Literature review of the possible advantages of silicon liner socket use in trans-tibial prostheses

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CRD summary
The authors concluded that in most studies liners improved suspension and walking outcomes but could cause skin problems; further research is required. The poor reporting of review methods, as well as reliance upon a small number of low-quality studies that generally measured subjective outcomes, mean that the authors’ conclusions about effectiveness may not be reliable.

Authors’ objectives
To evaluate objective data supporting the benefits of silicon liner sockets in patients with trans-tibial prostheses.

Searching
MEDLINE, EMBASE, AMED, CINAHL and the Cochrane Library were searched using the reported search terms. Reference lists were screened. Studies were included if they were published in English, Dutch or German.

Study selection
Study designs of evaluations included in the review
Prospective and retrospective studies and case series with more than 10 patients were eligible for inclusion in the review.

Specific interventions included in the review
Studies that evaluated silicon liner sockets in trans-tibial prosthesis were eligible for inclusion. Most of the included studies used the Icelandic Roll On Silicon Socket silicon liner and most used the shuttle lock mechanism to attach the silicon liner to the socket; one study used both shuttle lock plus cord lock. All but one of the included studies compared a silicon liner with patellar tendon bearing, Kondyl Bettung Munster or other type of socket.

Participants included in the review
Studies of patients with a trans-tibial prosthesis were eligible for inclusion. The participants in the included studies varied with respect to indications for amputation (trauma, vascular insufficiency, diabetes, infection, tumour, congenital limb defects and spina bifida), age (range: 15 to 80 years) and duration of prosthesis use (range: 10 days to 19 years).

Outcomes assessed in the review
Studies that assessed walking function, comfort, stump skin problems, pain in stump or phantom pain, prosthesis suspension, cosmesis, or doffing and donning were eligible for inclusion. Most of the included studies assessed outcomes using self-developed questionnaires; one study used clinical examination and function test in addition to the questionnaire, while another used clinical examination alone. The included studies used different measures to assess walking function.

How were decisions on the relevance of primary studies made?
The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
The authors did not state that they assessed validity.

Data extraction
The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction. For each study, individual patient data were extracted where possible; the reviewers calculated individual patient data for one study that reported percentage data. One study presented only group data. The percentage of patients reporting improvement or no improvement was presented graphically for each outcome of interest within each study.

Methods of synthesis
How were the studies combined?
The studies were grouped by outcome and combined in a narrative.

How were differences between studies investigated?
Differences between the studies were summarised in the text.

Results of the review
Six studies (n=259) were included: 1 prospective study (n=20), 2 retrospective studies (n=70) and 3 case series (n=169). The sample size ranged from 20 to 83.

Most of the studies included a sub-population from a larger group, but the methods used to select the participants were not clear.

Walking function: 5 studies reported improvements in various measures of walking function with the silicon liner compared with other types of prosthesis. The measures included walking ability indoors and on uneven surfaces, walking speed and distance, use of walking aids, general walking, and ascending and descending stairs and inclines.

Comfort: 3 studies found that between 7% and 53% of patients reported an increase in comfort; one of these studies also reported a decrease in comfort in some patients.

Skin: 3 studies assessed skin changes associated with silicon liner use. These reported increased skin problems from perspiration in 42% after liner use, creasing in the back of knee in 38%, and a decrease in local pressure points (1 study); a decrease in skin abrasion and irritation in some patients, but an increase in ulceration, itching, perspiration, blistering and irritation at the back of knees in other patients (1 study); and a general decrease in skin problems (1 study).

Pain: 3 studies assessed pain. These reported a decrease in stump pain in some patients (1 study), a decrease in phantom limb pain in 19% (1 study), and a decrease in pain sensation in 53% (1 study).

Suspension: 4 studies assessed suspension. One study that clinically examined the pistoning of prosthesis reported less pistoning (by 1.2 cm) with the silicon liner compared with the patellar tendon bearing socket. The other 3 studies did not assess pistoning clinically; they reported varying percentages of patients with improved suspension, with improvement noted in between 15% and 96% of patients.

Cosmesis: the authors stated that patients generally reported improvements in cosmesis. The studies reported improved appearance (1 study), no improvement (1 study), improvement in 63% of patients but decreased cosmesis in other patients (1 study), and improvement in a number of patients (1 study).

Donning and doffing: some studies reported problems with doffing and donning. Two studies reported a decrease in the ease of doffing and donning in 35% and 22% of patients, respectively, but both studies reported improvements in 31% of patients compared with other types of socket. One study reported improvements in some patients but decreases in others. One study reported a significant improvement when using silicon liners.

Authors’ conclusions
Most of the included studies showed that liners improved suspension and walking outcomes but could cause skin problems. Further research is required.
CRD commentary
The review addressed a clear question that was defined in terms of the participants, intervention, outcomes and study design. Inclusion criteria for the study design were broad, but this seemed appropriate given the field of the review. Several relevant sources were searched and some attempts were made to minimise language bias. Specific attempts to identify unpublished studies were not reported, thus raising the possibility of publication bias. The methods used to select studies and extract the data were not described, so it is not known whether any efforts were made to reduce reviewer errors and bias. Study validity was not assessed, thus the results from these studies and any synthesis may not be reliable.

A narrative synthesis was appropriate given the differences between the studies. The graphical display was difficult to interpret and it was not possible to easily confirm the results reported in the text. The authors did not explore potential reasons for differences of effect among patients. The included studies were of low quality and most studies did not use validated methods to measure the outcomes. The lack of reporting of review methods, as well as reliance upon a small number of low-quality studies that generally measured subjective outcomes, mean that the authors’ conclusions about effectiveness may not be reliable.

Implications of the review for practice and research
Practice: The authors did not state any implications for practice. Research: The authors stated that further studies with adequate design, homogeneous populations and objective outcome measures are needed to assess the advantages of silicon liner sockets in trans-tibial amputees.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.