



Centro Internazionale Nursing Vulnologico

Cura dei Fissatori Esterni: Prevenzione delle Infezioni

Rapid Review

Aprile 2022

“To make this world a better place for patients and family who are fighting against chronic wounds”

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“To make this world a better place for patients and family who are fighting against chronic wounds”

Saluti da Massimo Rivolo,

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A dicembre 2021 il CINV ha pubblicato una revisione rapida sull'utilità delle superfici antidecubito, razionale d'uso ed evidenze disponibili in letteratura. Il seguente documento è invece dedicato alla cura dei fissatori esterni e relativa prevenzione delle infezioni. Abbiamo scelto di approfondire questo argomento poiché sono molte le modalità con cui i fissatori vengono trattati sia in ambito di prevenzione delle infezioni sia nella gestione routinaria senza che vi sia però una chiara indicazione su quale sia l'intervento migliore e basato su prove di efficacia.



Il documento che abbiamo sviluppato deve servire al professionista a riflettere sugli interventi infermieristici da potere erogare quando si deve trattare un paziente con un fissatore esterno, chiedendosi in particolare:

- Quale trattamento è efficace (evidenze disponibili?) nel ridurre la comparsa delle infezioni sul sito dei fissatori?

La nostra speranza è di riuscire ad estrapolare dalla letteratura qualche documento in grado di fornire indicazioni utili alla pratica.

La cura dei fissatori esterni è un atto prevalentemente basato sull'esperienza in cui l'efficacia degli interventi è spesso dubbia o almeno poco dimostrata. Compito di questa revisione è di verificare se esista un protocollo standardizzato per la cura dei fissatori esterni di provata

efficacia o se ahimè il trattamento rimane pressoché un atto non è supportato da prove di efficacia.

Come sempre vi rinnovo i miei saluti e ringrazio i revisori che mi aiutano, mi supportano e mi sopportano nelle pubblicazioni.

Insieme possiamo edificare e “costruire un mondo migliore per i pazienti e le famiglie che lottano contro le ulcere cutanee croniche”

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I fissatori esterni.

Introduzione

I fissatori esterni sono usati da circa 2000 anni per il trattamento delle fratture, pur con modalità differenti e il miglioramento delle tecnologie, i principi della biodinamica che seguono rimangono pressoché identici (*Hadeed et al, 2021*).

I principali fissatori esterni si dividono in diverse subcategorie:

Uniplanari

Multiplanari

Unilaterali

Bilaterali

Circolari (*Hadeed et al, 2021*). In questo link potete vedere alcuni modelli di fissatori esterni (<https://tinyurl.com/4fwh5ee3>)

Le principali complicazioni associate ai fissatori esterni variano dal 7% al 100% con le infezioni che ricoprono la maggior parte dei rischi (*Walker, 2012*). In un articolo rinvenuto in letteratura, su circa 214 fissatori esaminati dopo la rimozione, il 74.8% presentava batteri e di essi il 37.5% erano rappresentati da *Stafilococchi Aurei* e il 9.4% da *Escheria Coli* con una correlazione positiva tra fissatori poco stabili e infezioni, a supporto della teoria secondo la quale la mobilità dei tessuti molli sarebbe un importante fattore per lo sviluppo di infezioni (*Bible et al, 2015*). Le infezioni sono una complicanza temibile che può compromettere la riparazione ossea o in taluni casi condurre ad osteomielite ed infezione sistemica. (*Lethaby et al, 2013*).

La cura dei fissatori varia considerevolmente, tanto che una revisione Cochrane (2008) che ha analizzato tutti i tipi di trattamenti locali dal 1950 in poi, **non ha trovato evidenze sufficienti** a favore di una strategia vs un'altra nel diminuire i tassi di infezione (*Lethaby et al, 2008*). Sempre nel 2013 la Cochrane ha svolto un update della precedente revisione giungendo pressoché alle stesse conclusioni ossia: scarse evidenze, studi di qualità molto bassa ed eterogenei con l'esplicita raccomandazione di creare RCTs di buona qualità (*Lethaby et al, 2013*).

La descrizione corretta di infezione dei fili metallici (Pin Tract Infection PTI) è poco chiara ed ha portato alla creazione di tre definizioni basate sul consenso degli esperti secondo i quali si possono rinvenire: reazione, colonizzazione e infezione (*Lee-Smith et al, 2001*) sul sito di inserzione.

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- Reazione: normale cambiamento (colore cutaneo, ipertermia locale o fuoriuscita di liquido) dopo posizionamento del filo metallico che regredisce nelle 72 ore. (*Lee-Smith et al, 2001*)
- Colonizzazione: presenza di calore attorno al filo metallico, secrezione con presenza di batteri alla cultura e dolore. (*Lee-Smith et al, 2001*)
- Infezione: tutti segni e sintomi precedenti con fuoriuscita di pus, allentamento dei fili e accresciuta carica microbica. (*Lee-Smith et al, 2001*)

Esistono altre classificazioni create per descrivere le PTIs, che si basano su segni clinici quali la classificazione di Clint che usa i termini “good”, “bad” or “ugly” (*Clint et al, 2010*), oppure quella di Santy che usa invece i termini “calm”, “irritated” or “infected” (*Santy et al, 2009*). In questo documento troverete ancora un'altra classificazione.

Nelle pagine seguenti cercheremo di fare una analisi ed un riassunto dei principali interventi volti a prevenire le PTIs. La strategia di ricerca verrà esplicitata nel documento.

Nota. Questa è una revisione narrativa (Rapid Review) della letteratura e non una revisione sistematica. Per ulteriori informazioni sulla natura delle due, si prega di prendere visione cliccando questo link: <https://tinyurl.com/mrxsdfnn>

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Strategie della Ricerca

In questo documento verrà analizzata la letteratura rinvenuta a favore dei possibili interventi volti a prevenire le PTIs. Verranno discussi i singoli studi (tutti in full text tranne uno) per valutare se vi siano raccomandazioni degne di nota da suggerire al lettore. Al termine cercheremo di trarre alcune conclusioni utili con relative implicazioni per la pratica.

La strategia di ricerca utilizzata è riassunta di seguito:

PICO: *“in patient with external fixators are topical antiseptics useful to prevent infection compared to saline solution?”*

PICO: *“in patient with external fixators are topical antiseptics useful to prevent infection compared to no intervention?”*

PICO: *“in patient with external fixators are topical antibiotics useful to prevent infection compared to saline solution?”*

PICO: *“in patient with external fixators are topical antibiofilm agents useful to prevent infection compared to saline solution?”*

Ricerca libera: *((Pressure relieving support surfaces) AND (Pressure ulcers)) AND (management)*

Database utilizzati: PubMed, Cochrane Wounds.

Limiti: Anno 2010-2022. Article Type: RCTs, Clinical Trial, Meta-Analysis, Review, Systematic Review.

PubMed. Clinical Queries: *((External fixators) AND (topical antiseptics)) AND (Saline Solution)) AND (Infection prevention). Risultati: 1*

PubMed. Clinical Queries: *((External Fixators) AND (topical antiseptics)) AND (no intervention)) AND (Infection prevention). Risultati 1*

PubMed. Clinical Queries: *((External Fixators) AND (topical antibiotics)) AND (saline solution)) AND (Infection prevention) Risultati 0*

PubMed. Clinical Queries: *((External Fixators) AND (topical antibiofilm)) AND (saline solution)) AND (Infection prevention) Risultati 0*

PubMed: Clinical Queries: *((External fixators) AND (topical antiseptics)) AND (Saline Solution)) AND (Pin tract infection). Risultati 0.*

PubMed: Clinical Queries: *((External Fixators) AND (topical antiseptics)) AND (no intervention)) AND (pin tract infection). Risultati 0*

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PubMed: (((*External Fixators*) AND (*topical antibiotics*)) AND (*saline solution*)) AND (*pin tract infection*). Risultati 0.

PubMed: (((*External Fixators*) AND (*topical antibiofilm*)) AND (*saline solution*)) AND (*pin tract infection*) Risultati 0.

PubMed: Key Word: *Pin Site Care*. Limiti: anno 2010-2022. Article Type: RCTs, Clinical Trial, Meta-Analysis, Review, Systematic Review. Risultati 22.

PubMed: Key Word: *Pin Site Infection*. Limiti: anno 2010-2022. Article Type: RCTs, Clinical Trial, Meta-Analysis, Review, Systematic Review. Risultati 45.

Nella tabella in **Appendice A** sono presenti gli studi che abbiamo rinvenuto, si ricorda che sono stati presi in considerazione solo RCTs, Meta-analisi, Clinical Trials, Revisioni Sistematiche (vedi sopra) per non appesantire questo lavoro con documenti di bassa solidità scientifica. Altri limiti inclusi sono: lingua inglese e Humans.

In **Appendice B** il PRISMA Flow Diagram.

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Prevenzione delle infezioni

Il primo articolo, un RCT (di piccolissime dimensioni 15 pazienti per gruppo), prende in considerazione l'efficacia dello iodio polivinilpirrolidone 10% vs soluzione salina per la prevenzione delle infezioni nei pazienti con Ilizarov (*Camilo et al, 2005*). Le infezioni che si localizzano attorno ai fili metallici sono spesso polimicrobiche, per questo motivo, gli autori hanno impiegato lo iodio che risulta essere attivo contro i *Gram positivi* e *Gram negativi*, virus, protozoi, lieviti e funghi, inoltre non è irritante, non corrode il metallo e non altera la funzione tiroidea (*Camilo et al, 2005*). Come misura aggiuntiva alla prima comparsa di infezione localizzata, sono stati somministrati antibiotici ed aumentato il numero cambi medicazione (*Camilo et al, 2005*). I risultati non hanno mostrato alcun cambiamento statisticamente significativo nei due gruppi in termini di comparsa di infezioni usando lo iodio vs la soluzione salina (*Camilo et al, 2005*). **Fonte: RCT** *Nota: questo articolo è datato 2005, ma è stato incluso poiché ritenuto interessante.*

Nella loro revisione, Ktistakis e collaboratori hanno analizzato 369 manoscritti con lo scopo di valutare quale protocollo per la cura dei fili metallici fosse efficace in termini di prevenzione delle infezioni; di questi soltanto 13 sono stati inclusi (*Ktistakis et al, 2015*). In linea di massima i protocolli comprendevano l'impiego di diverse soluzioni, quali: soluzione salina 0.9%, alcool 70%, nessun trattamento locale, garze impregnate di iodio povidone, Xeroform/Xeroflo, vaselina, saponi antibatterici, docce, perossido di idrogeno, rimozione delle croste, medicazioni impregnate con clorexidina, garze impregnate con PHMB, sulfadiazina argentea e la frequenza dei cambi medicazione variava da una a due volte al giorno (*Ktistakis et al, 2015*). Secondo gli autori il Gold Standard per la prevenzione delle PTIs non è ancora chiaro, pare comunque che anche la sede anatomica dove vengono posizionati i fissatori sia correlata con le infezioni: la porzione di coscia sembra meno interessata dalle infezioni rispetto alla porzione distale dell'arto inferiore (*Ktistakis et al, 2015*). Degno di nota è il metodo russo sulla gestione dei fili metallici che risulta essere pratica ben riconosciuta ed approvata dal Royal College of Nursing per la prevenzione delle infezioni (qui il link dell'articolo citato in questa revisione <https://tinyurl.com/5bppw7t9>) e che ha dimostrato essere statisticamente superiore (chi-squared test, $p = 0.003$) rifiutando l'ipotesi nulla sulla non differenza tra numero di infezioni nei due gruppi (*Ktistakis et al, 2015*). **Fonte: Review.**

La revisione della Cochrane sulla cura dei Pin Site (fili metallici) per la prevenzione delle infezioni ha analizzato 11 trials con rispettivi protocolli (*Lethaby et al, 2013*). Anche in questo caso le evidenze disponibili sono scarse, gli studi eterogenei e le raccomandazioni formulate dalla Cochrane suggeriscono la futura creazione di studi clinici adeguati che considerino i differenti protocolli e i co-interventi associati quali la terapia antibiotica. (*Lethaby et al, 2013*). **Fonte: Revisione Sistemica**

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Il Trial Randomizzato e Controllato (RCT) prodotto da Subramanyam e collaboratori ha comparato diverse modalità di gestione dei Pin Sites usando Clorexidina, Iodio Povidone, Argento Sulfadiazina e Clorexidina (*Subramanyam et al, 2019*). Nello studio proposto, il gruppo trattato con clorexidina ha avuto meno infezioni così come il gruppo che sostituiva giornalmente la medicazione rispetto al cambio settimanale, purtroppo in entrambi i casi non vi è significatività statistica quindi gli autori hanno concluso che gli antisettici topici non modificano il rischio di infezioni e il cambio giornaliero non incide sulla prevalenza delle infezioni rispetto ad un cambio settimanale (*Subramanyam et al, 2019*). **Fonte: RCT**

La gestione delle croste che si formano attorno ai Pin Sites sono fonte di discussione e la loro modalità di gestione è stata studiata in una Revisione Sistemática Integrativa in cui si prendeva in considerazione la crosta quale modalità di **medicazione biologica** da non rimuovere vs la loro rimozione per la prevenzione delle infezioni (*Georgiades, 2018*). Le croste che si formano sono costituite dall'essudato secco fermamente adeso ai Pin Sites (*Georgiades, 2018*). Alcuni autori sostengono che le croste siano in grado di prevenire le infezioni, mentre altri credono invece che ne aumentino la probabilità di comparsa (*Georgiades, 2018*). Secondo uno studio rinvenuto in questa revisione (l'unico a proporre questa metodica), le croste fungono da medicazioni biologiche ad effetto barriera contro le infezioni grazie all'effetto sigillante dei cheratinociti, la loro non rimozione potrebbe quindi essere di aiuto alla prevenzione delle infezioni, ma gli autori riconoscono che in caso di infezione, quest'ultima sia più refrattaria ai trattamenti quando le croste non vengono rimosse (*Georgiades, 2018*). Le conclusioni degli autori sono quindi a favore di studi ben disegnati, poiché la ritenzione delle croste trova la sua ipotesi in questo solo unico studio presente in letteratura (*Georgiades, 2018*). **Fonte: Review.**

Tra i documenti rinvenuti dalla ricerca, un RCT ha comparato l'uso di antisettici in soluzione per la cura dei Pin Sites nello specifico la Clorexidina al 2% in alcool vs Iodio Povidone 10%, con l'intenzione di dimostrare la superiorità della prima rispetto allo iodio (*Sáenz-Jalón et al, 2020*). L'end point primario era la comparsa di PTI nei due gruppi (*Sáenz-Jalón et al, 2020*). Come per gli studi presentati finora, anche in questo non vi è stata alcuna differenza statisticamente significativa tra i due preparati in termini di prevenzione delle infezioni, l'unica variabile degna di nota è il tempo di applicazione dei fissatori, maggiore il periodo trascorso con il dispositivo, maggiore il rischio di infezioni (*Sáenz-Jalón et al, 2020*). Gli autori hanno comunque esplicitato che questo studio presenta numerose limitazioni a causa di differenti bias (*Sáenz-Jalón et al, 2020*). **Fonte: RCT.**

Ferguson e collaboratori hanno sviluppato un trial randomizzato prospettico con l'intenzione di comparare la soluzione alcoolica di clorexidina vs un regime di cura

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della cute usando un emolliente (Dermol 500®, lozione a base di Benzalconio Cloruro con Clorexidina e paraffina liquida) per il trattamento dei Pin Sites (*Ferguson et al, 2021*). Anche in questo studio, non sono state riscontrate differenze statisticamente significative usando il Dermol 500® rispetto alla clorexidina ed è quindi difficoltoso fornire raccomandazioni in merito (*Ferguson et al, 2021*). **Fonte: RCT.**

Un altro RCT ha comparato la cura dei Pin Sites effettuata giornalmente versus l'assenza totale di qualsiasi trattamento locale (*Camathias et al, 2012*). Questo intra-subject, randomised, prospective controlled trial (ci abituiamo un po' alla volta alla terminologia inglese, indispensabile per qualsiasi ricerca scientifica) è unico nel suo genere poiché si è posto il compito di verificare se l'assenza di qualsiasi trattamento locale potesse risultare in outcomes differenti rispetto alla moltitudine di interventi, che, come il lettore ha potuto finora sperimentare, risultano essere pressoché tutti molto deludenti (*Camathias et al, 2012*). Gli end points considerati dal valutatore (in cecità) sono stati: 1) le condizioni del tessuto morbido, 2) la stabilità dei fili metallici, 3) la stabilità torsionale dei fili, 4) l'osteolisi pre-rimozione documentata radiograficamente, 5) il dolore sul sito d'inserzione (*Camathias et al, 2012*). Un importante aspetto riportato è la **presenza di tessuto di granulazione** e la **secrezione di fluidi attorno al Pin Site** che, secondo gli autori, richiederebbe una rapida valutazione poiché sarebbero segni di instabilità dei fili metallici (*Camathias et al, 2012*). Gli autori concludono questo studio dimostrando che **non esiste alcuna differenza** tra un regime di cura dei Pin Sites, con qualsivoglia prodotto, rispetto al non erogare alcun tipo di cura locale auspicando che questo RCT possa essere di aiuto nella gestione dei fissatori esterni (*Camathias et al, 2012*). **Fonte: RCT.**

Un'altra revisione (*Guerado et al, 2019*) che ha considerato la sostituzione dei fissatori esterni con i fissatori intramedullary (intramedullari), ha descritto le varie tecniche per la gestione dei Pin Sites prendendo in considerazione quelle già ampiamente menzionate in questo scritto, fornendo però aggiuntivi spunti di riflessione, quale per esempio l'inutilità dei tamponi culturali ai fini della diagnosi di infezione (*Guerado et al, 2019*). **Fonte: Review**

Un RCT sulla gestione dei Pin Sites nelle fratture dell'omero nella popolazione pediatrica ha effettuato la comparazione di tre metodi di cura dei Pin Sites: medicazione giornaliera, a giorni alterni o settimanale (*Lu et al, 2017*). Ogni gruppo era composto da 45 bambini e di essi 48 hanno avuto PTIs (35.6%) (*Lu et al, 2017*). La procedura di cura dei Pin Sites era: 1) irrigazione con soluzione salina, 2) asciugatura con tampone sterili, 3) rimozione delle croste dai siti, 4) applicazione di garze sterili attorno ai Pin Sites, 5) applicazione di medicazioni morbide attorno ai Pin Sites. I risultati non hanno dimostrato alcuna differenza nei tassi di infezione nei

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tre distinti gruppi ($p>0.05$) anche se il dolore riportato nei tre gruppi era maggiore nel primo (medicazione giornaliera) (Lu et al, 2017). Gli autori concludono sostenendo che questo RCT ha dei limiti legati al numero dei partecipanti (piccolo) e al fatto che la cecità non è stata inclusa nello studio (Lu et al, 2017). **Fonte: RCT**

Jennison e collaboratori hanno svolto una revisione considerando le potenziali future e correnti strategie per ridurre le PTIs (Jennison et al, 2014). Una infezione si sviluppa quando i batteri planctonici presenti sulla cute aderiscono al metallo creando il biofilm e proteggendo in questo modo i batteri dalle difese dell'ospite (Jennison et al, 2014). Gli autori hanno utilizzato la classificazione di Checketts and Otterburn per la valutazione delle infezioni, ritenuta secondo gli stessi la più attendibile (vedi tabella):

| Grade | Clinical appearance |
|-------|--|
| 1 | Slight redness - Little discharge |
| 2 | Redness - Discharge - Soft-tissue pain and tenderness |
| 3 | Grade 2 not responding to treatment |
| 4 | Soft-tissue infection involving several pins |
| 5 | Osteomyelitis |
| 6 | Breakdown and discharge after the completion of treatment Bone sequestrum |

Viene riportato che le infezioni minori possono essere trattate con antibiotici ma spesso senza successo e con rischi di resistenze e complicanze sistemiche (Jennison et al, 2014). Nel caso la terapia antibiotica e locale sia inefficace, il **Gold Standard risulta essere la rimozione dei fissatori** (Jennison et al, 2014). La revisione ha considerato in particolare l'impiego di materiali sviluppati in commercio per la riduzione delle infezioni, in particolare sono stati valutati: 1) fissatori in titanio e loro presunte capacità di limitare l'adesione dei batteri con conclusione di mancanza di studi in vivo, 2) acciaio inossidabile vs titanio, con outcomes negativi rispetto al titanio, 3) lega in rame, con studi contrastanti, 4) fissatori coperti di argento, con risultati poco chiari e relativo aumento della concentrazione ematica dell'argento 5) idrossiapatite, con risultati poco chiari sulla riduzione delle infezioni, 6) fissatori con copertura all'ossido nitrico avente effetto batteriostatico con evidenze limitate al suo impiego, 7) fissatori con copertura alla clorexidina e iodio con risultati sulla possibile tossicità ed effetti sulla osteointegrazione, 8) chitosano incorporato nella idrossiapatite con risultati promettenti ma scarse evidenze, 9) fissatori coperti da

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antibiotici con risultati promettenti ma pochi studi in vivo (*Jennison et al, 2014*). Gli autori concludono sostenendo che vi sono potenziali aree di sviluppo ma sono necessari studi in vivo ed in vitro per validare le potenzialità (*Jennison et al, 2014*).

Fonte: Review

Il trial randomizzato di Yuenyongviwat e collaboratori, ha comparato l'uso della sulfadiazina argentea (SA) vs garze pulite nella prevenzione delle infezioni dei fissatori in due gruppi formati rispettivamente da 15 persone, 30 soggetti in tutto, senza riscontrare alcuna differenza nei tassi di infezione concludendo che la SA non minimizza in alcun modo la prevalenza di infezioni (*Yuenyongviwat et al, 2011*) **Fonte: RCT.**

Un altro RCT ha comparato le garze impregnate di PHMB vs garze semplici impregnate di soluzione fisiologica per la prevenzione delle infezioni dei fissatori, nello specifico 22 pazienti nel gruppo sperimentale vs 18 nel gruppo di controllo (*Lee et al, 2012*). I risultati in questo RCT forniscono conclusioni interessanti poiché il gruppo trattato con il PHMB ha avuto una minor prevalenza di infezioni rispetto al controllo sebbene gli autori riferiscano esplicitamente che lo studio ha delle limitazioni. (*Lee et al, 2012*). **Fonte: RCT**

L'ultimo studio rinvenuto in letteratura, un altro RCT, ha studiato l'efficacia della clorexidina al 5% combinata con l'argento sulfadiazina 1% vs la clorexidina da sola nella prevenzione delle infezioni, concludendo che la combinazione dei due antisettici è risultata statisticamente significativa nella riduzione delle infezioni (*Ogbemudia et al, 2010*). Anche in questo caso lo studio è di piccole dimensioni. *Nota: non siamo riusciti ad avere il full text.* **Fonte: RCT**

Discussione.

La prevenzione delle PTIs risulta essere un problema immenso per i portatori di fissatori esterni e una strategia che si basi su solide prove di efficacia è lontana dall'essere disponibile. Nella nostra revisione rapida, abbiamo elencato una serie di studi e rispettive conclusioni in merito alla gestione e ai materiali da impiegare per prevenire le infezioni, perlopiù antisettici locali, senza essere certi su quale tipo di prodotto sia il migliore da impiegare. Uno studio ha evidenziato una certa efficacia usando il PHMB rispetto alle garze imbevibili di soluzione fisiologica (*Lee et al, 2012*), mentre un altro ha descritto la combinazione di due diversi antisettici vs uno solo dimostrando una certa superiorità dalla combinazione dei prodotti (*Ogbemudia et al, 2010*). A nostro avviso non è semplice giungere a conclusioni certe sulla miglior modalità da impiegare, vuoi per il tipo di studi (piccole dimensioni), vuoi per i limiti delineati dagli autori nei vari articoli.

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Implicazioni per la pratica.

La cura dei fissatori è parte fondamentale del nursing vulnologico e le procedure adottate finora sembrano poco chiare. Gli articoli rinvenuti forniscono poche indicazioni per la pratica quotidiana e la revisione sistematica della Cochrane, sebbene pubblicata nel 2013 non riesce a chiarire quale sia l'intervento migliore da adottare per prevenire le infezioni (Lethaby *et al*, 2013). Un dato importante che deve essere sottolineato attentamente è ad esempio l'insieme di criteri per definire quando sia necessario rimuovere i fissatori, nello specifico, in uno studio viene sottolineato che dopo aver trattato l'infezione dei fissatori per via sistemica con antibiotici senza ottenere alcun successo, il Gold Standard viene considerata la rimozione dei fissatori (Jennison *et al*, 2014). Risulta quindi importante essere in grado di riconoscere attentamente i segni che richiedono una valutazione rapida e appropriata al fine di evitare complicazioni più importanti quali l'osteomielite o le infezioni sistemiche, avvalendosi anche del supporto multidisciplinare e usando i principi cardine nel wound care quali il TIME per la valutazione locale della ferita (Moore *et al*, 2019). Tra le raccomandazioni più importanti che ci sentiamo di fornire, oltre alla cura locale volta a prevenire infezioni crociate, è proprio la conoscenza nel saper riconoscere rapidamente i segni che richiedono un intervento rapido.

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Appendice A

| Autore | Titolo | Abstract | Tipo di studio | Screening | Eleggibilità |
|-------------------------------|---|---|----------------|-----------|--------------|
| 1. Camilo AM, Bongiovanni JC. | Evaluation of effectiveness of 10% polyvinylpyrrolidone-iodine solution against infections in wire and pin holes for Ilizarov external fixators. Sao Paulo Med J. 2005 Mar 2;123(2):58-61. doi: 10.1590/s1516-31802005000200005. Epub 2005 Jun 8. PMID: 15947831. | <p>Context and objective: Superficial infection at wire and pin insertions in the skin is a frequent disorder among patients utilizing the Ilizarov method. The objective of this study was to evaluate the effectiveness of daily topical application of 10% polyvinylpyrrolidone-iodine solution against infections of the holes for Kirschner wires and Schanz pins among patients using Ilizarov external fixators, in comparison with cleaning these holes only with 0.9% sterile physiological saline solution.</p> <p>Design and setting: Controlled randomized clinical trial, in the Orthopedics and Traumatology Outpatient Clinic, Hospital São Paulo, and Orthopedics and Traumatology Center of Jundiaí.</p> <p>Methods: 30 patients were treated using the Ilizarov technique: 15 were instructed to apply 0.9% physiological saline dressing on the wire and pin insertions and 15 to apply 0.9% physiological saline plus 10%</p> | Clinical Trial | YES | YES N |

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| | | <p>polyvinylpyrrolidone-iodine. Patients were evaluated at outpatient return visits for identification of signs and symptoms of superficial infection at wire and pin insertion sites. Samples were collected from cases of purulent exudate secretion, for culturing and clinical tests.</p> <p>Results: The chi-squared and Fischer exact tests were applied, but no statistically significant association between the intervention of topical polyvinylpyrrolidone-iodine solution and the prevention of infections at wire and pin insertions could be found.</p> <p>Conclusions: Topical 10% polyvinylpyrrolidone-iodine solution applied daily to Kirschner wire and Schanz pin insertions did not reduce the incidence of superficial infection at these holes, in comparison with mechanical removal of dirt using 0.9% physiological saline solution.</p> | | | |
| 2. Camilo AM, Bongiovanni JC. | <p>Evaluation of effectiveness of 10% polyvinylpyrrolidone iodine solution against infections in wire and pin holes for Ilizarov external fixators. Sao Paulo Med J. 2005 Mar 2;123(2):58-61. doi: 10.1590/s1516-31802005000200005. Epub 2005 Jun 8. PMID: 15947831.</p> | | Clinical Trial | YES | YES |
| 3. Kistakis I, Guerado E, Giannoudis PV. | <p>Pin-site care: can we reduce the incidence of infections? Injury. 2015 Sep;46 Suppl 3:S35-9. doi: 10.1016/S0020-1383(15)30009-7. PMID: 26458298.</p> | <p>Background: This study was conducted to determine the pin-site care protocols currently in use and to analyse their effectiveness and outcomes.</p> | Review | YES | YES N |

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| | | <p>Methods: PubMed, the Cochrane Library and Embase databases were screened for manuscripts that described comparative studies of different methods of pin-site care and referred to complications related to any kind of external fixator application.</p> <p>Results: A total of 369 manuscripts were screened and only 13 of these met the inclusion criteria evaluating different protocols of pin-site care. This review is based on a total of 574 patients. Infection rates were very variable depending on the type of implant used and the protocol of pin-site care applied.</p> <p>Conclusions: None of the different protocols of pin-site care that were evaluated in this study were associated with a 0% infection rate. There is currently no consensus in the international literature about which protocol should be applied universally. Meticulous surgical technique during pin insertion and implementation of one of the existing protocols of pin-site care are the mainstay of prevention and/or reduction of the incidence of pin-site infections.</p> | | | |
| 4. Lethaby A, Temple J, Santy-Tomlinson J. | Pin site care for preventing infections associated with external bone fixators and pins. Cochrane Database Syst Rev. 2013 Dec 3;(12):CD004551. doi: 10.1002/14651858.CD004551.pub3. PMID: 24302374. | Background: Metal pins are used to apply skeletal traction or external fixation devices in the management of orthopaedic fractures. These percutaneous pins protrude through | Review | YES | YES N |

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| | | <p>the skin, and the way in which they are treated after insertion may affect the incidence of pin site infection. This review set out to summarise the evidence of pin site care on infection rates.</p> <p>Objectives: To assess the effect on infection rates of different methods of cleansing and dressing orthopaedic percutaneous pin sites.</p> <p>Search methods: In September 2013, for this third update, we searched the Cochrane Wounds Group Specialised Register; The Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library); Ovid MEDLINE; Ovid MEDLINE (In-Process & Other Non-Indexed Citations); Ovid EMBASE; and EBSCO CINAHL.</p> <p>Selection criteria: We evaluated all randomised controlled trials (RCTs) that compared the effect on infection and other complication rates of different methods of cleansing or dressing orthopaedic percutaneous pin sites.</p> <p>Data collection and analysis: Two review authors independently assessed the citations retrieved by the search strategies for reports of relevant RCTs, then independently selected trials that satisfied the inclusion criteria, extracted data and</p> | | | |
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| | | <p>undertook quality assessment.</p> <p>Main results: A total of eleven trials (572 participants) were eligible for inclusion in the review but not all participants contributed data to each comparison. Three trials compared a cleansing regimen (saline, alcohol, hydrogen peroxide or antibacterial soap) with no cleansing (application of a dry dressing), three trials compared alternative sterile cleansing solutions (saline, alcohol, peroxide, povidone iodine), three trials compared methods of cleansing (one trial compared identical pin site care performed daily or weekly and the two others compared sterile with non sterile techniques), one trial compared daily pin site care with no care and six trials compared different dressings (using different solutions/ointments and dry and impregnated gauze or sponges). One small blinded study of 38 patients found that the risk of pin site infection was significantly reduced with polyhexamethylene biguanide (PHMB) gauze when compared to plain gauze (RR 0.23, 95% CI 0.12 to 0.44) (infection rate of 1% in the PHMB group and 4.5% in the control group) but this study was at high risk of bias as the unit of analysis was observations rather</p> | | | |
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| | | <p>than patients. There were no other statistically significant differences between groups in any of the other trials.</p> <p>Authors' conclusions: The available trial evidence was not extensive, was very heterogeneous and generally of poor quality, so there was insufficient evidence to be able to identify a strategy of pin site care that minimises infection rates. Adequately-powered randomised trials are required to examine the effects of different pin care regimens, and co-interventions - such as antibiotic use - and other extraneous factors must be controlled in the study designs.</p> | | | |
| 5. Subramanyam KN, Mundargi AV, Potarlanka R, Khanchandani P. | No role for antiseptics in routine pin site care in Ilizarov fixators: A randomised prospective single blinded control study. Injury. 2019 Mar;50(3):770-776. doi: 10.1016/j.injury.2019.01.031. Epub 2019 Jan 23. PMID: 30711321. | <p>Introduction: Pin site infection is the commonest complication of Ilizarov external fixation. The aim of the study was to examine if use of antiseptics was superior over control and further if daily dressing was superior to weekly dressing in regular pin site care in reducing the burden of pin site infection in Ilizarov fixators.</p> <p>Patients and methods: A total of 114 patients (2363 pin sites) were randomised to receive regular pin site care alone (30 patients, 638 pin sites) or with additional application of povidone iodine (27 patients, 561 pin sites), silver sulfadiazine (27 patients, 570 pin sites)</p> | RCT | YES | YES N |

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| | | <p>and chlorhexidine (30 patients, 594 pin sites). The pin tracts were sub-randomised to receive daily (1212 pin sites) or weekly (1151 pin sites) dressings. The primary outcome was pin site infection days rate across all four groups. The secondary outcomes were - mean duration to first episode of infection, differences between daily and weekly dressing groups, mean duration of antibiotic therapy and incidence of re-interventions and sequelae. We also recorded frequency of bacterial pathogens in all microbiological samples submitted. Block randomization using computer-generated random numbers was used. The assessor of outcome was blinded.</p> <p>Results: All patients completed the study. Pin site infection rate days per 1000 pin site days observed was marginally less in chlorhexidine group, but was not statistically significant compared to other antiseptics and control group (Absolute value in control, povidone iodine, silver sulphadiazine and chlorhexidine groups were respectively 2.04 ± 4.27, 2.04 ± 3.65, 1.85 ± 3.37, 1.37 ± 2.35, p value 0.92). Daily dressing category showed slightly less pin site infection days rate within each group and overall, but this was also not statistically significant (1.56 ± 3.99</p> | | | |
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| | | <p>versus 2.10 ± 5.1, p value 0.35). There was no statistically significant difference among the groups with regard to other secondary outcomes. Methicillin Sensitive Staphylococcus aureus was the most common bacterial pathogen isolated.</p> <p>Conclusion: Use of antiseptics does not offer any advantage in regular pin site care in Ilizarov external fixation and daily pin site care is not superior to weekly pin site care. Empirical therapy in early and low grade pin site infections must be targeted against Staphylococcus.</p> | | | |
| 6. Georgiades DS. | <p>A Systematic Integrative Review of Pin Site Crusts. Orthop Nurs. 2018 Jan/Feb;37(1):36-42. doi: 10.1097/NOR.0000000000000416. PMID: 29369133.</p> | <p>There continues to be a lack of knowledge in the overall management of pin site crusts for orthopaedic clinicians to make evidence-based decisions on their retention or removal. The goal of pin site care is to reduce, or where possible, prevent pin site infection. Understanding the role of pin site crusts in the management of the pin site and prevention of pin site infection is important. The aim of this systematic integrative review is to explore the effectiveness of pin site crusts as a biological dressing versus the removal of pin site crusts in pin site care and prevention of pin site infection. Three electronic databases were used to conduct a systematic search. The methodologies of five studies that met</p> | Review | YES | YES N |

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| | | inclusion criteria were appraised using the Mixed Method appraisal Tool. Findings reveal that pin site crusts have similar properties to that of a dressing, as the crusts are able to act as a barrier between the insertion site of the pin and external environment, which can reduce infection. Additional high-quality evidence is required to solidify the effectiveness of pin site crusts as a biological dressing. | | | |
| 7. Sáenz-Jalón M, Sarabia-Cobo CM, Roscales Bartolome E, Santiago Fernández M, Vélez B, Escudero M, Miguel ME, Artabe P, Cabañas I, Fernández A, Garcés C, Couceiro J. | A Randomized Clinical Trial on the Use of Antiseptic Solutions for the Pin-Site Care of External Fixators: Chlorhexidine-Alcohol Versus Povidone-Iodine. J Trauma Nurs. 2020 May/Jun;27(3):146-150. doi: 10.1097/JTN.0000000000000503. PMID: 32371731. | Pin-site infections remain a common clinical complication in patients with external fixators. Pin-site care is commonly performed with either chlorhexidine-alcohol solution or povidone-iodine solution. This study aimed to investigate the superiority of chlorhexidine-alcohol solution versus povidone-iodine solution for external fixator pin-site care in pin-site infection. This prospective randomized clinical trial using an open, parallel-group design was conducted in a single Spanish hospital. Eligible consenting patients from November 2018 to May 2019 who underwent placement of an external fixator were included. Patients were randomly assigned to receive pin-site care using either a 2% chlorhexidine-alcohol solution or a 10% povidone-iodine solution. The primary | RCT | YES | YES N |

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| | | <p>endpoint was the development of a pin-site infection. In total, 568 pins were analyzed (128 patients, with a mean of 4.3 pins per patient). No significant differences were found between groups. However, statistically significant differences were found regarding time and infection variables. The longer the person had the fixator, the higher the risk of infection, $t(x) = 5.49$, $p = .002$. Both chlorhexidine-alcohol and povidone-iodine solutions are equally effective antiseptic agents for the prevention of infections in external fixators.</p> | | | |
| 8. Ferguson D, Harwood P, Allgar V, Roy A, Foster P, Taylor M, Moulder E, Sharma H. | <p>The PINS Trial: a prospective randomized clinical trial comparing a traditional versus an emollient skincare regimen for the care of pin-sites in patients with circular frames. Bone Joint J. 2021 Feb;103-B(2):279-285. doi: 10.1302/0301-620X.103B2.BJJ-2020-0680.R1. PMID: 33517738.</p> | <p>Aims: Pin-site infection remains a significant problem for patients treated by external fixation. A randomized trial was undertaken to compare the weekly use of alcoholic chlorhexidine (CHX) for pin-site care with an emollient skin preparation in patients with a tibial fracture treated with a circular frame.</p> <p>Methods: Patients were randomized to use either 0.5% CHX or Dermol (DML) 500 emollient pin-site care. A skin biopsy was taken from the tibia during surgery to measure the dermal and epidermal thickness and capillary, macrophage, and T-cell counts per high-powered field. The pH and hydration of the skin were measured preoperatively, at follow-up, and if pin-</p> | RCT | YES | YES N |

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| | | <p>site infection occurred. Pin-site infection was defined using a validated clinical system.</p> <p>Results: Out of 116 patients who were enrolled in the study, 23 patients (40%) in the CHX group and 26 (44%) in the DML group had at least one bad or ugly pin-site infection. This difference was not statistically significant ($p = 0.71$). There was no significant relationship between pH or hydration of the skin and pin-site infection. The epidermal thickness was found to be significantly greater in patients who had a pin-site infection compared with those who did not ($p = 0.01$). Skin irritation requiring a change of treatment occurred in four patients (7%) using CHX, and none using DML.</p> <p>Conclusion: We found no significant difference in the incidence of pin-site infection between the CHX and DML treatment groups. Dermol appeared to offer a small but significant advantage in terms of tolerability. We did not find a significant association between patient or treatment related factors and pin-site infection. It is therefore difficult to make specific recommendations based upon these results. The use of</p> | | | |
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| | | either cleaning agent appears to be appropriate. Cite this article: Bone Joint J 2021;103-B(2):279-285. | | | |
| 9. Camathias C, Valderrabano V, Oberli H. | Routine pin tract care in external fixation is unnecessary: a randomised, prospective, blinded controlled study. Injury. 2012 Nov;43(11):1969-73. doi: 10.1016/j.injury.2012.08.010. Epub 2012 Aug 16. PMID: 22901422. | <p>Introduction: Pin site infections are seen in up to 40% of external fixators (ExFix) and are therefore the most common complication with this device. There is no consensus in the literature as to the appropriate regimen for pin tract care and infection prevention. This study is the first intra-subject, randomised, prospective controlled trial comparing daily pin tract care to no pin tract care at all.</p> <p>Method: Consecutive patients series (56 patients, 16 female, age 4-68 y, mean 24 y, in total 204 pins) recruited in the National Referral Hospital in Honiara in the Solomon Islands over a 2 year period. Exclusion criteria were application of ExFix for less than two weeks or a non-standard ExFix. Pin treatment was allocated into groups anatomically, proximal and distal. Randomisation was intra-subject and intra-group: 101 pins had daily pin site care and 103 had no treatment at all.</p> <p>Endpoints: Soft-tissue interface, stability of the pins, torsional stability as determined with a torque metre, osteolysis and pain. Assessment of pin sites blinded. Statistical analysis using the paired t test for parametric data and the</p> | RCT | YES | YES N |

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| | | <p>Wilcoxon rank test for non-parametric data (Stat View).</p> <p>Results: No significant difference between the two groups. Soft-tissue interface 36% vs. 35% (granulation/secretion), stability 20 vs 25 pins with loosening. No significant osteolysis (7 vs. 6 pins). Torque: mean 0.75 Nm, max.: 3.05 Nm vs. 0.60 Nm, max.: 3.55 Nm, no significant difference. No differences in demographics (age, localisation, sex, time of fixation).</p> <p>Conclusion: This study shows that routine pin tract care is unnecessary in external fixation treatment of injuries.</p> | | | |
| 10. Guerado E, Cano JR, Fernandez-Sanchez F. | Pin tract infection prophylaxis and treatment. Injury. 2019 Jun;50 Suppl 1:S45-S49. doi: 10.1016/j.injury.2019.03.044. Epub 2019 Apr 1. PMID: 31003703. | <p>Pin tract infection in external fixation (ExFix) is a frequent finding which can eventually lead to loosening, osteomyelitis and loss of fixation. Its diagnosis is based on high empiricism and low validity, although it is possible to distinguish between minor and major infection. The first is limited to soft tissues, whereas the latter includes bone involvement. The rate of infection after conversion of external fixation to intramedullary nailing (IMN) is not well known. Unfortunately, papers referring to infection after the conversion of ExFix to intramedullary nailing (IMN) are of evidence level IV or V. It is suggested that conversion of ExFix to</p> | Review | YES | YES N |

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| | | IMN should be carried out in a 2 step regimen. The time interval of 2 step regimen is uncertain although some authors have recommended to occur within 9 days. There is no consensus as to which prophylaxis protocol should be applied prior to conversion. In order to throw more light into this important issue, registries capturing important related parameters to the development of infection should be established. | | | |
| 11. Lu D, Wang T, Chen H, Sun LJ. | Management of pin tract infection in pediatric supracondylar humerus fractures: a comparative study of three methods. Eur J Pediatr. 2017 May;176(5):615-620. doi: 10.1007/s00431-017-2884-1. Epub 2017 Mar 1. PMID: 28251295. | The objective of this study was to prospectively compare the incidence of pin tract infection in pediatric supracondylar humerus fractures managed with pin care daily or every other day or weekly. We hypothesized that there were some differences between these three methods. From June 2012 to May 2015, 135 children with supracondylar humerus fractures were randomized to postoperative pin care by cleaning pin tracts daily (group A, 45 cases) or cleaning every 2 days (group B, 45 cases) or cleaning weekly (group C, 45 cases). The three groups were comparable with respect to age, gender, affected side, body mass index (BMI), fracture type, injury to surgery time, number of intraoperative percutaneous pinning, and follow-up time. We collected data on pin | RCT | YES | YES N |

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| | | <p>retention time, union time, and pin tract infection. The average follow-up time of group A was 4.5 ± 1.3 and 4.2 ± 1.6 months in group B and 4.3 ± 1.4 months in group C. The patient demographics and intraoperative variables of three groups were comparable. No significant difference between these three groups was found in union time and pin fixation time. Of the 135 children, 48 (35.6%) cases had pin tract infection. Grade I infections (Checketts-Otterburns classification) occurred around 28.9% of 270 pin and grade II around 6.7%. We found no differences between three groups as regards frequency and severity of pin tract infections (both $P > 0.05$). However, complain of pain was more frequent in group A than other two groups ($P < 0.05$).</p> <p>Conclusions: All of the three methods were effective for the management of pin site infection in pediatric supracondylar humerus fractures. However, excessive frequent care as well as pin care daily had the disadvantages of child's fear and parental anxiety. What is Known: • Pin site infection is a common complication after fracture fixation and bone lengthening using percutaneous pins or wires. • Closed reduction and percutaneous K-wires fixation are the</p> | | | |
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| | | <p>mainstay of treatment in pediatric supracondylar humeral fractures. What is New:</p> <ul style="list-style-type: none"> • All of the three methods were effective for the management of pin site infection. • Excessive frequent care as well as pin care daily has the disadvantages of child's fear and parental anxiety. | | | |
| 12. Suson KD, Sponseller PD, Gearhart JP. | <p>Bony abnormalities in classic bladder exstrophy: the urologist's perspective. J Pediatr Urol. 2013 Apr;9(2):112-22. doi: 10.1016/j.jpurol.2011.08.007. Epub 2011 Nov 21. PMID: 22105005.</p> | <p>Introduction: As the primary practitioner managing patients with classic bladder exstrophy (CBE), it is incumbent upon the pediatric urologist to understand the associated orthopedic anomalies and their management.</p> <p>Methods: A Pubmed search was performed with the keyword exstrophy. Resulting literature pertaining to orthopedics and published references were reviewed.</p> <p>Results: Anatomic changes to the bony pelvis include outward rotation, acetabular retroversion with compensatory femoral anteversion, anterior pubic shortening, and pubic diastasis. Imaging options have improved, which impacts surgical planning. Surgical approach, including type of osteotomy and method of pubic approximation, is evolving. Most centers employ immobilization after surgery, with external fixation, Bryant's traction, Buck's traction, and spica casting being the most common methods. Orthopedic</p> | Review | YES | NO |

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| | | <p>complications range from minor pin-site infections to neurologic and vascular compromise. Most experts agree osteotomy aids bladder closure beyond 72 h of life, but effect on continence remains controversial. Although no significant orthopedic benefit has been expounded, it may be too early to appreciate improvement in frequency or severity of osteoarthritis or hip dysplasia.</p> <p>Conclusion: While orthopedic surgeons remain vital to managing exstrophy patients, knowledge of the anatomy, imaging, surgical approaches, and immobilization enable effective communication with parents and other physicians, improving care for these complicated patients.</p> | | | |
| 13. Pieske O, Kaltenhauser F, Pichlmaier L, Schramm N, Trentzsch H, Löffler T, Greiner A, Piltz S. | Clinical benefit of hydroxyapatite-coated pins compared with stainless steel pins in external fixation at the wrist: a randomised prospective study. Injury. 2010 Oct;41(10):1031-1036. doi: 10.1016/j.injury.2010.03.030. PMID: 20444448. | <p>Background: The purpose of this study was to determine the clinical benefit of hydroxyapatite (HA)-coated pins compared with standard stainless steel pins in external fixators applied for unstable fractures of the distal radius.</p> <p>Methods: A total of 40 patients (160 pins) with unstable wrist fractures were randomised for uniplanar fixator treatment with the use of identically designed, commercially available pins either composed of stainless steel (steel group) (n = 20) or coated by</p> | RCT | YES | NO |

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| | | <p>hydroxyapatite (HA group) (n = 20). Each pin site was clinically evaluated concerning erythema and grade of drainage as well as pain intensity (numeric rating scale (NRS) 0–10) and, additionally, radiological assessment was performed concerning pin-loosening/infection as well as fracture healing at T1 (Ø18 days), T2 (Ø44 days) and T3 (Ø65 days). In case of pintrack complication, the patient was followed continuously. The need for intensified pin-site care, oral or intravenous antibiotic medication, re-admission for additional surgery and premature fixator removal was documented. Bone mineral density (BMD) was determined by dual energy X-ray absorptiometry. At fixator removal (T2), the pin-extraction strength was measured by the use of an electronic torque wrench.</p> <p>Results: Two pin-track infections requiring daily pin-site care and oral antibiotics occurred in the HA group (2.6%) compared with four in the steel group (5.3%) (p = 0.601) and although a trend towards a superior performance of HA pins was detectable, the majority of clinical pin-site-parameters were comparable in both groups. At the end of the fixator therapy, the HA group showed a</p> | | | |
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| | | <p>non-significant lower rate of loose pins (n(steel group) = 9; n(HA group) = 6; p = 0.864) and both hydroxyapatite-coated pins showed at the radius a significantly stronger pin-bone bonding measured by the torque wrench (p(proximal radius pin) = 0.007; p(distal radius pin) = 0.031). Except for elderly patients of the steel group (p = 0.018), all demographic-, health- and injury-related data including BMD were not correlated to any type of pin-site complication in both groups (p > 0.05). Since all fracture healed uneventfully without any type of additional surgery, the number of patients suffering clinically relevant pin-related complications showed no significant difference between both groups (p = 0.707).</p> <p>Conclusions: The use of HA-coated pins compared with standard stainless-steel pins in external fixation for unstable wrist fractures yields only a trend towards a superior clinical outcome.</p> | | | |
| 14. Luwang AL, Saha PK, Rohilla M, Sikka P, Saha L, Gautam V. | Chlorhexidine-alcohol versus povidone-iodine as preoperative skin antisepsis for prevention of surgical site infection in cesarean delivery-a pilot randomized control trial. Trials. 2021 Aug 17;22(1):540. doi: 10.1186/s13063-021-05490-4. PMID: 34404473; PMCID: PMC8369632. | <p>Objectives: To compare the efficacy of chlorhexidine-alcohol and povidone-iodine as preoperative antiseptic skin preparation for prevention of surgical site infection (SSI) after cesarean delivery (CD).</p> <p>Materials and methods: A total of 311 eligible women who underwent</p> | RCT | YES | NO |

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| | | <p>CS were recruited in the study after fulfilling all the eligibility and exclusion criteria. Patients were randomized into two groups (153 in chlorhexidine-alcohol group and 158 in povidone-iodine group) by a computer-generated randomization table. Patients were followed for a period of 30 days in postoperative period to monitor for SSI.</p> <p>Results: The rate of SSI in the chlorhexidine-alcohol group is 5.4% and that of the povidone-iodine group is 8.6%. E. coli, K. pneumoniae, and Acinetobacter baumannii were the most common organisms isolated. E. coli was found in 9.5% of the total SSI cases.</p> <p>Conclusions: The study found that the patients who received chlorhexidine-alcohol as skin antiseptic had less chance of developing SSI than those who received povidone-iodine; however, it did not reach a statistical significance.</p> | | | |
| 15. Kuhn KM, Boudreau JA, Watson JT. | Rare combination of ipsilateral acetabular fracture-dislocation and pertrochanteric fracture. Am J Orthop (Belle Mead NJ). 2013 Aug;42(8):372-5. PMID: 24078956. | <p>Abstract</p> <p>Acetabular fracture-dislocations are severe injuries that require urgent closed reduction of the hip and often require surgery to restore hip stability. Other authors have described acetabular fracture-dislocations associated with femoral neck fractures, but to our knowledge, this case report is the first to</p> | Review | YES | NO |

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| | | <p>describe an acetabular fracture-dislocation in association with an ipsilateral pertrochanteric fracture and subtrochanteric extension. The polytraumatized patient initially was not stable enough for prolonged surgery. Through a 3-cm anterolateral hip incision, a 5-mm Schanz screw was introduced percutaneously into the femoral head through the primary fracture site under fluoroscopic guidance. With inline traction on the leg, the Schanz screw was used to manipulate the femoral head back into the acetabular fossa. The Schanz screw was removed, the head remained reduced, and a skeletal traction pin was placed to maintain length and alignment of the pertrochanteric fracture until definitive stabilization was possible. We propose a staged treatment strategy consisting of early closed reduction of the hip, and after the patient has been stabilized, reduction and fixation of the fractures. This strategy may be useful in managing an unstable polytraumatized patient or a patient who requires prolonged transfer to receive definitive care.</p> | | | |
| 16. Anto JM, Bousquet J, Akdis M, Auffray C, Keil T, Momas I, Postma DS, Valenta R, Wickman M, Cambon-Thomsen A, Haahtela T, Lambrecht BN, Lodrup Carlsen KC, Koppelman GH, Sunyer J, Zuberbier T, Annesi-Maesano I, Arno A, | Mechanisms of the Development of Allergy (MeDALL): Introducing novel concepts in allergy phenotypes. J Allergy Clin Immunol. 2017 Feb;139(2):388-399. doi: 10.1016/j.jaci.2016.12.940. PMID: 28183433. | Asthma, rhinitis, and eczema are complex diseases with multiple genetic and environmental factors interlinked through IgE-associated and non-IgE-associated mechanisms. | Review | YES | NO |

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| <p>Bindslev-Jensen C, De Carlo G, Forastiere F, Heinrich J, Kowalski ML, Maier D, Melén E, Smit HA, Standl M, Wright J, Asarnej A, Benet M, Ballardini N, Garcia-Aymerich J, Gehring U, Guerra S, Hohmann C, Kull I, Lupinek C, Pinart M, Skrindo I, Westman M, Smagghe D, Akdis C, Andersson N, Bachert C, Ballereau S, Ballester F, Basagana X, Bedbrook A, Bergstrom A, von Berg A, Brunekreef B, Burte E, Carlsen KH, Chatzi L, Coquet JM, Curin M, Demoly P, Eller E, Fantini MP, von Hertzen L, Hovland V, Jacquemin B, Just J, Keller T, Kiss R, Kogevinas M, Koletzko S, Lau S, Lehmann I, Lemonnier N, Mäkelä M, Mestres J, Mowinckel P, Nadif R, Nawijn MC, Pellet J, Pin I, Porta D, Rancière F, Rial-Sebbag E, Saey Y, Schuijs MJ, Siroux V, Tischer CG, Torrent M, Varraso R, Wenzel K, Xu CJ.</p> | | <p>Mechanisms of the Development of ALLergy (MeDALL; EU FP7-CP-IP; project no: 261357; 2010-2015) studied the complex links of allergic diseases at the clinical and mechanistic levels by linking epidemiologic, clinical, and mechanistic research, including in vivo and in vitro models. MeDALL integrated 14 European birth cohorts, including 44,010 participants and 160 cohort follow-ups between pregnancy and age 20 years. Thirteen thousand children were prospectively followed after puberty by using a newly standardized MeDALL Core Questionnaire. A microarray developed for allergen molecules with increased IgE sensitivity was obtained for 3,292 children. Estimates of air pollution exposure from previous studies were available for 10,000 children. Omics data included those from historical genome-wide association studies (23,000 children) and DNA methylation (2,173), targeted multiplex biomarker (1,427), and transcriptomic (723) studies. Using classical epidemiology and machine-learning methods in 16,147 children aged 4 years and 11,080 children aged 8 years, MeDALL showed the multimorbidity of eczema, rhinitis, and asthma and estimated that only 38% of multimorbidity was</p> | | | |
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| | | <p>attributable to IgE sensitization. MeDALL has proposed a new vision of multimorbidity independent of IgE sensitization, and has shown that monosensitization and polysensitization represent 2 distinct phenotypes. The translational component of MeDALL is shown by the identification of a novel allergic phenotype characterized by polysensitization and multimorbidity, which is associated with the frequency, persistence, and severity of allergic symptoms. The results of MeDALL will help integrate personalized, predictive, preventative, and participatory approaches in allergic diseases.</p> | | | |
| <p>17. Bousquet J, Schünemann HJ, Hellings PW, Arnavielhe S, Bachert C, Bedbrook A, Bergmann KC, Bosnic-Anticevich S, Brozek J, Calderon M, Canonica GW, Casale TB, Chavannes NH, Cox L, Chrystyn H, Cruz AA, Dahl R, De Carlo G, Demoly P, Devillier P, Dray G, Fletcher M, Fokkens WJ, Fonseca J, Gonzalez-Diaz SN, Grouse L, Keil T, Kuna P, Larenas-Linnemann D, Lodrup Carlsen KC, Meltzer EO, Mullol J, Muraro A, Naclerio RN, Palkonen S, Papadopoulos NG, Passalacqua G, Price D, Ryan D, Samolinski B, Scadding GK, Sheikh A, Spertini F, Valiulis A, Valovirta E, Walker S, Wickman M, Yorgancioglu A, Haahtela T, Zuberbier T; MASK study group*.</p> | <p>MACVIA clinical decision algorithm in adolescents and adults with allergic rhinitis. J Allergy Clin Immunol. 2016 Aug;138(2):367-374.e2. doi: 10.1016/j.jaci.2016.03.025. Epub 2016 Apr 23. PMID: 27260321.</p> | <p>The selection of pharmacotherapy for patients with allergic rhinitis (AR) depends on several factors, including age, prominent symptoms, symptom severity, control of AR, patient preferences, and cost. Allergen exposure and the resulting symptoms vary, and treatment adjustment is required. Clinical decision support systems (CDSSs) might be beneficial for the assessment of disease control. CDSSs should be based on the best evidence and algorithms to aid patients and health care professionals to jointly determine treatment and its step-up or step-</p> | Review | YES | NO |

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| | | down strategy depending on AR control. Contre les MALadies Chroniques pour un Vieillissement Actif en Languedoc-Roussillon (MACVIA-LR [fighting chronic diseases for active and healthy ageing]), one of the reference sites of the European Innovation Partnership on Active and Healthy Ageing, has initiated an allergy sentinel network (the MACVIA-ARIA Sentinel Network). A CDSS is currently being developed to optimize AR control. An algorithm developed by consensus is presented in this article. This algorithm should be confirmed by appropriate trials. | | | | |
| 18. | Bousquet J, Schunemann HJ, Fonseca J, Samolinski B, Bachert C, Canonica GW, Casale T, Cruz AA, Demoly P, Hellings P, Valiulis A, Wickman M, Zuberbier T, Bosnic-Anticevitch S, Bedbrook A, Bergmann KC, Caimmi D, Dahl R, Fokkens WJ, Gisle I, Lodrup Carlsen K, Mullol J, Muraro A, Palkonen S, Papadopoulos N, Passalacqua G, Ryan D, Valovirta E, Yorgancioglu A, Aberer W, Agache I, Adachi M, Akdis CA, Akdis M, Annesi-Maesano I, Ansotegui IJ, Anto JM, Arnavielhe S, Arshad H, Baiardini I, Baigenzhin AK, Barbara C, Bateman ED, Beghé B, Bel EH, Ben Kheder A, Bennoor KS, Benson M, Bewick M, Bieber T, Bindslev-Jensen C, Bjermer L, Blain H, Boner AL, Boulet LP, Bonini M, Bonini S, Bosse I, Bourret R, Bousquet PJ, Braido F, Briggs AH, Brightling CE, Brozek J, Buhl R, Burney PG, Bush A, Caballero-Fonseca | MACVIA-ARIA Sentinel NetworK for allergic rhinitis (MASK-rhinitis): the new generation guideline implementation. Allergy. 2015 Nov;70(11):1372-92. doi: 10.1111/all.12686. Epub 2015 Sep 13. PMID: 26148220. | Several unmet needs have been identified in allergic rhinitis: identification of the time of onset of the pollen season, optimal control of rhinitis and comorbidities, patient stratification, multidisciplinary team for integrated care pathways, innovation in clinical trials and, above all, patient empowerment. MASK-rhinitis (MACVIA-ARIA Sentinel NetworK for allergic rhinitis) is a simple system centred around the patient which was devised to fill many of these gaps using Information and Communications Technology (ICT) tools and a clinical decision support system (CDSS) based on the most widely used guideline in allergic rhinitis and its asthma comorbidity | Review | YES | NO |

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| <p>F, Calderon MA, Camargos PA, Camuzat T, Carlsen KH, Carr W, Cepeda Sarabia AM, Chavannes NH, Chatzi L, Chen YZ, Chiron R, Chkhartishvili E, Chuchalin AG, Ciprandi G, Cirule I, Correia de Sousa J, Cox L, Crooks G, Costa DJ, Custovic A, Dahlen SE, Darsow U, De Carlo G, De Blay F, Dedeu T, Deleanu D, Denburg JA, Devillier P, Didier A, Dinh-Xuan AT, Dokic D, Douagui H, Dray G, Dubakiene R, Durham SR, Dykewicz MS, El-Gamal Y, Emuzyte R, Fink Wagner A, Fletcher M, Fiocchi A, Forastiere F, Gamkrelidze A, Gemicioğlu B, Gereda JE, González Diaz S, Gotua M, Grouse L, Guzmán MA, Haahtela T, Hellquist-Dahl B, Heinrich J, Horak F, Hourihane JO, Howarth P, Humbert M, Hyland ME, Ivancevich JC, Jares EJ, Johnston SL, Joos G, Jonquet O, Jung KS, Just J, Kaidashev I, Kalayci O, Kalyoncu AF, Keil T, Keith PK, Khaltayev N, Klimek L, Koffi N'Goran B, Kolek V, Koppelman GH, Kowalski ML, Kull I, Kuna P, Kvedariene V, Lambrecht B, Lau S, Larenas-Linnemann D, Laune D, Le LT, Lieberman P, Lipworth B, Li J, Louis R, Magard Y, Magnan A, Mahboub B, Majer I, Makela MJ, Manning P, De Manuel Keenoy E, Marshall GD, Masjedi MR, Maurer M, Mavale-Manuel S, Melén E, Melo-Gomes E, Meltzer EO, Merk H, Miculinic N, Mihaltan F, Milenkovic B, Mohammad Y, Molimard M, Momas I, Montilla-Santana A, Morais-Almeida M, Mösges R, Namazova-Baranova L, Naclerio R, Neou A, Neffen H, Nekam K, Niggemann B, Nyembue TD, O'Hehir RE, Ohta K, Okamoto Y, Okubo K, Ouedraogo S, Paggiaro P, Pali-Schöll I, Palmer S,</p> | | <p>(ARIA 2015 revision). It is one of the implementation systems of Action Plan B3 of the European Innovation Partnership on Active and Healthy Ageing (EIP on AHA). Three tools are used for the electronic monitoring of allergic diseases: a cell phone-based daily visual analogue scale (VAS) assessment of disease control, CARAT (Control of Allergic Rhinitis and Asthma Test) and e-Allergy screening (premedical system of early diagnosis of allergy and asthma based on online tools). These tools are combined with a clinical decision support system (CDSS) and are available in many languages. An e-CRF and an e-learning tool complete MASK. MASK is flexible and other tools can be added. It appears to be an advanced, global and integrated ICT answer for many unmet needs in allergic diseases which will improve policies and standards.</p> | | | |
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| <p>Panzner P, Papi A, Park HS, Pavord I, Pawankar R, Pfaar O, Picard R, Pigearias B, Pin I, Plavec D, Pohl W, Popov TA, Portejoie F, Postma D, Potter P, Price D, Rabe KF, Raciborski F, Radier Pontal F, Repka-Ramirez S, Robalo-Cordeiro C, Rolland C, Rosado-Pinto J, Reitamo S, Rodenas F, Roman Rodriguez M, Romano A, Rosario N, Rosenwasser L, Rottem M, Sanchez-Borges M, Scadding GK, Serrano E, Schmid-Grendelmeier P, Sheikh A, Simons FE, Sisul JC, Skrindo I, Smit HA, Solé D, Sooronbaev T, Spranger O, Stelmach R, Strandberg T, Sunyer J, Thijs C, Todo-Bom A, Triggiani M, Valenta R, Valero AL, van Hage M, Vandenplas O, Vezzani G, Vichyanond P, Viegi G, Wagenmann M, Walker S, Wang DY, Wahn U, Williams DM, Wright J, Yawn BP, Yiallourous PK, Yusuf OM, Zar HJ, Zernotti ME, Zhang L, Zhong N, Zidarn M, Mercier J.</p> | | | | | |
| <p>19. Bousquet J, Anto JM, Wickman M, Keil T, Valenta R, Haahtela T, Lodrup Carlsen K, van Hage M, Akdis C, Bachert C, Akdis M, Auffray C, Annesi-Maesano I, Bindeslev-Jensen C, Cambon-Thomsen A, Carlsen KH, Chatzi L, Forastiere F, Garcia-Aymerich J, Gehrig U, Guerra S, Heinrich J, Koppelman GH, Kowalski ML, Lambrecht B, Lupinek C, Maier D, Melén E, Momas I, Palkonen S, Pinart M, Postma D, Siroux V, Smit HA, Sunyer J, Wright J, Zuberbier T, Arshad SH, Nadif R, Thijs C, Andersson N, Asarnoj A, Ballardini N, Ballereau S, Bedbrook A, Benet M, Bergstrom A, Brunekreef B, Burte E, Calderon M, De Carlo G, Demoly P, Eller E, Fantini MP, Hammad H, Hohman C,</p> | <p>Are allergic multimorbidities and IgE polysensitization associated with the persistence or re-occurrence of foetal type 2 signalling? The McDALL hypothesis. Allergy. 2015 Sep;70(9):1062-78. doi: 10.1111/all.12637. Epub 2015 Jul 14. PMID: 25913421.</p> | <p>Allergic diseases [asthma, rhinitis and atopic dermatitis (AD)] are complex. They are associated with allergen-specific IgE and nonallergic mechanisms that may coexist in the same patient. In addition, these diseases tend to cluster and patients present concomitant or consecutive diseases (multimorbidity). IgE sensitization should be considered as a quantitative trait. Important clinical and immunological differences exist between mono- and polysensitized subjects. Multimorbidities of allergic diseases share common causal mechanisms that are</p> | <p>Review</p> | <p>YES</p> | <p>NO</p> |

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| Just J, Kerkhof M, Kogevinas M, Kull I, Lau S, Lemonnier N, Mommers M, Nawijn M, Neubauer A, Oddie S, Pellet J, Pin I, Porta D, Saes Y, Skrindo I, Tischer CG, Torrent M, von Hertzen L. | | only partly IgE-mediated. Persistence of allergic diseases over time is associated with multimorbidity and/or IgE polysensitization. The importance of the family history of allergy may decrease with age. This review puts forward the hypothesis that allergic multimorbidities and IgE polysensitization are associated and related to the persistence or re-occurrence of foetal type 2 signalling. Asthma, rhinitis and AD are manifestations of a common systemic immune imbalance (mesodermal origin) with specific patterns of remodelling (ectodermal or endodermal origin). This study proposes a new classification of IgE-mediated allergic diseases that allows the definition of novel phenotypes to (i) better understand genetic and epigenetic mechanisms, (ii) better stratify allergic preschool children for prognosis and (iii) propose novel strategies of treatment and prevention. | | | |
| 20. Krappinger D, Zegg M, Smekal V, Huber B. Die Korrektur posttraumatischer Deformitäten am Unterschenkel mit dem "Taylor Spatial Frame" | [Correction of posttraumatic lower leg deformities using the Taylor Spatial Frame]. Oper Orthop Traumatol. 2014 Oct;26(5):520-31. German. doi: 10.1007/s00064-013-0233-8. PMID: 23801041. | Objective: Correction of posttraumatic lower leg deformities using percutaneous osteotomy, external fixation with a ring fixator, and computer-assisted gradual correction with the Taylor Spatial Frame (TSF). Indications: Posttraumatic lower leg deformities not suitable for acute correction and internal fixation or | Clinical trial | YES | NO |

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| | | <p>deformities that are suitable but have a significantly increased risk for complications: deformities with poor soft tissue coverage, rigid deformities that require gradual correction, complex multiplanar deformities, deformities with shortening, and periarticular juvenile deformities.</p> <p>Contraindications: Posttraumatic lower leg deformities which are suitable for acute correction and internal fixation are also suitable for deformity correction using the TSF. In these cases, however, we recommend acute correction and internal fixation in order to improve the patient comfort. Lack of patient compliance for self-contained correction and pin care.</p> <p>Surgical technique: Percutaneous fixation of the TSF rings to the main fragments using transosseous K-wires and half pins (hybrid fixation). Percutaneous osteotomy of the tibia either by drilling across both cortices and completion of the osteotomy using an osteotome (DeBastiani method) or by using the Gigli saw with preservation of the periosteal envelope. Connection of both rings with six oblique telescopic struts via universal joints (hexapod platform). Computer-assisted</p> | | | |
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| | | <p>planning of the correction.</p> <p>Postoperative management: Gradual postoperative correction of the deformity by changing the strut lengths according to the correction plan. Strut changes, if required. Osseous consolidation of the osteotomy site with the TSF or revision to internal fixation.</p> <p>Results: The correction of posttraumatic lower leg deformities using the TSF was performed in 6 cases. The mean deformity was 15° (12-22°) in the frontal plane and 6° (4-8°) in the sagittal plane. The correction time was 19 days (14-22 days). The deviation between planned and achieved correction was 0-3° in the frontal plane and 0-2° in the sagittal plane. The osseous consolidation of the osteotomy site was carried out in the TSF in 5 cases with a mean external fixation time of 112 days (94-134 days). In one case, the TSF was removed after the correction and the osteotomy site was fixed using an intramedullary nail. Pin site infections were observed in 3 cases. There were no further complications. The treatment goal was achieved in all cases. The examination at final follow-up was performed after 1 year. All patients were able to walk without walking aids and with no pain at</p> | | | |
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| | | that time. They were able to perform all of their activities of the daily life and their leisure activities without limitations. | | | |
| 21. Carella M, Tran G, Bonhomme VL, Franssen C. | Influence of Levobupivacaine Regional Scalp Block on Hemodynamic Stability, Intra- and Postoperative Opioid Consumption in Supratentorial Craniotomies: A Randomized Controlled Trial. Anesth Analg. 2021 Feb 1;132(2):500-511. doi: 10.1213/ANE.0000000000005230. PMID: 33060491. | <p>Background: The anesthetic management of supratentorial craniotomy (CR) necessitates tight intraoperative hemodynamic control. This type of surgery may also be associated with substantial postoperative pain. We aimed at evaluating the influence of regional scalp block (SB) on hemodynamic stability during the noxious events of supratentorial craniotomies and total intravenous anesthesia, its influence on intraoperative anesthetic agents' consumption, and its effect on postoperative pain control.</p> <p>Methods: Sixty patients scheduled for elective CR were prospectively enrolled. Patient, anesthesiologist, and neurosurgeon were blind to the random performance of SB with either levobupivacaine 0.33% (intervention group [group SB], n = 30) or the same volume of saline (control group [group CO], placebo group, n = 30). General anesthesia was induced and maintained using target-controlled infusions of remifentanyl and propofol that were adjusted according to hemodynamic parameters and state entropy of the electroencephalogram (SE), respectively.</p> | RCT | YES | NO |

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| | | <p>Mean arterial blood pressure (MAP), heart rate (HR), SE, and propofol and remifentanyl effect-site concentrations (Ce) were recorded at the time of scalp block performance (Baseline), and 0, 1, 3, and 5 minutes after skull-pin fixation (SP), skin incision (SI), CR, and dura-mater incision (DM). Morphine consumption and postoperative pain intensity (0-10 visual analog scale [VAS]) were recorded 1, 3, 6, 24, and 48 hours after surgery. Propofol and remifentanyl overall infusion rates were also recorded. Data were analyzed using 2-tailed Student unpaired t tests, 2-way mixed-design analysis of variance (ANOVA), and Tukey's honestly significant difference (HSD) tests for post hoc comparisons as appropriate.</p> <p>Results: Demographics and length of anesthetic procedure of group CO and SB were comparable. SP, SI, and CR were associated with a significantly higher MAP in group CO than in group SB, at least at one of the time points of recording surrounding those noxious events. This was not the case at DM. Similarly, HR was significantly higher in group CO than in group SB during SP and SI, at least at 1 of the points of recording, but not during CR and DM. Propofol and remifentanyl Ce and</p> | | | |
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| | | <p>overall infusion rates were significantly higher in group CO than in group SB, except for propofol Ce during SP. Postoperative pain VAS and cumulative morphine consumption were significantly higher in group CO than in group SB.</p> <p>Conclusions: In supratentorial craniotomies, SB improves hemodynamic control during noxious events and provides adequate and prolonged postoperative pain control as compared to placebo.</p> | | | | |
| 22. | <p>Bousquet J, Anto JM, Akdis M, Auffray C, Keil T, Momas I, Postma DS, Valenta R, Wickman M, Cambon-Thomsen A, Haahtela T, Lambrecht BN, Lodrup Carlsen KC, Koppelman GH, Sunyer J, Zuberbier T, Annesi-Maesano I, Arno A, Bindslev-Jensen C, De Carlo G, Forastiere F, Heinrich J, Kowalski ML, Maier D, Melén E, Palkonen S, Smit HA, Standl M, Wright J, Asarnoj A, Benet M, Ballardini N, Garcia-Aymerich J, Gehring U, Guerra S, Hohman C, Kull I, Lupinek C, Pinart M, Skrindo I, Westman M, Smagghe D, Akdis C, Albang R, Anastasova V, Anderson N, Bachert C, Ballereau S, Ballester F, Basagana X, Bedbrook A, Bergstrom A, von Berg A, Brunekreef B, Burte E, Carlsen KH, Chatzi L, Coquet JM, Curin M, Demoly P, Eller E, Fantini MP, Gerhard B, Hammad H, von Hertzen L, Hovland V, Jacquemin B, Just J, Keller T, Kerkhof M, Kiss R, Kogevinas M, Koletzko S, Lau S, Lehmann I,</p> | <p>Paving the way of systems biology and precision medicine in allergic diseases: the MeDALL success story: Mechanisms of the Development of ALLergy; EU FP7-CP-IP; Project No: 261357; 2010-2015. Allergy. 2016 Nov;71(11):1513-1525. doi: 10.1111/all.12880. Epub 2016 Aug 23. PMID: 26970340; PMCID: PMC5248602.</p> | <p>MeDALL (Mechanisms of the Development of ALLergy; EU FP7-CP-IP; Project No: 261357; 2010-2015) has proposed an innovative approach to develop early indicators for the prediction, diagnosis, prevention and targets for therapy. MeDALL has linked epidemiological, clinical and basic research using a stepwise, large-scale and integrative approach: MeDALL data of precisely phenotyped children followed in 14 birth cohorts spread across Europe were combined with systems biology (omics, IgE measurement using microarrays) and environmental data. Multimorbidity in the same child is more common than expected by chance alone, suggesting that these diseases share causal mechanisms irrespective of IgE</p> | Review | YES | NO |

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| <p>Lemonnier N, McEachan R, Mäkelä M, Mestres J, Minina E, Mowinckel P, Nadif R, Nawijn M, Oddie S, Pellet J, Pin I, Porta D, Rancière F, Rial-Sebbag A, Saey Y, Schuijs MJ, Siroux V, Tischer CG, Torrent M, Varraso R, De Vocht J, Wenger K, Wieser S, Xu C.</p> | | <p>sensitization. IgE sensitization should be considered differently in monosensitized and polysensitized individuals. Allergic multimorbidities and IgE polysensitization are often associated with the persistence or severity of allergic diseases. Environmental exposures are relevant for the development of allergy-related diseases. To complement the population-based studies in children, MeDALL included mechanistic experimental animal studies and in vitro studies in humans. The integration of multimorbidities and polysensitization has resulted in a new classification framework of allergic diseases that could help to improve the understanding of genetic and epigenetic mechanisms of allergy as well as to better manage allergic diseases. Ethics and gender were considered. MeDALL has deployed translational activities within the EU agenda.</p> | | | |
| <p>23. Fadel M, Ahmed MA, Al-Dars AM, Maabed MA, Shawki H.</p> | <p>Ilizarov external fixation versus plate osteosynthesis in the management of extra-articular fractures of the distal tibia. Int Orthop. 2015 Mar;39(3):513-9. doi: 10.1007/s00264-014-2607-4. Epub 2014 Dec 5. PMID: 25472753.</p> | <p>Purpose: The purpose of this study was to evaluate the outcome of Ilizarov external fixation (IE) versus dynamic compression plate (PO) in the management of extra-articular distal tibial fractures.</p> <p>Methods: Between 2010 and 2011, extra-articular distal tibial fractures in 40 consecutive patients</p> | <p>RCT</p> | <p>YES</p> | <p>NO</p> |

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| | | <p>met the inclusion criteria. They were classified according to AO classification fracture type A (A1, A2, and A3). In a randomized method, two equal groups were managed using either IE or PO. PO was performed using open reduction and internal fixation (ORIF) and DCP through anterolateral approach. IE was done using Ilizarov frame. For the PO group, non-weight bearing ambulation was permitted on the second postoperative day but partial weight bearing was permitted according to the progression in union criteria clinically and radiologically. For the IE group, weight bearing started as tolerated from the first postoperative day. Physiotherapy and pin-site care was performed by the patient themselves.</p> <p>Results: Modified Mazur ankle score was applied to IE (excellent 10, good 10) and in PO (excellent 2, good 8, poor 6). Data were statically analysed using (Mann-Whitney test). The rate of healing in the IE group (average 130) was higher than the PO (average 196.5); plus, there were no cases of delayed union or nonunion in the IE group (p value 0.003).</p> <p>Conclusion: It was found that IE compared with PO provides provision of immediate weight bearing as tolerated</p> | | | |
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| | | following postoperative recovery, irrespective of radiological or clinical healing with no infection, deformity or non-union. | | | |
| 24. Rukwied R, Mayer A, Kluschina O, Obreja O, Schley M, Schmelz M. | NGF induces non-inflammatory localized and lasting mechanical and thermal hypersensitivity in human skin. Pain. 2010 Mar;148(3):407-413. doi: 10.1016/j.pain.2009.11.022. Epub 2009 Dec 22. PMID: 20022698. | Nerve growth factor (NGF) modulates sensitivity and sprouting of nociceptors. We explored the spatial and temporal sensitization induced by NGF injection (1 microg) in human skin. Hyperalgesia was investigated in 16 volunteers (36+/-9 years) at day 1, 3, 7, 21, and 49. Areas of mechanical (brush, pin-prick) and heat (43 degrees C) sensitization were mapped and thermal (heat and cold) pain thresholds, mechanical (impact stimulation) and electrically evoked pain, and axon reflex flare were assessed. No spontaneous pain or local inflammation was recorded upon NGF injection and during 49 days. Sensitization to heat was maximum at day 3 and lasted 21 days. Hyperalgesia to cold was recorded at day 7 and 21. Hypersensitivity to mechanical impact stimuli developed delayed, reached maximum at day 21, and persisted throughout 49 days. Fifty percent of all volunteers reported a static allodynia to tonic pressure until day 21. Electrical stimulation at 7.5 mA was more painful at the NGF site at day 21, which correlated significantly to maximum impact | Clinical trial | YES | NO |

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| | | <p>pain. Axon reflex flare was unaffected by NGF. Sensitization was limited to the NGF injection site, no touch- or pin-prick evoked secondary hyperalgesia was observed. Spatially restricted hyperalgesia indicates a peripheral rather than central mechanism. The temporal profile of lasting nociceptor sensitization suggests an altered peripheral axonal expression of sensory proteins specifically leading to mechanical and thermal sensitization. Intradermal NGF administration provokes a pattern of sensitization that can be used as experimental model for neuropathic pain.</p> | | | |
| 25. Garg RK, Paliwal VK. | <p>Spectrum of neurological complications following COVID-19 vaccination. Neurol Sci. 2022 Jan;43(1):3-40. doi: 10.1007/s10072-021-05662-9. Epub 2021 Oct 31. PMID: 34719776; PMCID: PMC8557950.</p> | <p>COVID-19 vaccines have brought us a ray of hope to effectively fight against deadly pandemic of COVID-19 and hope to save lives. Many vaccines have been granted emergency use authorizations by many countries. Post-authorization, a wide spectrum of neurological complications is continuously being reported following COVID-19 vaccination. Neurological adverse events following vaccination are generally mild and transient, like fever and chills, headache, fatigue, myalgia and arthralgia, or local injection site effects like swelling, redness, or pain. The most devastating</p> | Review | YES | NO |

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| | | neurological post-vaccination complication is cerebral venous sinus thrombosis. Cerebral venous sinus is frequently reported in females of childbearing age, generally following adenovector-based vaccination. Another major neurological complication of concern is Bell's palsy that was reported dominantly following mRNA vaccine administration. Acute transverse myelitis, acute disseminated encephalomyelitis, and acute demyelinating polyneuropathy are other unexpected neurological adverse events that occur as result of phenomenon of molecular mimicry. Reactivation of herpes zoster in many persons, following administration of mRNA vaccines, has been also recorded. Considering the enormity of recent COVID-19-vaccinated population, the number of serious neurological events is miniscule. Large collaborative prospective studies are needed to prove or disprove causal association between vaccine and neurological adverse events occurring vaccination. | | | |
| 26. Georgiades DS. | A Systematic Integrative Review of Pin Site Crusts. Orthop Nurs. 2018 Jan/Feb;37(1):36-42. doi: 10.1097/NOR.0000000000000416. PMID: 29369133. | | | | |
| 27. Guerado E, Cano JR, Fernandez Sanchez F. | Pin tract infection prophylaxis and treatment. Injury. 2019 Jun;50 Suppl 1:S45-S49. doi: 10.1016/j.injury.2019.03.044. Epub 2019 Apr 1. PMID: 31003703. | Pin tract infection in external fixation (ExFix) is a frequent finding which can eventually lead to | Review | YES | YES |

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| | | loosening, osteomyelitis and loss of fixation. Its diagnosis is based on high empiricism and low validity, although it is possible to distinguish between minor and major infection. The first is limited to soft tissues, whereas the latter includes bone involvement. The rate of infection after conversion of external fixation to intramedullary nailing (IMN) is not well known. Unfortunately, papers referring to infection after the conversion of ExFix to intramedullary nailing (IMN) are of evidence level IV or V. It is suggested that conversion of ExFix to IMN should be carried out in a 2 step regimen. The time interval of 2 step regimen is uncertain although some authors have recommended to occur within 9 days. There is no consensus as to which prophylaxis protocol should be applied prior to conversion. In order to throw more light into this important issue, registries capturing important related parameters to the development of infection should be established. | | | |
| 28. Ktistakis I, Guerado E, Giannoudis PV. | Pin-site care: can we reduce the incidence of infections? Injury. 2015 Sep;46 Suppl 3:S35-9. doi: 10.1016/S0020-1383(15)30009-7. PMID: 26458298. | Background: This study was conducted to determine the pin-site care protocols currently in use and to analyse their effectiveness and outcomes. Methods: PubMed, the Cochrane Library and Embase databases were | Review | YES | YES |

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| | | <p>screened for manuscripts that described comparative studies of different methods of pin site care and referred to complications related to any kind of external fixator application.</p> <p>Results: A total of 369 manuscripts were screened and only 13 of these met the inclusion criteria evaluating different protocols of pin site care. This review is based on a total of 574 patients. Infection rates were very variable depending on the type of implant used and the protocol of pin site care applied.</p> <p>Conclusions: None of the different protocols of pin site care that were evaluated in this study were associated with a 0% infection rate. There is currently no consensus in the international literature about which protocol should be applied universally. Meticulous surgical technique during pin insertion and implementation of one of the existing protocols of pin site care are the mainstay of prevention and/or reduction of the incidence of pin site infections.</p> | | | |
| 29. Jennison T, McNally M, Pandit H. | Prevention of infection in external fixator pin sites. Acta Biomater. 2014 Feb;10(2):595-603. doi: 10.1016/j.actbio.2013.09.019. Epub 2013 Sep 26. PMID: 24076071. | Infection in external fixator pins is known to be a significant problem, with incidences between 3% and 80% reported in the literature. An infection occurs when planktonic bacteria adhere to external fixator pins and subsequently produce a | Review | YES | YES N |

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| | | <p>biofilm which protects the bacteria from host defences. The most commonly implicated organisms are Staphylococcus aureus and Staphylococcus epidermidis. Once an infection occurs, treatment is difficult. Systemic antibiotics have limited benefits and considerable side-effects. The only definitive management is removal of the pin. This review will consider the current and potential future strategies for reducing pin site infection. Techniques to prevent infection must prevent bacterial adhesion, allow good osteointegration and have a low toxicity. Current areas of interest reviewed are titanium-copper alloys, nanosilver coatings, nitric oxide coatings, chitosan coatings, chlorhexidine and iodine, hydroxyapatite and antibiotic coatings. At present there is no consensus on the prevention of pin site infection, and there is a paucity of randomized controlled trials on which to draw a conclusion. Whilst a number of these strategies have potential future use, many of the above strategies need further studies in animal models to ensure no cytotoxicity and prevention of osteointegration. Following this, well-designed randomized controlled clinical trials are required to give future ways to prevent</p> | | | |
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| | | external fixator pin site infections. | | | |
| 30. Lethaby A, Temple J, Santy-Tomlinson J. | Pin site care for preventing infections associated with external bone fixators and pins. Cochrane Database Syst Rev. 2013 Dec 3;(12):CD004551. doi: 10.1002/14651858.CD004551.pub3. PMID: 24302374. | | | | |
| 31. Yuenyongviwat V, Tangtrakulwanich B. | Prevalence of pin-site infection: the comparison between silver sulfadiazine and dry dressing among open tibial fracture patients. J Med Assoc Thai. 2011 May;94(5):566-9. PMID: 21675445. | <p>Objective: Pin-site infection is one of the most troublesome complications of external fixation. The present study aimed to compare the rate of pin-site infection following silver sulfadiazine with dry dressing.</p> <p>Material and method: This was a prospective randomized controlled study among 30 clients that compared the outcome of pin dressing using silver sulfadiazine (study group = 15) with dry dressing (control = 15). All eligible subjects of open tibial fracture had an emergency debridement with external fixation. Pin tract infection was considered to be present if superficial inflammation (erythema, cellulitis), serous or purulent discharge occurred around a pin site and deep infection of osteolysis around the pin, and sequestrum.</p> <p>Results: Seven subjects (46.7%) had pin-site infection in the present study group while six subjects (40.0%) had it in the control group, with comparable severity.</p> <p>Conclusion: There was no significant difference in prevalence</p> | RCT | YES | YES N |

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| | | of pin-site infection between both groups ($p = 0.97$). Therefore, either silver sulfadiazine or dry dressing could be advocated. | | | |
| 32. Lu D, Wang T, Chen H, Sun H. | Management of pin tract infection in pediatric supracondylar humerus fractures: a comparative study of three methods. Eur J Pediatr. 2017 May;176(5):615-620. doi: 10.1007/s00431-017-2884-1. Epub 2017 Mar 1. PMID: 28251295. | The objective of this study was to prospectively compare the incidence of pin tract infection in pediatric supracondylar humerus fractures managed with pin care daily or every other day or weekly. We hypothesized that there were some differences between these three methods. From June 2012 to May 2015, 135 children with supracondylar humerus fractures were randomized to postoperative pin care by cleaning pin tracts daily (group A, 45 cases) or cleaning every 2 days (group B, 45 cases) or cleaning weekly (group C, 45 cases). The three groups were comparable with respect to age, gender, affected side, body mass index (BMI), fracture type, injury to surgery time, number of intraoperative percutaneous pinning, and follow-up time. We collected data on pin retention time, union time, and pin tract infection. The average follow-up time of group A was 4.5 ± 1.3 and 4.2 ± 1.6 months in group B and 4.3 ± 1.4 months in group C. The patient demographics and intraoperative variables of three groups were comparable. No significant difference between these three | RCT | YES | YES |

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| | | <p>groups was found in union time and pin fixation time. Of the 135 children, 48 (35.6%) cases had pin tract infection. Grade I infections (Cheeketts-Otterburns classification) occurred around 28.9% of 270 pin and grade II around 6.7%. We found no differences between three groups as regards frequency and severity of pin tract infections (both $P > 0.05$). However, complain of pain was more frequent in group A than other two groups ($P < 0.05$).</p> <p>Conclusions: All of the three methods were effective for the management of pin site infection in pediatric supracondylar humerus fractures. However, excessive frequent care as well as pin care daily had the disadvantages of child's fear and parental anxiety. What is Known: • Pin site infection is a common complication after fracture fixation and bone lengthening using percutaneous pins or wires. • Closed reduction and percutaneous K-wires fixation are the mainstay of treatment in pediatric supracondylar humeral fractures. What is New: • All of the three methods were effective for the management of pin site infection. • Excessive frequent care as well as pin care daily has the disadvantages of child's fear and parental anxiety.</p> | | | |
| 33. Lee CK, Chua YP, Saw A. | Antimicrobial gauze as a dressing reduces pin site infection: a | Background: Pin site infection is a common | RCT | YES | YES N |

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| | <p>randomized controlled trial. Clin Orthop Relat Res. 2012 Feb;470(2):610-5. doi: 10.1007/s11999-011-1990-z. Epub 2011 Aug 13. PMID: 21842299; PMCID: PMC3254747.</p> | <p>problem in external fixation. Plain gauze wetted with normal saline is commonly used for a pin site dressing owing to the simplicity and low cost. Evidence to support adding an antimicrobial agent in the dressing material is lacking.</p> <p>Questions/purposes: We compared the rate of pin tract infection using plain gauze and gauze impregnated with polyhexamethylene biguanide in patients undergoing limb lengthening procedures.</p> <p>Patients and methods: We included 38 patients (40 limbs) undergoing limb lengthening or deformity correction using an external fixator between July 2009 and June 2010. There were 23 male patients and 15 female patients, with a mean age of 26.3 years (range, 5-68 years). The patients were randomized into two groups: a polyhexamethylene biguanide group (22 limbs) and a control group (18 limbs). The metal-skin interfaces were assessed by a researcher blinded to the type of gauze at 2, 4, 8, and 12 weeks after surgery for the pin site infection based on a predetermined grading system. There were a total of 483 metal-skin interfaces, with 1932 total observations. Infection rates were compared using the chi square test and relative risk with 95% confidence interval.</p> | | | |
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| | | <p>Results: The infection rate was lower (χ^2 [1, n = 1932] = 23.00) and the risk for infection was lower (relative risk, 0.228; 95% confidence interval, 0.118, 0.443) for the polyhexamethylene biguanide group (n = 1068; 1.0%) than for the control group (n = 864; 4.5%).</p> <p>Conclusions: Use of polyhexamethylene biguanide-impregnated gauze can reduce the risk of pin tract infection in external fixation.</p> <p>Level of evidence: Level I, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.</p> | | | |
| 34. Subramanyam KN, Mundargi AV, Potarlanka R, Khanchandani P. | No role for antiseptics in routine pin site care in Ilizarov fixators: A randomised prospective single-blinded control study. Injury. 2019 Mar;50(3):770-776. doi: 10.1016/j.injury.2019.01.031. Epub 2019 Jan 23. PMID: 30711321. | <p>Introduction: Pin site infection is the commonest complication of Ilizarov external fixation. The aim of the study was to examine if use of antiseptics was superior over control and further if daily dressing was superior to weekly dressing in regular pin site care in reducing the burden of pin site infection in Ilizarov fixators.</p> <p>Patients and methods: A total of 114 patients (2363 pin sites) were randomised to receive regular pin site care alone (30 patients, 638 pin sites) or with additional application of povidone iodine (27 patients, 561 pin sites), silver sulfadiazine (27 patients, 570 pin sites) and chlorhexidine (30</p> | RCT | YES | YES |

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| | | <p>patients, 594 pin sites). The pin tracts were sub-randomised to receive daily (1212 pin sites) or weekly (1151 pin sites) dressings. The primary outcome was pin site infection days rate across all four groups. The secondary outcomes were mean duration to first episode of infection, differences between daily and weekly dressing groups, mean duration of antibiotic therapy and incidence of re-interventions and sequelae. We also recorded frequency of bacterial pathogens in all microbiological samples submitted. Block randomization using computer-generated random numbers was used. The assessor of outcome was blinded.</p> <p>Results: All patients completed the study. Pin site infection rate days per 1000 pin site days observed was marginally less in chlorhexidine group, but was not statistically significant compared to other antiseptics and control group (Absolute value in control, povidone iodine, silver sulphadiazine and chlorhexidine groups were respectively 2.04 ± 4.27, 2.04 ± 3.65, 1.85 ± 3.37, 1.37 ± 2.35, p value 0.92). Daily dressing category showed slightly less pin site infection days rate within each group and overall, but this was also not statistically significant (1.56 ± 3.99 versus 2.10 ± 5.1, p</p> | | | |
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| | | <p>value 0.35). There was no statistically significant difference among the groups with regard to other secondary outcomes. Methicillin Sensitive Staphylococcus aureus was the most common bacterial pathogen isolated.</p> <p>Conclusion: Use of antiseptics does not offer any advantage in regular pin site care in Hizarov external fixation and daily pin site care is not superior to weekly pin site care. Empirical therapy in early and low grade pin site infections must be targeted against Staphylococcus.</p> | | | |
| 35. Ogbemudia AO, Bafor A, Edomwonyi E, Enemudo R. | Prevalence of pin tract infection: the role of combined silver sulphadiazine and chlorhexidine dressing. Niger J Clin Pract. 2010 Sep;13(3):268-71. PMID: 20857782. | <p>Objective: Infection at the pin tract is a common complication of external fixation. This study was done to compare the rate of pin site infection following combined 1% silver sulphadiazine and 5 % chlorbexidine dressing with 5% chlorhexidine dressing alone.</p> <p>Method: This was a prospective controlled study which compared the results of pin site dressing using a combination of chlorhexidine and silver sulphadiazine cream (Study group) with dressing using chlorhexidine alone. Eligible patients had external fixation in the treatment of open fractures or orthopaedic conditions. Pin-tract infection was deemed to be present if erythema, cellulitis or purulent discharge occurred around a pin</p> | RCT | YES | YES N |

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| | | <p>site. We did not distinguish between deep and superficial infection.</p> <p>Results: The study group had one hundred and seventy pin sites while the control group had one hundred and sixty-four pin sites. Thirty-eight patients, in whom thirty-seven uniplanar external fixators and one Ilizarov ring fixator were used, made up both groups. Three patients (7.9%) had pin tract infection in the study group while nine patients (23.7%) had pin tract infection in the control group.</p> <p>Conclusion: There was a significantly lower prevalence of pin-tract infection amongst patients whose external fixation pins were dressed with 1% silver sulphadiazine and 5% chlorhexidine than in those dressed with chlorhexidine alone ($P = 0.03$). Therefore, we advocate the use of a combination of silver sulphadiazine and chlorhexidine for pin site dressing.</p> | | | |
| 36. Sáenz-Jalón M, Sarabia-Cobo CM, Roscales Bartolomé E, Santiago Fernández M, Vélez B, Escudero M, Miguel ME, Artabe P, Cabañas I, Fernández A, Garcés C, Couceiro J. | A Randomized Clinical Trial on the Use of Antiseptic Solutions for the Pin Site Care of External Fixators: Chlorhexidine Alcohol Versus Povidone-Iodine. J Trauma Nurs. 2020 May/Jun;27(3):146-150. doi: 10.1097/JTN.0000000000000503. PMID: 32371731. | Pin-site infections remain a common clinical complication in patients with external fixators. Pin-site care is commonly performed with either chlorhexidine-alcohol solution or povidone-iodine solution. This study aimed to investigate the superiority of chlorhexidine-alcohol solution versus povidone iodine solution for external | RCT | YES | YES |

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| | | <p>fixator pin site care in pin-site infection. This prospective randomized clinical trial using an open, parallel-group design was conducted in a single Spanish hospital. Eligible consenting patients from November 2018 to May 2019 who underwent placement of an external fixator were included. Patients were randomly assigned to receive pin-site care using either a 2% chlorhexidine alcohol solution or a 10% povidone-iodine solution. The primary endpoint was the development of a pin-site infection. In total, 568 pins were analyzed (128 patients, with a mean of 4.3 pins per patient). No significant differences were found between groups. However, statistically significant differences were found regarding time and infection variables. The longer the person had the fixator, the higher the risk of infection, $t(x) = 5.49$, $p = .002$. Both chlorhexidine alcohol and povidone iodine solutions are equally effective antiseptic agents for the prevention of infections in external fixators.</p> | | | |
| 37. Kim YH, Yoon SH, Park JW. | <p>Does Robotic-assisted TKA Result in Better Outcome Scores or Long-Term Survivorship Than Conventional TKA? A Randomized, Controlled Trial. Clin Orthop Relat Res. 2020 Feb;478(2):266-275. doi: 10.1097/CORR.0000000000000916. Erratum in: Clin Orthop Relat Res. 2021 Jun 1;479(6):1407. PMID: 31389889; PMCID: PMC7438149.</p> | <p>Background: Robotic-assisted TKA was introduced to enhance the precision of bone preparation and component alignment with the goal of improving the clinical results and survivorship of TKA. Although numerous reports</p> | RCT | YES | NO |

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| | | <p>suggest that bone preparation and knee component alignment may be improved using robotic assistance, no long-term randomized trials of robotic-assisted TKA have shown whether this results in improved clinical function or survivorship of the TKA.</p> <p>Questions/purposes: In this randomized trial, we compared robotic-assisted TKA to manual-alignment techniques at long-term follow-up in terms of (1) functional results based on Knee Society, WOMAC, and UCLA Activity scores; (2) numerous radiographic parameters, including component and limb alignment; (3) Kaplan-Meier survivorship; and (4) complications specific to robotic-assistance, including pin-tract infection, peroneal nerve palsy, pin-site fracture, or patellar complications.</p> <p>Methods: This study was a registered prospective, randomized, controlled trial. From January 2002 to February 2008, one surgeon performed 975 robotic-assisted TKAs in 850 patients and 990 conventional TKAs in 849 patients. Among these patients 1406 patients were eligible for participation in this study based on prespecified inclusion criteria. Of those, 100% (1406) patients agreed to participate and were randomized, with 700 patients (750 knees)</p> | | | |
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| | | <p>receiving robotic-assisted TKA and 706 patients (766 knees) receiving conventional TKA. Of those, 96% (674 patients) in the robotic-assisted TKA group and 95% (674 patients) in the conventional TKA group were available for follow-up at a mean of 13 (\pm 5) years. In both groups, no patient older than 65 years was randomized because we anticipated long-term follow-up. We evaluated 674 patients (724 knees) in each group for clinical and radiographic outcomes, and we examined Kaplan-Meier survivorship for the endpoint of aseptic loosening or revision. Clinical evaluation was performed using the original Knee Society knee score, the WOMAC score, and the UCLA activity score preoperatively and at latest follow-up visit. We also assessed loosening (defined as change in the position of the components) using plain radiographs, osteolysis using CT scans at the latest follow-up visit, and component, and limb alignment on mechanical axis radiographs. To minimize the chance of type-2 error and increase the power of our study, we assumed the difference in the Knee Society score to be 25 points to match the MCID of the Knee Society score with a SD of 5; to be able to detect a difference of this size, we calculated that a</p> | | | |
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| | | <p>total of 628 patients would be needed in each group in order to achieve 80% power at the $\alpha = 0.05$ level.</p> <p>Results: Clinical parameters at the latest follow-up including the Knee Society knee scores (93 ± 5 points in the robotic-assisted TKA group versus 92 ± 6 points in the conventional TKA group [95% confidence interval 90 to 98]; $p = 0.321$) and Knee Society knee function scores (83 ± 7 points in the robotic-assisted TKA group versus 85 ± 6 points in the conventional TKA group [95% CI 75 to 88]; $p = 0.992$), WOMAC scores (18 ± 14 points in the robotic-assisted TKA group versus 19 ± 15 points in the conventional TKA group [95% CI 16 to 22]; $p = 0.981$), range of knee motion ($125 \pm 6^\circ$ in the robotic-assisted TKA group versus $128 \pm 7^\circ$ in the conventional TKA group [95% CI 121 to 135]; $p = 0.321$), and UCLA patient activity scores (7 points versus 7 points in each group [95% CI 5 to 10]; $p = 1.000$) were not different between the two groups at a mean of 13 years' follow-up. Radiographic parameters such as the femorotibial angle (mean $2^\circ \pm 2^\circ$ valgus in the robotic-assisted TKA group versus $3^\circ \pm 3^\circ$ valgus in the conventional TKA group [95% CI 1 to 5]; $p = 0.897$), femoral</p> | | | |
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| | | <p>component position (coronal plane: mean 98° in the robotic-assisted TKA group versus 97° in the conventional TKA group [95% CI 96 to 99]; $p = 0.953$; sagittal plane: mean 3° in the robotic-assisted TKA group versus 2° in the conventional TKA group [95% CI 1 to 4]; $p = 0.612$) and tibial component position (coronal plane: mean 90° in the robotic-assisted TKA group versus 89° in the conventional TKA group [95% CI 87 to 92]; $p = 0.721$; sagittal plane: 87° in the robotic-assisted TKA group versus 86° in the conventional TKA group [95% CI 84 to 89]; $p = 0.792$), joint line (16 mm in the robotic-assisted TKA group versus 16 mm in the conventional TKA group [95% CI 14 to 18]; $p = 0.512$), and posterior femoral condylar offset (24 mm in the robotic-assisted TKA group versus 24 mm in the conventional TKA group [95% CI 21 to 27]; $p = 0.817$) also were not different between the two groups ($p > 0.05$). The aseptic loosening rate was 2% in each group, and this was not different between the two groups. With the endpoint of revision or aseptic loosening of the components, Kaplan-Meier survivorship of the TKA components was 98% in both groups (95% CI 94 to 100) at 15 years ($p = 0.972$). There were</p> | | | |
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| 38. Luwang AL, Saha PK, Rohilla M, Sikka P, Saha L, Gautam V. | Chlorhexidine alcohol versus povidone-iodine as preoperative skin antisepsis for prevention of surgical site infection in cesarean delivery: a pilot randomized control trial. Trials. 2021 Aug 17;22(1):540. doi: 10.1186/s13063-021-05490-4. PMID: 34404473; PMCID: PMC8369632. | <p>Objectives: To compare the efficacy of chlorhexidine alcohol and povidone-iodine as preoperative antiseptic skin preparation for prevention of surgical site infection (SSI) after cesarean delivery (CD).</p> <p>Materials and methods: A total of 311 eligible women who underwent CS were recruited in the study after fulfilling all the eligibility and exclusion criteria. Patients were randomized into two groups (153 in chlorhexidine alcohol group and 158 in povidone-iodine group) by a computer-generated randomization table. Patients were followed for a period of 30 days in postoperative period to monitor for SSI.</p> <p>Results: The rate of SSI in the chlorhexidine alcohol group is 5.4% and that of the povidone-iodine group is 8.6%. E. coli, K. pneumoniae, and Acinetobacter baumannii were the most common organisms isolated. E. coli was found in 9.5% of the total SSI cases.</p> <p>Conclusions: The study found that the patients who received chlorhexidine alcohol as skin antiseptic had less chance of developing SSI than those who received povidone-iodine; however, it did not reach a statistical significance.</p> | RCT | YES | NO |
| 39. Ferguson D, Harwood P, Algar V, Roy A, Foster P, | The PINS Trial: a prospective randomized clinical trial comparing a | <p>Aims: Pin site infection remains a significant</p> | RCT | YES | YES |

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| <p>Taylor M, Moulder E, Sharma H.</p> | <p>traditional versus an emollient skincare regimen for the care of pin-sites in patients with circular frames. Bone Joint J. 2021 Feb;103-B(2):279-285. doi: 10.1302/0301-620X.103B2.BJJ-2020-0680.R1. PMID: 33517738.</p> | <p>problem for patients treated by external fixation. A randomized trial was undertaken to compare the weekly use of alcoholic chlorhexidine (CHX) for pin-site care with an emollient skin preparation in patients with a tibial fracture treated with a circular frame.</p> <p>Methods: Patients were randomized to use either 0.5% CHX or Dermol (DML) 500 emollient pin site care. A skin biopsy was taken from the tibia during surgery to measure the dermal and epidermal thickness and capillary, macrophage, and T-cell counts per high-powered field. The pH and hydration of the skin were measured preoperatively, at follow up, and if pin-site infection occurred. Pin-site infection was defined using a validated clinical system.</p> <p>Results: Out of 116 patients who were enrolled in the study, 23 patients (40%) in the CHX group and 26 (44%) in the DML group had at least one bad or ugly pin-site infection. This difference was not statistically significant ($p = 0.71$). There was no significant relationship between pH or hydration of the skin and pin-site infection. The epidermal thickness was found to be significantly greater in patients who had a pin-site infection compared</p> | | | |
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| | | <p>with those who did not ($p = 0.01$). Skin irritation requiring a change of treatment occurred in four patients (7%) using CHX, and none using DML.</p> <p>Conclusion: We found no significant difference in the incidence of pin-site infection between the CHX and DML treatment groups. Dermol appeared to offer a small but significant advantage in terms of tolerability. We did not find a significant association between patient or treatment-related factors and pin-site infection. It is therefore difficult to make specific recommendations based upon these results. The use of either cleaning agent appears to be appropriate. Cite this article: Bone Joint J 2021;103-B(2):279-285.</p> | | | |
| 40. Sidhu VS, Cheng TL, Lillia J, Bridge C, Little DG, Gray RJ. | 3D printed models can guide safe halo pin placement in patients with diastrophic dysplasia. Spine Deform. 2021 May;9(3):841-849. doi: 10.1007/s43390-020-00269-0. Epub 2021 Jan 19. PMID: 33464553. | <p>Purpose: To trial the use of three-dimensional (3D) printed skull models to guide safe pin placement in two patients with diastrophic dysplasia (DTD) requiring prolonged pre-fusion halo-gravity traction (HGT).</p> <p>Methods: Two sisters aged 8 (ML) and 4 (BL) with DTD were planned for staged fusion for progressive kyphoscoliosis. Both sisters were admitted for pre-fusion HGT. Models of their skulls were generated from</p> | Clinical Trial | YES | NO |

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| | | <p>computer tomography (CT) scans using Mimics Innovation Suite and printed on a Guider II in polylactic acid. The 3D models were cut axially proximal to the skull equator, in-line where pins are usually inserted, allowing identification of the thickest skull portion to guide pin placement.</p> <p>Results: Eight pins were inserted into each patient's skull. Postoperative CT scans demonstrated adequate pin position. Pre-traction Cobb angles were 122° and 128° for ML and BL, improving to 83° and 86° following traction. Duration of HGT was 182 and 238 days for ML and BL. Prior to fusion, both patients returned to theatre twice for exchange of loose pins and there was one incidence of pin site infection. Surgery was performed via a posterior instrumented fusion. Postoperatively, both patients remained in their halos for 3 months. One pin in BL was removed for loosening. Both patients achieved fusion union by 9 months.</p> <p>Conclusion: 3D models of the skull can be a useful tool to guide safe pin placement in patients with skeletal dysplasias, who require prolonged pre-fusion HGT for severe deformity correction.</p> | | | |
| 41. Bhattacharjee S, Chattaraj S. | Entry, infection, replication, and egress of human polyomaviruses: an update. | Polyomaviruses (PyVs), belonging to the family | Review | YES | NO |

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| | <p>Can J Microbiol. 2017 Mar;63(3):193-211. doi: 10.1139/cjm-2016-0519. Epub 2016 Oct 29. PMID: 28177804.</p> | <p>Polyomaviridae, are a group of small, nonenveloped, double-stranded, circular DNA viruses widely distributed in the vertebrates. PyVs cause no apparent disease in adult laboratory mice but cause a wide variety of tumors when artificially inoculated into neonates or semipermissive animals. A few human PyVs, such as BK, JC, and Merkel cell PyVs, have been unequivocally linked to pathogenesis under conditions of immunosuppression. Infection is thought to occur early in life and persists for the lifespan of the host. Over evolutionary time scales, it appears that PyVs have slowly co-evolved with specific host animal lineages. Host cell surface glycoproteins and glycolipids seem to play a decisive role in the entry stage of viral infection and in channeling the virions +to specific intracellular membrane-bound compartments and ultimately to the nucleus, where the genomes are replicated and packaged for release. Therefore the transport of the infecting virion or viral genome to this site of multiplication is an essential process in productive viral infection as well as in latent infection and transformation. This review summarizes the major findings related to the characterization</p> | | | |
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| | | of the nature of the interactions between PyV and host protein and their impact in host cell invasion. | | | |
| 42. Myatt A, Saleeb H, Robertson GAJ, Bourhill JK, Page PRJ, Wood AM. | Management of Gustilo-Anderson IIIB open tibial fractures in adults-a systematic review. Br Med Bull. 2021 Sep 10;139(1):48-58. doi: 10.1093/bmb/ldab013. PMID: 34227647. | <p>Introduction: Open tibial fractures are the most common open long bone fracture, despite this, the management of these complex injuries still remains a topic of discussion amongst orthopaedic surgeons.</p> <p>Sources of data: We searched the EMBASE, MEDLINE and Google Scholar and a systematic review of 7500 articles, leaving 23 after exclusion criteria were applied, in order to analyse the management of open tibial fractures.</p> <p>Areas of agreement and controversy: Infection was noted to be the most significant concern amongst authors, with definitive external fixation having a high rate of superficial pin-site infection and internal fixation having a high deep infection rate.</p> <p>Growing points: It is essential to have a combined ortho-plastic approach to the management of these fractures as muscle flaps were the most common form of soft tissue coverage.</p> <p>Areas timely for developing research: A national pragmatic trial into the management of open tibial fractures is required looking at fixation methods and soft tissue coverage,</p> | Systematic review | YES | NO |

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| | | with at least a 2-year follow-up in order to ascertain the most appropriate management of these fractures and patient-related outcomes. | | | |
| 43. Lee C, Sciadini M. | The Use of External Fixation for the Management of the Unstable Anterior Pelvic Ring. J Orthop Trauma. 2018 Sep;32 Suppl 6:S14-S17. doi: 10.1097/BOT.0000000000001251. PMID: 30095676. | The objective of this article was to highlight the indications and various methods of external fixation for management of the unstable anterior pelvic ring. Although most often used temporarily in the setting of significant hemorrhage from a pelvic ring fracture, external fixation remains an option for definitive stabilization of select pelvic ring injuries. Classically, the iliac crest frame has been used, although use of the supra-acetabular frame has gained favor due to its superior bone purchase and improved biomechanics. Common complications from external fixation include pin site infections, loss of reduction, and the "external fixator deformity." | Review | YES | NO |
| 44. Stewart RG, Hammer N, Kieser DC. | External fixation of unstable pelvic fractures: a systematic review and meta-analysis. ANZ J Surg. 2019 Sep;89(9):1022-1027. doi: 10.1111/ans.15027. Epub 2019 Feb 12. PMID: 30756458. | Background: Unstable pelvic fractures are typically caused by high-impact trauma. Early stabilization is required to prevent further neurological or visceral injury, haemorrhage, reduce pain, infection and long-term deformity and disability. The aim was to review the optimal external fixation techniques and management for unstable pelvic fractures. | Meta-Analysis | YES | NO |

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| | | <p>Methods: A total of 28 studies were identified from the initial database search. Seventeen studies met our inclusion criteria - eight prospective cohorts, four retrospective cohorts and five in vitro studies. This equated to 539 patients and 38 cadaveric (in vitro) models.</p> <p>Results: Type B and double vertical fractures have less re-displacement (43.7% and 68.2% <5 mm, respectively) than Type C fractures (55.7% >15 mm) regardless of pin placement. Greater than 50% experience a complication with the most common being pin site infection (36%) and a trend towards increased infection with increasing pins was seen. Most can be managed with antibiotics alone (93%). A minimum time of 6-8 weeks in frame was required for definitive management of all fractures.</p> <p>Conclusion: This review supports the use of supra-acetabular pins over iliac crest pins to decrease re-displacement, the least number of pins for the shortest amount of time and the largest size pin where possible. Type B fractures will generally have a better outcome than Type C fractures. Definitive management in a frame should be at least 8 weeks. Further studies directly comparing iliac crest and supra-acetabular pin</p> | | | |
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| | | placement are recommended. | | | |
| 45. Sason KD, Sponseller PD, Gearhart JP. | Bony abnormalities in classic bladder exstrophy: the urologist's perspective. J Pediatr Urol. 2013 Apr;9(2):112-22. doi: 10.1016/j.jpurol.2011.08.007. Epub 2011 Nov 21. PMID: 22105005. | <p>Introduction: As the primary practitioner managing patients with classic bladder exstrophy (CBE), it is incumbent upon the pediatric urologist to understand the associated orthopedic anomalies and their management.</p> <p>Methods: A Pubmed search was performed with the keyword exstrophy. Resulting literature pertaining to orthopedics and published references were reviewed.</p> <p>Results: Anatomic changes to the bony pelvis include outward rotation, acetabular retroversion with compensatory femoral anteversion, anterior pubic shortening, and pubic diastasis. Imaging options have improved, which impacts surgical planning. Surgical approach, including type of osteotomy and method of pubic approximation, is evolving. Most centers employ immobilization after surgery, with external fixation, Bryant's traction, Buck's traction, and spica casting being the most common methods. Orthopedic complications range from minor pin-site infections to neurologic and vascular compromise. Most experts agree osteotomy aids bladder closure beyond 72 h of life, but effect on continence remains controversial. Although</p> | Review | YES | NO |

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| | | <p>no significant orthopedic benefit has been expounded, it may be too early to appreciate improvement in frequency or severity of osteoarthritis or hip dysplasia.</p> <p>Conclusion: While orthopedic surgeons remain vital to managing exstrophy patients, knowledge of the anatomy, imaging, surgical approaches, and immobilization enable effective communication with parents and other physicians, improving care for these complicated patients.</p> | | | |
| 46. Camathias C, Valderrabano V, Oberli H. | <p>Routine pin tract care in external fixation is unnecessary: a randomised, prospective, blinded controlled study. Injury. 2012 Nov;43(11):1969-73. doi: 10.1016/j.injury.2012.08.010. Epub 2012 Aug 16. PMID: 22901422.</p> | <p>Introduction: Pin site infections are seen in up to 40% of external fixators (ExFix) and are therefore the most common complication with this device. There is no consensus in the literature as to the appropriate regimen for pin tract care and infection prevention. This study is the first intra-subject, randomised, prospective controlled trial comparing daily pin tract care to no pin tract care at all.</p> <p>Method: Consecutive patients series (56 patients, 16 female, age 4-68 y, mean 24 y, in total 204 pins) recruited in the National Referral Hospital in Honiara in the Solomon Islands over a 2 year period. Exclusion criteria were application of ExFix for less than two weeks or a non-standard ExFix. Pin treatment was allocated into</p> | RCT | YES | YES |

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| | | <p>groups— anatomically, proximal and distal. Randomisation was intra-subject and intra-group: 101 pins had daily pin site care and 103 had no treatment at all.</p> <p>Endpoints: Soft-tissue interface, stability of the pins, torsional stability as determined with a torque metre, osteolysis and pain. Assessment of pin sites blinded. Statistical analysis using the paired t test for parametric data and the Wilcoxon rank test for non-parametric data (Stat View).</p> <p>Results: No significant difference between the two groups. Soft tissue interface 36% vs. 35% (granulation/secretion), stability 20 vs 25 pins with loosening. No significant osteolysis (7 vs. 6 pins). Torque: mean 0.75 Nm, max.: 3.05 Nm vs. 0.60 Nm, max.: 3.55 Nm, no significant difference. No differences in demographics (age, localisation, sex, time of fixation).</p> <p>Conclusion: This study shows that routine pin tract care is unnecessary in external fixation treatment of injuries.</p> | | | |
| 47. Vrouwe SQ, Pham CH, Gillenwater TJ, Yenikomshian HA. | Techniques for Patient Positioning During Burn Surgery: A Systematic Review. Ann Plast Surg. 2020 Jul;85(1):24-28. doi: 10.1097/SAP.0000000000002193. PMID: 31913885. | <p>Introduction: Patient positioning in the operating room remains a challenge for burn surgeons; burn surgery involves critically ill patients who require close monitoring, difficult exposures, and careful handling of grafted areas. Various techniques to optimize</p> | Systematic Review | YES | NO |

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| | | <p>intraoperative positioning during burn surgery have been described in the literature. The aim of this review was to outline these positioning techniques and report on their complications.</p> <p>Methods: A systematic review was performed by 2 independent reviewers using PubMed, Scopus, and OvidSP MEDLINE databases. Articles were included if they described intraoperative techniques to position patients undergoing burn surgery. The primary variable of interest was complications related to positioning during surgery.</p> <p>Results: The search identified 1855 nonduplicate citations, of which 29 underwent full-text review, and 10 met inclusion criteria. Three studies described overhead suspension techniques, including a hook-and-pulley system, ceiling chains, weighted IV poles, and mounted crossbars; no complications were reported. Six studies described limb fixation techniques, including Steinmann pins, finger traps, wrist/ankle wraps, towel clips through eschar or distal phalanges, and external fixators. Complications included one case of hardware failure of external fixation and several pin site infections. Four studies described table</p> | | | |
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| | | <p>modification techniques, including a modified Stryker frame, a fracture table, the Mayfield headrest, and the recliner position; no complications were reported.</p> <p>Discussion: Numerous techniques have been described to improve patient positioning during burn surgery. No major complications were identified in this systematic review. Most techniques use standard operating room equipment and can aid in safe and easier operations.</p> | | | |
| 48. Pieske O, Pichlmaier L, Kaltenhauser F, Schramm N, Rubenbauer B, Greiner A, Piltz S. | Hydroxyapatite-coated pins versus titanium alloy pins in external fixation at the wrist: a controlled cohort study. J Trauma. 2011 Apr;70(4):845-51. doi: 10.1097/TA.0b013e3181e97761. PMID: 20805762. | <p>Background: The purpose of this study was to analyze whether the prevalence of pin-related complications can be reduced by the use of hydroxyapatite (HA)-coated pins in external fixators applied for unstable wrist fractures.</p> <p>Methods: Forty patients (160 pins) were randomized for standard uniplanar fixator treatment with the use of identically designed pins either composed of titanium-alloy (Ti6Al4V) (n = 20) or coated by HA (n = 20). Each pin site was clinically evaluated with regard to erythema, drainage, pain value, and radiologically assessed concerning loosening at T1 (mean, 9 days), T2 (mean, 43 days), and T3 (mean, 56 days). In case of pin-track complication, the patient was followed continuously. The need for antibiotics or</p> | RCT | YES | NO |

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| | | <p>additional surgery was documented. Bone mineral density was analyzed by Dual Energy X-ray Absorptiometry. At fixator removal (T2), the pin-extraction strength was measured by the use of a digital-torque-wrench.</p> <p>Results: Two minor pin-track infections requiring oral antibiotics occurred in the HA-pin group (2.7%) ($p > 0.05$). The vast majority of clinical pin-site parameters were comparable in both groups. At the end of the fixator therapy, there were 16 loose pins ($n(\text{Ti6AL4V-group}) = 10$; $n(\text{HA-group}) = 6$). The rate of loose pins was correlated to patient's age ($p < 0.05$) but not to bone mineral density values or the occurrence of pin-site infection. Finally, no significant difference between the two groups was detected with regard to the prevalence of clinical relevant pin-site complications ($p = 0.80$).</p> <p>Conclusions: In external fixation of the wrist, the use of HA-coated pins yields no clinical advantages: there is a trend toward a superior pin-bone anchorage, but a tendency of increased susceptibility for minor pin-track infections.</p> | | | |
| 49. Takahashi T, Baboolal TG, Lamb J, Hamilton TW, Pandit HG. | Is Knee Joint Distraction a Viable Treatment Option for Knee OA?-A Literature Review and Meta-Analysis. J Knee Surg. 2019 Aug;32(8):788-795. doi: 10.1055/s-0038-1669447. Epub 2018 Aug 29. PMID: 30157528. | Knee joint distraction (KJD) is a new application of an established technique to regenerate native cartilage using an external fixator. The | Review | YES | NO |

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| | | <p>purpose of this study is to perform a systematic review and meta-analysis of the literature to determine whether KJD is beneficial for knee osteoarthritis and how results compare with established treatments. Studies assessing the outcomes of KJD were retrieved, with three studies (one cohort and two randomized controlled trials), 62 knees, meeting the inclusion criteria. The primary outcome was functional outcome, assessed using a validated outcome score, at 1 year. Secondary outcomes included pain scores, structural assessment of the joint, and adverse events. KJD is associated with improvements in Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) from baseline to 1 year as well as reductions in pain scores and improvements in structural parameters assessed radiographically and by magnetic resonance imaging. KJD is not associated with decreased knee flexion, but is associated with a high risk of pin site infection. In patients aged 65 years or under at 1 year, no differences in WOMAC or pain scores was detected between patients managed with KJD compared with high tibial osteotomy or total knee arthroplasty. KJD may represent a potential treatment for knee arthritis, though</p> | | | |
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| | | further trials with longer term follow-up are required to establish its efficacy compared with contemporary treatments. This is a Level I (systematic review and meta-analysis) study. | | | |
| 50. Pieske O, Kaltenhauser F, Pichlmaier L, Schramm N, Trentzsch H, Löffler T, Greiner A, Piltz S. | Clinical benefit of hydroxyapatite-coated pins compared with stainless steel pins in external fixation at the wrist: a randomised prospective study. Injury. 2010 Oct;41(10):1031-1036. doi: 10.1016/j.injury.2010.03.030. PMID: 20444448. | <p>Background: The purpose of this study was to determine the clinical benefit of hydroxyapatite (HA)-coated pins compared with standard stainless steel pins in external fixators applied for unstable fractures of the distal radius.</p> <p>Methods: A total of 40 patients (160 pins) with unstable wrist fractures were randomised for uniplanar fixator treatment with the use of identically designed, commercially available pins either composed of stainless steel (steel group) (n = 20) or coated by hydroxyapatite (HA group) (n = 20). Each pin site was clinically evaluated concerning erythema and grade of drainage as well as pain intensity (numeric rating scale (NRS) 0-10) and, additionally, radiological assessment was performed concerning pin-loosening/infection as well as fracture healing at T1 (Ø18 days), T2 (Ø44 days) and T3 (Ø65 days). In case of pintrack complication, the patient was followed continuously. The need for intensified pin-site care, oral or intravenous antibiotic medication, re-admission for additional surgery and</p> | RCT | YES | NO |

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| | | <p>premature fixator removal was documented. Bone mineral density (BMD) was determined by dual energy X-ray absorptiometry. At fixator removal (T2), the pin-extraction strength was measured by the use of an electronic torque wrench.</p> <p>Results: Two pin-track infections requiring daily pin-site care and oral antibiotics occurred in the HA group (2.6%) compared with four in the steel group (5.3%) ($p = 0.601$) and although a trend towards a superior performance of HA pins was detectable, the majority of clinical pin-site parameters were comparable in both groups. At the end of the fixator therapy, the HA group showed a non-significant lower rate of loose pins ($n(\text{steel group}) = 9$; $n(\text{HA group}) = 6$; $p = 0.864$) and both hydroxyapatite-coated pins showed at the radius a significantly stronger pin-bone bonding measured by the torque wrench ($p(\text{proximal radius pin}) = 0.007$; $p(\text{distal radius pin}) = 0.031$). Except for elderly patients of the steel group ($p = 0.018$), all demographic, health- and injury-related data including BMD were not correlated to any type of pin-site complication in both groups ($p > 0.05$). Since all fracture healed uneventfully without</p> | | | |
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| | | <p>any type of additional surgery, the number of patients suffering clinically relevant pin-related complications showed no significant difference between both groups ($p = 0.707$).</p> <p>Conclusions: The use of HA coated pins compared with standard stainless-steel pins in external fixation for unstable wrist fractures yields only a trend towards a superior clinical outcome.</p> | | | |
| 51. Aktuglu K, Erol K, Vahabi A. | Ilizarov bone transport and treatment of critical-sized tibial bone defects: a narrative review. J Orthop Traumatol. 2019 Apr 16;20(1):22. doi: 10.1186/s10195-019-0527-1. PMID: 30993461; PMCID: PMC6468024. | <p>Background: Critical-sized bone defects of the tibia are complex injuries associated with significant problems that are difficult to treat, and they are associated with a significant burden of disease in clinical practice; however, the treatment of these cases has still been a challenge for orthopedic surgeons. The aim of this review was to evaluate the current available studies reporting on classical Ilizarov methods in the treatment of infected or noninfected critical-sized bone defects of the tibia, and to perform an analysis of treatment period and complications.</p> <p>Methods: This is a narrative review based on a comprehensive literature search among the studies in Pubmed, Scopus and Web of Science articles. The studies included were written in the English language or translated to English and they</p> | Review | YES | NO |

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| | | <p>were published between 2008 and 2018. They were appraised with narrative data synthesis. The primary outcome measures were the external fixation time (EFT), bone union rate, and bone and functional results. Secondary outcomes were complications including docking site problems and solutions. The heterogeneity of the data in the studies which were taken into consideration allowed a narrative analysis.</p> <p>Results: Twenty-seven articles with 619 patients were included in this study. These included 6 prospective and 21 retrospective case series. Mean age was 36.1 (range 13-89) years. Of the cases, 88.8% were infected and the remaining 11.2% were noninfected. The external fixation time was 10.75 (range 2.5-23.2) months. The mean bone union rate was 90.2% (range 77-100)%. Radiographic outcome measures were reported in 20 studies. Functional outcome measures were reported in 18 studies. ASAMI (Association for the Study of the Method of Ilizarov) criteria are useful and give reproducible data on patient outcome measurements. Data collected from these studies showed excellent radiological outcomes in 303, good in 143, fair in 31, and</p> | | | |
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| | | <p>poor in 25 patients. Functional outcomes were excellent in 200, good in 167, fair in 58, and poor in 19, where reported. The excellent and good rate in bone results and functional results were 88.8% and 82.6%, respectively. The poor rate in bone results and functional results were 5% and 4.5%. Mean complication rate per patient was 1.22 (range 3-60). The most common complication was pin tract infection (PTI). Its occurrence was 46.6%. Joint stiffness followed PTI with a 25% incidence. The rates of refracture, malunion, infectious recurrence, and amputation, were 4%, 8.4%, 4.58%, and 1%, respectively.</p> <p>Conclusions: This narrative review shows that the patients with infected or noninfected critical-sized tibial bone defects treated by Ilizarov methods had a low rate of poor bone and functional results. Therefore, Ilizarov methods may be a good choice for the treatment of infected or noninfected tibial bone defects. The small number of cases in some studies, the absence of homogeneity between studies and the fact that most data available are derived from retrospective studies are some of the difficulties encountered in the evaluation of evidence.</p> | | | |
| 52. Kapur B, Paniker J, Casaletto J. | An Alternative Technique for External Fixation of Traumatic Intra-articular Fractures of Proximal and Middle | Background: Intra-articular fractures of the proximal | Review | YES | NO |

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| | <p>Phalanx. Tech Hand Up Extrem Surg. 2015 Dec;19(4):163-7. doi: 10.1097/BTH.0000000000000102. PMID: 26492600.</p> | <p>interphalangeal (PIP) joint are commonly treated with dynamic external fixation. Most commonly used is the Suzuki modification of the pins and rubber traction system (PRTS). There are a few other modifications of the PRTS external fixators. We present an alternative pin external fixator that is simple and effective.</p> <p>Methods: Under a suitable anesthesia and image intensification a true lateral view of the head of the proximal phalanx is obtained. A K-wire construct holds the affected digit out to length with the fracture reduced and Jurgan pin-balls hold the construct into position. Under image intensification the whole device is checked to ensure the joint and fracture is reduced and the joint is not over distracted. The PIP joint is also checked to ensure good range of motion. The device was checked in clinic at 1 week with radiographs. The wires are removed at 4 weeks followed by intensive hand physiotherapy.</p> <p>Results: Over 20 patients with intra-articular fractures of the proximal and middle phalangeal were treated with this technique. In all cases the fracture healed with good joint congruency. All patients achieved good range of motion of the PIP joint but with some restriction of full flexion (mean, 20 degrees). There was no</p> | | | |
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| | | <p>loss of position or pin-site infections. There was good compliance with the treatment.</p> <p>Discussion: The main advantages of the technique we describe are: (1) the compact design, making it less cumbersome for the patient compared with other PRTS external fixators; (2) it is straightforward to assemble and the device is easy to adjust in clinic if there is any loss of reduction; (3) the pin-balls prevent sharp ends of the wire protruding causing morbidity to the patient; (4) there is less chance of loss of traction compared with traction devices using rubber bands. It is a dynamic device, which allows mobilization of the joints reducing stiffness.</p> | | | |
| 53. Hardeki D, Gaski G, Joshi M, Venezia R, Nascone JW, Sciadini MF, O'Toole RV. | Can applied external fixators be sterilized for surgery? A prospective cohort study of orthopaedic trauma patients. Injury. 2016 Dec;47(12):2679-2682. doi: 10.1016/j.injury.2016.07.009. Epub 2016 Jul 7. PMID: 27461780. | <p>Background: Temporary external fixators are often used to stabilize fractures when definitive fracture surgery must be delayed. Sometimes, external fixators are left in place during repeat operations, including definitive internal fixation of tibial pilon and tibial plateau fractures. It is unknown how well current surgical preparation sterilizes these devices, which become part of the surgical field. Our hypothesis was that our institution's standard surgical preparation creates a low rate of culture-positive environments on external fixators at the</p> | Clinical Trial | YES | NO |

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| | | <p>time of surgical skin incision.</p> <p>Methods: We prospectively consented and enrolled patients to obtain cultures (48 patients, 55 external fixators, 165 sets of culture data). After standard preparation and immediately before incision, cultures were obtained from three sites on each external fixator: 1) most distal pin 1cm from pin-skin interface, 2) most distal bar at midpoint between pin and clamp connectors, and 3) most distal clamp at bar-clamp interface. Our standard preparation for patients with external fixation in place is to don sterile gloves and wipe down all components of the external fixator with 70% alcohol-soaked sterile 4×4in gauze sponges before skin preparation. The skin and external fixator are then prepped in the usual fashion with ChloroPrep for closed wounds or with povidone iodine scrub and paint for open wounds. Swabs were processed and organisms from cultures identified. Clinicians were blinded to study results until study completion.</p> <p>Results: Two of 165 cultures (1.2%; 95% confidence interval [CI]: 0-2.9%) were positive for common pathogens sometimes observed in surgical site infection. Four cultures (2.4%; 95% CI: 0-4.8%)</p> | | | |
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| | | <p>had pathogens that are rarely associated with surgical site infection, and four (2.4%; 95% CI: 0-4.8%) had nonpathogenic organisms.</p> <p>Conclusion: Using 70% alcohol on external fixators plus either ChloroPrep for closed wounds or povidone iodine for open wounds seems to result in a low rate of positive cultures. Most species that were isolated are infrequently identified as sources of surgical site infections. This preparation protocol might be effective at producing a relatively clean environment at the time of surgery for patients with external fixators already in place.</p> | | | |
| 54. Chung KC, Malay S, Shauver MJ, Kim HM; | <p>WRIST Group. Assessment of Distal Radius Fracture Complications Among Adults 60 Years or Older: A Secondary Analysis of the WRIST Randomized Clinical Trial. JAMA Netw Open. 2019 Jan 4;2(1):e187053. doi: 10.1001/jamanetworkopen.2018.7053. PMID: 30657531; PMCID: PMC6484535.</p> | <p>Importance: Complications affect treatment outcomes and quality of life in addition to increasing treatment costs.</p> <p>Objectives: To evaluate complication rates after the treatment of a distal radius fracture, to determine whether the rate or complication type is associated with treatment method, and to determine predictors of complications.</p> <p>Design, setting, and participants: The multicenter Wrist and Radius Injury Surgical Trial (WRIST), a randomized clinical trial, enrolled participants from April 10, 2012, to December 31, 2016. The study included 304 adults 60 years or older with isolated unstable distal</p> | RCT | YES | NO |

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| | | <p>radius fractures; 187 were randomized and 117 opted for casting. The study was conducted at 24 health systems in the United States, Canada, and Singapore. Data for this secondary analysis were collected from April 24, 2012, to February 28, 2018.</p> <p>Interventions: Participants opting for surgery were randomized to receive the volar locking plate system (n = 65), percutaneous pinning (n = 58), or bridging external fixation with or without supplemental pinning (n = 64). Patients who chose not to have surgery (n = 117) were not randomized and were enrolled for casting.</p> <p>Main outcomes and measures: Complication rate.</p> <p>Results: The WRIST enrolled a total of 304 participants, of whom 8 casting group participants were later found to be ineligible and were excluded from the analysis, leaving 296 participants. Randomized participants' mean (SD) age was 68 (7.2) years, 163 (87%) were female, and 165 (88%) were white. Casting participants' mean (SD) age was 75.6 (9.6) years, 93 (84%) were female, and 85 (85%) were white. The most common type of complications varied by treatment. Twelve of 65 participants (18.5%) in</p> | | | |
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| | | <p>the internal fixation group reported a median nerve compression, while 16 of 26 participants (25.8%) who received external fixation and 13 of 56 participants (23.2%) who received pinning sustained pin site infections. Compared with the internal fixation group, complication rate for any severity complication was higher in participants who initially received casting (adjusted rate ratio, 1.88; 95% CI, 1.22-2.88), whereas the rate for moderate complications was higher in the external fixation group (adjusted rate ratio, 2.52; 95% CI, 1.25-5.09).</p> <p>Conclusions and relevance: The distal radius fracture treatment decision-making process for older patients should incorporate a complication profile for each treatment type. For example, external fixation and pinning could be used for patients after apprising them of pin site infection risk. Internal fixation can be done in patients with high functional demands who are willing to receive surgery. Internal fixation use should be substantiated owing to the time and cost involved.</p> | | | |
| 55. Muir RL, Forrester R, Sharma H. | Fine Wire Circular Fixation for Displaced Intra-Articular Calcaneal Fractures: A Systematic Review. J Foot Ankle Surg. 2019 Jul;58(4):755-761. doi: 10.1053/j.jfas.2018.11.030. Epub 2019 May 23. PMID: 31130477. | Intra-articular calcaneal fractures represent an ongoing challenge for the orthopedic community, with the benefits of the previous "gold standard" | Systematic Review | YES | NO |

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| | | <p>treatment of open reduction and internal fixation having been called into question in several large randomized controlled trials. Fine wire circular fixation may represent a useful alternative treatment for these injuries, combining minimally invasive application with rigid fixation, which allows the possibility of early weight bearing. We performed a systematic review of published studies that used circular fixation for calcaneal fractures and recorded functional outcomes at follow-up. In a total of 11 studies with 255 calcaneal fractures for which there was follow-up, our inclusion criteria were met: 8.2% of fractures were bilateral, 11.9% of fractures were open fractures, and 12.6% of patients had multiple orthopedic injuries. Functional outcomes were assessed with the use of a variety of tools across the different studies, but outcomes compared favorably with those seen with open reduction and internal fixation. Although pin site infections were common (22.6%), serious complications, including deep infection (0.8%), wound infection (1.6%), and complex regional pain syndrome (0.8%), were exceedingly rare. The results suggest that this is a viable alternative treatment for calcaneal fractures, but higher-</p> | | | |
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| | | quality randomized controlled trials are required before the technique can enter mainstream use. | | | |
| 56. Ferchaud F, Rony L, Ducellier F, Cronier P, Steiger V, Hubert L; Orthopedics and Traumatology Society of Western France (SOO). | Reconstruction of large diaphyseal bone defect by simplified bone transport over nail technique: A 7-case series. Orthop Traumatol Surg Res. 2017 Nov;103(7):1131-1136. doi: 10.1016/j.otsr.2017.05.016. Epub 2017 Jun 20. PMID: 28645704. | Reconstruction of large diaphyseal bone defect is complex and the complications rate is high. This study aimed to assess a simplified technique of segmental bone transport by monorail external fixator over an intramedullary nail. A prospective study included 7 patients: 2 femoral and 5 tibial defects. Mean age was 31 years (range: 16-61 years). Mean follow-up was 62 months (range: 46-84 months). Defects were post-traumatic, with a mean length of 7.2 cm (range: 4 to 9.5 cm). For 3 patients, reconstruction followed primary failure. In 4 cases, a covering flap was necessary. Transport used an external fixator guided by an intramedullary nail, at a rate of 1 mm per day. One pin was implanted on either side of the distraction zone. The external fixator was removed 1 month after bone contact at the docking site. Mean bone transport time was 11 weeks (range: 7-15 weeks). Mean external fixation time was 5.1 months (range: 3.5 to 8 months). Full weight-bearing was allowed 5.7 months (range: 3.5-13 months) after initiation of transport. In one patient, a pin had to be repositioned. In 3 patients, the transported segment re- | Clinical trial | YES | NO |

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| | | <p>ascended after external fixatorablation, requiring repeat external fixation and resumption of transport. There was just 1 case of superficial pin infection. Reconstruction quality was considered "excellent" on the Paley-Marr criteria in 6 cases. The present technique provided excellent reconstruction quality in 6 of the 7 cases. External fixation time was shorter and resumption of weight-bearing earlier than with other reconstruction techniques, notably including bone autograft, vascularized bone graft or the induced membrane technique. Nailing facilitated control of limb axis and length. The complications rate was 50%, comparable to other techniques. This study raises the question of systematic internal fixation of the docking site, to avoid any mobilization of the transported segment. The bone quality, axial control and rapidity shown by the present technique make it well-adapted to reconstruction of diaphyseal bone defect.</p> | | | |
| 57. Mikamo H, Yamagishi Y, Murata S, Yokokawa R, Han SR, Wakana A, Sawata M, Tanaka Y. | Efficacy, safety, and immunogenicity of a quadrivalent HPV vaccine in Japanese men: A randomized, Phase 3, placebo-controlled study. Vaccine. 2019 Mar 14;37(12):1651-1658. doi: 10.1016/j.vaccine.2019.01.069. Epub 2019 Feb 20. PMID: 30797638. | <p>Background: The quadrivalent (q) human papillomavirus (HPV) vaccine protects against infection and disease related to HPV types 6, 11, 16, and 18. We report efficacy, immunogenicity, and safety of qHPV vaccine in a Phase 3 study in Japanese men.</p> | Clinical Trial | YES | NO |

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| | | <p>Methods: In this randomized, double-blind trial (NCT01862874), Japanese men (aged 16-26 years) were randomized in a 1:1 ratio to receive three doses of qHPV vaccine or placebo (Day 1, Month 2, Month 6). The primary efficacy endpoint was the combined incidence of HPV6/11/16/18-related persistent anogenital infection (detected at ≥ 2 consecutive visits ≥ 6 months apart), assessed in the per-protocol population of men who received all three vaccinations, and were seronegative at Day 1 and PCR negative from Day 1 to Month 7 to the relevant HPV type. Results are from the interim and final analyses.</p> <p>Results: In total, 1124 participants were randomized. The vaccine demonstrated 83.3% (95% confidence interval: 24.9, 98.2; $p = 0.007$) and 85.9% (95% confidence interval: 52.7, 97.3; $p < 0.001$) efficacy against HPV6/11/16/18-related persistent infection in the interim and final analyses, respectively. Two cases of HPV6/11/16/18-related external genital lesions (condyloma and PIN 1) were observed in the placebo group and none in the qHPV vaccine group at study end. At Month 7, $>97\%$ of participants who received qHPV vaccine seroconverted to each</p> | | | |
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| | | <p>of the vaccine HPV types. Most participants remained seropositive at Month 36, although the seropositivity rate declined between Months 7 and 36. Vaccination-related adverse events were reported in 60.8% and 56.5% of participants in the qHPV vaccine and placebo groups, respectively; most commonly mild to moderate injection-site pain, erythema, and swelling. Injection-site pain and swelling were more common with qHPV vaccine than placebo (each $p < 0.05$).</p> <p>Conclusions: Results suggest qHPV vaccine is efficacious against HPV6/11/16/18-related persistent infections, immunogenic, and well-tolerated in Japanese men. Clinical trial registration identifier: NCT01862874.</p> | | | |
| 58. Chounta V, Overton ET, Mills A, Swindells S, Benn PD, Vanveggel S, van Solingen-Ristea R, Wang Y, Hudson KJ, Shaefer MS, Margolis DA, Smith KY, Spreen WR. | <p>Patient-Reported Outcomes Through 1 Year of an HIV-1 Clinical Trial Evaluating Long-Acting Cabotegravir and Rilpivirine Administered Every 4 or 8 Weeks (ATLAS-2M). Patient. 2021 Nov;14(6):849-862. doi: 10.1007/s40271-021-00524-0. Epub 2021 May 31. PMID: 34056699; PMCID: PMC8563641.</p> | <p>Background: Advances in HIV-1 therapeutics have led to the development of a range of daily oral treatment regimens, which share similar high efficacy rates. Consequently, more emphasis is being placed upon the individual's experience of treatment and impact on quality of life. The first long-acting injectable antiretroviral therapy for HIV-1 (long-acting cabotegravir + rilpivirine [CAB + RPV LA]) may address challenges associated with oral treatment for HIV-1, such as stigma, pill burden/fatigue,</p> | RCT | YES | NO |

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| | | <p>drug-food interactions, and adherence. Patient-reported outcomes (PROs) collected in an HIV-1 clinical trial (ATLAS-2M; NCT03299049) comparing participants' experience with two dosing regimens (every 4 weeks [Q4W] vs. every 8 weeks [Q8W]) of CAB + RPV LA are presented herein.</p> <p>Methods: PRO endpoints evaluated through 48 weeks of therapy included treatment satisfaction (HIV Treatment Satisfaction Questionnaire [HIVTSQ]), treatment acceptance ("General Acceptance" domain of the Chronic Treatment Acceptance [ACCEPT®] questionnaire), acceptability of injections (Perception of Injection [PIN] questionnaire), treatment preference (questionnaire), and reasons for switching to/continuing long-acting therapy (exploratory endpoint; questionnaire).</p> <p>Participants were randomized 1:1 to receive CAB + RPV LA Q8W or Q4W. Results were stratified by prior CAB + RPV exposure in either preplanned or post hoc analyses.</p> <p>Results: Overall, 1045 participants were randomized to the Q8W (n = 522) and Q4W (n = 523) regimens; 37% (n = 391/1045) had previously received</p> | | | |
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| | | <p>CAB + RPV in ATLAS. For participants without prior CAB + RPV exposure, large increases from baseline were reported in treatment satisfaction in both long-acting arms (HIVTSQ status version), with Q8W dosing statistically significantly favored at Weeks 24 ($p = 0.036$) and 48 ($p = 0.004$). Additionally, improvements from baseline were also observed in the "General Acceptance" domain of the ACCEPT questionnaire in both long-acting arms for participants without prior CAB + RPV exposure; however, no statistically significant difference was observed between arms at either timepoint (Week 24, $p = 0.379$; Week 48, $p = 0.525$). Significant improvements ($p < 0.001$) in the "Acceptance of Injection Site Reactions" domain of the PIN questionnaire were observed from Week 8 to Weeks 24 and 48 in both arms for participants without prior CAB + RPV exposure. Participants with prior CAB + RPV exposure reported high treatment satisfaction (mean [HIVTSQ status version]: Q8W 62.2/66.0; Q4W 62.0/66.0), treatment acceptance (mean: Q8W 89.3/100; Q4W 91.2/100), and acceptance of injection site reactions (mean [5 = not at all acceptable;</p> | | | |
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| | | <p>1 = totally acceptable]; Q8W 1.72; Q4W 1.59) at baseline/Week 8 that were maintained over time. Participants without prior CAB + RPV exposure who received Q8W dosing preferred this regimen over oral CAB + RPV (98%, n = 300/306). Among those with prior Q4W exposure, 94% (n = 179/191) preferred Q8W dosing versus Q4W dosing (3%, n = 6/191) or oral CAB + RPV (2%, n = 4/191).</p> <p>Conclusions: Both long-acting regimens provided high treatment satisfaction and acceptance, irrespective of prior CAB + RPV exposure, with most participants preferring Q8W dosing over both the Q4W regimen and their previous daily oral regimen. The PRO data collected at Week 48 support the therapeutic potential of CAB + RPV LA.</p> | | | |
| 59. Xu J, Sun X, Xin Q, Cheng Y, Zhan Z, Zhang J, Wu J. | Effect of immunonutrition on colorectal cancer patients undergoing surgery: a meta-analysis. Int J Colorectal Dis. 2018 Mar;33(3):273-283. doi: 10.1007/s00384-017-2958-6. Epub 2018 Jan 15. PMID: 29335838; PMCID: PMC5816768. | <p>Purpose: Immunonutrition has been used to prevent the complications after colorectal elective surgery. This systematic review aimed to analyze and assess the effect of immunonutrition on colorectal cancer patients who received elective surgery.</p> <p>Methods: Three electronic databases (Medline, Embase, Cochrane) were used to search the latent studies which investigated the effects of enteral immunonutrition (EIN) compared with</p> | Meta-Analysis | YES | NO |

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| | | <p>standard enteral nutrition (EN) or parenteral immunonutrition (PIN) compared with standard parenteral nutrition (PN) on colorectal cancer patients who are undergoing surgery until 21st of April, 2017. Meta-analysis was conducted to calculate odd risk (OR), mean difference (MD), or standard mean difference (SMD) with 95% confidence interval (CI), and heterogeneity was tested by Q test.</p> <p>Results: Nine publications were included. The meta-analysis results presented that EIN improved the length of hospital stay (pooled MD, 2.53; 95% CI, 1.29-3.41), infectious complications (pooled OR, 0.33; 95% CI, 0.21-0.53) which contains the Surgical Site Infections (pooled OR, 0.25; 95% CI, 0.22-0.58) and Superficial/Deep incisional infections (pooled OR, 0.27; 95% CI, 0.12-0.64); meanwhile, PIN improved the length of hospital stay (pooled MD, 2.66; 95% CI, 0.62-4.76), IL-6 (pooled MD, - 6.09; 95% CI, - 10.11 to - 2.07), CD3 (pooled MD, 7.50; 95% CI, 3.57-11.43), CD4 (pooled MD, 5.47; 95% CI, 2.54-8.40), and CD4/CD8 (pooled MD, 0.50; 95% CI, 0.22-0.78); the level of CD8 was lower (pooled MD, - 4.32; 95% CI, - 7.09 to - 1.55) in PIN.</p> | | | |
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| | | <p>Conclusion:</p> <p>Immunonutrition could be an effective approach to enhance the immune function of colorectal cancer patients undergoing elective surgery and to improve the clinical and laboratory outcomes.</p> | | | |
| 60. Hamdy RC, Montpetit K, Aiona MD, MacKenzie WG, van Bosse HJ, Narayanan U, Raney EM, Chafetz RS, Thomas SE, Weir S, Gregory S, Yorgova P, Takahashi S, Rinaldi M, Zhang X, Dahan-Oliel N. | <p>Safety and Efficacy of Botulinum Toxin A in Children Undergoing Lower Limb Lengthening and Deformity Correction: Results of a Double-blind, Multicenter, Randomized Controlled Trial. J Pediatr Orthop. 2016 Jan;36(1):48-55. doi: 10.1097/BPO.0000000000000398. PMID: 25730290.</p> | <p>Background:</p> <p>Lengthening of the lower limb is a complex procedure in which pain management and complications such as pin-site infections and muscle contractures impact the family and affect the child's quality of life. As a result, the paralytic and antinociceptive actions of neurotoxins may be indicated in managing these complications; however, few studies have explored ways to improve outcomes after lengthenings. The objective of this study was to evaluate the safety and efficacy of botulinum toxin A (BTX-A) in children undergoing lower limb lengthenings and deformity correction.</p> <p>Methods: Participants with a congenital or acquired deformity of the lower extremity requiring surgery to one limb were randomized to receiving either BTX-A as a single dose of 10 units per kilogram body weight, or an equivalent volume of saline solution. Pain, medication, quality of life, and physical function were assessed at different time-points. Adverse events were recorded in all participants. T test and</p> | RCT | YES | NO |

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| | | <p>χ tests were used to compare potential differences across both groups.</p> <p>Results: Mean age of the 125 participants was 12.5 years (range, 5 to 21 y), and lengthenings averaged 4.2 cm. Maximum pain scores on day 1 postoperatively were lower in the BTX-A group ($P=0.03$) than in the placebo group, and remained significant favoring botox when stratifying by location of lengthening (femur vs. tibia). Clinical benefits for BTX-A were found for 3 quality of life domains at mid-distraction and end-distraction. When stratifying according to location of lengthening, there were significantly fewer pin-site infections in the tibia favoring botox ($P=0.03$). The amount of adverse events and bone healing indices were no different in both groups.</p> <p>Conclusions: The clinical differences in quality of life, the lower pain on the first postoperative day, and the lower number of pin-site infections in the tibia favoring BTX-A support its use as an adjunctive treatment to the lengthening process. The detailed analyses of pain patterns help inform families on the pain expectations during lower limb lengthenings. The amount of adverse events were no different in both</p> | | | |
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| | | groups, and bone healing rates were similar, indicating that the use of BTX-A in children undergoing limb lengthening and deformity correction is safe. | | | |
| 61. Krappinger D, Zegg M, Smekal V, Huber B. Die Korrektur posttraumatischer | Deformitäten am Unterschenkel mit dem "Taylor Spatial Frame" [Correction of posttraumatic lower leg deformities using the Taylor Spatial Frame]. Oper Orthop Traumatol. 2014 Oct;26(5):520-31. German. doi: 10.1007/s00064-013-0233-8. PMID: 23801041. | <p>Objective: Correction of posttraumatic lower leg deformities using percutaneous osteotomy, external fixation with a ring fixator, and computer-assisted gradual correction with the Taylor Spatial Frame (TSF).</p> <p>Indications: Posttraumatic lower leg deformities not suitable for acute correction and internal fixation or deformities that are suitable but have a significantly increased risk for complications: deformities with poor soft tissue coverage, rigid deformities that require gradual correction, complex multiplanar deformities, deformities with shortening, and periarticular juvenile deformities.</p> <p>Contraindications: Posttraumatic lower leg deformities which are suitable for acute correction and internal fixation are also suitable for deformity correction using the TSF. In these cases, however, we recommend acute correction and internal fixation in order to improve the patient comfort. Lack of patient compliance for self-contained correction and pin care.</p> | Clinical Trial | YES | NO |

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| | | <p>Surgical technique: Percutaneous fixation of the TSF rings to the main fragments using transosseous K wires and half pins (hybrid fixation). Percutaneous osteotomy of the tibia either by drilling across both cortices and completion of the osteotomy using an osteotome (DeBastiani method) or by using the Gigli saw with preservation of the periosteal envelope. Connection of both rings with six oblique telescopic struts via universal joints (hexapod platform). Computer-assisted planning of the correction.</p> <p>Postoperative management: Gradual postoperative correction of the deformity by changing the strut lengths according to the correction plan. Strut changes, if required. Osseous consolidation of the osteotomy site with the TSF or revision to internal fixation.</p> <p>Results: The correction of posttraumatic lower leg deformities using the TSF was performed in 6 cases. The mean deformity was 15° (12-22°) in the frontal plane and 6° (4-8°) in the sagittal plane. The correction time was 19 days (14-22 days). The deviation between planned and achieved correction was 0-3° in the frontal plane and 0-2° in the sagittal plane. The osseous</p> | | | |
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| | | <p>consolidation of the osteotomy site was carried out in the TSF in 5 cases with a mean external fixation time of 112 days (94-134 days). In one case, the TSF was removed after the correction and the osteotomy site was fixed using an intramedullary nail. Pin site infections were observed in 3 cases. There were no further complications. The treatment goal was achieved in all cases. The examination at final follow up was performed after 1 year. All patients were able to walk without walking aids and with no pain at that time. They were able to perform all of their activities of the daily life and their leisure activities without limitations.</p> | | | |
| 62. Farrow L, Ablett AD, Mills L, Barker S. | <p>Early versus delayed surgery for paediatric supracondylar humeral fractures in the absence of vascular compromise: a systematic review and meta-analysis. Bone Joint J. 2018 Dec;100-B(12):1535-1541. doi: 10.1302/0301-620X.100B12.BJJ-2018-0982.R1. PMID: 30499316.</p> | <p>Aims: We set out to determine if there is a difference in perioperative outcomes between early and delayed surgery in paediatric supracondylar humeral fractures in the absence of vascular compromise through a systematic review and meta-analysis.</p> <p>Materials and methods: A literature search was performed, with search outputs screened for studies meeting the inclusion criteria. The groups of early surgery (ES) and delayed surgery (DS) were classified by study authors. The primary outcome measure was open reduction requirement. Meta-analysis was performed</p> | Meta-Analysis | YES | NO |

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| | | <p>in the presence of sufficient study homogeneity. Individual study risk of bias was assessed using the Risk of Bias in Non-Randomised Studies - of Interventions (ROBINS-I) criteria, with the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) criteria used to evaluate outcomes independently.</p> <p>Results: A total of 12 studies met the inclusion criteria (1735 fractures). Pooled mean time to surgery from injury was and 10.7 hours for ES and 91.8 hours for DS. On meta-analysis there was no significant difference between ES versus DS for the outcome of open reduction requirement. There was also no significant difference for the outcomes: Iatrogenic nerve injury, pin site infection, and re-operation. The quality of evidence for all the individual outcomes was low or very low.</p> <p>Conclusions: There is no evidence that delaying supracondylar fracture surgery negatively influences outcomes in the absence of vascular compromise. There are, however, notable limitations to the existing available literature.</p> <p>Keywords: Delay; Distal humerus; Elbow; Gartland; Orthopaedics;</p> | | | |
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| | | Paediatrics; Supracondylar; Systematic review; Timing; Trauma. | | | |
| 63. Bousquet J, Schunemann HJ, Fonseca J, Samolinski B, Bachert C, Canonica GW, Casale T, Cruz AA, Demoly P, Hellings P, Valiulis A, Wickman M, Zuberbier T, Bosnic Anticevitch S, Bedbrook A, Bergmann KC, Caimmi D, Dahl R, Fokkens WJ, Gisle I, Lodrup Carlsen K, Mullol J, Muraro A, Palkonen S, Papadopoulos N, Passalacqua G, Ryan D, Valovirta E, Yorgancioglu A, Aberer W, Agache I, Adachi M, Akdis CA, Akdis M, Annesi-Maesano I, Ansotegui IJ, Anto JM, Arnavielhe S, Arshad H, Baiardini I, Baigenzhin AK, Barbara C, Bateman ED, Beghé B, Bel EH, Ben Kheder A, Bennoor KS, Benson M, Bewick M, Bieber T, Bindeslev-Jensen C, Bjerner L, Blain H, Boner AL, Boulet LP, Bonini M, Bonini S, Bosse I, Bourret R, Bousquet PJ, Braido F, Briggs AH, Brightling CE, Brozek J, Buhl R, Burney PG, Bush A, Caballero-Fonseca F, Calderon MA, Camargos PA, Camuzat T, Carlsen KH, Carr W, Cepeda Sarabia AM, Chavannes NH, Chatzi I, Chen YZ, Chiron R, Chkhartishvili E, Chuchalin AG, Ciprandi G, Cirule I, Correia de Sousa J, Cox I, Crooks G, Costa DJ, Custovic A, Dahlen SE, Darsow U, De Carlo G, De Blay F, Dedeu T, Deleanu D, Denburg JA, Devillier P, Didier A, Dinh-Xuan AT, Dokic D, Douagui H, Dray G, Dubakiene R, Durham SR, Dykewicz MS, El Gamal Y, Emuzyte R, Fink-Wagner A, Fletcher M, Fiocchi A, Forastiere F, Gamkrelidze A, Gemicioğlu B, Gereda JE, González-Díaz S, Gotua M, Grouse L, Guzmán MA, | MACVIA-ARIA Sentinel Network for allergic rhinitis (MASK-rhinitis): the new generation guideline implementation. Allergy. 2015 Nov;70(11):1372-92. doi: 10.1111/all.12686. Epub 2015 Sep 13. PMID: 26148220. | Several unmet needs have been identified in allergic rhinitis: identification of the time of onset of the pollen season, optimal control of rhinitis and comorbidities, patient stratification, multidisciplinary team for integrated care pathways, innovation in clinical trials and, above all, patient empowerment. MASK-rhinitis (MACVIA-ARIA Sentinel Network for allergic rhinitis) is a simple system centred around the patient which was devised to fill many of these gaps using Information and Communications Technology (ICT) tools and a clinical decision support system (CDSS) based on the most widely used guideline in allergic rhinitis and its asthma comorbidity (ARIA 2015 revision). It is one of the implementation systems of Action Plan B3 of the European Innovation Partnership on Active and Healthy Ageing (EIP on AHA). Three tools are used for the electronic monitoring of allergic diseases: a cell phone-based daily visual analogue scale (VAS) assessment of disease control, CARAT (Control of Allergic Rhinitis and Asthma Test) and e-Allergy screening (premedical system of early diagnosis of allergy and asthma based on online | Review | YES | NO |

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| <p>Hahtela T, Hellquist Dahl B, Heinrich J, Horak F, Hourihane JO, Howarth P, Humbert M, Hyland ME, Ivancevich JC, Jares EJ, Johnston SL, Joos G, Jonquet O, Jung KS, Just J, Kaidashev I, Kalayci O, Kalyonec AF, Keil T, Keith PK, Khaltayev N, Klimck L, Koffi N'Goran B, Kojak V, Koppelman GH, Kowalski ML, Kull I, Kuna P, Kvedariene V, Lambrecht B, Lau S, Larenas-Linnemann D, Laune D, Le LT, Lieberman P, Lipworth B, Li J, Louis R, Magard Y, Magnan A, Mahboub B, Majer I, Makela MJ, Manning P, De Manuel Keenoy E, Marshall GD, Masjedi MR, Maurer M, Mavale-Manuel S, Melén E, Melo-Gomes E, Meltzer EO, Merk H, Miculinic N, Mihaltan F, Milenkovic B, Mohammad Y, Molimard M, Momas I, Montilla-Santana A, Morais-Almeida M, Mösges R, Namazova-Baranova I, Naclerio R, Neou A, Neffen H, Nekam K, Niggemann B, Nyembue TD, O'Hehir RE, Ohta K, Okamoto Y, Okubo K, Ouedraogo S, Paggiaro P, Pali-Schöll I, Palmer S, Panzner P, Papi A, Park HS, Pavord I, Pawankar R, Pfaar O, Picard R, Pigearias B, Pin I, Plavec D, Pohl W, Popov TA, Portejoie F, Postma D, Potter P, Price D, Rabe KH, Raciborski F, Radier Pontal F, Repka-Ramirez S, Robalo-Cordeiro C, Rolland C, Rosado Pinto J, Reitamo S, Rodenas F, Roman Rodriguez M, Romano A, Rosario N, Rosenwasser I, Rottem M, Sanchez-Borges M, Scadding GK, Serrano E, Schmid-Grendelmeier P, Sheikh A, Simons FE, Sisul JC, Skrinde I, Smit HA, Solé D, Sooronbaev T, Spranger O, Stelmach R, Strandberg T, Sunyer J, Thijs C, Todo-Bom A, Triggiani M, Valenta R, Valero AL, van Hage M,</p> | | <p>tools). These tools are combined with a clinical decision support system (CDSS) and are available in many languages. An e-CRF and an e-learning tool complete MASK. MASK is flexible and other tools can be added. It appears to be an advanced, global and integrated ICT answer for many unmet needs in allergic diseases which will improve policies and standards.</p> <p>Keywords: ARIA; Information and communications technology; MACVIA-IR; allergic rhinitis; asthma.</p> | | | |
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| Vandenplas O, Vezzani G, Vichyanond P, Viegi G, Wagenmann M, Walker S, Wang DY, Wahn U, Williams DM, Wright J, Yawn BP, Yiallouris PK, Yusuf OM, Zar HJ, Zernotti ME, Zhang L, Zhong N, Zidarn M, Mercier J. | | | | | |
| 64. Schottel PC, Smith CS, Helfet DL. | Symptomatic hip impingement due to exostosis associated with supra-acetabular pelvic external fixator pin. Am J Orthop (Belle Mead NJ). 2014 Jan;43(1):33-6. PMID: 24490184. | Expedient stabilization of unstable pelvic fractures has been shown to significantly reduce morbidity and mortality in the polytrauma patient. Application of a pelvic external fixator is one of the methods used to provide effective pelvic stability. However, pelvic external fixators are not without drawbacks. While pin tract infections and pin loosening are frequent complications, we describe a unique complication consisting of the formation of a symptomatic exostosis at the supra-acetabular pin site in a 35-year-old male with a pelvic fracture. To our knowledge this is the first description of hip impingement due to reactive bone formation secondary to a supra-acetabular pelvic external fixation pin. The impinging bone was completely excised utilizing the anterior approach to the hip. A 40° improvement in the patient's hip flexion range of motion was noted after exostosis excision. | Review | YES | NO |
| 65. Fadel M, Ahmed MA, Al Dars AM, Maabed MA, Shawki H. | Ilizarov external fixation versus plate osteosynthesis in the management of extra articular fractures of the distal tibia. Int Orthop. 2015 Mar;39(3):513-9. doi: 10.1007/s00264-014-2607-4. Epub 2014 Dec 5. PMID: 25472753. | Purpose: The purpose of this study was to evaluate the outcome of Ilizarov external fixation (IE) versus dynamic compression plate (PO) in the | RCT | YES | NO |

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| | | <p>management of extra-articular distal tibial fractures:</p> <p>Methods: Between 2010 and 2011, extra-articular distal tibial fractures in 40 consecutive patients met the inclusion criteria. They were classified according to AO classification fracture type A (A1, A2, and A3). In a randomized method, two equal groups were managed using either IE or PO. PO was performed using open reduction and internal fixation (ORIF) and DCP through anterolateral approach. IE was done using Hizarov frame. For the PO group, non weight bearing ambulation was permitted on the second postoperative day but partial weight bearing was permitted according to the progression in union criteria clinically and radiologically. For the IE group, weight bearing started as tolerated from the first postoperative day. Physiotherapy and pin-site care was performed by the patient themselves.</p> <p>Results: Modified Mazur ankle score was applied to IE (excellent 10, good 10) and in PO (excellent 2, good 8, poor 6). Data were statically analysed using (Mann Whitney test). The rate of healing in the IE group (average 130) was higher than the PO (average 196.5); plus, there were no cases of delayed union</p> | | | |
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| | | <p>or nonunion in the IE group (p value 0.003).</p> <p>Conclusion: It was found that IE compared with PO provides provision of immediate weight bearing as tolerated following postoperative recovery, irrespective of radiological or clinical healing with no infection, deformity or non-union.</p> | | | |
| 66. Ramos T, Eriksson BI, Karlsson J, Nistor L. | <p>Ilizarov external fixation or locked intramedullary nailing in diaphyseal tibial fractures: a randomized, prospective study of 58 consecutive patients. Arch Orthop Trauma Surg. 2014 Jun;134(6):793-802. doi: 10.1007/s00402-014-1970-3. Epub 2014 Mar 25. PMID: 24664228.</p> | <p>Purpose: The aim of this study was to compare the Ilizarov circular fixator (IL) and locked intramedullary nailing (IM).</p> <p>Patients and methods: Patients with isolated tibia shaft fractures were randomly allocated to either the IL (n = 31) or IM (n = 27) method. Conventional radiographs, postoperative pain assessment, self-appraisal scores and complications were evaluated. At the clinical 1-year follow-up, the patients were also evaluated by an independent observer.</p> <p>Results: The minority of patients had open fractures, two and nine patients in the IM and IL groups, respectively. Eight patients in the IM group and four in the IL group sustained major complications (p = 0.107). In the IM group, two patients developed compartment syndrome, one deep infection, one hardware failure, one delayed union, one pseudarthrosis and two</p> | RCT | YES | NO |

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| | | <p>had a malunion. In the IL group, two patients developed pseudarthrosis and two had a malunion. Superficial pin-site infections were observed in 16 patients in the IL group. The fractures had healed radiographically at 12 weeks in both groups. At the 1-year follow-up, there were differences in pain (VAS) and satisfaction (VAS) scores in favor of IL treatment (VAS, $p = 0.03$ and $p = 0.02$, respectively). There were no differences between the groups with regard to range of motion (ROM) in the knee and ankle joints. The registration of local tenderness and pain revealed that there were 19 patients with anterior knee pain in the IM group and one in the IL group at the 1-year follow-up ($p < 0.001$).</p> <p>Conclusion: The IL is a safe and reliable alternative to IM for the treatment of tibial shaft fractures, with a low complication rate and good clinical outcome. Both treatments were well tolerated, but at the 1-year follow-up the patients in the IM group had more pain and were less satisfied. Finally, there was a high frequency of anterior knee pain in the IM group.</p> | | | |
| 67. Su YC, Guo YH, Hsieh PC, Lin YC. | Efficacy and safety of botulinum toxin type A in distraction osteogenesis of the lower extremities: a meta-analysis of randomized controlled trials. BMC Musculoskelet Disord. 2022 Mar 25;23(1):286. doi: 10.1186/s12891- | Background: To explore the efficacy and safety of botulinum toxin in patients who received distraction osteogenesis of the lower extremities. | Meta-Analysis | YES | NO |

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| | 022-05175-2. PMID: 35337325; PMCID: PMC8953065. | <p>Methods: We searched the PubMed, Medline, Cochrane Library, and Web of Science databases for randomized controlled trials that administered botulinum toxin to individuals who underwent distraction osteogenesis of the lower limbs. The final search was conducted on July 6, 2021. Quality assessments were conducted using the Cochrane risk of bias tool and the Jadad scale. We performed random-effects meta-analysis to calculate the standardized mean differences (SMDs) and confidence intervals (CIs) of the pooled effect sizes, and subgroup analysis and meta-regression were performed for potential moderators.</p> <p>Results: Our analysis of four randomized controlled trials, which enrolled a total of 257 participants, revealed that the difference in pain during the distraction phase was not statistically significant between groups (SMD, - 0.165; 95% CI, - 0.379 to 0.050, $p = 0.133$, $I^2 = 0.0\%$). The meta-regression analyses did not find any influence on the effect size, considering age ($\beta = -0.0092$; $p = 0.61$) and the amount of lengthening ($\beta = 0.0023$; $p = 0.99$). Subgroup analysis did not reveal difference between different doses of botulinum toxin and single or multi-site</p> | | | |
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| | | <p>study design. An analysis of two randomized controlled trials enrolling a total of 177 individuals demonstrated a limited effect of botulinum toxin in reducing postoperative pain (SMD, - 0.239; 95% CI, - 0.641 to 0.162, $p = 0.24$, $I^2 = 37.6\%$), total adverse events (SMD, - 0.207; 95% CI, - 0.505 to 0.090, $p = 0.17$, $I^2 = 0.0\%$), and infection of pin site (SMD, - 0.131; 95% CI, - 0.428 to 0.165, $p = 0.39$, $I^2 = 0.0\%$). No botulinum toxin-related adverse events were reported.</p> <p>Conclusions: The current evidence does not support the administration of botulinum toxin in patients who receive distraction osteogenesis of the lower limbs. However, we were unable to draw decisive conclusions because of the limitations of our meta-analysis. Future well-designed, large-scale randomized controlled trials are necessary to confirm our conclusions.</p> | | | |
| 68. Wani N, Baba A, Kangoo K, Mir M. | <p>Role of early Ilizarov ring fixator in the definitive management of type II, IIIA and IIIB open tibial shaft fractures. Int Orthop. 2011 Jun;35(6):915-23. doi: 10.1007/s00264-010-1023-7. Epub 2010 May 6. PMID: 20445978; PMCID: PMC3103954.</p> | <p>We evaluated the results of patients with Gustilo types II, IIIA and IIIB open tibial fractures managed early with the Ilizarov external fixator (IEF). Sixty patients (51 males, nine females; age range 20-62 years; mean age 32.8 years) with type II (11 patients), type IIIA (13) and type IIIB (36) tibial diaphyseal fractures underwent emergency debridement and minimal bone fixation</p> | Clinical Trial | YES | NO |

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| | | <p>(with external fixator), followed by definite fixation with the IEF after three to five days. Average duration of the hospital stay was 8.6 days. All fractures united with an average union time of 21.1 weeks (standard deviation [SD] 3.18) in type II, 21.7 weeks (SD 3.57) in IIIA and 24.9 weeks (SD 5.14) in IIIB fractures. The difference between union time in type II and IIIA was not significant ($p > 0.05$), but that between IIIA (and also type II) and IIIB was significant ($p < 0.05$). The healing index in patients who underwent lengthening was 1.5 months/cm. The wounds in 27 patients were managed by delayed primary closure, in 19 patients with second intent (all IIIB), in 11 patients with skin grafting (mostly type IIIB fractures) and in three patients with musculocutaneous flaps. The most common complications of the procedure were pin tract infection and pain at the fracture site. Most of the patients were able to achieve good knee and ankle range of motion. Early application of the Ilizarov fixator constitutes an excellent management of open tibial fractures, especially types II, IIIA and IIIB, due to good functional and radiological results. Despite the technical difficulties and some complications (which are mostly minor) IEF</p> | | | |
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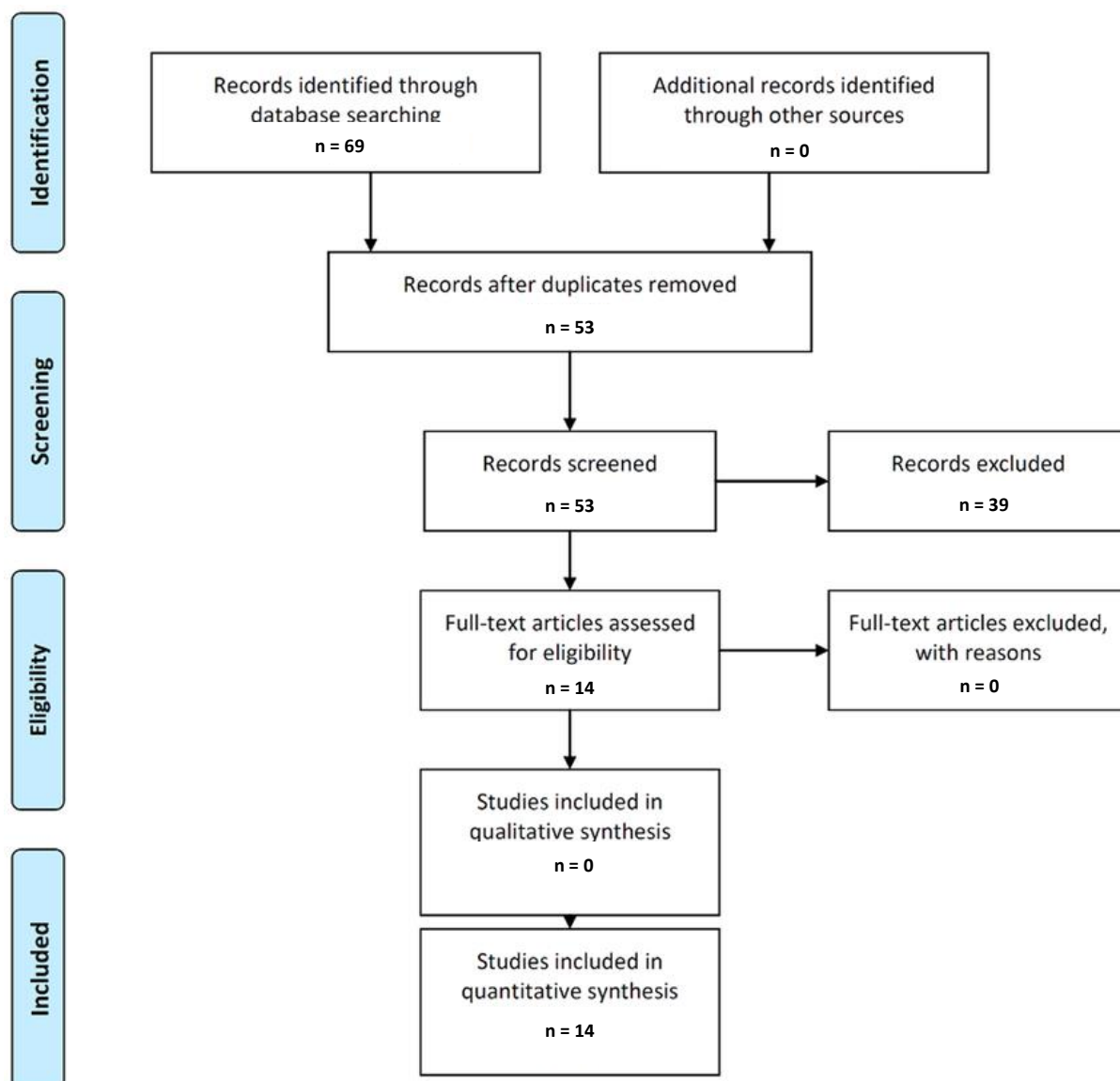
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| | | may be the preferred method in open tibial fractures, especially types II and III. | | | |
| 69. Lohia LK, Meena S, Kanojia RK. | Comparative study of complete subtalar release and Joshi's external stabilization system in the management of neglected and resistant idiopathic clubfoot. Foot Ankle Surg. 2015 Mar;21(1):16-21. doi: 10.1016/j.fas.2014.08.007. Epub 2014 Aug 27. PMID: 25682401. | <p>Background: Various procedures have been used for the management of neglected and resistant clubfoot. The aim of our study was to assess the clinical and radiological correction by Joshi's external stabilization system (JESS fixator) and Simons subtalar release in resistant and neglected idiopathic congenital talipes equinovarus in children between the ages of 1 and 2 years.</p> <p>Methods: A total of 50 resistant and neglected clubfeet were randomly divided into two equal groups of 25 feet each. Group I was treated with JESS fixator and group II was treated with complete subtalar release as described by Simons. Assessment of correction achieved was done both clinically and radiologically. Functional outcome was assessed with Ponseti scale.</p> <p>Results: The change in clinical deformity and radiological correction of deformity were statistically significant within each group, but not significant when compared to each other. In group I excellent results were obtained in 17 (68%) and good in 8 (32%) of the feet. In group II, excellent results were found in 16 (64%) and good in 9 (36%) feet out of the 25 feet. Pin-</p> | RCT | YES | NO |

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| | | <p>site infections were seen in two cases in group I and serious skin problems occurred in two feet in group II.</p> <p>Conclusion: We conclude that there were no statistical significant differences between the outcomes of the two techniques in this short-term follow-up of 2.4 years. Thus, functional distraction using JESS can be utilized as an alternative method in cases of neglected and resistant clubfoot.</p> | | | |
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Appendice B



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CINV What's New?

“CINV What's New?” e' una mini rubrica che propone una lista di lavori di interesse vulnologico. I titoli presenti in essa sono stati scelti dal direttore clinico. I criteri di selezione danno preferenza a linee guida, RCTs, revisioni sistematiche, medical technology guidance. Sono stati scelti poiché si ritiene possano essere di interesse e utili a supportare le pratiche basate sulle evidenze scientifiche.

Buona lettura.

Si ringraziano i membri dell'Expert Panel per il supporto nella revisione degli articoli.

Massimo Rivolo.

- *Prontosan for treating acute and chronic wounds Medical technologies guidance [MTG67] Published: 08 March 2022 [LINK](#)*
- *Effectiveness of a multi-layer silicone-adhesive polyurethane foam dressing as prevention for sacral pressure ulcers in at-risk in-patients: Randomized controlled trial. Key Primary Research 2022 [LINK](#)*
- *3C Patch for treating diabetic foot ulcers. Evidence Based Synopsis 2022 [LINK](#)*
- *Comparing the standard surgical dressing with dehydrated amnion and platelet-derived growth factor dressings in the healing rate of diabetic foot ulcer: A randomized clinical trial. Key primary research 2022 [LINK](#)*
- *Best Practice Statement: Management of lower limb skin tears in adults. UK Guidelines. Wounds UK [LINK](#)*
- *A systematic review of guidelines for lymphedema and the need for contemporary intersocietal guidelines for the management of lymphedema. 01 July, 2020 [LINK](#)*

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