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Assignment 2
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The Effectiveness of Removable Walking Casts and Total Contact Casts in Decreasing Healing Times of Diabetic Foot Ulcers

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CLINICAL SCENARIO:

Untreated ulcers in the diabetic foot can deteriorate and lead to amputation. Total Contact Casting (TCC), a method where the lower limb is encased in either plaster or fibreglass bandage, has been considered the “gold standard” in pressure redistribution to allow for ulcer healing (Armstrong et al., 2001). A Removable Cast Walker (RCW) is another pressure-relieving device. How does the RCW compare against the TCC to redistribute pressure away from diabetic ulcer and encourage wound healing?

FOCUSED CLINICAL QUESTION:

Is a total contact cast (TCC) more effective in decreasing the healing time of foot ulcers in diabetic adults when compared with a removable cast walker (RCW)?

SUMMARY of Search, ‘Best’ Evidence’ Appraised, and Key Findings

Armstrong, D. G., Hienvu, C. N., Lavery, L. A., van Schie, H. M. C., Boulton, A. J. M., & Harkless, L. B. (2001). Off-loading the diabetic foot wound. *Diabetes Care*, 25(6), 1019-1022.

- found that the TCC is more effective than a RCW or half-shoes in diabetic wound healing
- proposed that TCC’s effectiveness comes from its “forced compliance”

Katz, I. A., Harlan, A., Miranda-Palma, B., Prieto-Sanchez, L., Armstrong, D. G., Bowker, J. H., Mizel, M.S., & Boulton, A. (2005). A randomized trial of two irremovable off-loading devices in the management of plantar neuropathic diabetic foot ulcers. *Diabetes Care*, 28(3), 555-559.

- found that when a RCW was made irremovable there was no significant difference between TCCs and RCW in their effectiveness at reducing wound healing times

Armstrong, D. G., Lavery, L. A., Wu, S., & Boulton, A. J. M. (2005) Evaluation of Removable and Irremovable Cast Walkers in the Healing of Diabetic Foot Wounds. *Diabetic Care*, 28(3), 551-554

- wearing a modified RCW to make it irremovable led to a higher proportion of healed ulcers at the end of 12 weeks than those patients wearing a normal RCW.

Piaggese, A., Macchiarini, S., Rizzo, L., Palumbo, F., Tedeschi, A., Nobili, L. A., Leporati, E., Scire, V., Teobaldi, I., & Del Prato, S. (2007). An off-the-shelf instant contact casting device for the management of diabetic foot ulcers. *Diabetes Care*, 30(3), 586-590.

- TCCs did not show a significantly higher rate of ulcer healing than a new, off-the-shelf, irremovable RCW

Faglia, E., Caravaggi, C., Clerici, G., Sganzeroli, A., Curci, V., Vailati, W., Simonetti, D., & Sommalvico, F. (2010). Effectiveness of removable walker cast versus nonremovable fiberglass off-bearing cast in the healing of diabetic plantar foot ulcer. *Diabetes Care*, 33(7), 1419-1423.

- TCCs did not show a significantly higher rate of ulcer healing than a new removable RCW called the Stabil-D.

CLINICAL BOTTOM LINE:

Total Contact Casts have traditionally shown to decrease healing times of ulcers in adults with diabetes over Removable Cast Walkers, primarily because of a patient's "forced compliance" to wear the device. However, recent evidence points to new RCWs that are as effective as TCCs in reducing healing time of diabetic foot ulcers.

Limitation of this CAT: This critically appraised paper (or topic) was prepared for a graduate course assignment and has /has not been peer-reviewed by one other independent person/an instructor.

SEARCH STRATEGY:**Terms used to guide Search Strategy:**

- **P**atient/Client Group: Diabetic Adults (age 50+)
- **I**ntervention (or Assessment): Removable Walker Casts
- **C**omparison: Total Contact Casts
- **O**utcome(s): Foot ulcer healing time

Databases and Sites Searched	Search Terms	Limits Used
Medline OvidSP Cochrane Central Register of Controlled trials RCT & Cochrane Database of Systematic Reviews RehabDATA CINAHL	Diabetic Foot and Surgical Casts and Foot Ulcer AND Wound healing and Diabetic Foot and Orthotic Devices Casts, surgical and Pressure and Diabetic Foot Total Contact Cast and Pressure Sores and Orthotic Total Contact Cast AND Diabetes Mellitus and Orthoses and Cast and Diabetic foot AND Diabetic Foot and Orthopedic fixation devices	English Abstracts Humans Linked full text, Scholarly journals, Abstract available

INCLUSION and EXCLUSION CRITERIA

- Inclusion:
 - 50 years +
 - individuals with diabetes
 - human subjects

- Exclusion:
 - animal studies
 - research before 1990

RESULTS OF SEARCH

5 relevant studies were located and categorised as shown in Table 1.

Table 1: Summary of Study Designs of Articles Retrieved

Study Design/ Methodology of Articles Retrieved	Level* (CMAJ)	Number Located	Author (Year)
Randomized Control Trial	1b	1	Armstrong et al. (2001)
Randomized Control Trial	1b	1	Armstrong et al. (2005)
Randomized Control Trial	1b	1	Piaggese et al. (2007)
Randomized Control Trial	1b	1	Katz et al. (2005)
Randomized Control Trial	1b	1	Faglia et al. (2010)

BEST EVIDENCE

The following study was identified as the ‘best’ evidence and selected for critical appraisal. Reasons for selecting this study were:

- **a high level of research, a randomized control trial**
- **the most recent RCT addressing my clinical question**
- **a clear study design and forthcoming with information (patients demographics, study location, etc.)**

SUMMARY OF BEST EVIDENCE

Table 2: Description and appraisal of “Effectiveness of removable walker cast versus nonremovable fibreglass off-bearing cast in the healing of diabetic plantar foot ulcer” by Faglia, E. et al. (2010)

Aim/Objective of the Study/Systematic Review:

The objective of this study is to compare the effectiveness of total contact casts (a nonremovable fibreglass off-bearing cast) with a removable cast walker (the Stabil-D) in the treatment of diabetic plantar foot ulceration.

Study Design: This study is a randomized control trial. Because the devices were worn during the week, neither the patients nor those evaluating wound healing were blinded. The device each patient received was determined by opening randomization codebreak envelopes containing one of the two options. Outcomes were measured weekly for 90 days.

Setting: The study took place at two centres specializing in diabetic foot management in the Italian cities of Sesto San Giovanni and Milan.

Participants: This study included 48 adults diagnosed with diabetes. Peripheral neuropathy was verified based on sensitivity to a 10-g Semmes-Weinstein monofilament in 6 areas of the foot and by a vibration perception threshold (using a biothesiometer) at the malleolus of greater than 25V. The patients were recruited at the two clinics from February 2008 to March 2009.

Inclusion criteria:

- the presence of a neuropathic forefoot ulcer with an area graded 1A based on the University of Texas Classification of Diabetic Wounds

Exclusion criteria:

- presence of an ankle-brachial pressure index of less than 0.9 and/or a transcutaneous oxygen tension of less than 50 mmHg at the dorsum of the foot
- wound infection
- vision problems
- contralateral foot ulcers
- contralateral limb amputation
- previous or current deep venous thrombosis of the leg
- osteomyelitis
- mental disorders that would interfere with compliance
- the use of steroids or antimetabolic drugs

The groups at baseline were comparable in age, sex, diabetes therapy, duration of the disease, BMI, AIC (%Hb), whether they had previous foot ulcers, previous amputations and the mean area of the lesion. The average age of the participants was 60.4 years, with an average duration of the disease of 17.5 years. The study had 15 females and 30 males. There were three patients who were treated as dropouts due to removal of consent, contralateral ulcer formation and infection.

Intervention Investigated

Patients were divided into the TCC group and the RCW (or Stabil-D) group. Patients in the TCC group were casted using a standard casting technique by trained casting personnel, one at each centre. The casts varied in layers (from 3 to 8) of fiberglass. A side support made of aluminum was anchored to the structure. After brief training, all patients were able to walk. Patients in the RCW group were fit with an off-the-shelf Stabil-D, a removable cast walker. Patients in this group were trained for the proper donning of the device as well as the proper closure of the velcro straps. Patients were allowed to remove the cast only while they slept at night.

At the initial visit, each patient had their ulcer debrided to remove dead tissue. Before the off-loading device was donned, ulcers were dressed with gauze. The article did not make it clear whether the same individuals were responsible for wound dressing, device training, and ulcer measurement. This will have an effect on data collection consistency.

The patient fittings, castings and wound measurements all took place at the two clinics.

Outcome Measures

The primary outcome measures were the percent reduction in ulcer surface area and total healing rates. The ulcer was photographed and measured using the Vistrak system, an electronic device that measures wound area and wound healing progress. Initially the mean areas of the lesion for the TCC and the Stabil-D groups were 1.4 ± 1.2 and 2.2 ± 2.2 cm². Total healing was measured by the complete reepithelialization of the wound, as measured by the clinicians. The study also measured the average visit time per group, and the average cost of each device over the treatment period.

Main Findings:

Ulcer surface area decreased significantly in both groups: from 1.41 to 0.21 cm² (P<0.001) in the TCC group and from 2.18 to 0.45 cm² (P<0.001) in the RCW group. Between the two groups there was no significant difference (P=0.72). Percent reduction of the wounds in the TCC group (73.6%) and the RCW group (90%) did not show significant differences between groups (P=0.321). The mean ulcer healing time for the TCC group and the RCW was 35.3 ± 3.1 days and 39.7 ± 4.2 days, respectively. Again, these two values do not differ significantly (P=0.78).

Original Authors' Conclusions

"The results of our study indicate that pressure off-loading using Stabil-D and pressure off-loading using total contact casting are equally effective in the treatment of neuropathic forefoot ulcers, thus proving that optimal results may be obtained with a removable cast walker." Pg 1423.

Critical Appraisal:

Validity

PEDro score 6/10

Study Question:

- a good presentation of the current, applicable literature

Study Design:

- the purpose was clear, and the methods understandable.

- a randomized controlled trial, where patients were randomized to two groups

- neither patients nor treatment providers were blinded, leading to possible detection bias by the treatment team

- electronic system used to measure ulcer size

Subjects

- clear presentation of population demographics, but not clear how they were recruited for the study.

- sample bias (attention bias) might exist as those wearing the RCW knew the study's intent to compare their treatment with a nonremovable cast and may have been more likely to keep the RCW on, rather than remove it

- inclusion/exclusion criteria clearly explained

- 3 dropouts, not included in statistical analysis

Intervention

- intervention (casting and RCW fitting) was undertaken by two therapists, one at each clinic

- casting technique followed defined guidelines

- patients trained in walking in both the RCW and TCC

- frequency of follow-up was consistent with all subjects, except dropouts

Outcomes

- rate of ulcer healing was a good indicator of pressure reduction at the wound

- outcome measures were measured on a weekly basis, in a consistent, clearly described manner

Analysis

- sample size was not justified

- significant reduction in wound size was seen in both groups, however no significant difference was shown between the two groups.

- means and p-values provided (significance <0.05)

- authors discussed their differing results from other studies and provided reason why their study points in this new direction

Interpretation of Results

- The results were reported in terms of statistical significance, but differed from other studies

- Though well-designed, this study has a fairly small population and transferability is questionable

- from two cities in Italy, and may not be representative of all RCWs (in this case the Stabil-D) and all TCC techniques, as there are different methods to cast a TCC.

Summary/Conclusion:

The conclusion that removable cast walkers are as effective as total contact casts in encouraging diabetic foot ulcer healing is a different conclusion from previous research. The authors speculate that perhaps it is the unique design of this new RCW (the Stabil-D) that allows for better ulcer healing results than previous RCW designs. The authors suggest that more effective, less immobilizing, methods/devices are available to increase wound healing time in the diabetic feet than the TCC.

IMPLICATIONS FOR PRACTICE, EDUCATION and FUTURE RESEARCH

Diabetes is a growing concern in Canada. Between 1995 and 2005 the incidence of diabetes grew by 70% in Ontario alone (Lanscombe, 2007). Diabetes causes peripheral neuropathy, which among other complications, reduces feeling in the extremities and can lead to foot

ulcers and possibly amputation. Hospitalization due to diabetic foot ulcers and amputation is increasingly a strain on the health care system (Howard, 2009).

In 2000 a systematic review was published that looked into the different pressure relieving interventions for preventing and treating diabetic foot ulcers (Spencer, 2000). This review found that there was relatively little research comparing these treatments. Up to this point, total contact casting had been considered the “gold standard” in diabetic foot ulcer treatment (Armstrong, 2001). Since Spencer’s review a flurry of studies have been investigating the effectiveness of different pressure-relieving treatments. In a significant RCT completed by Armstrong et al, it found that the TCC healed a higher proportion of wounds than did either the RCW or the half shoe. He proposed that the TCC was more effective than the RCW because it immobilized the healing leg within the cast, and “forced compliance” of the patient, while RCW’s were not as effective because of the patient’s ability to remove the device and carry on active lifestyles. (Armstrong, 2001). Katz et al. found that there was no significant difference in healing times when they forced patient compliance using an RCW by making it irremovable and comparing it to a TCC (Katz, 2005). This confirmed Armstrong’s hypothesis that it was primarily cast removability (ie. compliance) that decreased the RCW’s effectiveness, not its superior ability to redistribute pressure. However in 2010, Faglia et al. found no significant difference between the effectiveness of a new RCW, called the Stabil-D, which a patient could don and doff throughout the week, and a traditional TCC. This study’s findings could mean that newer RCWs are more effective at encouraging ulcer healing.

Despite the difference in findings, these studies do indicate that increasing pressure distribution along the leg seems to be the most effective method at encouraging diabetic foot ulcer healing (Armstrong et al, 2001) whether using a TCC or RCW (Faglia et al, 2010).

Although known to be an effective treatment, the TCC is rarely used. It requires specific training to cast patients, regular patient visits and involves a substantial cost (Piaggese et al, 2007). One study found that an RCW was about half the price of a TCC regimen. The findings of these studies are important as they show that RCWs are an equally effective treatment alternative for treating diabetic foot ulcers. The findings of these studies should be made known to health care professionals who treat patients with diabetes.

REFERENCES

- Armstrong, D. G., Hienvu, C. N., Lavery, L. A., van Schie, H. M. C., Boulton, A. J. M., & Harkless, L. B. (2001). Off-loading the diabetic foot wound. *Diabetes Care*, 25(6), 1019-1022.
- Armstrong, D. G., Lavery, L. A., Wu, S., & Boulton, A. J. M. (2005) Evaluation of Removable and Irremovable Cast Walkers in the Healing of Diabetic Foot Wounds. *Diabetic Care*, 28(3), 551-554
- Faglia, E., Caravaggi, C., Clerici, G., Sganzaroli, A., Curci, V., Vailati, W., Simonetti, D., & Sommalvico, F. (2010). Effectiveness of removable walker cast versus nonremovable fiberglass off-bearing cast in the healing of diabetic plantar foot ulcer. *Diabetes Care*, 33(7), 1419-1423.
- Howard, I. (2009) The Prevention of Foot Ulceration in Diabetic Patients. *Physical Medicine and Rehabilitation Clinics of North America*, 20(4), 595-609
- Katz, I. A., Harlan, A., Miranda-Palma, B., Prieto-Sanchez, L., Armstrong, D. G., Bowker, J. H., Mizel, M.S., & Boulton, A. (2005). A randomized trial of two irremovable off-loading devices in the management of plantar neuropathic diabetic foot ulcers. *Diabetes Care*, 28(3), 555-559.
- Lipscombe, L. & Hux, J. E. (2007) Trends in diabetes prevalence, incidence, and mortality in Ontario, Canada 1995-2005: a population-based study. *Lancet*, 369, 750-756.
- Piaggese, A., Macchiarini, S., Rizzo, L., Palumbo, F., Tedeschi, A., Nobili, L. A., Leporati, E., Scire, V., Teobaldi, I., & Del Prato, S. (2007). An off-the-shelf instant contact casting device for the management of diabetic foot ulcers. *Diabetes Care*, 30(3), 586-590.
- Spencer, S. (2000) Pressure relieving interventions for preventing and treating diabetic foot ulcers. *Cochrane Database Systematic Reviews*, (3).

Addendum

Further studies that would help answer my clinical question:

- a study to distinguish between the differing results from Armstrong and Faglia.
- a study that looks into the structural differences between RCWs. What makes one RCW more effective than another?
- a study looking into the various TCC techniques. There are a variety of described casting techniques. It would be good to find a study that compared the different techniques and determined which technique was the most effective at pressure distribution.

Search strategy

I mainly used Medline for my search. I began by using terms that I was familiar with (like total contact casting, orthopaedic devices, diabetic foot ulcer) then used the suggested terms in databases to complete the search (ie. MeSH terms). This let the database determine the direction of the search. After finding some good articles in the different databases, I read through them carefully and looked into their references to find other studies that I had missed. I found some of my best articles through scanning these references. I found Medline to provide the highest quality of evidence, with the exception of the Cochrane Database, where I found a systematic review. RehabData and CINAHL had some good papers, but also included lower levels of evidence. The inclusion and exclusion criteria were effective at keeping the papers relevant to my patient population.

My initial clinical question asked whether foot orthotics helped reduce the rate of amputations in diabetic adults. My first search of the literature showed very few quality studies related to the topic. Also, more papers used the healing time of an ulcer as an outcome as opposed to amputation. I changed the outcome in my search. I also realized that I needed a comparison for my intervention so I chose Total Contact Cast as the ideal treatment I was comparing against. Still, “foot orthotics” or “foot orthopaedic devices” did not produce many studies. I wanted to study the effects of some type of bracing, so I switched to a walker and discovered that there has been some high quality research comparing total contact casts and removable cast walkers. By changing the treatment and adding the comparison, I was able to complete a much more refined, successful search. In my next search, I will begin with a more refined clinical question and utilize more databases earlier on.