OPERATION NAMASTE
Collaborative Orthotic and Prosthetic Care Alliance

Measuring Current Usage of Silicone Gel Liners and the Potential Impact of Access to a Low-Cost Version for Prosthesis Users in Low-Income Settings: Results from a Survey of International Direct Care Providers

BACKGROUND

In the developing world, prosthetic care is far less accessible than in middle and high income countries[1]. This includes a critical component, the elastomeric liner, which serves as a cushioning layer between the residual limb and the prosthetic socket to protect the limb from force, and increase the stability and comfort of the prosthesis enabling higher levels of activity.[2] For lower-limb amputees a quality liner is critical to standing for long periods and being productive at work and play. A standard component available to amputees in wealthy countries for more than 30 years – silicone gel prosthetic liners, are still not readily available in many low-resource settings. Financially disadvantaged amputees are often using liners made of inferior materials or using their liner long beyond its recommended lifespan reducing prosthesis performance and limiting the ability to secure gainful employment and enjoy an active family and social life.

In April 2022 Operation Namaste launched a research effort to gather data to guide distribution planning and funding development for the 'Namaste Liner' and 'Namaste Limb Solutions'; the low-cost silicone prosthetic liner and DIY manufacturing package developed by Operation Namaste. This survey, designed to quantify the current availability of silicone gel liners in the developing world and estimate the potential impact of a low-cost version, is a key element of that market research.

SURVEY METHOD

An online survey was distributed to all members of the International Society for Prosthetics and Orthotics (ISPO), and to subscribers of the OandP-L forum group. The survey sample base included over 3,000 prosthetics and orthotics industry professionals who deliver care in 80 countries across the Americas, Europe, Africa & Middle East, Asia and Oceania.

This survey was designed to gather feedback from practitioners who provide prosthetic devices in the developing world – specifically those serving patients who struggle to pay for basic prosthetic care. The 12-question survey was delivered to prospective respondents via email link. We received responses from 102 prosthetic clinicians representing their experience providing a lower-limb prosthesis to 27,000+ financially disadvantaged amputees annually.

KEY FINDINGS

Survey respondents verified that access to silicone gel liners for amputees in the developing world is very limited with only 20% of amputees currently using a silicone/gel liner on average. At the extreme end of the scale, 45% of respondents indicated less than 10% of their patients benefit from this basic prosthetic component; cost was the most common obstacle. Survey participants said the current cost of providing a silicone liner in the communities they serve averages $352 USD. For a component requiring frequent replacement, this cost is prohibitive for low-income patients according to 89% of responding clinicians.

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[1] *Global report on assistive technology. Geneva: World Health Organization and the United Nations Children's Fund (UNICEF), 2022. License: CC BY-NC-SA 3.0 IGO.*

[2] *Elastomeric Liners for People with Transtibial Amputation: Survey of Prosthetists' Clinical Practices.* Hafner BJ, Cagle JC, Allyn KJ, Sanders JE. Prosthet Orthot Int. 2017 Apr; 41(2):149-156. doi: 10.1177/0309364616661256. Epub 2016 Sep 24. PMID: 27613589; PMCID: PMC5344787.

When asked about the potential impact of a ~$50 silicone liner, 90% of survey respondents said availability at that price would increase the number of patients to whom they could provide one; projecting a 105% increase in use from an average 20% at current pricing to 41% among their patients who struggle to pay for basic prosthetic care. The number of caregivers reporting that fewer than 10% of their patients could access a silicone liner drops from 45% to 6% if the cost is reduced to ~$50.

To quantify the economic impact of access to a ~$50 silicone gel liner the survey asked responding clinicians to estimate the percent of their patients who return to work currently (most without a silicone gel liner) and the number likely to return to work with a low-cost silicone gel liner. Responding providers indicated that currently an average 33% of their patients return to work after rehabilitation, and the availability of the Namaste Liner at ~$50 could increase that likelihood to an average 46%. This 39% increase would result in an additional 13 amputees being gainfully employed for every 100 prosthesis delivered with a Namaste Liner.

'Reduced Cost' was the Namaste Liner benefit mentioned as most impactful by 90% of survey respondents. 'Improved Functionality', 'Local Sourcing', and 'Durability', were also highly ranked benefits, while 'Quicker Delivery and Reduced Shipping Time' were seen as less critical benefits but still listed as important by 65% of respondents.

The survey also measured clinician preference for fabricating Namaste liners and molds on-site at their own facility versus ordering from a wholesale source. Fabricating liners on-site using the Namaste Limb Solutions package was preferred by 85% of respondents while 30% indicated a preference for purchasing liners from a wholesaler.

Fewer respondents were interested in manufacturing replacement liner molds using a 3D printer at their own clinic/facility (28%), preferring instead to order replacement molds from a wholesale source (34%) or use a local 3D printer to manufacture replacement molds (32%).

CONCLUSIONS/IMPLICATIONS

Expanded distribution of the Namaste Limb Solutions package would increase the number of amputees who would benefit from a silicone gel liner. At ~$50 per liner, more financially disadvantaged amputees would enjoy an active family and community life and more would return to work. Overall results support investment in the broad market delivery of the Namaste Liner package through providers serving amputees in developing countries.

The 39% increase in the likelihood of lower-limb prosthesis patients returning to work is projected to generate an annual 5:1 return on investment based on the incremental income potential of just the immediate beneficiaries of a Namaste Liner[(3)]. As noted in the Global Report on Assistive Technology - there are also 'ripple effects' that would dramatically increase this ROI and accelerate national-level economic growth including reduced medical care costs and the income generating capacity of family care-givers who will also be able to return to school or work.[(4)]

While the majority of clinicians indicated they would prefer to manufacture the Namaste Liners on site, the 30% indicating they would purchase liners from a wholesaler signifies the need for that option in addition to the DIY Namaste Liner package. The low percent of clinicians indicating the availability of a 3D printer in-house or a preference for manufacturing replacement molds on-site signals a need for ensuring replacement molds can also be ordered from Operation Namaste or obtained from a local 3D printer.

[(3)] ROI calculation based on 100 Namaste liners costing $5,000 per year and the average salary of a Factory & Manufacturing Assembly Line Worker in Cambodia earning $2,300 per year (SalaryExplorper.com 2022 Salary survey)

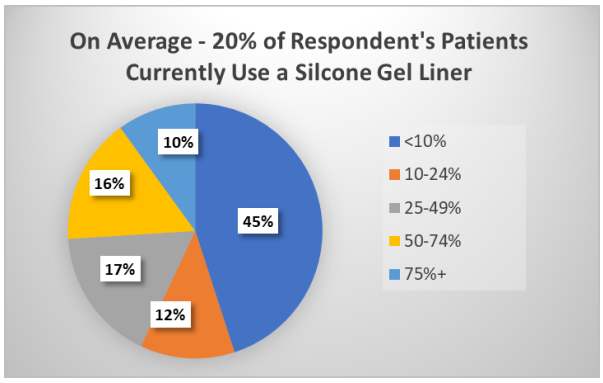
[(4)] Global Report on Assistive Technology: WHO/UNICEF/ATscale 2022

APPENDIX

Data Tables/Charts: Responses by Question

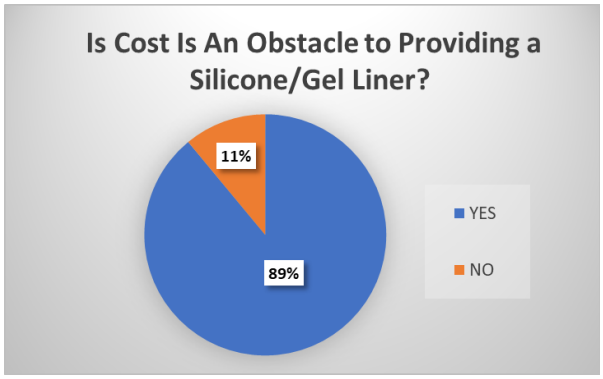
1) Approximately what % of your patients currently use a silicone/gel liner:

<10% = 31 (45%)
10-24% = 8 (12%)
25-49% = 12 (17%)
50-74% = 11 (16%)
75%+ = 7 (10%)
Weighted Average: 20%
Responses: 69



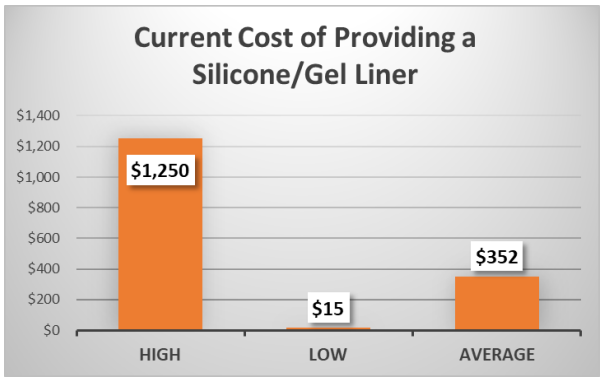
2) Is cost an obstacle to providing a silicone/gel liner for your patients?

YES - 91 - 89%
NO - 11 - 11%
Responses: 102



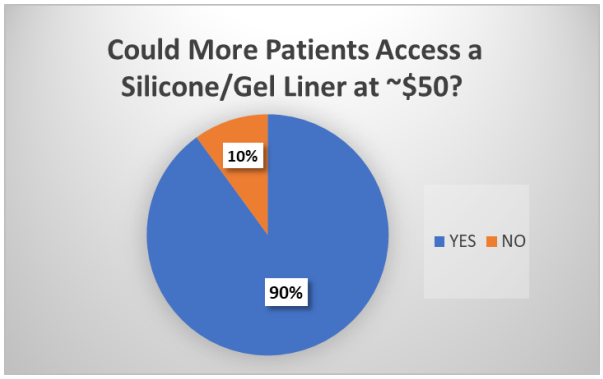
3) Approximately how much does it currently cost to provide a silicone/gel liner (including import fees and shipping) for your patients?

Current Cost Average: $352
Responses: 77



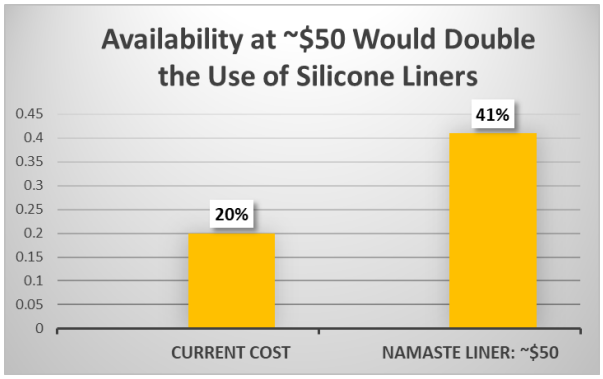
4) Would the availability of a ~$50 silicone/gel liner allow you to provide liners to more patients?

YES - 81 - 90%
NO - 9 - 10%
Responses: 90



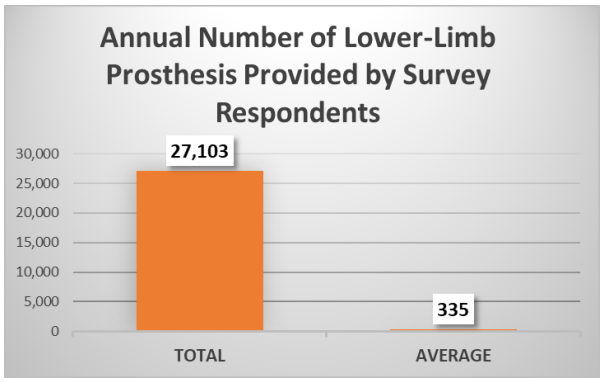
5) If yes, approximately what % of your patients would use a silicone/gel liner at ~$50?

<10% = 4 (6%)
10-24% = 5 (7%)
25-49% = 11 (16%)
50-74% = 27 (39%)
75%+ = 22 (32%)
Weighted Average: 41%
Increases vs Q1 = 105%
Responses: 69



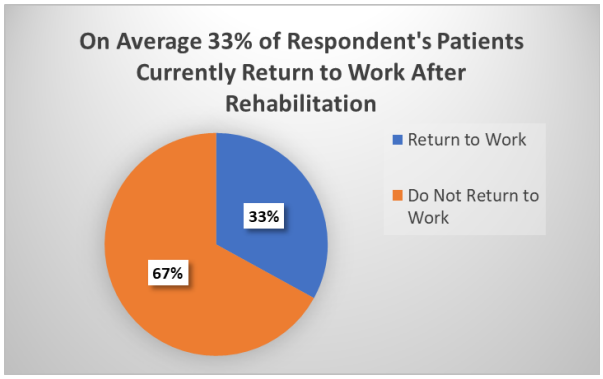
6) Approximately how many lower-limb prostheses does your organization deliver each year?

Total = 27,103
Average: 335
Responses: 81



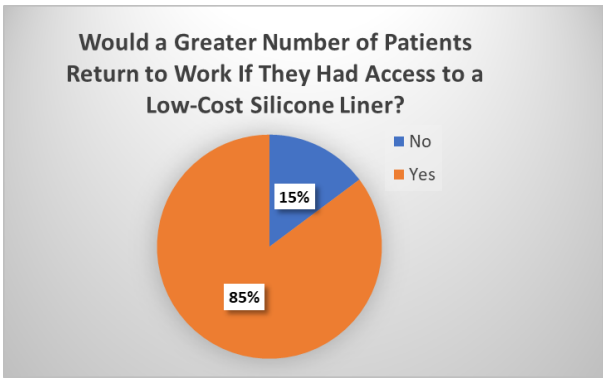
7) Currently, approximately what % of your prosthesis patients return to work after rehabilitation:

<10% = 6 - 9%
10-24% = 8 - 12%
25-49% = 17 - 25%
50-74% = 29 - 42%
75+% = 8 - 12%
Weighted Average: 33%
Responses: 68



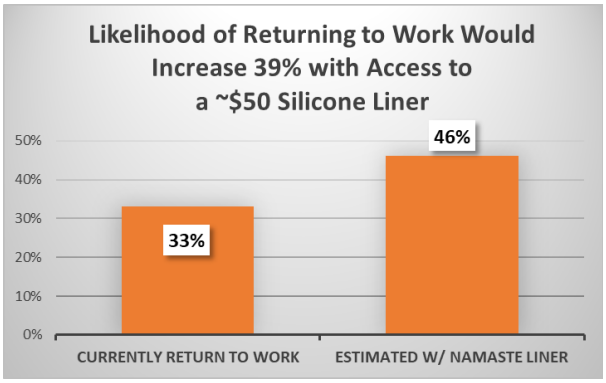
8) Would a greater % of your patients return to work after rehabilitation if they had access to a low-cost, high-activity silicone/gel liner?

No = 13 - 15%
Yes = 75 - 85%
Responses: 88



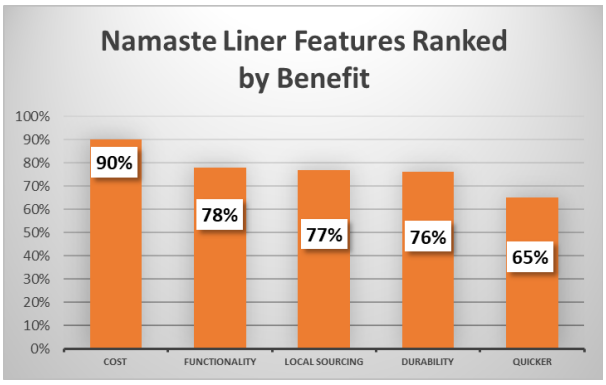
9) If yes, approximately what % of your patients would return to work if they had access to a low-cost, high-activity, silicone/gel liner:

<10% = 3 - 4%
10-24% = 2 - 3%
25-49% = 6 - 9%
50-74% = 27 - 40%
75+% = 30 - 44%
Weighted Average: 46%
Responses: 68



10) Relative to the liners you currently provide – please review the Namaste Liner features below and select all that you feel may be beneficial to your organization/patients:

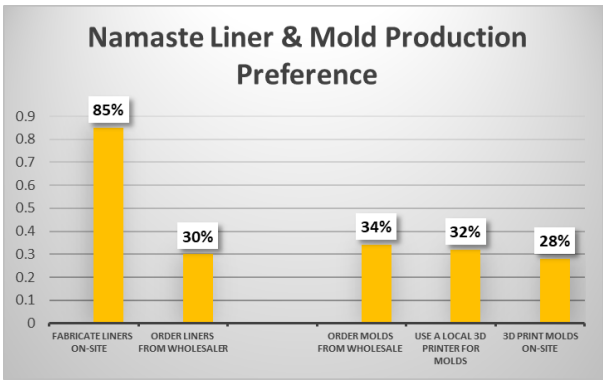
Features Beneficial to Patients:
#1 Reduced Cost (90%)
#2 Improved Functionality for Increased Activity (78%)
#3 Local Sourcing (77%)
#4 Increased Durability (76%)
#5 Quicker delivery/reduced shipping time (65%)
Responses: 88



11) Fabricating a liner on-site using the Namaste Limb Solutions system requires approximately 1.5 hours from a low/moderate skilled technician for whom Operation Namaste will provide training. With that in mind please check all of the boxes below which would apply to you/your practice:

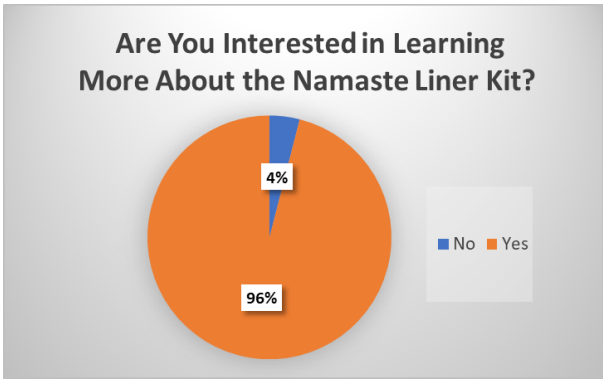
85% Fabricate liners on-site
30% Order liners wholesale source

34% Order replacement molds from wholesale source
32% Use local 3D print vendor for replacement molds
28% Use own 3D printer to manufacture molds
Responses: 88



12) Are you interested in learning more about Namaste Limb Solutions?

NO = 4 - 4%
YES = 97 - 96%
Responses: 101



Survey Tool Analysis Protocol

This survey was designed to gather qualitative feedback and establish estimated values to project demand for, and impact of, a low-cost silicone liner in low-to-moderate income countries. The results do not represent a statistical sampling of all prosthetic care providers serving the developing world. Overall, the survey results include feedback from 102 providers who represent care provided to more than 27,000 financially disadvantaged amputees annually which provided formulas Operation Namaste will use to estimate need and impact for distribution planning.

Survey responses (105) were scrubbed using the following rules:

- Duplicate entries were removed (3)
- Response basis (divisor) for all questions excludes known HIC providers and replies from respondents whose answer to Q2 was *'cost is not an obstacle'* (12) except for Q2 itself and Q10 = 90 QUALIFIED RESPONSES
- Numeric/percent responses provided as a range were averaged using the midpoint of the range and then weighted by number of responses
- If no response was provided for a given question - that respondent was removed for analysis for THAT question (unless the number '0' was provided) but retained for other questions

Responses were cross-tabulated for conditional questions (eg: Q2 / Q4 & Q10 / Q11). As a result, respondent totals/divisors used to calculate results vary for some questions. Following are the divisor/total respondent adjustments applied to analyze the results for each survey question:

Question #	Divisor Adjustment
1)	Divisor excludes those who answered 'no' to Q2 & Q4 and/or provided a higher % for Q5 than provided for Q1 after answering 'yes' to Q2 (respondent error)
2)	Divisor includes all respondents
3)	Divisor includes qualified respondents who entered a cost. All currency converted to USD; blanks and unknown currency removed for cost averaging
4)	Divisor includes all qualified responses
5)	Divisor includes respondents who also answered yes to Q4, and excludes answers that were a lower % than answer to Q1 (respondent error)
6)	Divisor includes all qualified respondents that provided a # (blank does not = zero)
7)	Divisor all qualified responses less 2 'no answer', and excludes responses that did not also reply to Q9, replied with a higher % to Q9 after answering 'yes' to Q8 (respondent error) and those answering 'no' to Q8.
8)	Divisor = qualified reponses less 2 'no answer'
9)	Divisor = qualified responses less responses that did not also reply to #7, answered 'no' to Q8 or replied with a lower % to #9 after answering 'yes' to 8
10)	Divisor includes all qualified responses less 2 'no answer'
11)	Divisor includes all qualified responses less 1 'no answer'
12)	Divisor includes all responses less 1 'no answer'

CONTACT FOR MORE INFORMATION

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