standardized abrasions. J Athl Train 2008; 43: 6, 600–607.

87 Eaglstein, W.H. Moist wound healing with occlusive dressings: a clinical focus. Dermatol Surg 2001; 27: 2, 175–182.

88 Ågren, M.S., Karlsmark, T., Hansen, J.B., Rygaard, J. Occlusion versus air exposure on full-thickness biopsy wounds. J Wound Care 2001; 10: 8, 301–304.

89 Varghese, M.C., Balin, A.K., Carter, D.M., Caldwell, D. Local environment of chronic wounds under synthetic dressings. Arch Dermatol 1986; 122: 1, 52–57.

90 Rubio, P.A. Use of semiocclusive, transparent film dressings for surgical wound protection: experience in 3637 cases. Int Surg 1991; 76: 4, 253–254.

91 Madden, M.R., Nolan, E., Finkelstein, J.L. et al. Comparison of an occlusive and semi-occlusive dressing and the effect of the wound exudate upon keratinocyte proliferation. J Trauma 1989; 29: 7, 924–931.

92 Wigger-Alberti, W., Kuhlmann, M., Ekanayake, S., Wilhelm, D. Using a novel wound model to investigate the healing properties of products for superficial wounds. J Wound Care. 2009; 18: 3, 123–131.

93 Dyson, M., Young, S.R., Hart, J. et al. Comparison of the effects of moist and dry conditions on the process of angiogenesis during dermal repair. J Invest Dermatol 1992; 99: 6, 729–733.

94 Mosti, G. Wound care in venous ulcers. Phlebology 2013; 28: Suppl 1, 79–85.

95 Korting, H.C., Schöllmann, C., White, R.J. Management of minor acute cutaneous wounds: importance of wound healing in a moist environment. J Eur Acad Dermatol Venereol 2011; 25: 2, 130–137.

96 Chen, W.Y.J., Rogers, A.A., Lydon, M.J. Characterization of biologic properties of wound fluid collected during early stages of wound healing. J Invest Dermatol 1992; 99: 5, 559–564.

97 Leung, B.K., LaBarbera, L.A., Carroll, C.A. et al. The effects of normal saline instillation in conjunction with negative pressure wound therapy on wound healing in a porcine model. Wounds 2010; 22: 7, 179–187.

98 Field, C.K., Kerstein, M.D. Overview of wound healing in a moist environment. Am J Surg 1994; 167: 1A Suppl, 2S–6S.

99 Dowsett, C., Ayello, E. TIME principles of chronic wound bed preparation and treatment. Br J Nurs 2004; 13: 15, S16–S23.

100 Katz, M.H., Alvarez, A.F., Kirsner, R.S. et al. Human wound fluid from acute wounds stimulates fibroblast and endothelial cell growth. J Am Acad Dermatol 1991; 25: 6 Part 1, 1054–1058.

101 Atiyeh, B.S., Dham, R., Costagliola, M. et al. Moist exposed therapy: an effective and valid alternative to occlusive dressings for postlaser resurfacing wound care. Dermatol Surg 2004; 30: 1, 18–25.

102 Atiyeh, B.S., El-Musa, K.A., Dham, R. Scar quality and physiologic barrier function restoration after moist and moist-exposed dressings of partial-thickness wounds. Dermatol Surg 2003; 29: 1, 14–20.

103 O'Shaughnessy, K.D., De La Garza, M., Roy, N.K., Mustoe, T.A. Homeostasis of the epidermal barrier layer: a theory of how occlusion reduces hypertrophic scarring. Wound Repair Regen 2009; 17: 5, 700–708.

104 Mustoe, T.A., Gurjala, A. The role of the epidermis and the mechanism of action of occlusive dressings in scarring. Wound Repair Regen 2011; 19: Suppl 1, s16-s21.

105 Tandara, A.A., Kloeters, O., Mogford, J.E., Mustoe, T.A. Hydrated keratinocytes reduce collagen synthesis by fibroblasts via paracrine mechanisms. Wound Repair Regen 2007; 15: 4, 497–504.

106 Hoeksema, H., De Vos, M., Verbelen, J. et al. Scar management by means of occlusion and hydration: a comparative study of silicones versus a hydrating gel-cream. Burns 2013; 39: 7, 1437–1448.

107 Hackl, F., Kiwanuka, E., Philip, J. et al. Moist dressing coverage supports proliferation and migration of transplanted skin micrografts in full-thickness porcine wounds. Burns 2014; 40: 2, 274–280.

108 Powers, J.G., Morton, L.M., Phillips, T.J. Dressings for chronic wounds. Dermatol Ther 2013; 26: 3, 197–206.

109 Attinger, C.E., Janis, J.E., Steinberg, J. et al. Clinical approach to wounds: debridement and wound bed preparation including the use of dressings and wound-healing adjuvants. Plast Reconstr Surg 2006; 117: 7 Suppl, 72S–109S.

110 Wiechula, R. The use of moist wound-healing dressings in the management of split-thickness skin graft donor sites: a systematic review. Int J Nurs Pract 2003; 9: 2, S9–S17.

111 Metzger, S. Clinical and financial advantages of moist wound management. Home Healthc Nurse 2004; 22: 9, 586–590.

112 Leaper, D.J., Schultz, G., Carville, K. et al. Extending the TIME concept: what have we learned in the past 10 years? Int Wound J 2012; 9: Suppl. 2, 1–19.

113 Coutts, P., Woo, K.Y., Bourque, S. Treating patients with painful chronic wounds. Nurs Stand 2008; 23: 10, 42–46.

114 Feldman, D.L. Which dressing for split-thickness skin graft donor sites? Ann Plast Surg 1991; 27: 3, 288–291.

115 Nemeth, A.J., Eaglstein, W.H., Taylor, J.R., et al. Faster healing and less pain in skin biopsy sites treated with an occlusive dressing. Arch Dermatol 1991; 127: 11, 1679–1683.

116 King, A., Stellar, J.J., Blevins, A., Shah, K.N. Dressings and products in pediatric wound care. Adv Wound Care (New Rochelle) 2014; 3: 4, 324–334.

117 Gray, D., White, R., Cooper, P., Kingsley, A. Applied wound management and using the wound healing continuum in practice. Wound Essentials 2010; 5: 131–139.